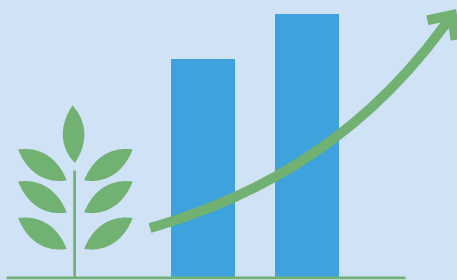




WHO GLOBAL REPORT ON TRADITIONAL AND COMPLEMENTARY MEDICINE 2019



World Health
Organization

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**World Health
Organization**

WHO global report on traditional and complementary medicine 2019

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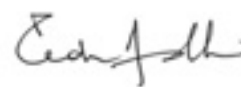
FOREWORD

Traditional and complementary medicine (T&CM) is an important and often underestimated health resource with many applications, especially in the prevention and management of lifestyle-related chronic diseases, and in meeting the health needs of ageing populations. Many countries are seeking to expand coverage of essential health services at a time when consumer expectations for care are rising, costs are soaring, and most budgets are either stagnant or being reduced. Given the unique health challenges of the 21st century, interest in T&CM is undergoing a revival.

Monitoring health trends is a core function of the World Health Organization (WHO) and is key to supporting countries in generating evidence-based policies and strategic plans. This report reviews global progress in T&CM over the past two decades and is based on contributions from 179 WHO Member States. It clearly shows that more and more countries are recognizing the role of T&CM in their national health systems. For instance, by 2018, 98 Member States had developed national policies on T&CM, 109 had launched national laws or regulations on T&CM, and 124 had implemented regulations on herbal medicines.

Countries aiming to integrate the best of T&CM and conventional medicine would do well to look not only at the many differences between the two systems, but also at areas where both converge to help tackle the unique health challenges of the 21st century. In an ideal world, traditional medicine would be an option offered by a well-functioning, people-centred health system that balances curative services with preventive care.

WHO is halfway through implementing the WHO Traditional Medicine Strategy 2014–2023. Our current focus is to develop norms, standards and technical documents based on reliable information and data, to support Member States in providing safe, qualified and effective T&CM services and their appropriate integration into health systems for achieving universal health coverage and the Sustainable Development Goals. I am very pleased to introduce the *WHO global report on traditional and complementary medicine 2019*. I believe that this report provides valuable information for policy-makers, health professionals and the public for capitalizing on the potential contribution of T&CM to health and well-being.



Tedros Adhanom Ghebreyesus
Director-General
World Health Organization

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Thanks are due to the regional offices and WHO representative offices for actively and diligently overseeing the distribution and return of the second survey and the update survey on T&CM, as well as the data verification and updates provided over recent years.

The preparation of the report including compiling, analysing and drafting was contributed by Qi Zhang and Aditi Sharan under the guidance of Edward Kelley, with translation support provided by Stéphane Espinosa. The questionnaire design of the second WHO global survey was contributed by Xiaorui Zhang, Qi Zhang, Yukiko Maruyama and Molly Robinson Nicol. The questionnaire design of the update survey was contributed by Qi Zhang, Aditi Sharan and Stéphane Espinosa. Key contributors to the report in the WHO regional offices were:

WHO African Region: Ossy Kasilo

WHO Region of the Americas: Daniel Gallego and Ricardo Fabrega

WHO Eastern Mediterranean Region: Adi Al-Nuseirat

WHO European Region: Olexandr Polishchuk and Hanne Bak Pedersen

WHO South-East Asia Region: Sungchol Kim

WHO Western Pacific Region: Yu Lee Park

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ACRONYMS AND ABBREVIATIONS

ADR	adverse drug reaction
AIDS	acquired immunodeficiency syndrome
cGMP	current good manufacturing practice
CAM	complementary and alternative medicine
CM	complementary medicine
EMA	European Medicines Agency
EU	European Union
GACP	good agriculture and collection practice
GMP	good manufacturing practice
HIV	human immunodeficiency virus
MoH	ministry of health
MoPH	ministry of public health
NEML	national essential medicines list
OTC	over-the-counter
R&D	research and development
SDG	Sustainable Development Goal
T&CM	traditional and complementary medicine
TM	traditional medicine
UHC	universal health coverage
WHO	World Health Organization

GLOSSARY

Complementary medicine

The terms “complementary medicine” and “alternative medicine” refer to a broad set of health care practices that are not part of that country’s own traditional or conventional medicine and are not fully integrated into the dominant health care system. They are used interchangeably with traditional medicine in some countries.¹

Conventional pharmaceuticals

Conventional pharmaceuticals are defined as medicinal drugs used in conventional systems of medicine with the intention to treat or prevent disease, or to restore, correct or modify physiological function.

Herbal medicines

Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain, as active ingredients, parts of plants, other plant materials or combinations thereof. In some countries, herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials).

Indigenous traditional medicine

Indigenous traditional medicine is defined as the sum total of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating physical, mental and social diseases. This knowledge or practice may rely exclusively on past experience and observation handed down orally or in writing from generation to generation. These practices are native to the country in which they are practised. The majority of indigenous traditional medicine has been practised at the primary health care level.

Second survey

The Second WHO Global Survey on National Policy and Regulation for Traditional and Complementary/Alternative Medicine, distributed during 2010–2012.

Traditional medicine

Traditional medicine has a long history. It is the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.¹

Traditional and complementary medicine

T&CM merges the terms TM and CM, encompassing products, practices and practitioners.

Update survey

A voluntary update to the second survey, distributed during 2016–2018.

¹ See <http://www.who.int/medicines/areas/traditional/definitions/en>.

WHO REGIONS

WHO African Region: Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cabo Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, South Africa, South Sudan,¹ Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.

WHO Region of the Americas: Antigua and Barbuda, Argentina, Bahamas, Barbados, Belize, Bolivia (Plurinational State of), Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, United States of America, Uruguay, Venezuela (Bolivarian Republic of).

WHO Eastern Mediterranean Region: Afghanistan, Bahrain, Djibouti, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Kuwait, Lebanon, Libya, Morocco, Oman, Pakistan, Qatar, Saudi Arabia, Somalia, Sudan, Syrian Arab Republic, Tunisia, United Arab Emirates, Yemen.

WHO European Region: Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Luxembourg, Malta, Monaco, Montenegro, Netherlands, Norway, Poland, Portugal, Republic of Moldova, Republic of North Macedonia, Romania, Russian Federation, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Tajikistan, Turkey, Turkmenistan, Ukraine, United Kingdom of Great Britain and Northern Ireland, Uzbekistan.

WHO South-East Asia Region: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste.

WHO Western Pacific Region: Australia, Brunei Darussalam, Cambodia, China, Cook Islands, Fiji, Japan, Kiribati, Lao People's Democratic Republic, Malaysia, Marshall Islands, Micronesia (Federated States of), Mongolia, Nauru, New Zealand, Niue, Palau, Papua New Guinea, Philippines, Republic of Korea, Samoa, Singapore, Solomon Islands, Tonga, Tuvalu, Vanuatu, Viet Nam.

¹ Not a WHO Member State at the time of distribution of the second survey questionnaire and therefore not included in the 2012 data figures. In 1999 and 2005 there were 191 WHO Member States, the number became 193 in 2012 and currently, as of 2018, there are 194 WHO Member States.

EXECUTIVE SUMMARY

WHO's 13th General Programme of Work (GPW13) came into effect this year for 2019–2023. As a strategic priority, GPW13 sets an overarching goal of reaching 3 billion more people, to move towards Sustainable Development Goal 3 (SDG 3) – *ensuring healthy lives and promoting well-being for all at all ages* – by achieving universal health coverage (UHC), addressing health emergencies and promoting healthier populations. Traditional and complementary medicine (T&CM) can make a significant contribution to the goal of UHC by being included in the provision of essential health services.

Improving equitable access to safe, quality and effective T&CM services can potentially meet communities' needs and build sustainable and culturally sensitive primary health care. The Declaration of Astana, adopted at the Global Conference on Primary Health Care in October 2018, made clear that the success of primary health care will be driven by applying scientific as well as traditional knowledge, and extending access to a range of health care services, which include traditional medicines.

In 2005, WHO published a report on national policies on traditional medicine and regulation of herbal medicines, based on the first global survey on T&CM. To identify global trends and the current situation in the area of T&CM, WHO conducted a second global survey during 2010–2012 (second survey), and a further survey during 2016–2018 (update survey). This made it possible to compare the information and data in the two most recent surveys with those in the first global survey, and thus identify global trends.

Globally, the landscape for T&CM has been improving consistently. In line with the WHO Traditional Medicine Strategy 2002–2005 and the WHO Traditional Medicine Strategy 2014–2023, and relevant World Health Assembly resolutions, Member States took steps between 2005 and 2018 to promote the safety, quality and effectiveness of T&CM. They also took steps for the appropriate integration of T&CM into health systems (particularly health services) by developing national policies, regulatory frameworks and strategic plans for T&CM products, practices and practitioners.

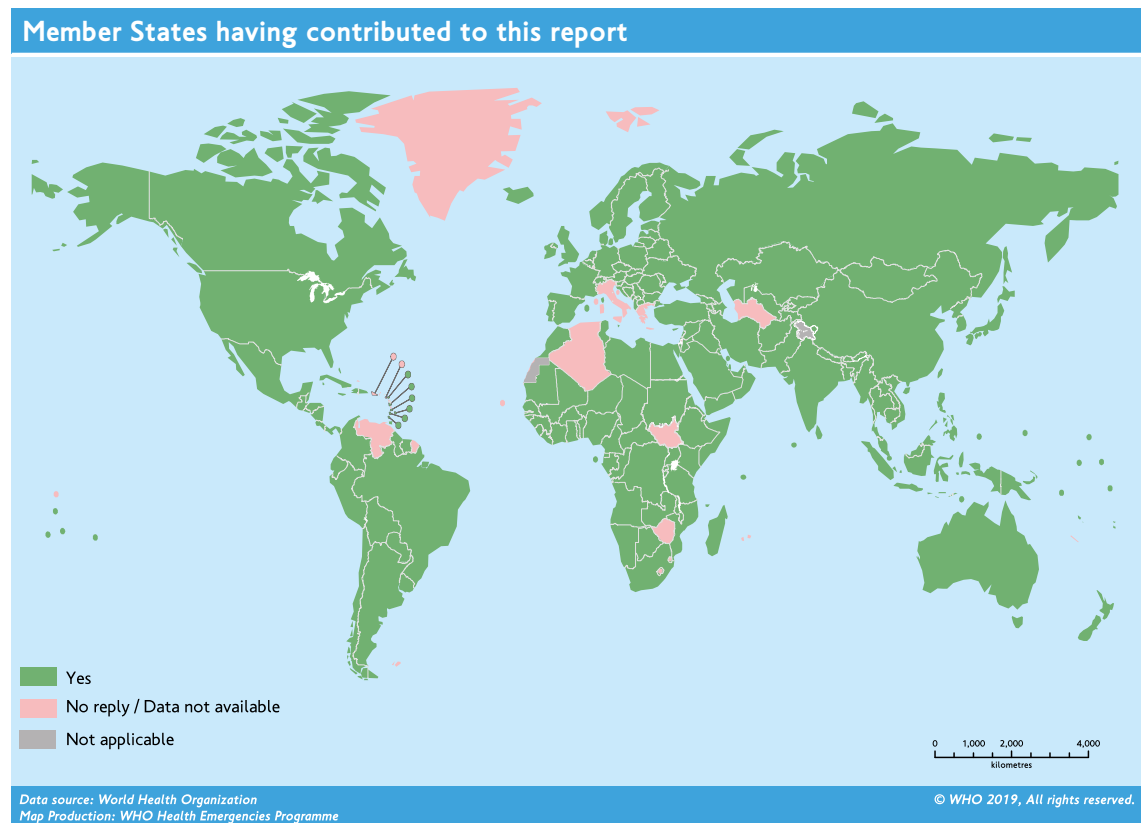
Based on current information, **88% Member States have acknowledged their use of T&CM which corresponds to 170 Member States**. These are the countries that have, for example, formally developed policies, laws, regulations, programmes and offices for T&CM, and the actual number of countries using T&CM is likely to be even higher.

This report represents a unique milestone.

- It is the most comprehensive report on T&CM, with 179¹ of the 194 Member States officially contributing information; thus, it addresses the challenge of lack of credible data and information in this field.
- It captures the three phases of progress made by Member States; that is, before and after the first WHO Traditional Medicine Strategy (1999–2005), from the first global survey to the second global survey (2005–2012) and from the second survey to the most recent update survey (2012–2018).
- It covers not only policy and regulation, but also products, practices and practitioners of T&CM.
- It is the most current and up-to-date report, based on information from most Member States across the six WHO regions.

¹ 179 represents the number of Member States for which WHO has information through an official response to at least one of the three WHO surveys. The 15 Member States that did not reply to any of the three surveys were Algeria, Cabo Verde, Eswatini, Greece, Italy, Lesotho, Luxembourg, Mauritius, Monaco, Saint Kitts and Nevis, San Marino, South Sudan, Turkmenistan, Venezuela (Bolivarian Republic of) and Zimbabwe.

The map below shows the 179 countries that have contributed to this report:



It is clear that the role of traditional medicine in meeting the health needs of populations has come to the fore, and this report is another call to harness its potential to contribute to UHC and the SDGs through primary health care.

Edward Kelley
Director
Department of Service Delivery and Safety
World Health Organization

INTRODUCTION

Background and methodology

This report is structured in five parts: national framework for traditional and complementary medicine (T&CM); product regulation; practices and practitioners; the challenges faced by countries; and, finally, the country profiles. Apart from the section on practices and practitioners, the report is consistent with the format of the report of the first global survey in order to provide a useful comparison. The section on practices and practitioners, which covers providers, education and health insurance, is a new section incorporated to reflect the emerging trends in T&CM and to gather new information regarding these topics at a national level. All new information received has been incorporated into individual country profiles and data graphs.

The report captures the **three phases of progress** made by Member States; that is, before and after the first WHO Traditional Medicine Strategy (1999–2005), from the first global survey to the second global survey (2005–2012) and from the second survey to the most recent timeline (2012–2018).

Information sources

Information came from three main sources: the first and second WHO global surveys, the most recent update survey and additional sources, as outlined below.

First and second WHO global surveys on T&CM

A total of 141 countries replied to the first survey in 2005. Thanks to collaboration with the WHO regional offices, responses to the second global survey in 2012 were received from 133 countries, representing 69% of the 193 Member States of WHO at that time.¹ Of these 133 countries, 29 were responding for the first time. Hence, the data set (N) for the 2012 figure in most of the data graphs is 170 countries (i.e. the 141 responding to the first survey plus the 29 responding for the first time in the second survey). Where specified (e.g. in many of the graphs in Section 3), the data set is limited to respondents to the second survey, because these topics were not part of the first survey.

The response to the second survey was geographically uniform, with more than 50% of Member States across all six WHO regions participating. There was also a response of more than 90% from Member States in the WHO South-East Asia Region, and of more than 80% from Member States in the regions of the Eastern Mediterranean and the Western Pacific.

Update survey

During the compilation and verification of the second survey data, some of the Member States expressed a desire to update their information and showcase recent progress in their T&CM landscapes. Cognisant of the evolving global situation regarding T&CM, and to provide Member States an opportunity to share any significant updates, we designed a short and concise questionnaire comprising 13 key T&CM parameters that focused on the indicators for monitoring the WHO Traditional Medicine Strategy 2014–2023, to facilitate the mid-term review of the implementation of the strategy worldwide.² The questionnaire was shared with regional focal points for traditional medicine (TM), to further communicate with Member States and invite a response on a voluntary basis. Member States were asked to share their most up-to-date information.

Of the 194 Member States, 61 countries (across six WHO regions) provided a voluntary response to the update survey, and nine of these provided information for the first time (i.e. they had not replied to the first or second surveys). However, there may be Member States in which the T&CM situation has changed significantly, that did not respond to the update survey.

¹ The text of the second survey is given in Annex 1, and a regional breakdown of countries responding to that survey is given in Annex 2.

² See the text of the update survey in Annex 3.

Additional sources

In this report the data from the surveys were supplemented by information from WHO global and regional reports, WHO regional and country offices and WHO collaborating centres for traditional medicine. Additional information was also obtained during data verification through national health authorities, for example.

For five Member States¹ that did not officially respond to any of the three surveys, information on select data points was provided by the WHO regional offices and official records, and this information has been added to the figure and data set for 2018. In addition, the territories of Bermuda, Cayman Islands, and Turks and Caicos Islands, which are not WHO Member States, replied to the update survey; their information is shared under the country profiles section.

Some key findings

As at 2018, besides the national policies and regulations on T&CM that had been developed in more and more Member States, the infrastructure on governance of T&CM at national level had also been significantly improved (e.g. 107 Member States had a national office for TM and 75 Member States had a national research institute). A total of 34 Member States across the six WHO regions included traditional or herbal medicines in their national essential medicines lists (NEMLs), and many Member States, such as Ghana, had a separate list of essential herbal medicines. Also, the indicator figures for national policy and regulation on T&CM had quickly caught up with the figure for regulation on herbal medicines.

Progress as at 2018, was broadly based across all six WHO regions.

- **Within the WHO African Region**, between 2005 and 2018, significant progress was made in the development of national policies, laws and regulations and national programmes for T&CM. The region fares significantly better than the global scenario in most of the measurement indicators of T&CM, apart from regulation and registration of herbal medicines, which remain a challenge for the region.
- **In the WHO Region of the Americas**, there was an increase in the number of Member States developing national policies, programmes, laws and regulations, and offices for T&CM since 2005. The region lagged slightly behind the global scenario for all indicators, but it is anticipated that T&CM will be steadily recognized as a valuable contributor to health care.
- **In the WHO Eastern Mediterranean Region**, marked progress was seen in the area of regulation and registration of herbal medicines since 2005 (where the region fares better than the global scenario). Of the 21 countries in this region, nine reported having a national policy for T&CM, and 12 countries reported laws and regulations governing T&CM.
- **In the WHO European Region**, there was a marked increase in the number of Member States with a registration system and regulation for herbal medicines, with 45 of the 53 Member States reporting having both. However, indicators such as national policies, offices, programmes and research institutes for T&CM lag significantly behind the global averages.
- **The WHO South-East Asia Region**, which has several historical systems of traditional medicine in the region and a strong policy focus, fared better than the global averages on all indicators. Of the 11 Member States in the region, 10 reported national policies, programmes, office, expert committee, regulation and registration of herbal medicines.
- **The WHO Western Pacific Region** had a strong policy focus, with 17 of the 27 Member States reporting a national policy for T&CM. The region lags behind the global scenario in registration and regulation of herbal medicines but is comparable on all other indicators.

In the second survey, Member States were also asked about the major difficulties they faced regarding regulatory issues related to the practice of T&CM. Of the 133 respondent Member States, 99 quoted **lack of research data as their top challenge**. This was followed by lack of financial support for research on T&CM, lack of mechanisms to monitor safety of T&CM practices, and lack of education and training for T&CM providers (among other challenges).

¹ Cabo Verde, Italy, Lesotho, Mauritius and Zimbabwe.

To provide continuous support in the future, WHO also asked Member States to define their assistance needs. The responses included requests for support and general technical guidance for research and evaluation of T&CM, information sharing on regulatory issues, workshops on national capacity-building, and provision of research databases.

Points to be noted

In mid-2017, WHO's Traditional and Complementary Medicine unit was renamed to include the term "Integrative Medicine", to cover the integrative approaches of both T&CM and conventional medicine regarding policy, knowledge and practice. The unit is now officially referred to as **Traditional, Complementary and Integrative Medicine (TCI)**. However, the primary sources for this report are the second survey and the update survey, both of which focused primarily on T&CM; hence, this report is titled the *WHO global report on traditional and complementary medicine 2019*. Currently, a separate project is underway to define and understand "integration as well as integrative medicine", and to provide guidance to Member States on the criteria and elements of best practices for integrating T&CM into national health systems, if or when they decide to do so.

For a few indicators in the report, the figures for 2012 are not exactly the same with the numbers stated in the WHO Traditional Medicine Strategy 2014–2023. There are several reasons for this. During the verification of the data, some discrepancies were found in the replies to the second survey questionnaire; to resolve these issues, a detailed verification exercise was undertaken during 2015–2018 through respondents' national health authorities. Also, in some Member States, the situation with respect to certain T&CM indicators had changed since the first survey, where the response had previously been in the affirmative. Wherever a respondent has indicated such changes, the changes have been mentioned in that respondent's country profile. For the remaining respondents, it was assumed that a Member State's affirmative response to an indicator in the first survey had not changed by the time of the second survey. Taking all this into account, some data needed to be adjusted; the 2018 data shown in figures and tables are comprehensive, and include, as far as possible, all the Member States that replied affirmatively to an indicator.

Every effort was made to ensure the clarity and accuracy of the data used in the analysis and presented here. WHO welcomes any updates and clarifications and plans to continue to update and expand the information from Member States.

With this report, WHO has taken a further step towards an increased understanding of the T&CM landscape at global and national levels. WHO remains committed to supporting Member States in developing proactive policies and implementing action plans that will strengthen the role T&CM plays in keeping populations healthy.



Zhang Qi

Coordinator

Unit of Traditional, Complementary and Integrative Medicine
Department of Service Delivery and Safety
World Health Organization

1. NATIONAL FRAMEWORK FOR TRADITIONAL AND COMPLEMENTARY MEDICINE

This chapter outlines the various parts of national approaches to traditional and complementary medicine (T&CM); that is, national policy, laws, office, expert committee, research institute, government and public research funding, and a plan for integrating T&CM into national health service delivery.

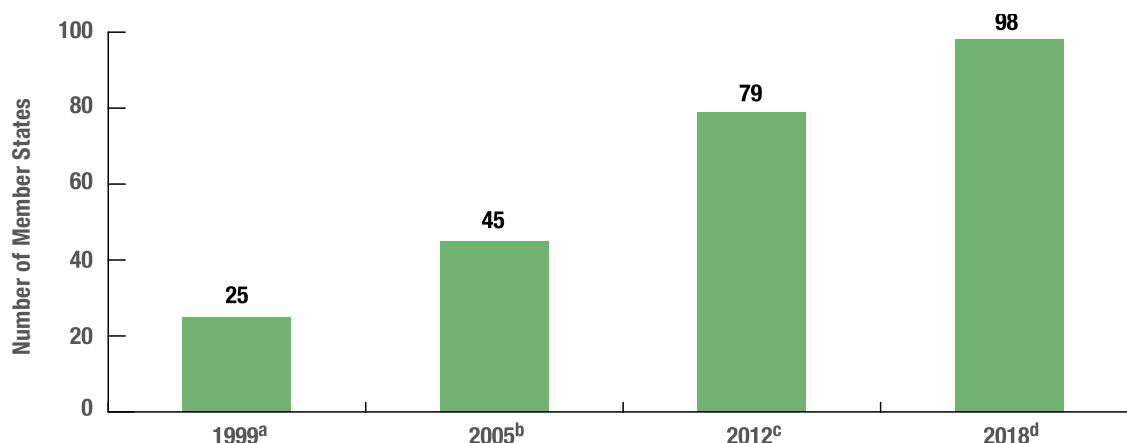
1.1 National policy on T&CM

A national policy on T&CM will contain guiding principles on policy, planning or future direction of T&CM, and will be created by the relevant government authority of the country. It may be a policy designed exclusively for T&CM, or it may be integrated into other national policies such as the national medicines policy or trade policy.

In general, the national policy should include a definition of the role of the government in the development of T&CM in the health care delivery system. Safety and efficacy may be stated as guiding principles, and the policy may also include vision and mission statements, as well as goals and objectives.¹

The trend in the development of national policies on T&CM among Member States from 1999 to 2018 is shown in Fig. 1.1. There was a consistent increase in the number of Member States having a national policy on T&CM, with the number almost doubling between 1999 and 2005, and then doubling again between 2005 and 2018. By 2018, a total of 98 countries, more than 50% of the 194 Member States, had a national policy on T&CM.

Fig. 1.1. Growth in the number of Member States with a national policy on T&CM, 1999–2018



Sources:

^a WHO Traditional Medicine Strategy 2002–2005.

^b National policy on traditional medicine and regulation of herbal medicines – Report of a WHO global survey (N=141).

^c Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141 + 29, the 29 being respondents exclusive to the second survey).

^d Includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018).

¹ For the guidelines provided to Member States on how to define national policy, see the text of the second survey in Annex 1.

In the second survey, those Member States that reported a national policy were asked whether the policy was an exclusive policy for T&CM or was integrated into another national policy (Fig. 1.2). Of the 133 respondents, 65 Member States provided this information, and many of these countries (e.g. Lao People's Democratic Republic, Thailand and Ukraine) selected multiple options.

In cases where Member States reported that the T&CM policy was integrated with another policy, the T&CM policy generally formed part of the national drug, medicine or health policy.

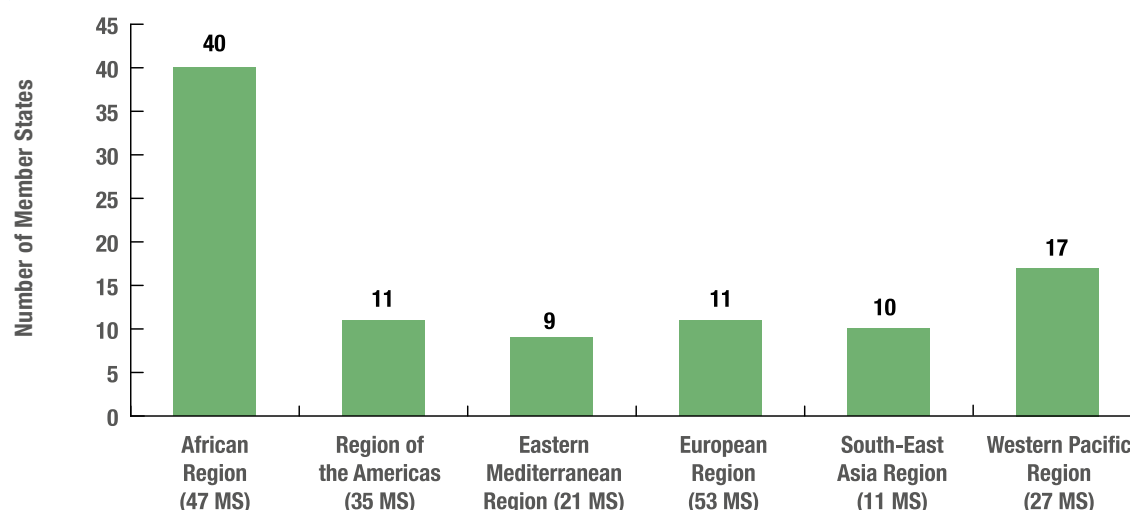
Under "Others", some Member States mentioned inclusion of T&CM policy in primary health care programmes (e.g. in Sudan), but others included T&CM in different types of programmes (e.g. in Canada, T&CM is integrated into the country's "Policy Pathway to Licensing").

Fig. 1.2. Type of national policies reported by Member States in the second global survey, 2012



By 2018, more than 85% of the total Member States in the WHO African Region and South-East Asia Region reported having a national policy for T&CM (Fig. 1.3). In the WHO Western Pacific Region and the Eastern Mediterranean Region, 63% and 43% of Member States, respectively, had in place a national policy framework, while in the WHO Region of the Americas and the European Region the percentages were 31% and 21%, respectively.

Fig. 1.3. Distribution by WHO region of Member States with national policies on T&CM, as at 2018

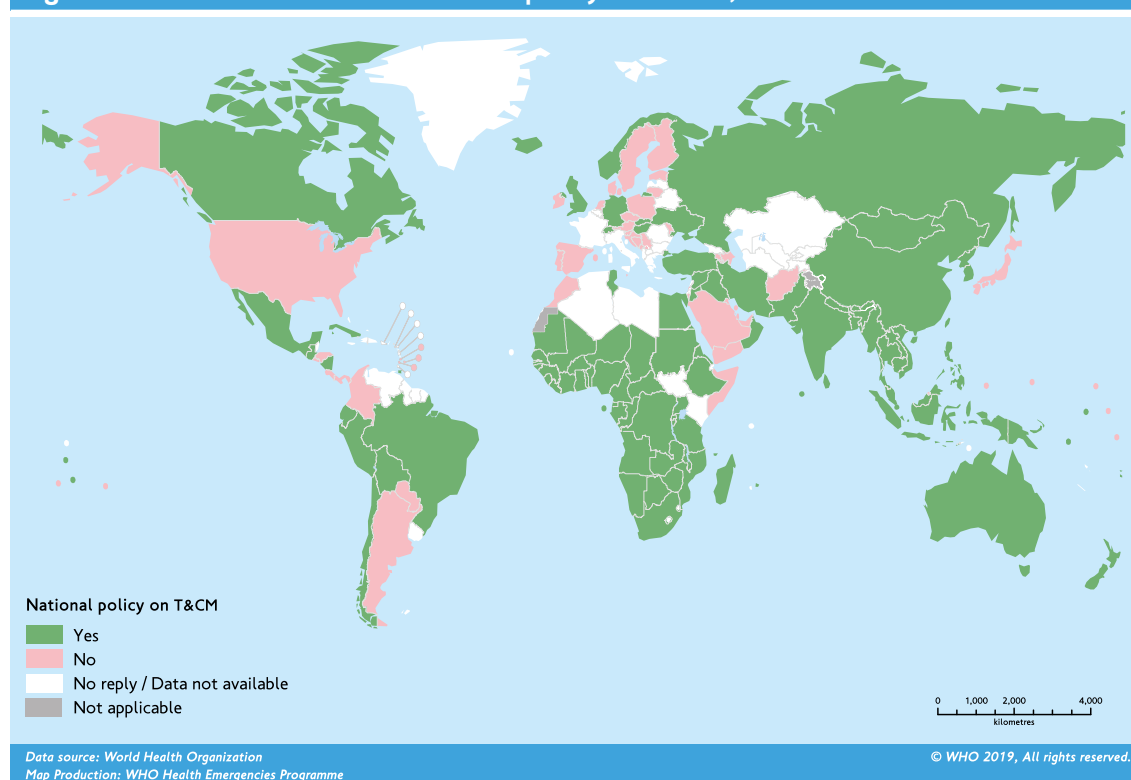


MS: Member States

Certain Member States that do not have a centralized health care system (e.g. the United States of America) replied that they did not have “one” national policy but had “several significant initiatives” taking place across the country, within specific health systems (e.g. the Veterans Administration in the United States).

Finally, Fig. 1.4 indicates those Member States with a national level policy for T&CM, those without and those that did not reply to either the question or the survey.

Fig. 1.4. Member States with a national policy on T&CM, 2018



1.2 National or state level laws or regulations on T&CM

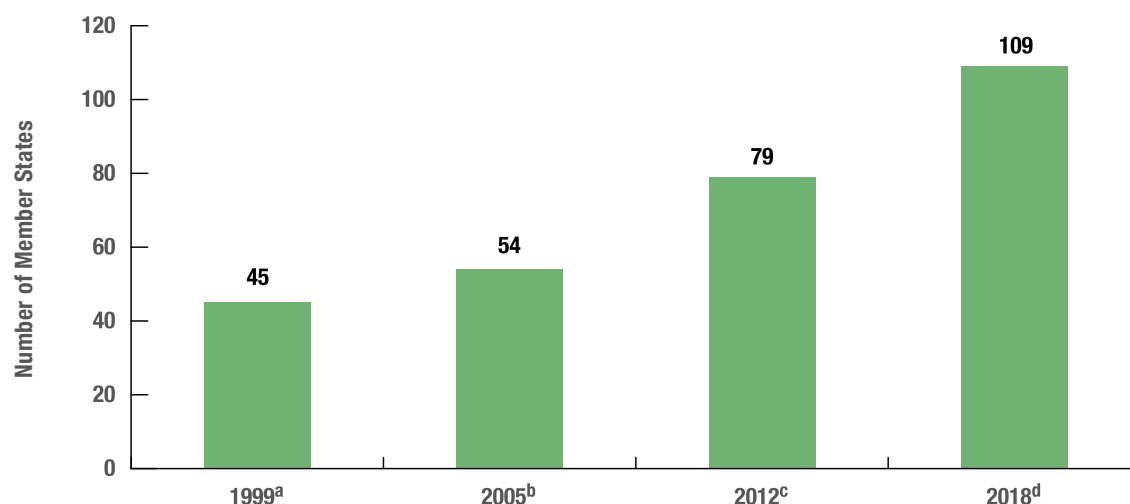
Member States were asked whether they had national laws or regulations on T&CM. The term “law” was defined as follows: “A set of rules concerning areas of T&CM. These rules are established by an authority, usually the government and advisory committees, and are enforced by the judicial and legal systems of that country. The laws can cover a wide range of topics such as education of professionals, licensing of providers or manufacturers, sale of herbal medicines, and so forth”.¹ The term “regulation” was defined as “A principle, rule or law designed to control or govern conduct”.² In the context of T&CM, regulation means a set of rules specifically governing the conduct of the wide range of topics related to T&CM.

The number of countries with a legal and regulatory framework for T&CM has increased gradually since 1999 (Fig. 1.5).

¹ See the text of the second survey in Annex 1.

² See the text of the second survey in Annex 1.

Fig. 1.5. Growth in the number of Member States with national or state level laws or regulations for T&CM, 1999–2018

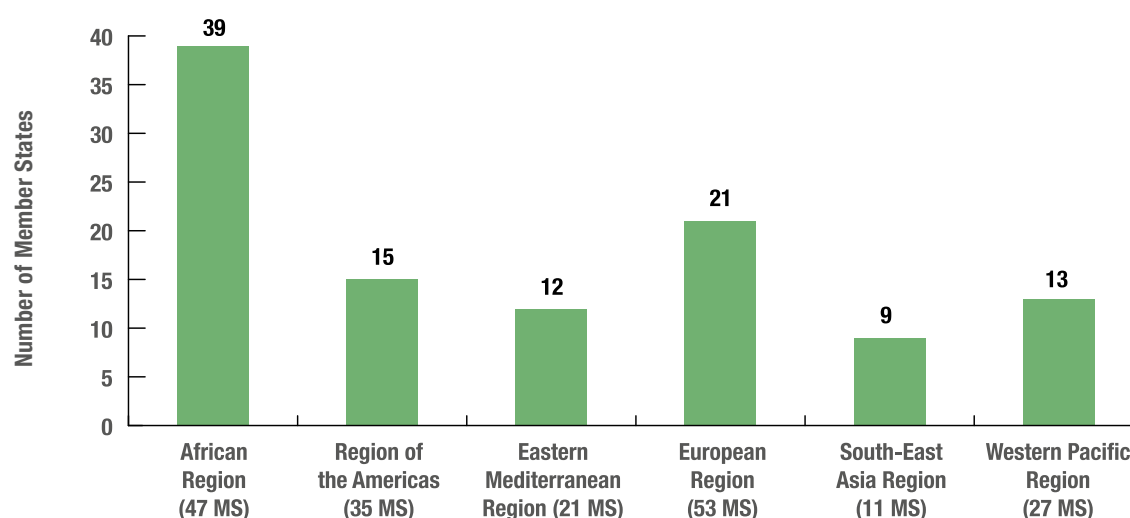


Sources: As for Fig. 1.1.

As at 2018, 109 Member States reported the presence of a legal or regulatory framework for T&CM. In many Member States, the national laws and regulations for T&CM are integrated into the national drug or medicine laws (similar to integration of national policy). However, many countries have an exclusive framework for T&CM. In Colombia, for instance, Law 1164 (of 2007) “[b]y which provisions are made in the field of Human Talent in Health” dictates provisions on the practice of T&CM. These provisions are taken up by the regulation that defines the standards of quality of health services, and includes standards of human talent in health for medicines and alternative and complementary therapies (Resolution 2003 of 2014).

For countries such as Canada and the United States, the T&CM legal framework is the responsibility of state, provincial or territorial jurisdictions, and regulation varies from jurisdiction to jurisdiction.

Fig. 1.6. Distribution by WHO region of Member States with national or state level laws or regulations for T&CM, 2018

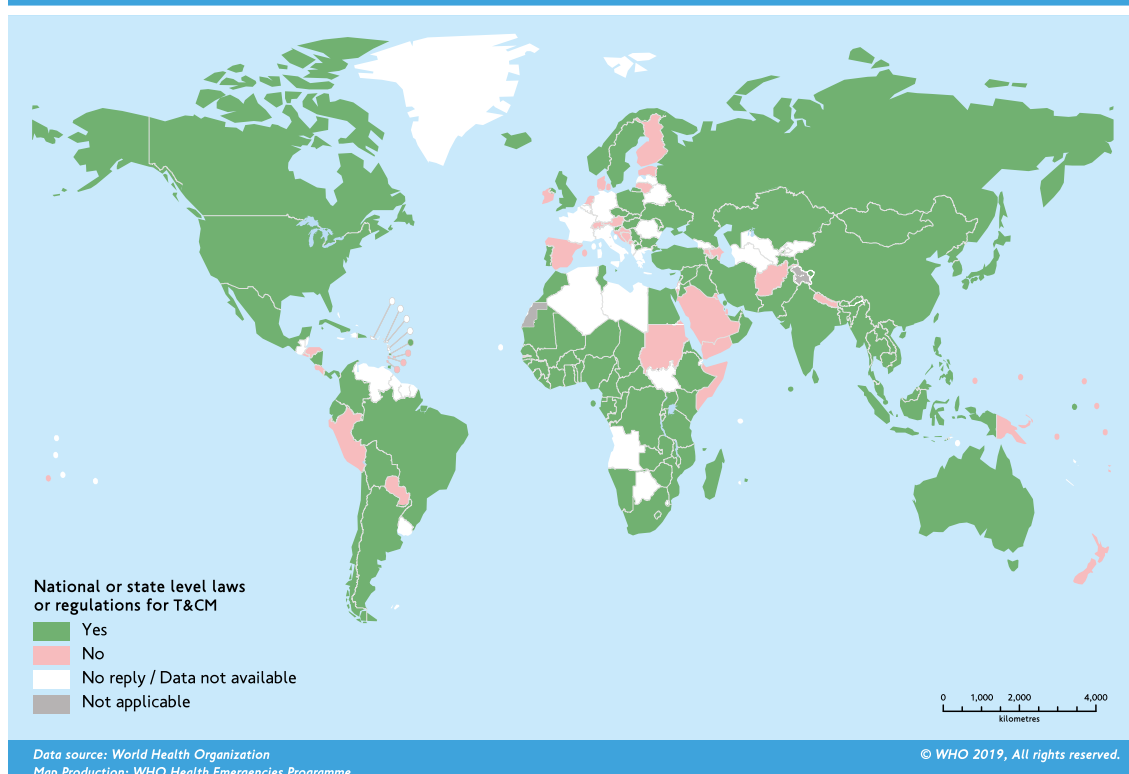


MS: Member States

The WHO African Region and South-East Asia Region reported the highest percentage (>80%) of countries with national or state level laws and regulations for T&CM. In the WHO Region of the Americas and the Eastern Mediterranean Region, the percentage of countries was 43% and 57%, respectively. Although the WHO European Region had the second highest number of countries with T&CM laws and regulations, as a percentage of the region this came to 40%. In the WHO Western Pacific Region, just under 50% of the region's Member States responded affirmatively.

Finally, Fig. 1.7 indicates those Member States with national or state level laws or regulations for T&CM, those without and those that did not reply to either the question or the survey.

Fig. 1.7. Member States with a national or state level laws or regulations for T&CM, 2018



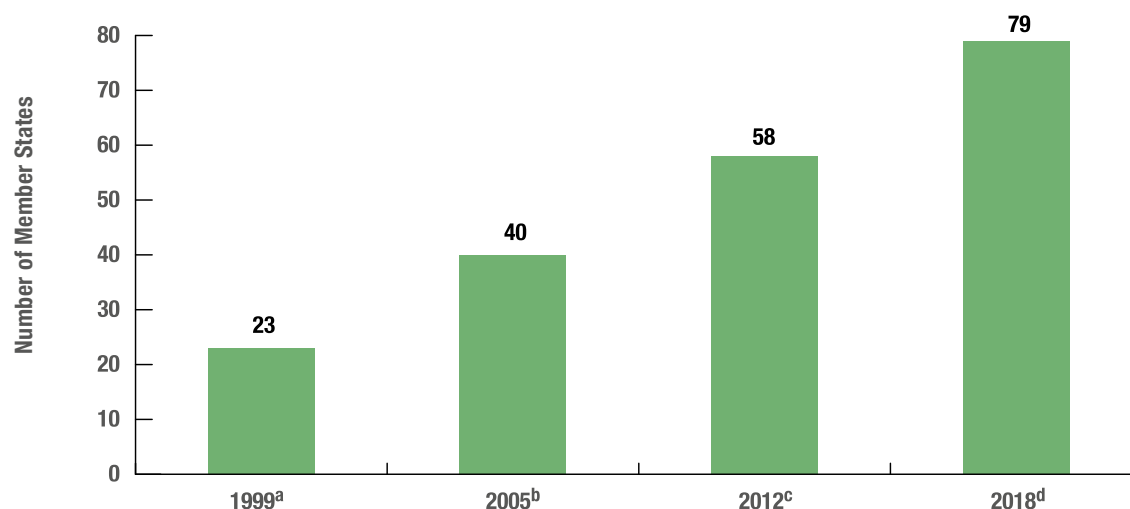
1.3 National programme on T&CM

Any programme performed on the local or national level by the ministry of health (MoH), by other ministries or by local government bodies, whose mandate is to take concrete action in order to achieve the objectives outlined in the national T&CM policy, can be defined as a national programme for T&CM.¹

Although many Member States reported having an exclusive programme for T&CM, some had integrated their T&CM programme into their long-term health plans or national strategic health plans. As shown in Fig. 1.8, as of 2018, 79 out of the 194 Member States (40%) reported having a national programme for T&CM.

¹ See the text of the second survey in Annex 1.

Fig. 1.8. Growth in the number of Member States with a national programme for T&CM, 1999–2018

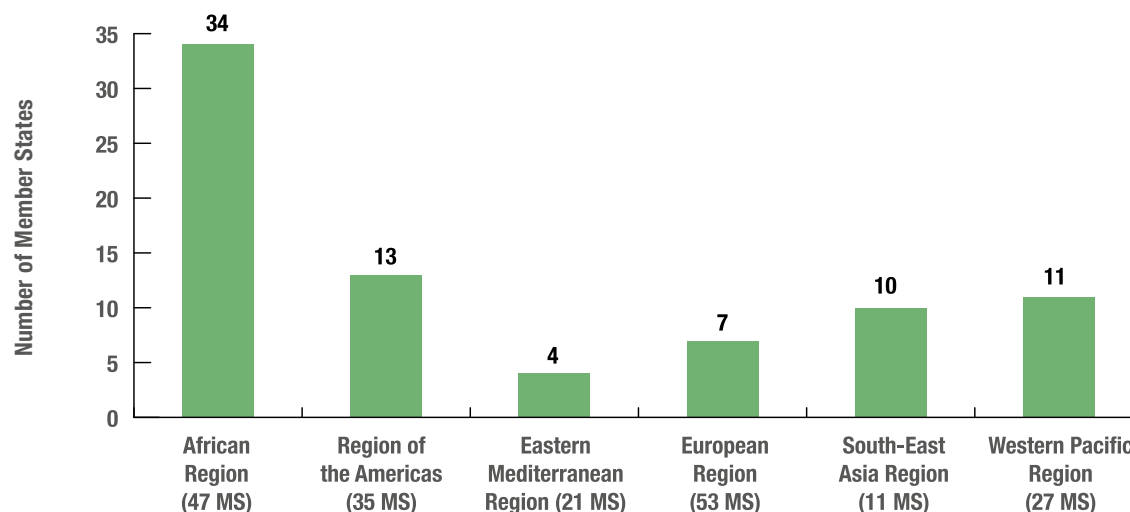


Sources: As for Fig. 1.1.

In Indonesia, for example, under the national programme for T&CM, the Center of Traditional Medicine Development (SP3T) has implemented traditional medicine (TM) practice at 13 provinces since 1995 and complementary medicine (CM) practices were introduced in 12 pilot hospitals in 2010.

Fig. 1.9 shows how Member States with a national programme for T&CM are distributed among the WHO regions.

Fig. 1.9. Distribution by WHO region of Member States with a national programme for T&CM, 2018

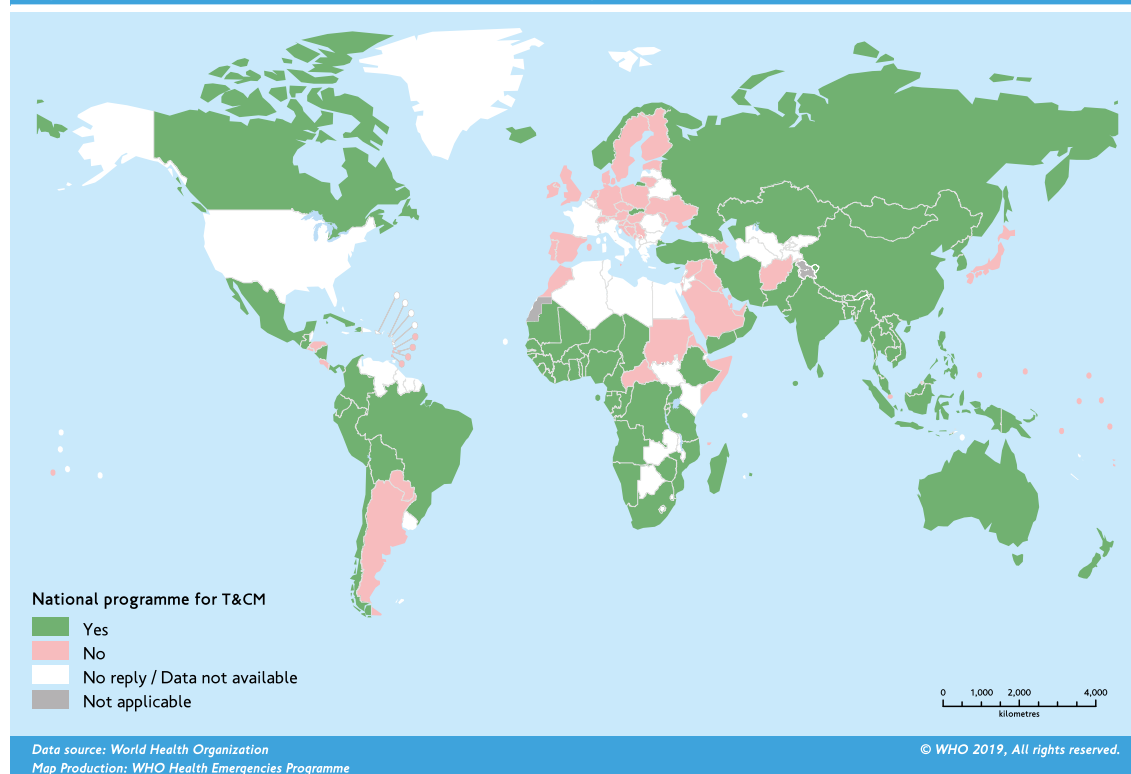


MS: Member States

As a region, South-East Asia reported the highest percentage of countries (91%) with a national programme on T&CM, followed by the WHO African Region (72%), Western Pacific Region (41%), Region of the Americas (37%), Eastern Mediterranean Region (19%) and European Region (13%).

Finally, Fig. 1.10 indicates those Member States with a national programme for T&CM, those without and those that did not reply to either the question or the survey.

Fig. 1.10. Member States with a national programme for T&CM, 2018



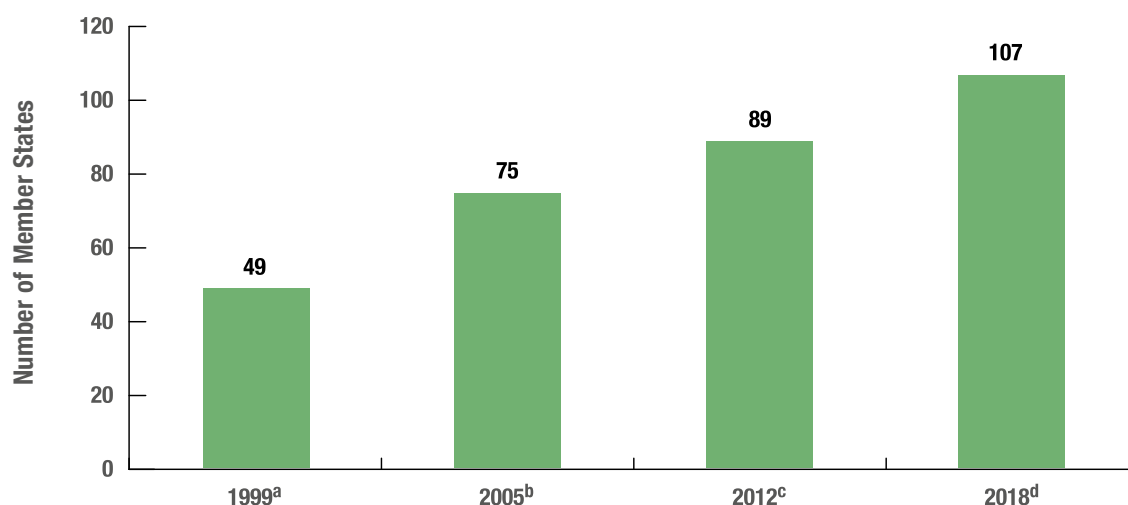
1.4 National office on T&CM

Any government-sponsored office that is officially mandated and in charge of issues related to T&CM can be defined as a national office for T&CM. This office is usually located in the MoH, or is part of other ministries or government authorities.¹

As at 2018, 107 countries (55%) of all Member States reported the presence of a national office for T&CM (Fig. 1.11).

¹ See the text of the second survey in Annex 1.

Fig. 1.11. Growth in the number of Member States with a national office for T&CM, 1999–2018

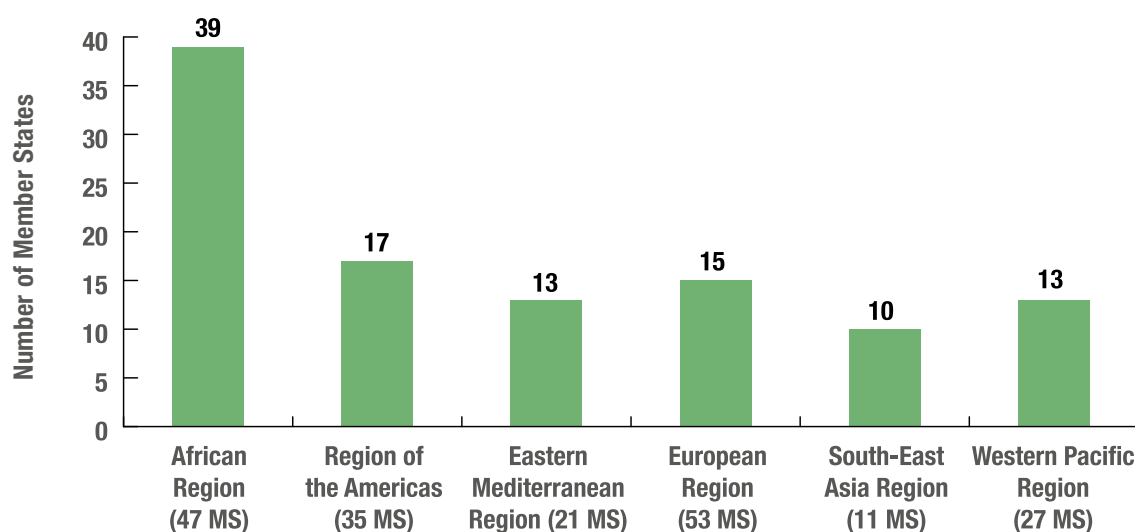


Sources: As for Fig. 1.1.

For most of the Member States, the national office for T&CM formed part of the MoH, which looked after all policy-related matters, whereas regulation of herbal medicines came under the purview of the food and drug regulatory authorities. For instance, in Peru, the National Institute of Health (*Instituto Nacional de Salud, Órgano desconcentrado del ministerio de Salud*), which is a decentralized agency of the MoH, serves as the national office for T&CM; in Indonesia, the National Agency of Drug and Food Control serves that role.

Some Member States that reported not having a designated national office for T&CM as such (e.g. New Zealand) have national oversight functions within the MoH. More recently, in New Zealand a new national rongoa governance body – Te Kāhui Rongoā Trust – was established to protect, nurture and promote rongoa Māori in December 2011.

Fig. 1.12. Distribution by WHO region of Member States with a national office for T&CM, 2018



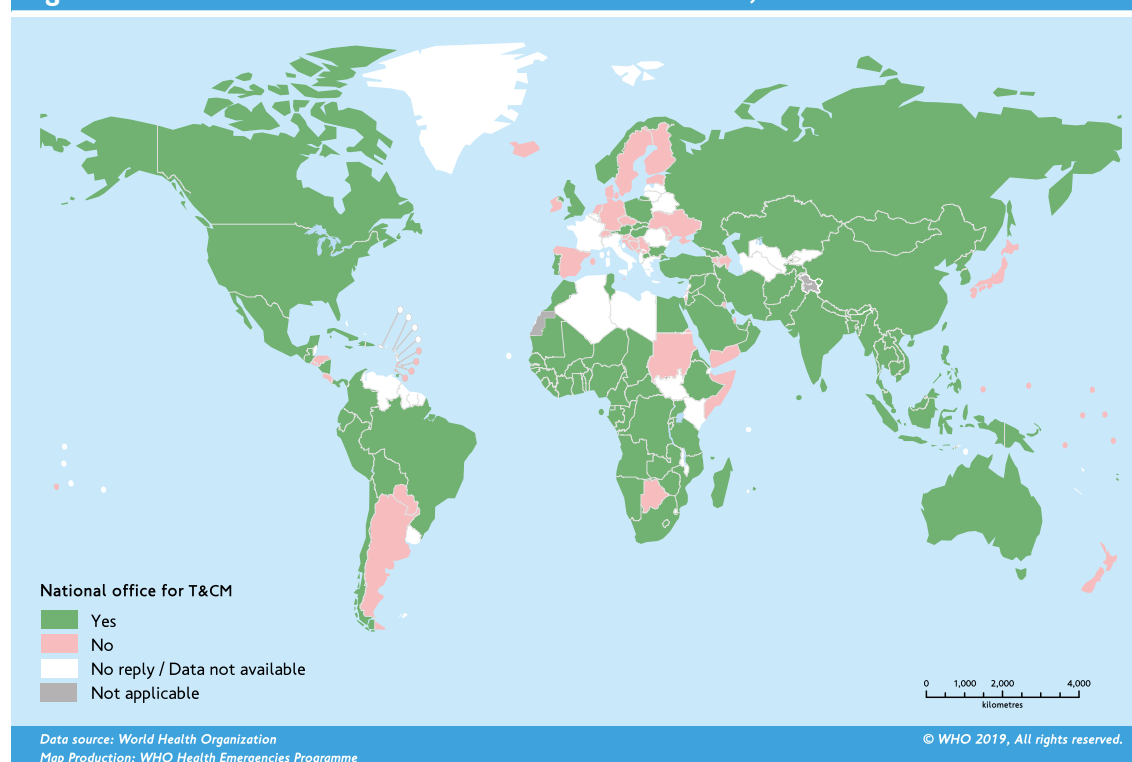
MS: Member States

Between 2001 and 2012, countries in the WHO African Region implemented the first regional strategy on TM, raising awareness and the profile of TM; developed national policies and regulatory frameworks for the practice of TM; and established and strengthened their institutional capacity. Countries also established national programmes, national offices and expert committees, in ministries of health, for the development of TM. By 2012, 39 countries in the region (1) had established national TM offices, as compared with 15 in 2000.

When considering the number of Member States with a national office for T&CM as a percentage of the total number of Member States in each WHO region, the South-East Asia Region reported the highest percentage (91%), followed by the African Region (83%), the Eastern Mediterranean Region (62%), the Region of the Americas (49%), the Western Pacific Region (48%) and the European Region (28%).

Finally, Fig. 1.13 indicates those Member States with a national office for T&CM, those without and those that did not reply to either the question or the survey.

Fig. 1.13. Member States with a national office for T&CM, 2018



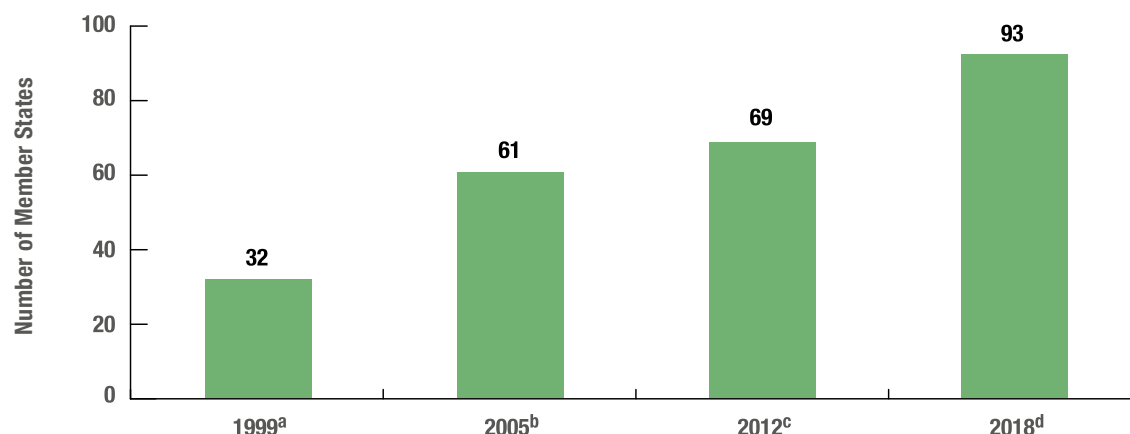
1.5 National expert committee on T&CM

Member States were asked to indicate whether they have an expert committee on T&CM. The working definition of an expert committee is a group of experts convened by the national government for the purpose of reviewing and making policy and technical recommendations (on T&CM topics).¹

Of the respondent Member States, 93 (48%) reported that such a group or committee existed in their country (Fig. 1.14). Other Member States (e.g. Burundi) reported that there was no formalized group of experts, but there were individual researchers and experts working in a private capacity. New Zealand reported that an expert committee, the Ministerial Expert Advisory Committee on Complementary and Alternative Health, had previously existed but was disestablished shortly after providing its final advice to the MoH in 2004. A new expert committee, the Natural Health and Supplementary Products Advisory Committee, will be established once the New Zealand Parliament passes the Natural Health and Supplementary Products Bill.

¹ See the text of the second survey in Annex 1.

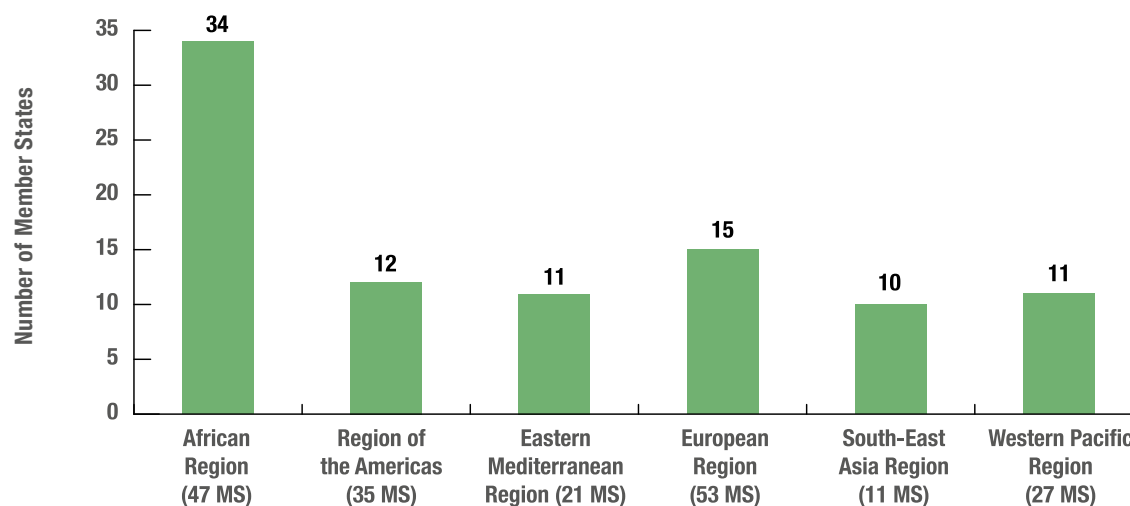
Fig. 1.14. Growth in the number of Member States with an expert committee for T&CM, 1999-2018



Sources: As for Fig. 1.1.

Fig. 1.15 shows the *number* of Member States with an expert committee for T&CM. As a *percentage* of Member States in each WHO region, the highest was the South-East Asia Region (91%), followed by the African Region (72%), the Eastern Mediterranean Region (52%), the Western Pacific Region (41%), the Region of the Americas (34%) and the European Region (28%).

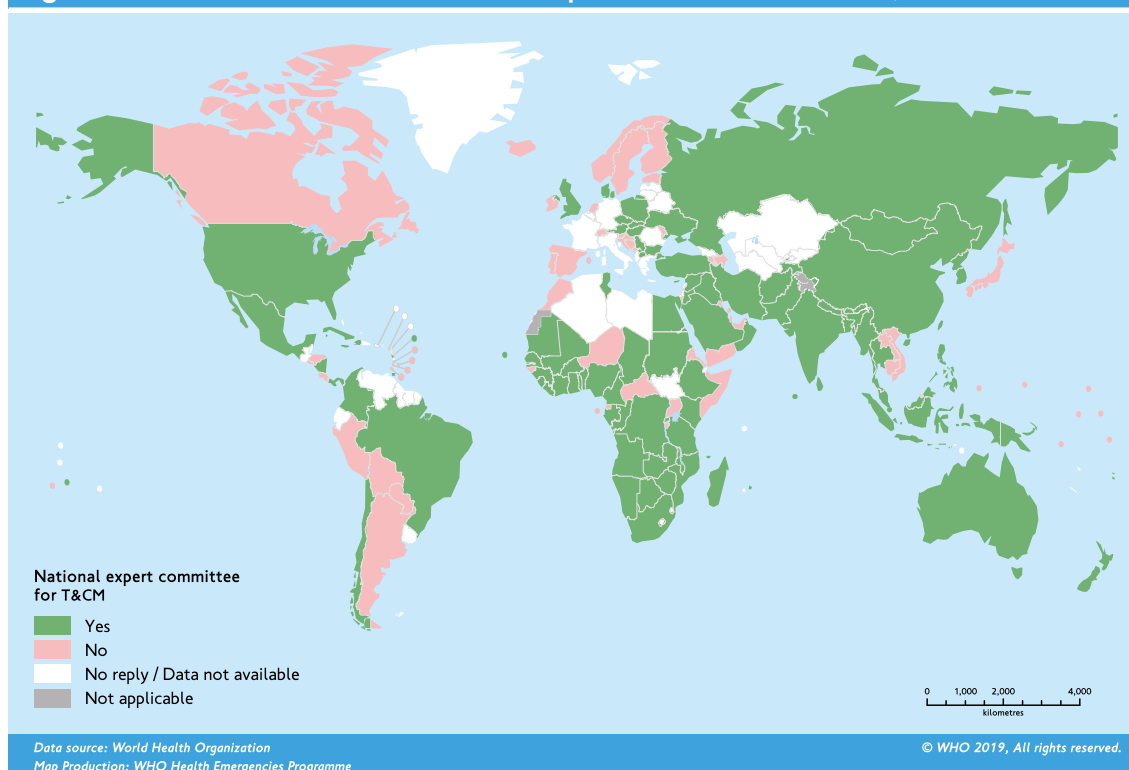
Fig. 1.15. Distribution by WHO region of Member States with an expert committee for T&CM, 2018



MS: Member States

Finally, Fig. 1.16 indicates those Member States with an expert committee for T&CM, those without and those that did not reply to either the question or the survey.

Fig. 1.16. Member States with a national expert committee for T&CM, 2018



1.6 National research institute for T&CM

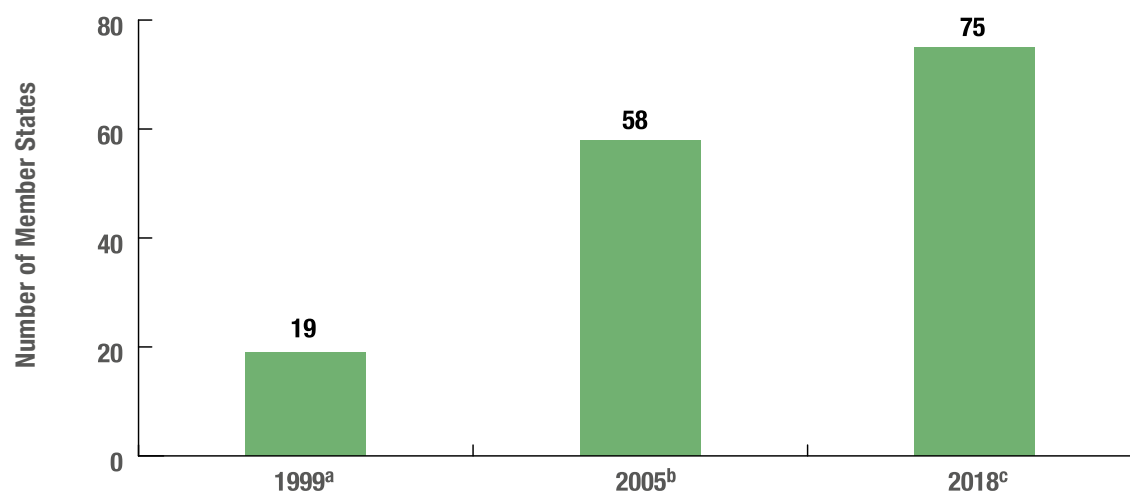
A national research institute for T&CM is one that is either fully or partially funded by the government.¹ As shown in Fig. 1.17, a total of 75 Member States (almost 40%) reported the presence of a national research institute for T&CM.

Many of the Member States reported that they did not have a national research institute for T&CM but that they had research policies relevant to T&CM research. For example, Canada's Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada.

In Saudi Arabia, the Medicinal Aromatic and Poisonous Plants Research Center (MAPPRC) was established in 1985 in the college of pharmacy in King Saud University, while in the United Kingdom, the Department of Health has a programme to develop research expertise in T&CM and to strengthen the evidence base. It also commissions periodic surveys of the use of T&CM in the United Kingdom.

¹ See the text of the second survey in Annex 1.

Fig. 1.17. Growth in the number of Member States with a national research institute for T&CM, 1999-2018



Sources:

^a WHO Traditional Medicine Strategy 2002–2005.

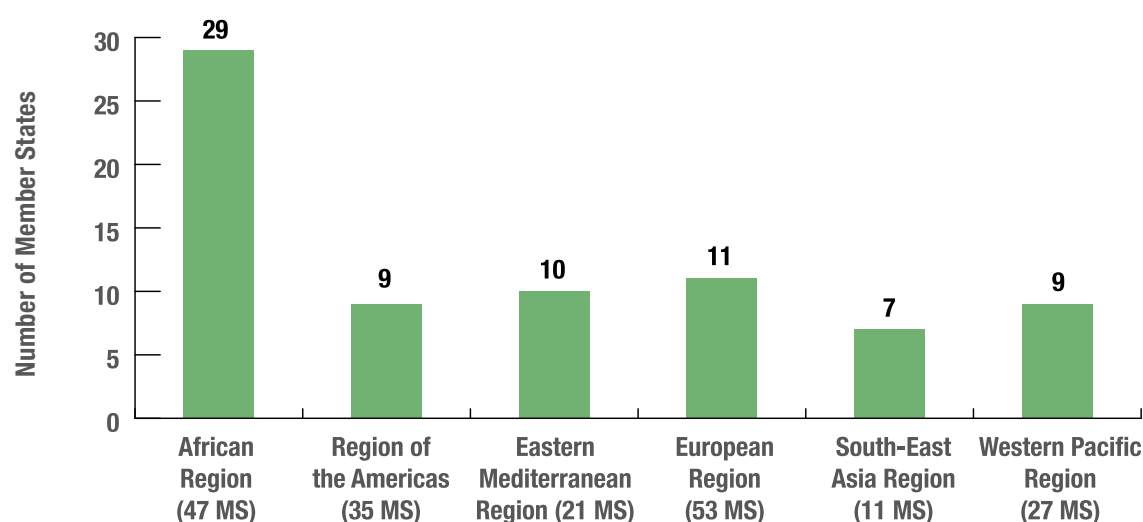
^b National policy on traditional medicine and regulation of herbal medicines – report of a WHO global survey (N=141).

^c Includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018).

Note: The national research institute figure for 2012 could not be verified conclusively, so it has not been shown here.

In India, four national institutes undertake research for T&CM. These are the Central Council for Research in Ayurveda and Siddha, the Central Council for Research in Unani Medicine, the Central Council for Research in Yoga and Naturopathy, and the Central Council for Research in Homeopathy.

Fig. 1.18. Distribution by WHO region of Member States with a national research institute for T&CM, 2018

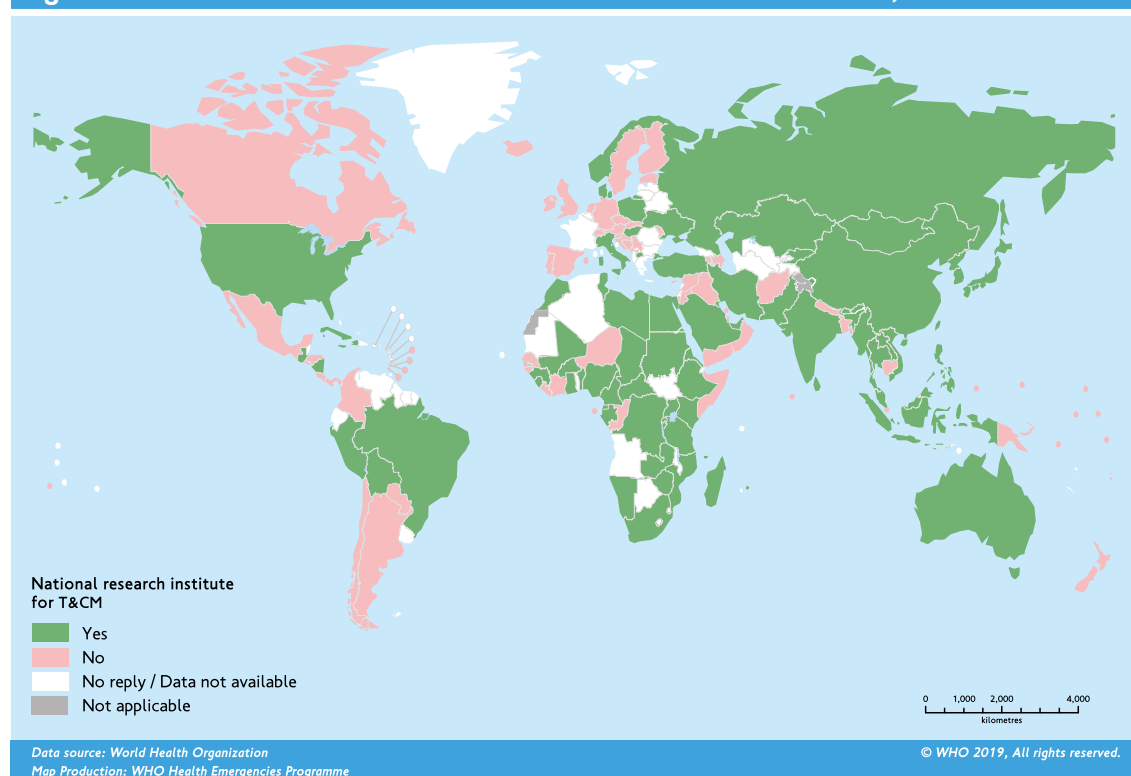


MS: Member States

Where Member States with a research institute for T&CM (see Fig. 1.18) were expressed as a percentage in each WHO region, the highest was the South-East Asia Region (64%), followed by the African Region (62%), the Eastern Mediterranean Region (48%), the Western Pacific Region (33%), the Region of the Americas (26%) and the European Region (21%). In comparison to other indicators, this is an area of progress for most Member States.

Finally, Fig. 1.19 indicates those Member States with a research institutes for T&CM, those without and those that did not reply to either the question or the survey.

Fig. 1.19. Member States with a national research institute for T&CM, 2018



1.7 Government and public research funding for T&CM

This section is a new question that was introduced in the update survey. As a result, the data set comprises only the 61 Member States, across six WHO regions, that provided a voluntary reply to the update survey.

One of the three strategic objectives of the WHO Traditional Medicine Strategy 2014–2023 is “To build the knowledge base for active management of T&CM through appropriate national policies”. As a result, a key priority identified for Member States is the strategic gathering, analysis and synthesis of data on T&CM use, and the development of a national research agenda.

In the update survey, Member States were asked whether they had government or public research funding for T&CM and, if so, what was the yearly allocation from 2010 to 2016. Of the 61 respondents, 12 Member States – Benin, Brazil, Chile, China, Cuba, Democratic People’s Republic of Korea, India, Mali, Oman, Peru, Thailand and the United States – replied in the affirmative and provided this information.

For instance, Chile indicated that between 2006 and 2013, the MoH allocated resources for the elaboration of basic epidemiological profiles by indigenous peoples and areas of coverage of its health services; there are currently 11 epidemiological profiles. In the United States – according to information from the National Institutes of Health (NIH) categorical spending under “Complementary and Alternative Medicine” – US\$ 366 million was allocated in 2016 (includes only funding figures for the NIH by fiscal year; i.e. October 1 through September 30).

1.8 National plan for integrating T&CM into national health service delivery

This section is another new question that was introduced in the update survey. As a result, the data set comprises only the 61 Member States that provided a voluntary reply to the update survey.

Another strategic objective of the WHO Traditional Medicine Strategy 2014–2023 is “To promote universal health coverage by integrating T&CM services into health care service delivery and self-health care”. Capitalizing on the potential contribution of T&CM to improve health services and health outcomes was identified as a strategic direction for this objective.

Member States were asked whether they had an existing national plan for integrating T&CM into their national health service delivery. Of the 61 respondent Member States, 13 replied in the affirmative; these were Benin, Bolivia (Plurinational State of), Brazil, Cuba, Democratic People’s Republic of Korea, Ghana, Guatemala, Haiti, India, Mali, Mexico, Nicaragua and Thailand.

Many other countries reported that they are in the process of developing guidelines to lead the harmonization of T&CM therapies within their health systems. For example, in Ecuador there is no explicit integration plan, but there is a law that provides for implementing alternative medicine in health services, and connecting with traditional (indigenous) medicines. Ecuador also has a normative framework related to regulation of the exercise of alternative therapies (2016); also, the country’s National Plan for Good Living 2013–2017 contemplated aspects related to the integration of T&CM, as part of other objectives and strategic lines.

In Chile, the MoH has been working (since 2015) on the development of a regulation that establishes the right of indigenous peoples to receive health care with cultural relevance (article 7 of Law 20 584). This regulation is intended to regulate health care provided in the public sector, and is in no way intended to regulate the health systems of indigenous or native peoples; rather, it recognizes, protects and respects the ancestral systems of healing and the religious, cultural and spiritual practices of these peoples. The proposed regulation was developed in consultation with indigenous peoples and is currently in administrative proceedings for implementation.

2. REGULATORY STATUS OF HERBAL MEDICINES

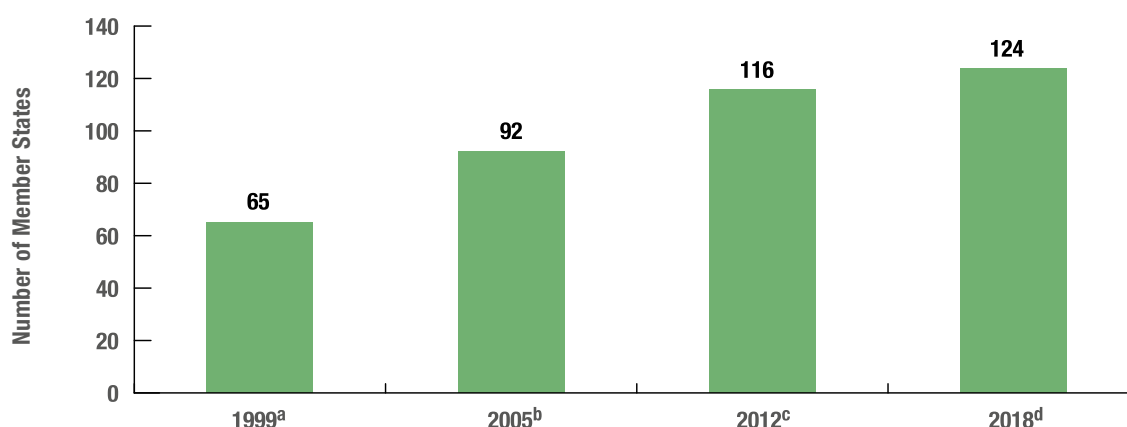
Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain, as active ingredients, parts of plants, other plant materials or combinations thereof. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials).

Conventional pharmaceuticals are medicinal drugs used in conventional systems of medicine with the intention to treat or prevent disease, or to restore, correct or modify physiological function.¹

2.1 Regulation of herbal medicines

Regulation of herbal medicines is defined as a principle, rule or law designed to control or govern manufacturers and producers of herbal medicines. For example, a regulation would state that herbal medicines must have been proven to be safe, effective and of good quality before reaching the public.¹

Fig. 2.1. Growth in the number of Member States with regulation of herbal medicines, 1999-2018



Sources:

^a WHO Traditional Medicine Strategy 2002–2005.

^b National policy on traditional medicine and regulation of herbal medicines – Report of a WHO global survey (N=141).

^c Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141 +29, the 29 being respondents exclusive to the second survey).

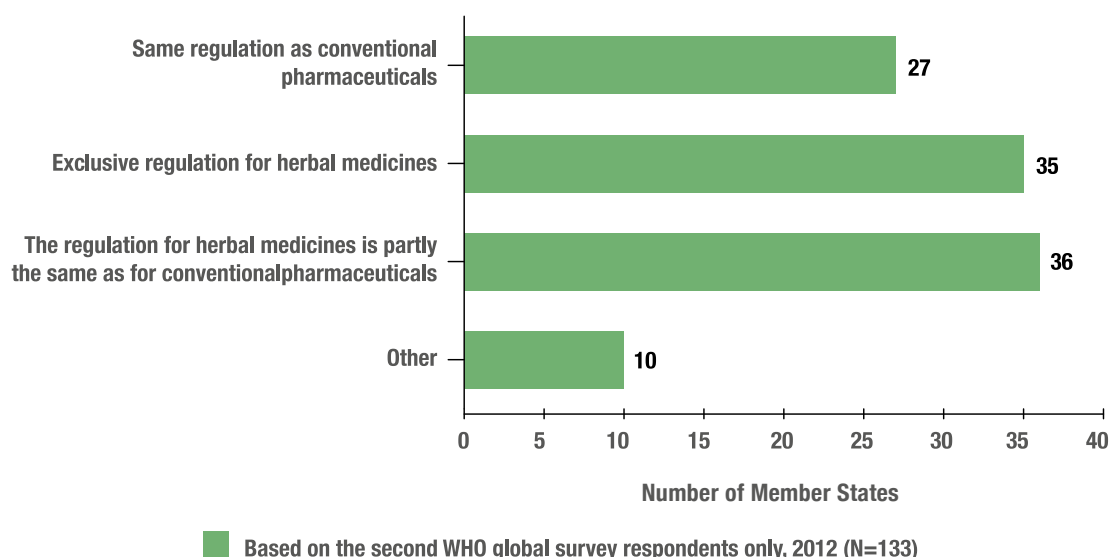
^d Includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018).

As of 2018, 124 Member States (64%) responded that they had laws or regulations on herbal medicines. In the second survey, those Member States that reported national regulation of herbal medicines were further asked about the type of regulation in place – specifically, whether herbal medicines regulation was the same as for conventional pharmaceuticals, or partly the same, or exclusive to herbal medicines, or of another type.

¹ See the text of the second survey in Annex 1.

A total of 90 out of the 133 respondent Member States provided this information, and many countries, such as Mozambique, selected multiple options.

Fig. 2.2. Type of herbal medicines regulation in Member States, 2012



An almost equal number of Member States responded that they had an exclusive regulation for herbal medicines or partly the same regulation as for conventional pharmaceuticals. This was followed by the third category of Member States that responded that they had the same regulation as for conventional pharmaceuticals.

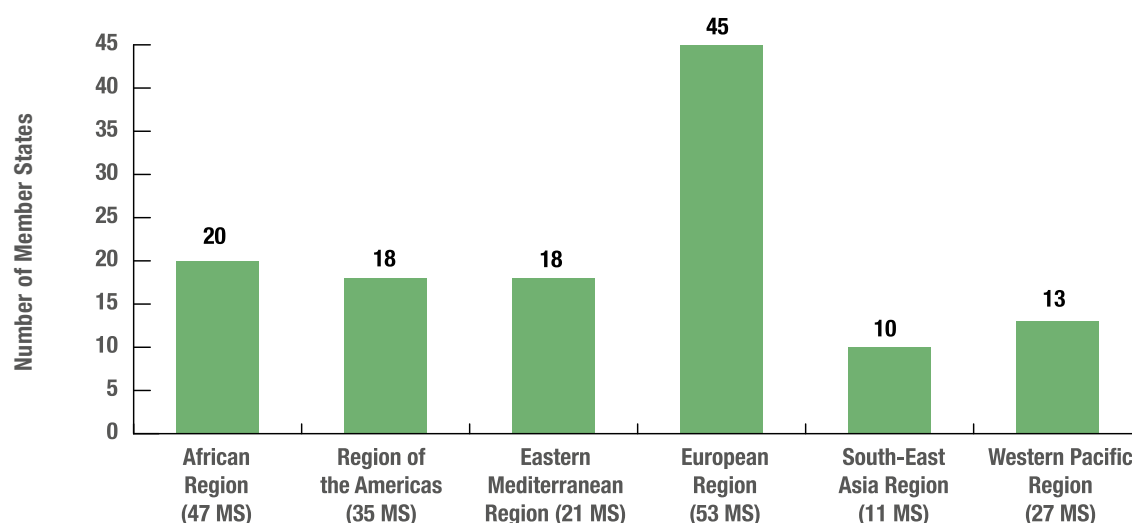
For some Member States that replied that they did not have a national regulation for herbal medicines (e.g. New Zealand), the situation is unique. Many “natural health products” (as they are termed in New Zealand) in oral dose forms are regulated as dietary supplements under the Dietary Supplements Regulations 1985 (under the Food Act 1981). Other natural health products are regulated as related products, medicines or herbal remedies under the Medicines Act of 1981. There is currently no specific regulatory framework for herbal medicines, complementary medicines or any other similar product category in New Zealand. Although these products are regulated through other frameworks, there is no separate category of “herbal medicines” as such.

South Africa reported that its regulation, which is in drafting stage, is partly the same as for conventional pharmaceuticals.

In Mexico, the document *Toward a pharmaceutical policy*, which includes a chapter on herbal medicines, was published officially in 2005. Herbal medicines regulation is partly the same as for conventional pharmaceuticals, as specified in the regulation of health commodities, together with allopathic and homeopathic medicines (Regulation of health products).

EU provisions apply to herbal medicinal products in Belgium through being embedded in Belgian legislation on medicinal products.

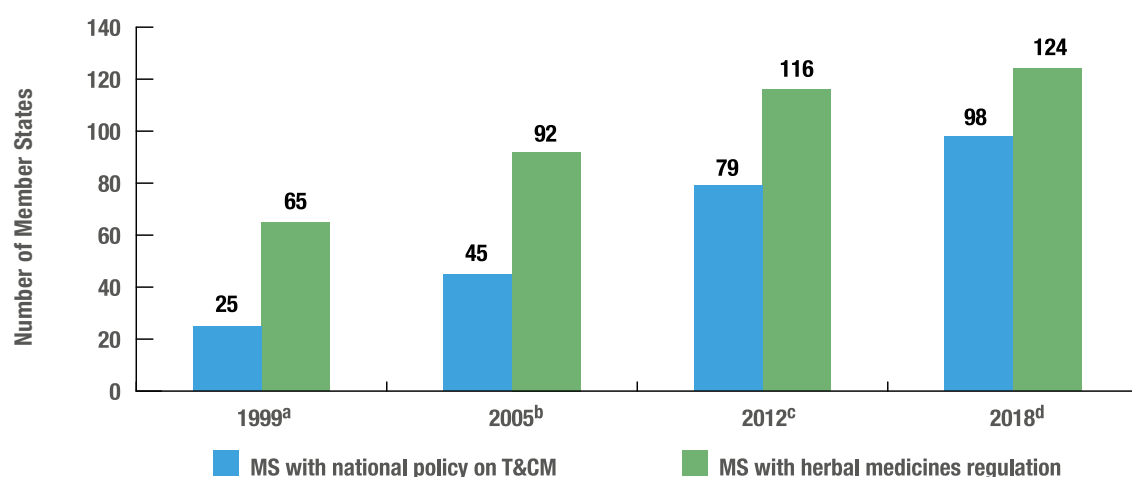
Fig. 2.3. Distribution by WHO region of Member States with herbal medicines regulation, 2018



MS: Member States

As shown in Fig. 2.3, the WHO European Region had the highest *number* of countries with a national regulation for herbal medicines, followed by the African Region, the Region of the Americas and the Eastern Mediterranean Region, the Western Pacific Region and then the South-East Asia Region. As a *percentage* of the region, the order was South-East Asia Region (91%), Eastern Mediterranean Region (86%), European Region (85%), Region of the Americas (51%), Western Pacific Region (48%) and African Region (43%).

Fig. 2.4. Number of respondent Member States with national policy on T&CM compared with number with herbal medicines regulation, 1999–2018



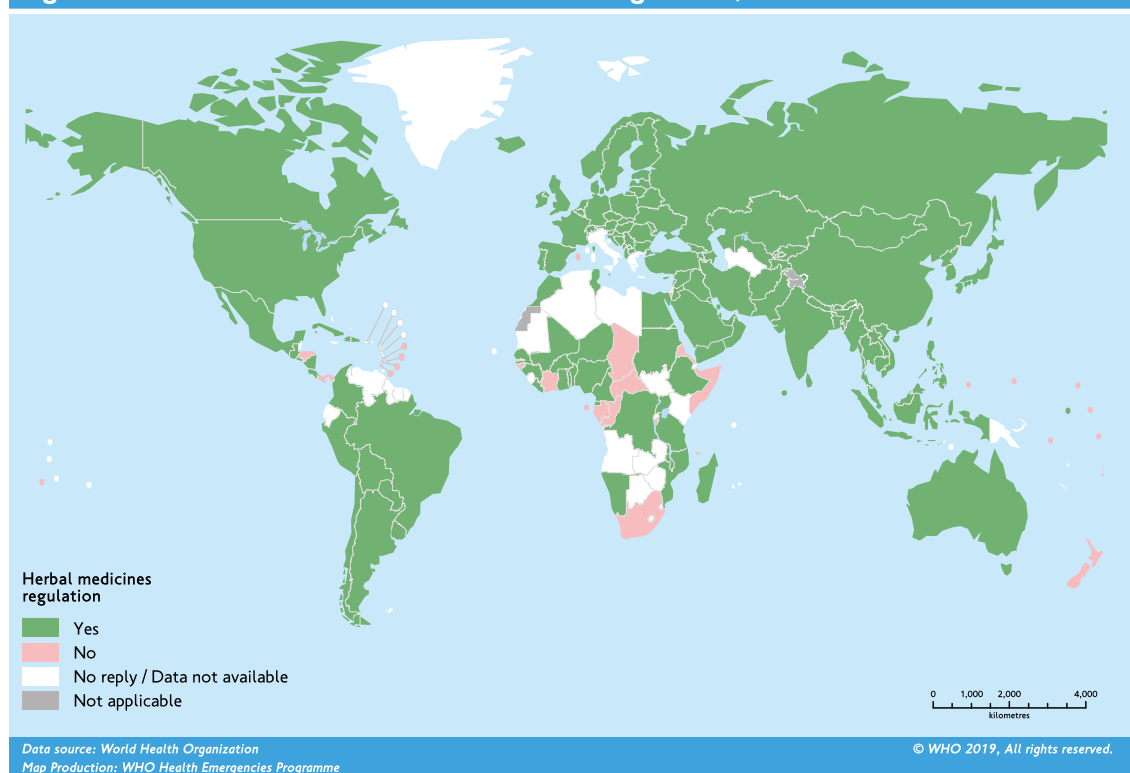
MS: Member States

Sources: As for Fig. 1.1.

The growth in the number of Member States that are developing regulation for herbal medicines has been faster than the number developing national policies for T&CM. However, as of 2018, more than 50% of the respondent Member States had developed both, highlighting the recognition of the role and importance of T&CM in health systems.

Finally, Fig. 2.5 indicates those Member States with herbal medicines regulation, those without and those that did not reply to either the question or the survey.

Fig. 2.5. Member States with herbal medicines regulation, 2018



2.2 Regulatory categories given to herbal medicines

This section was part of the first and second surveys only; thus, the data set is only from 2005 to 2012.

In the second survey, Member States were asked about the categories given to herbal medicines in their regulatory frameworks. This question was similar to the equivalent question in the first survey, but with some changes to the categories. For example, the separate categories of “over-the-counter (OTC)” and “self-medication” in the first survey were combined as a single category of “non-prescription medicines” in the second survey; also, a new category of “general food products” was added to the second survey.

Detailed descriptions of eight possible regulatory categories for herbal medicines were given on the survey form.¹ The definitions were as follows:

Regulatory status: A legislative procedure designed to provide the procedure under which to administer a law or procedure. Regulations may include things such as descriptions or obligations for products or producers, or the title a product must use.

Prescription medicines: Medicines/drugs which can only be purchased with a prescription or a physician’s order.

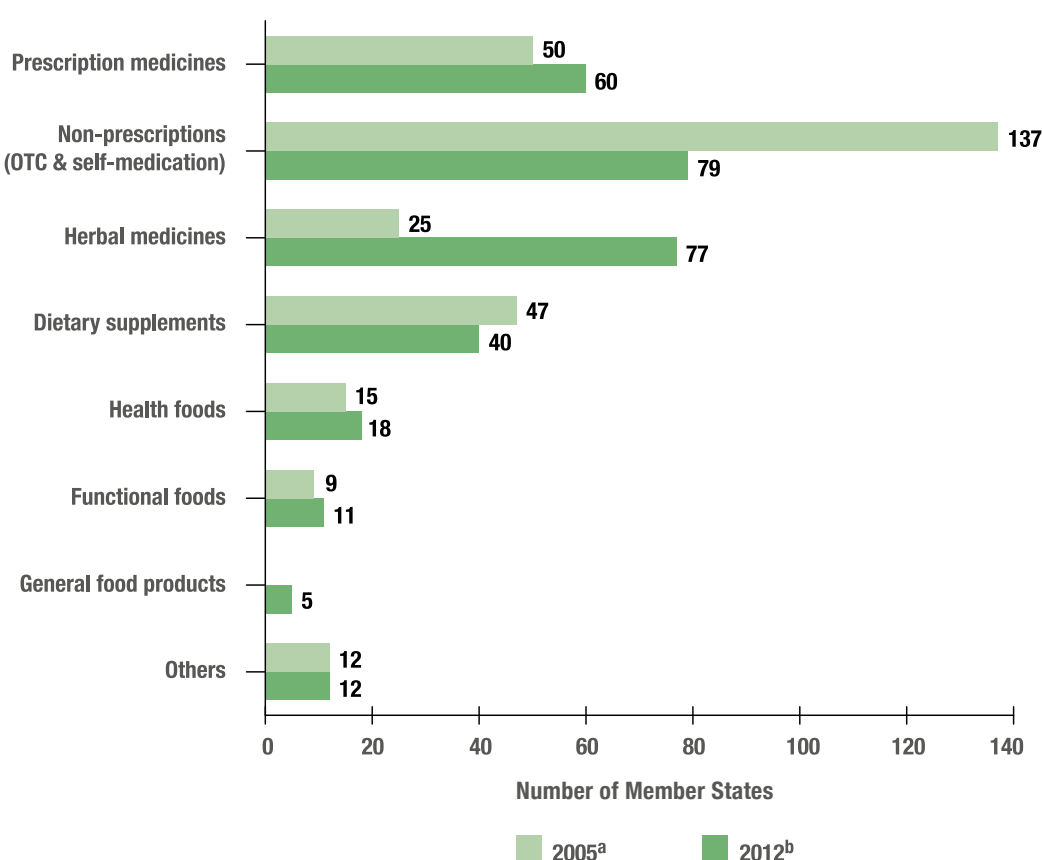
¹ See the text of the second survey in Annex 1.

Non-prescription medicines: Medicines/drugs which can be purchased without a prescription or a physician's order, often at a pharmacy. The definition of "non-prescription medicines" may also often include the terms "self-medication" and/or "over-the-counter (OTC)" medicines.

Dietary supplements: A dietary supplement could be intended to supplement the diet and will contain, for instance, a vitamin, a mineral, a herb, a botanical or an amino acid. A dietary supplement might also be intended to supplement the diet by increasing the total daily intake of a concentrate, a metabolite, a constituent, an extract or a combination of these ingredients.

Health foods (including functional foods): Any natural food popularly believed to promote or sustain good health by containing vital nutrients. Functional foods also include any foodstuff enhanced by additives and marketed as beneficial to health or longevity. Examples include cereals, breads or beverages which are fortified with vitamins and herbs. Health foods and/or functional foods may be advertised or marketed with specific health claims and may therefore be regulated differently than other foods.

Fig. 2.6. Regulatory categories given to herbal medicines, 2005-2012



OTC: over-the-counter.

Sources:

^a National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey (N=141).

^b Includes Member States who 1) responded "Yes" to the second survey on T&CM, and 2) responded "Yes" to the first survey but did not respond to the second survey (N=170; i.e. 141 +29, the 29 being respondents exclusive to the second survey).

Note: "General food products" was not a category in the first survey; hence, there are no data available for this category for 2005.

Regulatory categories given to herbal medicines as of 2012 and the situation in 2005 were compared, as shown in Fig. 2.6. It can be seen that 137 Member States were regulating herbal medicines as non-prescription medicines (OTC and self-medication) in 2005. By 2012, there was a noted dip in their regulation as non-prescription medicines (from 137 to 79), but a significant increase in those being regulated as "herbal medicines" (from 25 to 77); this could be attributed to tighter regulatory criteria and monitoring.

2.3 Regulatory claims made about herbal medicines

This section was part of the first and second surveys only; thus, the data set is only from 2005 to 2012.

These questions focused on the types of claims that may be made about herbal medicines under laws or regulations. Definitions of the different types of claims were provided on the survey form, as follows:¹

Medical claims: Medical claims are here defined as those claims specified to treat, cure or prevent a disease or restore, correct or modify physiological functions. Frequently, products with medical claims have to be registered by the medical products agency before being allowed onto the market.

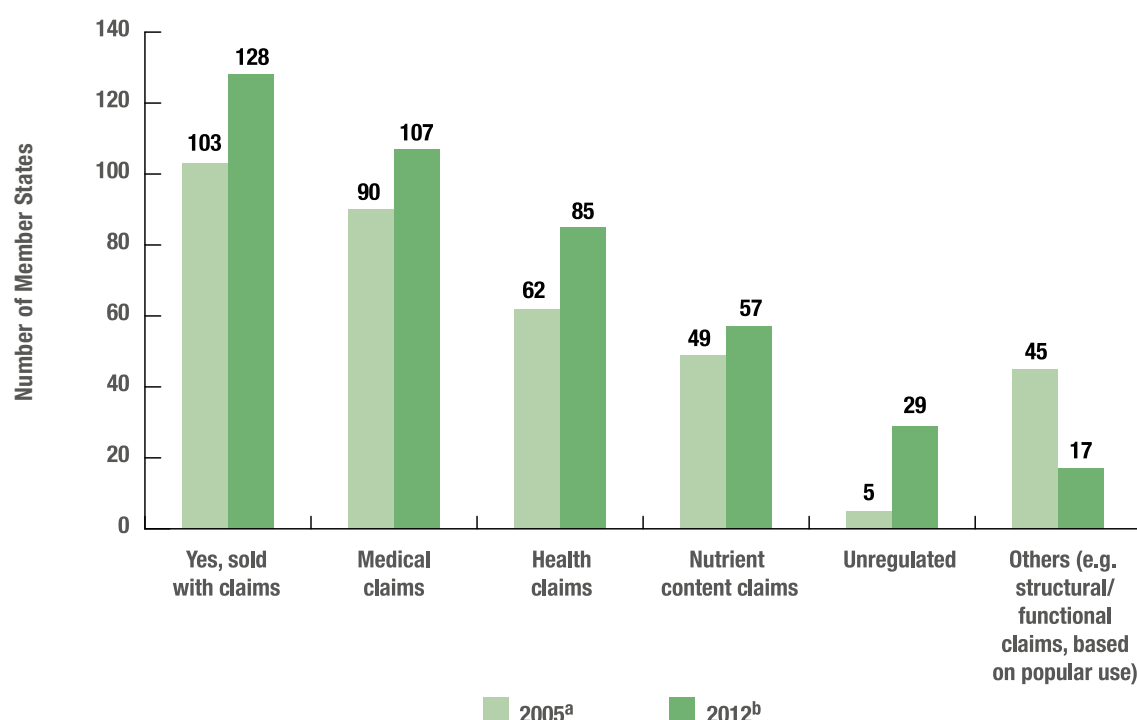
Health claims: Health claims could, for instance, include “any statement, suggestion, or implication in labelling or advertising that a product carries a specific health benefit, but not nutritional claims nor medical claims. The term “health claims” further includes claims which refer to nutrient function and recommended dietary practice.

Nutrient content claims: Nutrient content claims, for instance, indicate that a certain product is particularly rich or low in a nutritional component such as fibre or fat.

Fig. 2.7 shows that, by 2012, there was an increase in the number of Member States reporting the sale of herbal medicines with claims. Medical claims remained the most popular type of claim used for herbal medicines, followed by health claims and nutrient claims.

In 2012, a larger number of Member States reported the use of claims that are unregulated. This could be a factor of increased surveillance in recent years and tighter control mechanisms by regulatory authorities. Other claims used for herbal medicines included those based on popular use.

Fig. 2.7. Types of claims used for herbal medicines, 2005-2012



Sources:

^a National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey (N=141).

^b Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141 + 29, the 29 being respondents exclusive to the second survey).

¹ See the text of the second survey in Annex 1.

2.4 Pharmacopoeia and monographs

This section was part of the first and second surveys only; thus, the data set is only from 2005 to 2012.

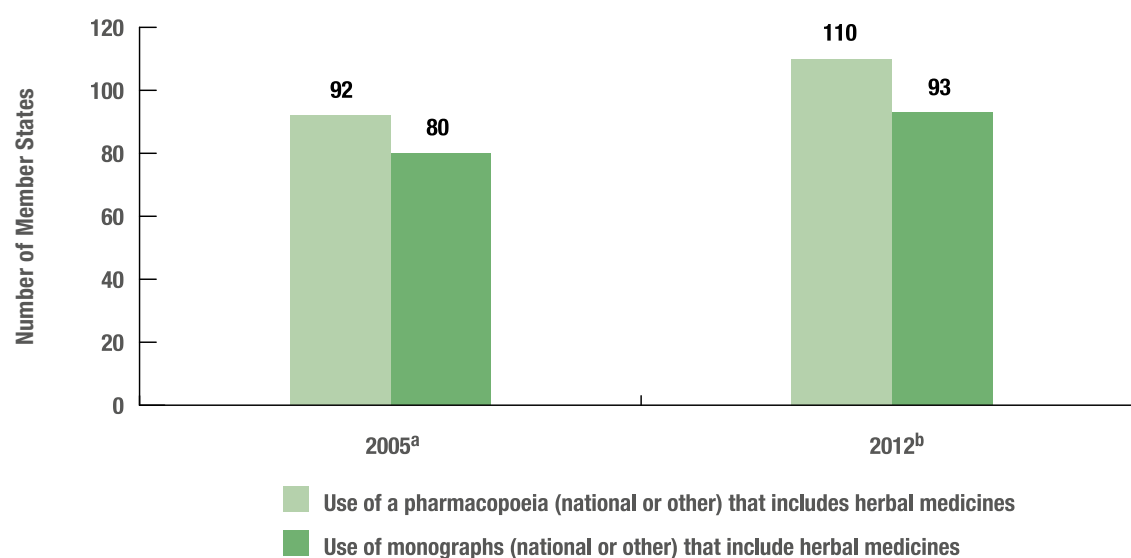
Member States were asked a series of questions concerning the existence of pharmacopoeias and monographs that include herbal medicines. They were asked about the presence of a national pharmacopoeia or monograph, and other pharmacopoeias or monographs used by the country.

As defined in the survey form:¹

- A national pharmacopoeia is a formulary, usually having legal force in all pharmacies of a given country, containing a description of drugs in current medical practice and noting their formulae, analytical composition if known, physical constants, main chemical properties useful in identification and mode of preparation of compound or combination products. Details may also include specifications of assay methods to regulate purity, content of active constituents, preservation of quality, and, where appropriate, biological potency.
- Monographs are descriptions of different herbal medicinal formulae which can either be included in a pharmacopoeia or exist separately.

The Member States that responded in the affirmative in the second survey were further asked about the legal status of any pharmacopoeia or monograph being used.

Fig. 2.8. Number of Member States using pharmacopoeias and monographs, 2005-2012



Sources:

^a National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey (N=141).

^b Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141 +29, the 29 being respondents exclusive to the second survey).

Fig. 2.8 shows that as of 2012, 110 Member States reported the use of a national or other pharmacopoeia that includes herbal medicines; 65 of those respondents stated the pharmacopoeia to be legally binding. The most commonly used “other” pharmacopoeias were those from Britain, the United States and Europe. A WHO list of pharmacopoeias can be found online.²

¹ See the text of the second survey in Annex 1.

² See https://www.who.int/medicines/publications/pharmacopoeia/en/pharmacop_index.pdf

There was also an increase in the use of national and other monographs on herbal medicines, with 93 Member States responding in the affirmative at the end of 2012, and 39 of these Member States reported the monograph in use to be legally binding. Among the “other” monographs, the most commonly used by Member States were the *WHO monographs on selected medicinal plants* (2-5), followed by the community herbal monographs published by the European Medicine Agency’s Committee on Herbal Medicinal Products.

Some respondent Member States used both pharmacopoeias and monographs specific to their region. For example, Ghana reported using the *Ghana herbal pharmacopoeia* (2nd ed., 2007) as its national pharmacopoeia, and *Ethnobotanical and floristic studies in Ghana* as the national monograph. These publications are authoritative and respected, but not legally binding. Apart from these, the *Nigerian herbal pharmacopoeia* (2008), the *African herbal pharmacopoeia* (1995) and the *West African herbal pharmacopoeia* are also in use. As of 2012, 120 national monographs had been issued as part of the series titled *Monographs on medicinal plants of Ghana*.

2.5 Manufacturing of herbal medicines

This section was part of the first and second surveys only; thus, the data set is only from 2005 to 2012.

Member States were asked about the existence of good manufacturing practices (GMPs) and the regulatory requirements for the manufacture of herbal medicines.

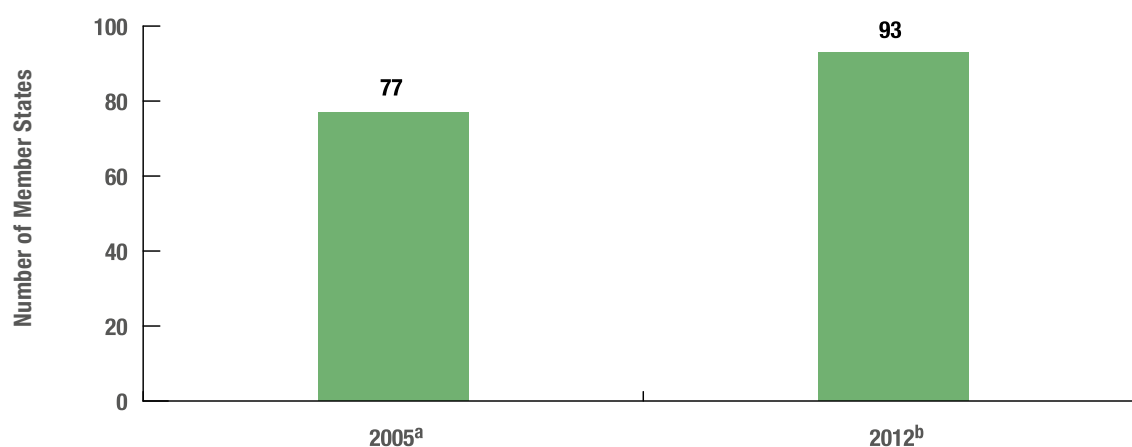
GMPs were defined¹ as codes of practice designed to reduce to a minimum the chance of procedural, instrument or manufacturing plant problems that could adversely affect a manufactured product. They specify “many requirements for quality control of starting materials, including correct identification of species of medicinal plants, special storage and special sanitation and cleaning methods for various materials”.

As of 2012, 83 Member States responded in the affirmative to having GMPs in place. In particular, Member States in the WHO European Region reported following European Union (EU) guidelines for GMP, and many indicated using WHO guidelines for GMP as well.

Member States were further asked whether there were mechanisms in place to ensure compliance with manufacturing requirements. There was an increase in affirmative responses from 2005 to 2012, which may indicate stricter monitoring of regulatory requirements for manufacturing of herbal medicines. For example, Switzerland uses the GMP guides of the Pharmaceutical Inspection Convention and the Pharmaceutical Inspection Co-operation Scheme. Regulations on manufacturing of herbal medicines to ensure their quality require adherence to manufacturing information in pharmacopoeias and monographs, and the same regulations for GMP apply to both herbal medicines and conventional pharmaceuticals.

¹ See the text of the second survey in Annex 1.

Fig. 2.9. Number of Member States having mechanisms to ensure compliance with manufacturing requirements, 2005-2012



Sources:

^a National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey (N=141).

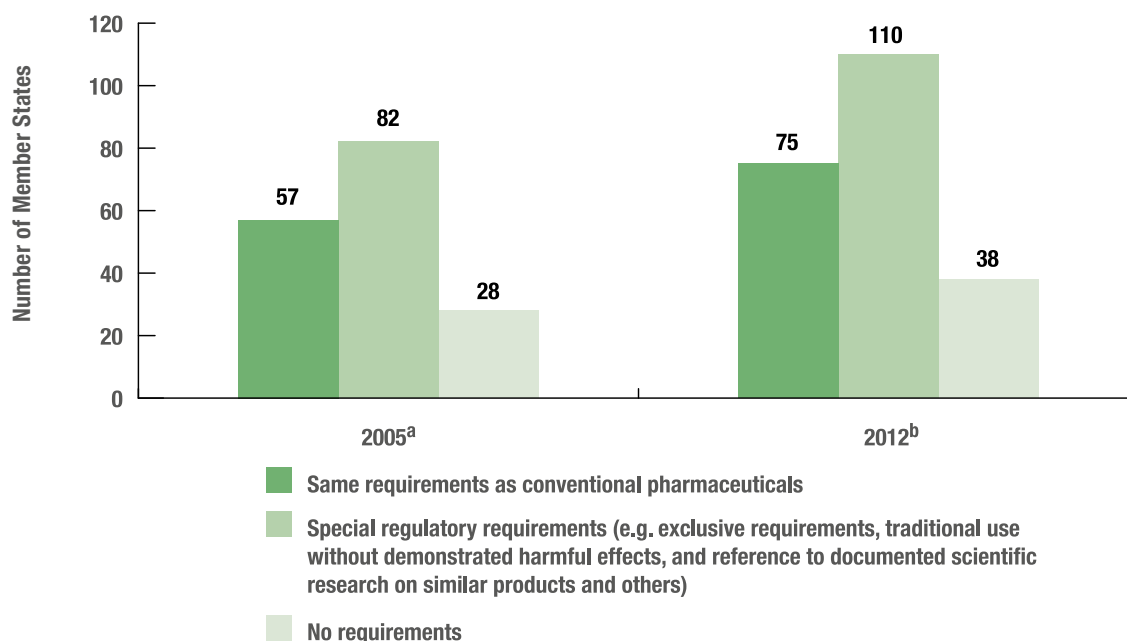
^b Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141 +29, the 29 being respondents exclusive to the second survey).

In China, the Good Agricultural Practice (GAP) for Chinese Crude Drugs (For Trial) regulation was issued in September 2003. For safety assessment, the Good Laboratory Practice (GLP) compliance programme for drug safety studies covered both traditional Chinese medicines and conventional pharmaceuticals.

2.6 Safety assessment of herbal medicines

This section was part of the first and second surveys only; thus, the data set is only from 2005 to 2012.

Member States were asked a series of questions related to the regulatory requirements for safety assessment of herbal medicines, such as whether the same requirements as for conventional pharmaceuticals, special requirements or no requirements applied to herbal medicines. Four additional options were added in the second survey: exclusive safety requirements, traditional use without demonstrated harmful effects, reference to safety data in documented scientific research on similar products, and “other” safety requirements. For the purpose of comparison with responses to the first survey, these four options were combined into a “special regulatory requirements” category.

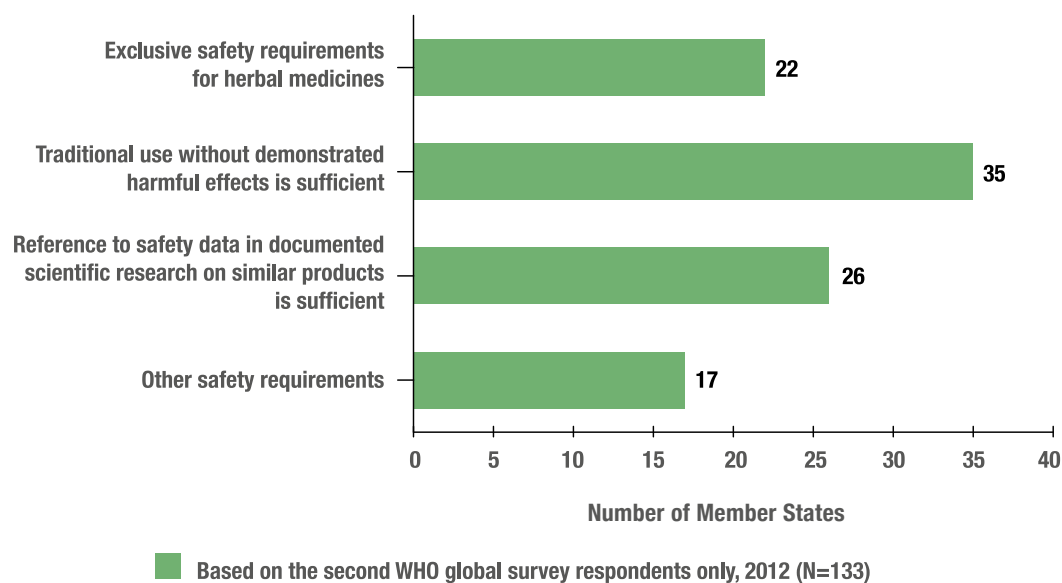
Fig. 2.10. Regulatory requirements for safety assessment of herbal medicines, 2005-2012

Sources:

^a National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey (N=141).

^b Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141 +29, the 29 being respondents exclusive to the second survey).

Fig. 2.10 shows that the option of special regulatory requirements was reported by the highest number of Member States in both 2005 and 2012. The distribution of this category in responses to the second survey can be seen in Fig. 2.11.

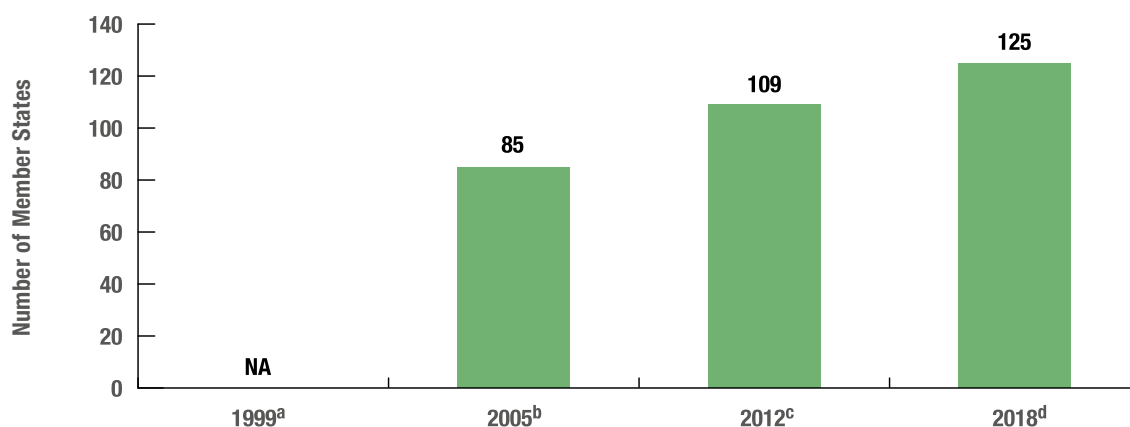
Fig. 2.11. Special regulatory requirements for safety assessment of herbal medicines, 2012

Many Member States selected multiple options in response to this question. In “other” safety requirements, Member States listed criteria such as chronic, sub-chronic and organ-specific toxicity profile; scientific follow-up or monitoring of patients treated by traditional health care workers; laboratory analysis of market samples if doubts are raised by user complaints; requirements specified in the relevant monograph; monitoring the levels of harmful organisms, microorganisms and chemical substances; and sample testing during pre-registration.

2.7 Registration systems for herbal medicines

In this section, Member States were asked whether they had a registration system for herbal medicines. As of 2018, 125 or almost 65% of Member States reported having a registration system for herbal medicines (Fig. 2.12).

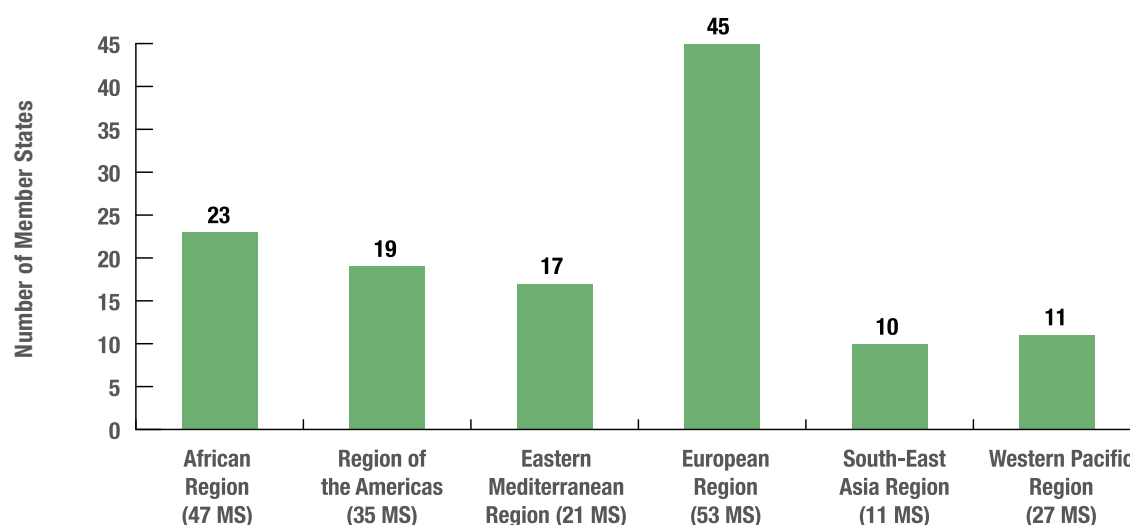
Fig. 2.12. Number of Member States with a registration system for herbal medicines, 2005-2018



Sources: As for Fig. 1.1.

In Canada as of 2012, more than 56 000 products registered in the Licensed Natural Health Products Database were available for sale (not all are herbal medicines). In Chile, phytopharmaceuticals are registered with the Public Health Institute of Chile. In Turkey, to qualify for registration under traditional use, the product itself or the active ingredients should have been in medicinal use throughout a period of 30 years, including at least 15 years within Turkey or the European Community (EC) and designed for self-medication. EU Directive 2004/24/EC sets down a simplified registration procedure for traditional herbal medicinal products and a definition of such medicinal products. In Australia, there are 128 “Registered” and 11 493 “Listed” herbal medicines (as of 2018).

Fig. 2.13. Distribution by WHO region of Member States with a registration system for herbal medicines, 2018

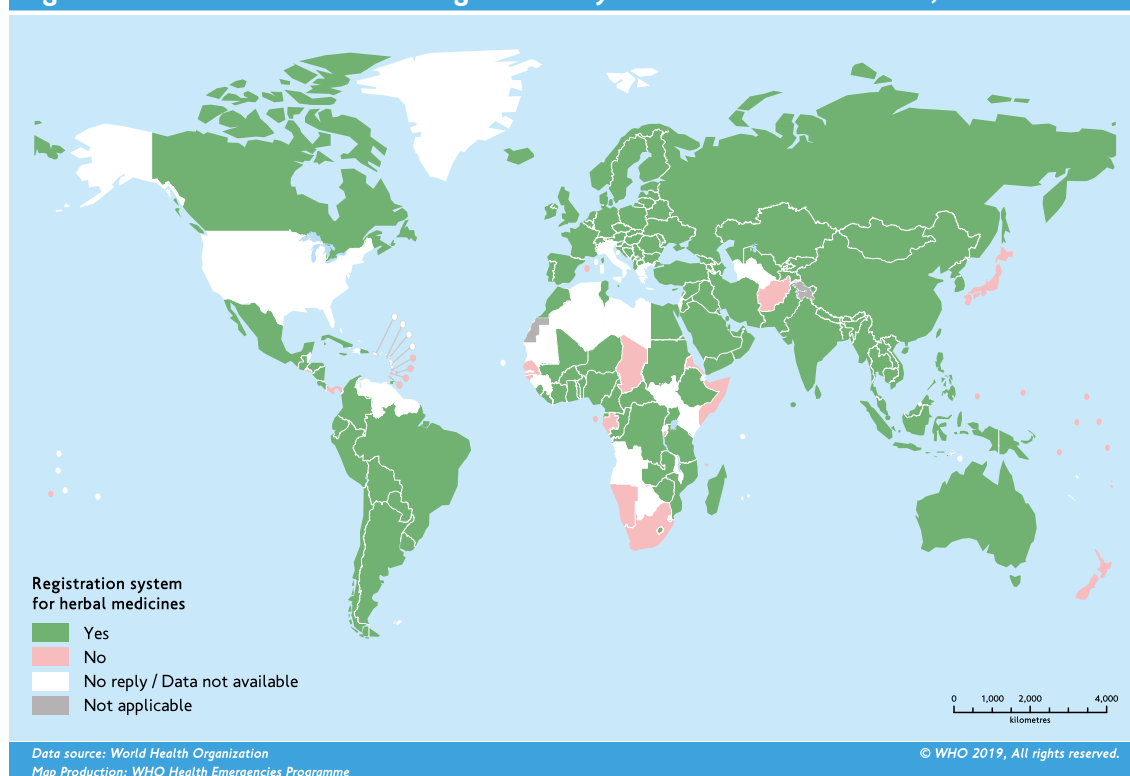


MS: Member States

The number of Member States with a registration system for herbal medicines is shown in Fig. 2.13. Expressed as a percentage of each WHO region, the highest was the South-East Asia Region (91%), followed by the European Region (85%), the Eastern Mediterranean Region (81%), the Region of the Americas (54%), the African Region (49%) and the Western Pacific Region (41%).

Finally, Fig 2.14 indicates those Member States with a registration system for herbal medicines, those without and those that did not reply to either the question or the survey.

Fig. 2.14. Member States with a registration system for herbal medicines, 2018



2.8 National essential medicines list

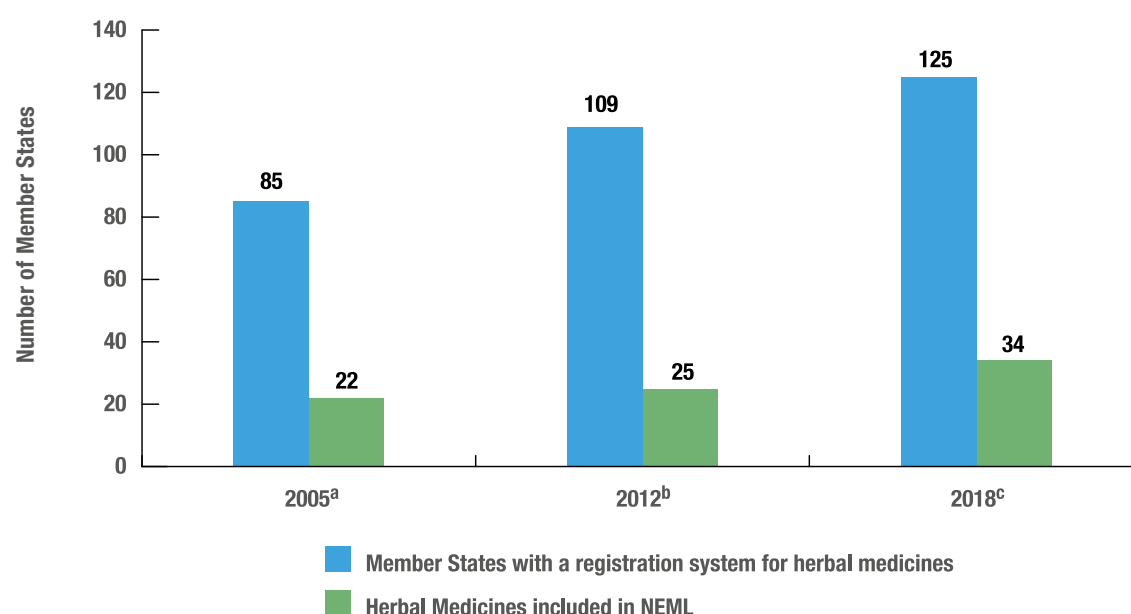
Essential medicines are defined as those medicines that satisfy the priority health care needs of the population (6). Member States were asked whether herbal medicines are included in their NEML.

As of 2018, 34 Member States replied in the affirmative to having herbal medicines included in their NEML (see Fig. 2.15). The distribution across WHO regions was as follows:

- seven in the WHO African Region – Burkina Faso, Cameroon, Democratic Republic of the Congo, Ghana, Madagascar, Mali and Niger;
- five in the WHO Region of the Americas – Bolivia (Plurinational State of), Brazil, Cuba, Mexico and Peru;
- five in the WHO Eastern Mediterranean Region – Bahrain, Iran (Islamic Republic of), Iraq, Pakistan and Tunisia;
- seven in the WHO European Region – Armenia, Kazakhstan, Republic of Moldova, Russian Federation, Tajikistan, Ukraine and Uzbekistan;
- five in the WHO South-East Asia Region – Bangladesh, Bhutan, Democratic People's Republic of Korea, India and Thailand; and
- five in the WHO Western Pacific Region – China, Lao People's Democratic Republic, Mongolia, Philippines and Viet Nam.

Many Member States, such as Ghana, also reported a list of essential herbal medicines separate from their NEML.

Fig. 2.15. Number of Member States with a herbal medicines registration system compared with the number including herbal medicines in their NEML, 2005–2018



NEML: national essential medicines list.

Sources:

^a National policy on traditional medicine and regulation of herbal medicines – Report of a WHO global survey (N=141).

^b Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141 +29, the 29 being respondents exclusive to the second survey).

^c Includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018).

Of the 34 countries that have included herbal medicines in their NEMLs, 20 countries reported that the selection for inclusion was based on the traditional use of the herbal medicines, 18 based it on clinical data, 17 on long-term historical use, 13 on laboratory testing and five on other criteria such as reference books, cost and criteria set by expert groups (with some countries making multiple selections).

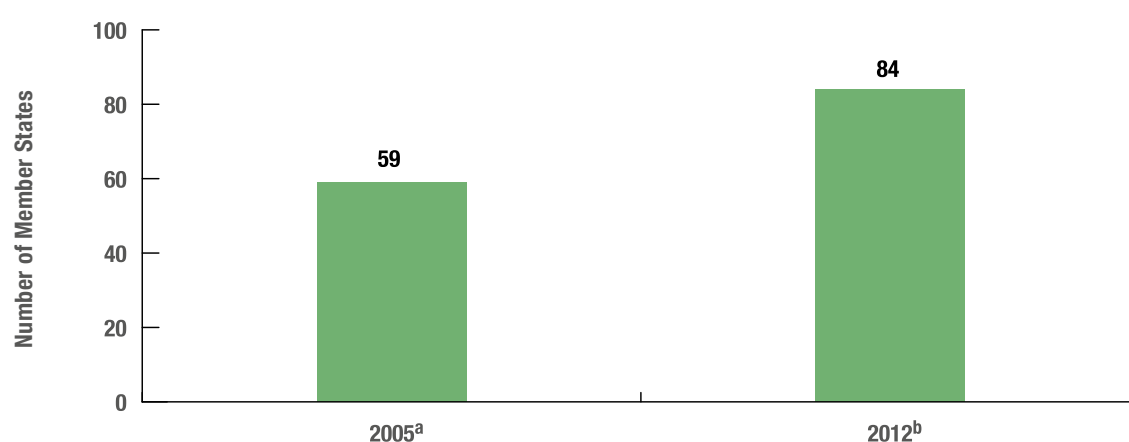
2.9 Market surveillance system for safety of herbal medicines

This section was part of the first and second surveys only; thus, the data set is only from 2005 to 2012.

Member States were asked whether they had a “post-marketing surveillance system” for herbal medicines. This is defined as a system to monitor the ongoing safety of products in the market that requires manufacturers, importers and distributors to keep distribution records, to have written procedures to handle and investigate product complaints, and to recall defective products from the market.¹

As of 2012, 84 countries responded in the affirmative to having a market surveillance system for herbal medicines (Fig. 2.16).

Fig. 2.16. Number of Member States with a market surveillance system for safety of herbal medicines, 2005–2012



Sources:

^a National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey (N=141).

^b Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141 +29, the 29 being respondents exclusive to the second survey).

In Morocco, the ongoing safety of herbal medicines in the market is monitored by a national pharmacovigilance centre within the Centre Anti Poison et de Pharmacovigilance Du Maroc (Poison Control and Pharmacovigilance Centre of Morocco). In Pakistan, an online reporting form for adverse drug reactions (ADRs), including reactions to herbal medicines, has been available on an official government website since early 2018, enabling the collection of ADR reports. In Malaysia, herbal medicines are subject to similar criteria for regulation, surveillance, pharmacovigilance, licensing and ADR reporting that has been established for conventional pharmaceuticals.

2.10 Marketing and sales of herbal medicines

This section was part of the first and second surveys only; thus, the data set is only from 2005 to 2012.

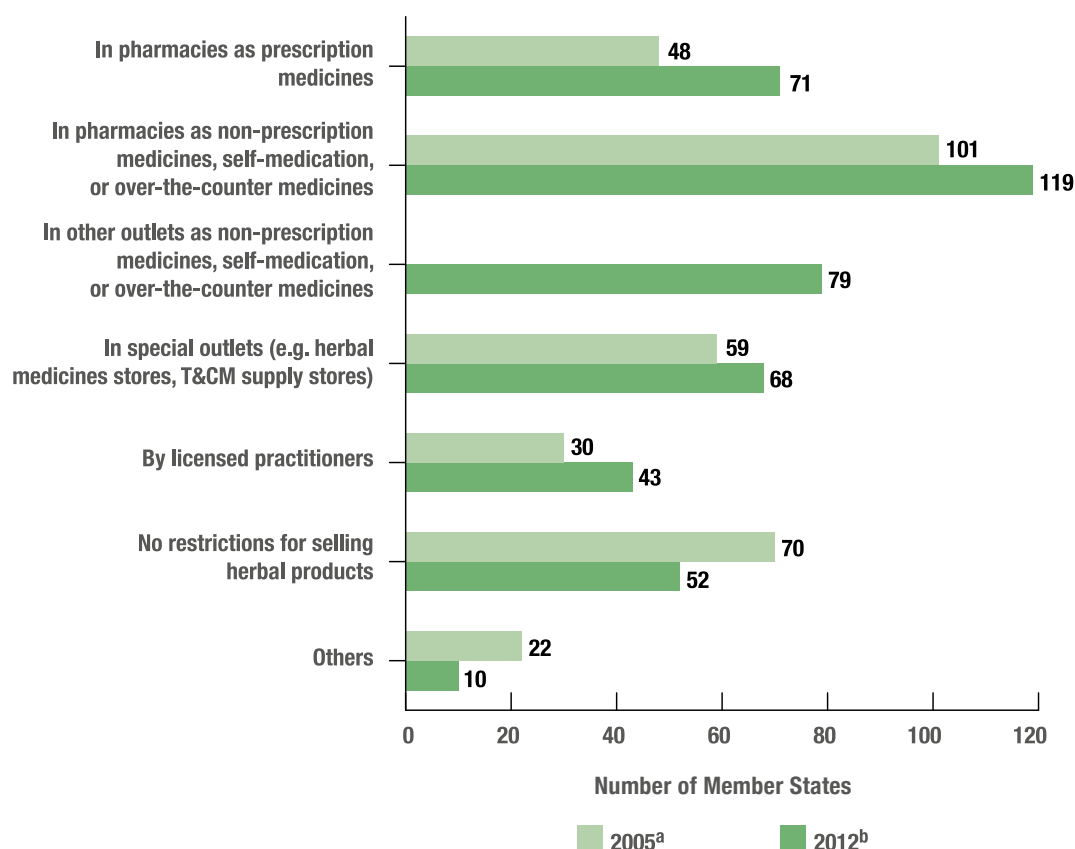
In this section of the survey, Member States were asked how herbal medicines were sold within their territories. They were asked to select all methods of sale employed in their territory.

Fig. 2.17 provides details of how countries responded to the second survey compared with the first survey. The most commonly selected category in both surveys was that of sale in pharmacies as non-prescription

¹ See the text of the second survey in Annex 1.

medicines, self-medication or OTC medicines; in 2012, 119 Member States reported this method of sale, up from 101 in 2005. The next most common method of sale in 2012 was the new category of other outlets as non-prescription medicines, followed by sales in pharmacies as prescription medicines. There was a reduction in the number of Member States reporting no restrictions on the sale of herbal medicines, from 70 in 2005 down to 52 in 2012. The option “other ways” was selected by 10 Member States in 2012 (a reduction from 22 in 2005); these alternative modes included the sale of herbal medicines in the market, directly from the therapists, from traditional practitioners, and from other unregulated marketplaces (e.g. online, via telemarketing or on the street).

Fig. 2.17. Methods of sale of herbal medicines, 2005–2012



Sources:

^a National Policy on Traditional Medicine and Regulation of Herbal Medicines – Report of a WHO Global Survey (N=141).

^b Includes Member States who 1) responded “Yes” to the second survey on T&CM, and 2) responded “Yes” to the first survey but did not respond to the second survey (N=170; i.e. 141+29, the 29 being respondents exclusive to the second survey).

Note: The category “In other outlets as non-prescription medicines, self-medication, or over-the-counter medicines” was a new category in the second survey; hence, no data are available for 2005.

In Croatia, the Agency for Medicinal Products and Medical Devices (HALMED) lists the total market sales of herbal medicines (in Euros) as 3.1 million, 2.95 million and 4.01 million in 2007, 2008 and 2009, respectively. In Mali, estimates shared by the Traditional Medicine Department show that the annual market sales of herbal medicines in 2007, 2008 and 2009 were US\$ 97 200, US\$ 106 920 and US\$ 117 612, respectively.

In Yemen, the Supreme Board for Drugs and Medical Appliances’ annual report for 2009 reported the total market sales of herbal medicines in 2009 to be 1 287 630 958 Yemeni rials.

3. PRACTICE, PROVIDERS, EDUCATION AND HEALTH INSURANCE

This is a new section that was added in the second survey. Unless otherwise indicated, the data are based on the response to the second survey only, or on the responses to the second survey and the update survey.

3.1 T&CM practices

In this section, Member States were asked about the use of indigenous TM and T&CM practices. The terms for these medicines may vary from country to country and region to region, so specific definitions were used for each in the second survey.¹

“Indigenous traditional medicine” was defined as the sum total of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating physical, mental and social diseases. This knowledge or practice may rely exclusively on past experience and observation handed down orally or in writing from generation to generation. These practices are native to the country in which they are practised. The majority of indigenous traditional medicine has been practised at the primary health care level.

Based on the WHO Traditional Medicine Strategy 2014–2023, “TM” was defined as the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness (7).

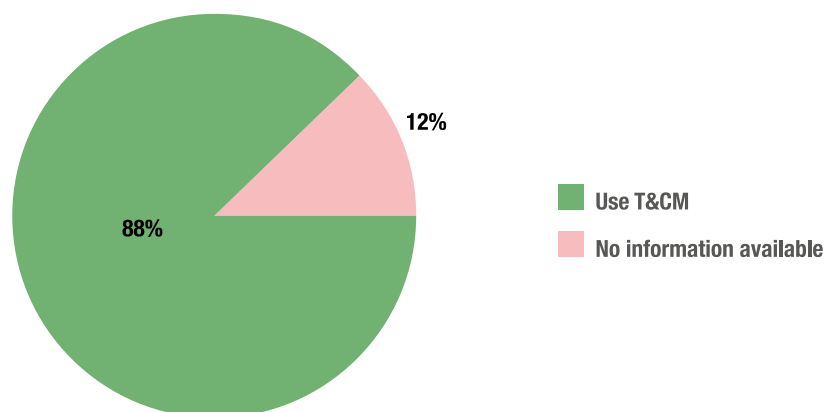
“Complementary medicine” (CM) was defined as a broad set of health care practices that are not part of a country’s own tradition nor part of conventional medicine, and are not fully integrated into the dominant health care system. CM practices are used interchangeably with TM practices in some countries (8).

The term T&CM encompasses both TM and CM products, practices and practitioners.

Member States were first asked whether the use of indigenous TM was considered important in their country, and if so, what percentage of their population uses indigenous TM. They were then asked whether T&CM was used in their country, and if so, what percentage of their population uses a particular T&CM practice (e.g. acupuncture).

As at 2018, 170 or 88% of all Member States acknowledged the use of T&CM (Fig. 3.1). These 170 Member States are the ones that formally acknowledged their use of T&CM through development of national policies, laws, regulations, programmes and so on for T&CM. It is likely that the actual number of countries where T&CM is used is higher.

¹ See the text of the second survey in Annex 1.

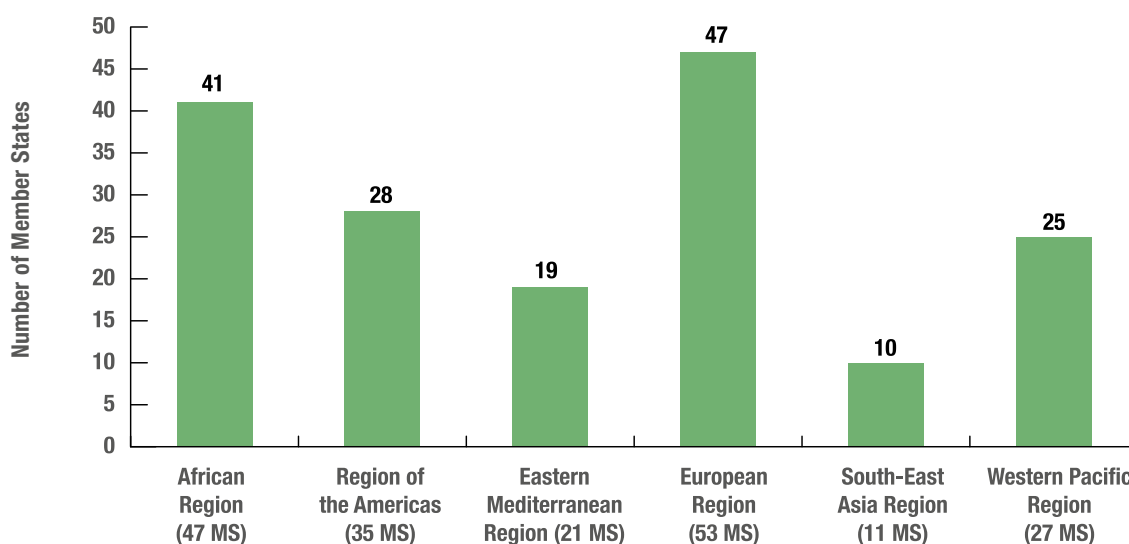
Fig. 3.1. Use of T&CM acknowledged by Member States, 2018

T&CM: traditional and complementary medicine (which here includes indigenous traditional medicines). N=194

Sources:

Includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016- 2018).

Note: In the second survey, Member States that left this question blank (or replied “No”), but replied “Yes” to any of the indicators for T&CM (i.e. national policy, laws or regulations; national office, programme, expert committee or research institute; herbal medicines regulation; regulation of indigenous TM or T&CM providers; health insurance coverage of indigenous TM or T&CM) were assumed to use T&CM if it was clear from these affirmative responses that T&CM was not prohibited. For example, in a country that replied “No” to T&CM use but responded “Yes” to having a national policy, law, national programme, office and expert committee for T&CM; it was concluded that T&CM is used in that country.

Fig. 3.2. Distribution by WHO region of Member States using T&CM, 2018

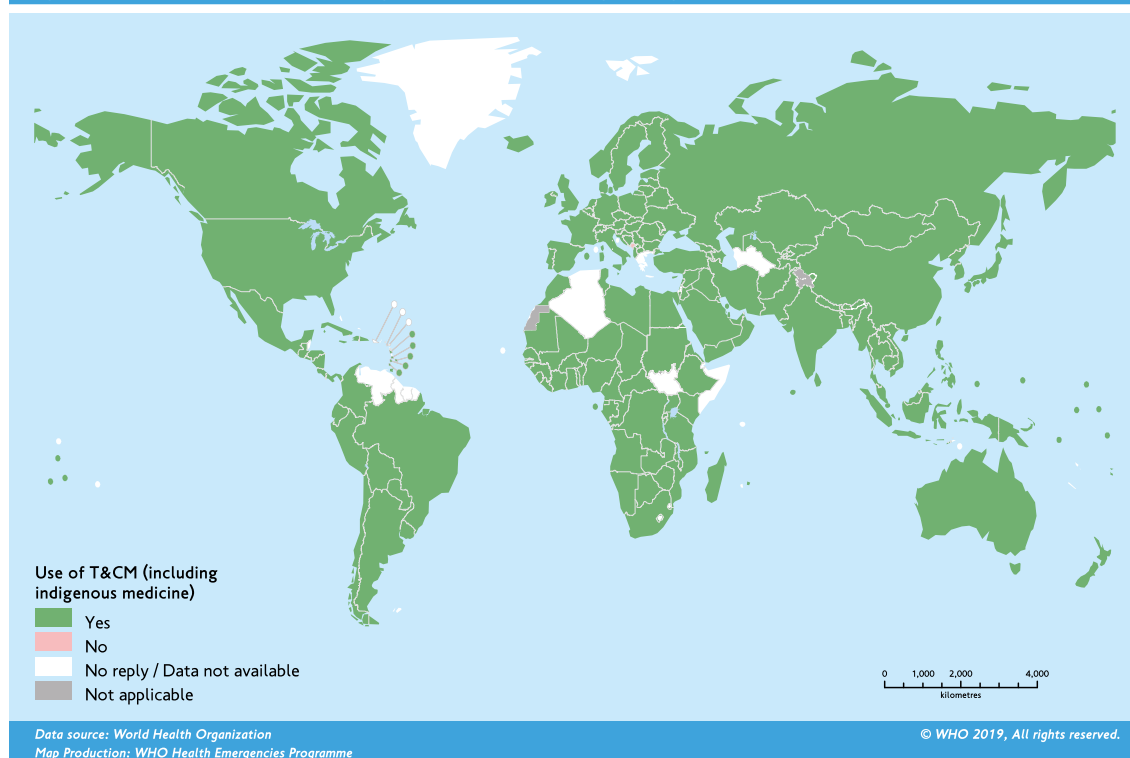
MS: Member States

T&CM is used by at least 80% of the Member States across all WHO regions, with more than 90% of Member States in the Eastern Mediterranean, South-East Asia and Western Pacific regions reporting use of T&CM. This uniformly high use of T&CM across all regions reinforces the need for policy development, appropriate laws and regulations, safety and monitoring systems, and integration of T&CM products, practices and practitioners into health systems.

In Cuba, “Natural and Traditional Medicine” is practised within the national health system by professionals and sanitary technicians, according to their specialty and practice scope profiles. In the Democratic People’s Republic of Korea, an exclusive national policy on T&CM, titled “Developing Koryo Traditional Medicine”, was issued in 1979. According to data from 2000, 60–79% of the population in Germany uses indigenous TM (9).

Finally, Fig. 3.3 indicates those Member States using T&CM, those not using and those that did not reply to either the question or the survey.

Fig. 3.3. Member States using T&CM (including indigenous medicine), 2018



3.2 Types of T&CM practices used in Member States

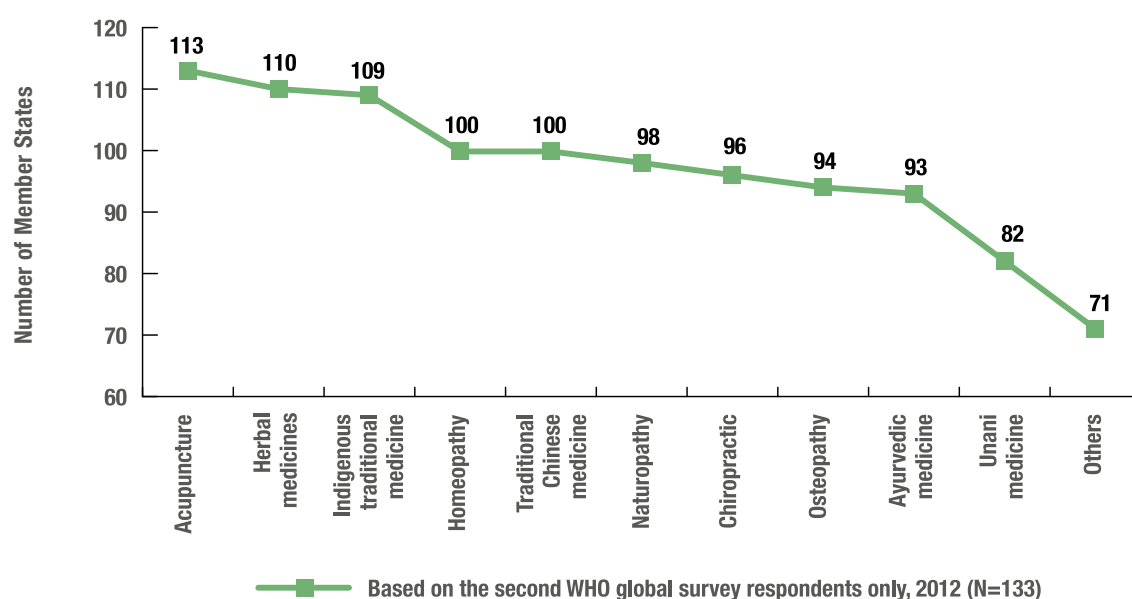
Member States were asked about whether indigenous TM and other types of T&CM practices are used by people in their country. They were given nine T&CM practices to select from (and an option to select “others” for other forms of practices); the nine practices were:

- acupuncture
- ayurvedic medicine
- chiropractic
- herbal medicine
- homeopathy
- naturopathy
- osteopathy
- traditional Chinese medicine
- Unani medicine.

For indigenous TM and for each T&CM practice in use, respondents were then asked what percentage of their population uses that practice (in percentiles of 20), with an option to select “Unknown/Data not available” where the percentage was not known.

Fig. 3.4 plots the number of Member States that formally acknowledged that their population uses indigenous TM and other T&CM practices. Acupuncture was the most common form of practice (reported by 113 Member States), closely followed by herbal medicines (110) and indigenous TM (109). Homeopathy and traditional Chinese medicine came in next, each used by 100 Member States, while more than 90 Member States reported use of naturopathy, chiropractic, osteopathy and ayurvedic medicine, in that order. The use of Unani medicine was reported by 82 Member States.

Fig. 3.4. Types of T&CM used by Member States’ populations, in decreasing order, 2012



Note: The number of Member States with acknowledged use of a particular type of T&CM was calculated by including Member States who 1) responded “Yes” to use of that type of T&CM; 2) responded “Unknown/Data not available” to percentage of population using the practice (and not 0%); 3) responded “Yes” to regulation of that type of T&CM provider; 4) responded “Yes” to that type of T&CM provider practicing in the country; and 5) responded “Yes” in the second survey to insurance coverage for that type of T&CM practice.

Other forms of practices were reported by 71 Member States; these practices included prayer, spiritualism, traditional midwives, therapeutic massage, hypnotherapy, reiki, reflexology, hands-on healing, hydrotherapy, Feldenkrais, biofeedback, Rolfing, Bach flower remedies, anthroposophic medicine, neural therapy, gSo-ba Rig-pa (traditional Bhutanese medicine), Siddha medicine, Iranian TM, cupping and ozone therapy. More details can be found in the country summaries in Section 5.

3.3 T&CM providers – regulation, practice settings and licensing

In this section, Member States were asked about the providers of indigenous TM and T&CM practices, including the regulation of providers, the level at which regulation is enforced, the setting (private, public or both) in which providers practise, whether a licence or certificate is required for practice, and which authority issues the licences or certificates.

The following definitions were provided to aid the understanding of the term “providers”:

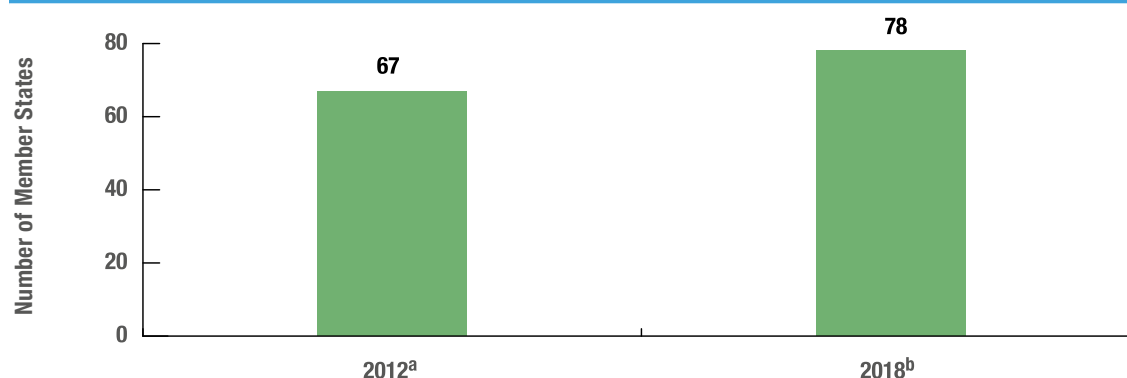
Indigenous traditional medicine providers: Generally understood to include those who practice indigenous traditional medicine, such as traditional healers, bonesetters, herbalists and traditional birth attendants. Usually, most of these practitioners have been practising at the primary health care level.¹

[T&CM] providers: Includes both [T&CM] practitioners, allopathic medicine professionals and health care workers such as doctors, dentists, nurses, midwives, pharmacists and physical therapists who provide [T&CM] services to their patients (e.g. medical doctors who use acupuncture to treat their patients, or traditional Chinese medicine doctors who provide services in clinics and hospitals).²

3.3.1 Regulation of T&CM providers

As shown in Fig. 3.5, 78 Member States reported regulation of T&CM providers as at 2018, up from 67 in 2012.

Fig. 3.5. Number of Member States with regulation of T&CM providers, 2012–2018



T&CM: traditional and complementary medicine (which here includes indigenous traditional medicines).

Sources:

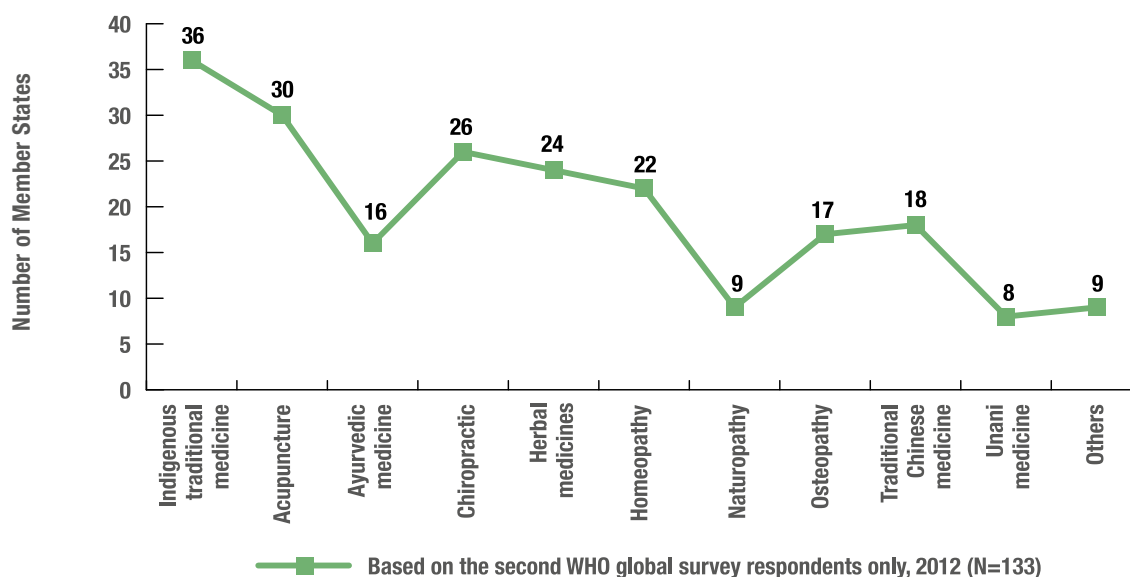
^a Based on the second WHO global survey respondents only (N=133).

^b Includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016-2018).

Member States that responded in the affirmative to having regulation of T&CM providers were further asked which types of providers were regulated. Fig. 3.6 shows that the providers most commonly regulated were indigenous TM providers, reported by 36 Member States, followed by acupuncture and chiropractic providers, reported by 30 and 26 Member States, respectively.

¹ See the text of the second survey in Annex 1.

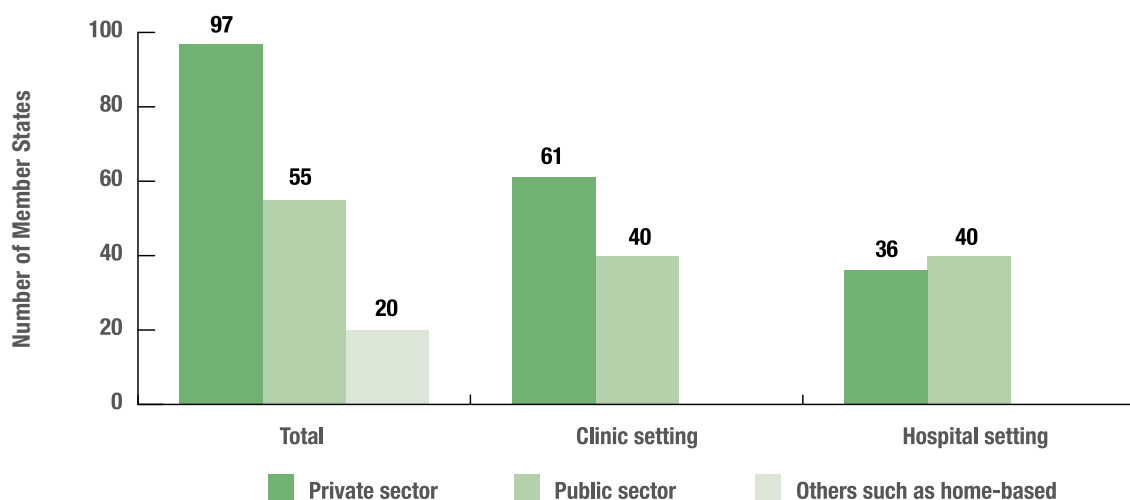
² See the text of the second survey in Annex 1; note that in the survey, the term is not T&CM but “TM/CAM” (for traditional medicine and complementary and alternative medicine).

Fig. 3.6. Types of T&CM providers regulated by Member States, 2012

3.3.2 T&CM practice settings

Member States were asked about the settings in which T&CM providers practise – whether private sector or public sector or both, and for each sector, whether in a hospital or a clinic or both, or in any other kind of settings.

Fig. 3.7 shows that of the 107 Member States that replied to this question, 97 reported T&CM providers to be practising in the private sector, 55 in the public sector and 20 in other settings, such as home-based settings and traditional healing centres. Many Member States selected multiple options; 43 reported that their T&CM providers practise in both public and private settings.

Fig. 3.7. Practice settings of T&CM providers, 2012

Source: Based on the second WHO global survey respondents only (N=133).

The distribution shown in Fig. 3.7 across clinic and hospital settings reveals that the most popular practice setting for T&CM providers was private clinics (61 Member States), followed by public clinics and public hospitals (40 Member States each), and then private hospitals (36 Member States).

3.3.3 T&CM licence or certification for practice

As of 2012, 66 Member States reported that providers require a licence for T&CM practice. Such licences were issued mostly by the national government, and in some cases by the state government and others. As at 2018, the number of Member States requiring a licence for T&CM practice is reported to be 70, taking into account additional information that came in from Hungary, Iran (Islamic Republic of), Malaysia and Portugal.

In Malaysia, as per their Traditional and Complementary Medicine Act, 2016 [Act 775], a registered practitioner shall not practice a recognised practice area unless they hold a valid and subsisting practicing certificate issued by the Traditional and Complementary Medicine Council (10). The country summaries in Section 5 provide more detail. In Portugal, the Central Administration of the Health System is the MoH body responsible for issuing professional titles for diagnostic and therapeutic technicians, nonconventional-conventional therapeutics and podiatrists.

3.4 Education of T&CM providers

Member States were asked if T&CM education was provided at the university level; those that responded in the affirmative were asked to provide the type of higher education degree – bachelor's, master's, PhD, clinical doctorate or other degrees – that a student of T&CM would obtain. Member States that replied in the negative (i.e. that T&CM education is not available at university level) were asked whether any other T&CM training programmes were provided that their government officially recognizes.

As of 2012, 63 Member States reported availability of some form of T&CM education. Of these, 41 provided T&CM education at university level, and 36 provided non-university training programmes that were officially recognized by the government. These figures include the 14 Member States that reported having T&CM education both at university level and in officially recognized training programmes.

Fig. 3.8. Availability of T&CM education, 2012

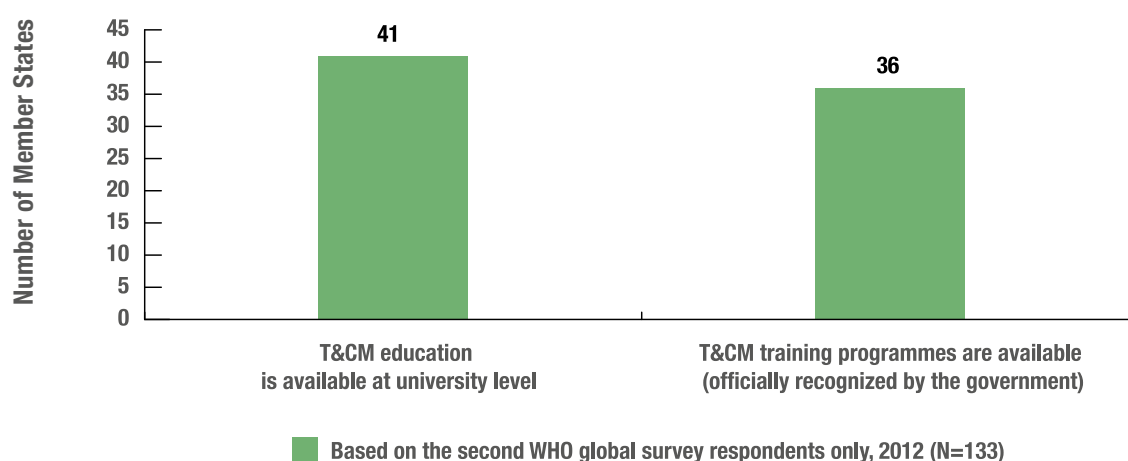
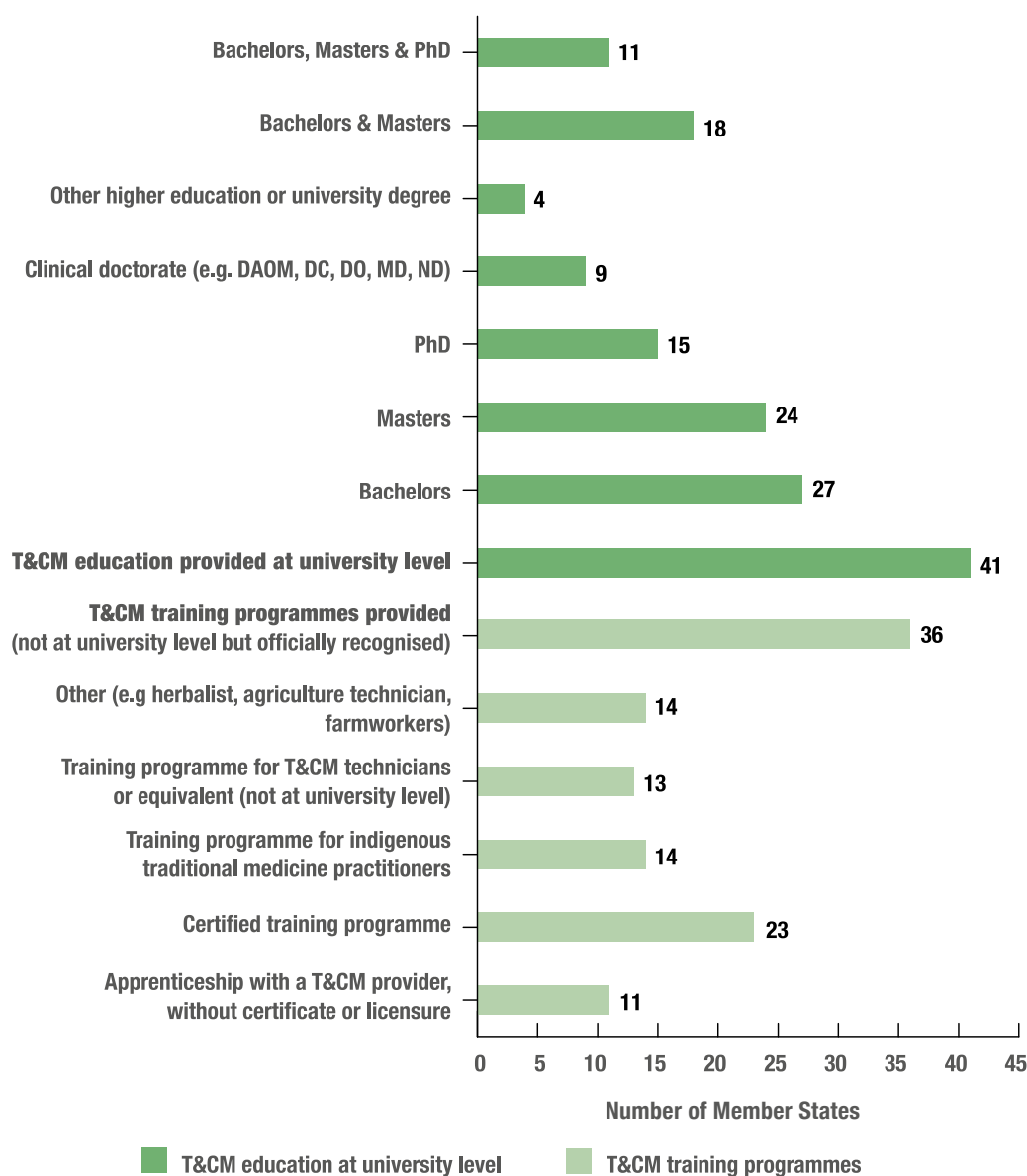


Fig. 3.9 shows that, at university level, it was most common for Member States to offer a bachelor's degree (27 Member States) or a master's degree (24 Member States). A doctorate (PhD) could be obtained in 15 Member States, and a clinical doctorate in nine Member States; four Member States offered some other kind of degree. As of 2012, 18 Member States offered both bachelor's and master's degrees, and 11 offered bachelor's and master's degrees, and PhDs.

At a non-university level, Member States reported the existence of officially recognized training programmes such as advanced certificates in TM; education programmes on hygiene, anatomy, herb conservation, data collection and management; training of herbalists, agricultural technicians and farmworkers; pharmacognosy at pharmacy colleges; and integrated lectures. Some Member States also recognized internationally approved certificates and licences, and T&CM qualifications awarded by foreign universities.

Fig. 3.9. Types of T&CM degrees and training programmes provided by Member States, 2012



DAOM: Doctorate of Acupuncture and Oriental Medicine; DC: Doctor of Chiropractic; DO: Doctor of Osteopathic Medicine; MD: Doctor of Medicine; ND: Doctor of Naturopathy; PhD: Doctor of Philosophy.

Source: Based on the second WHO global survey respondents only (N=133).

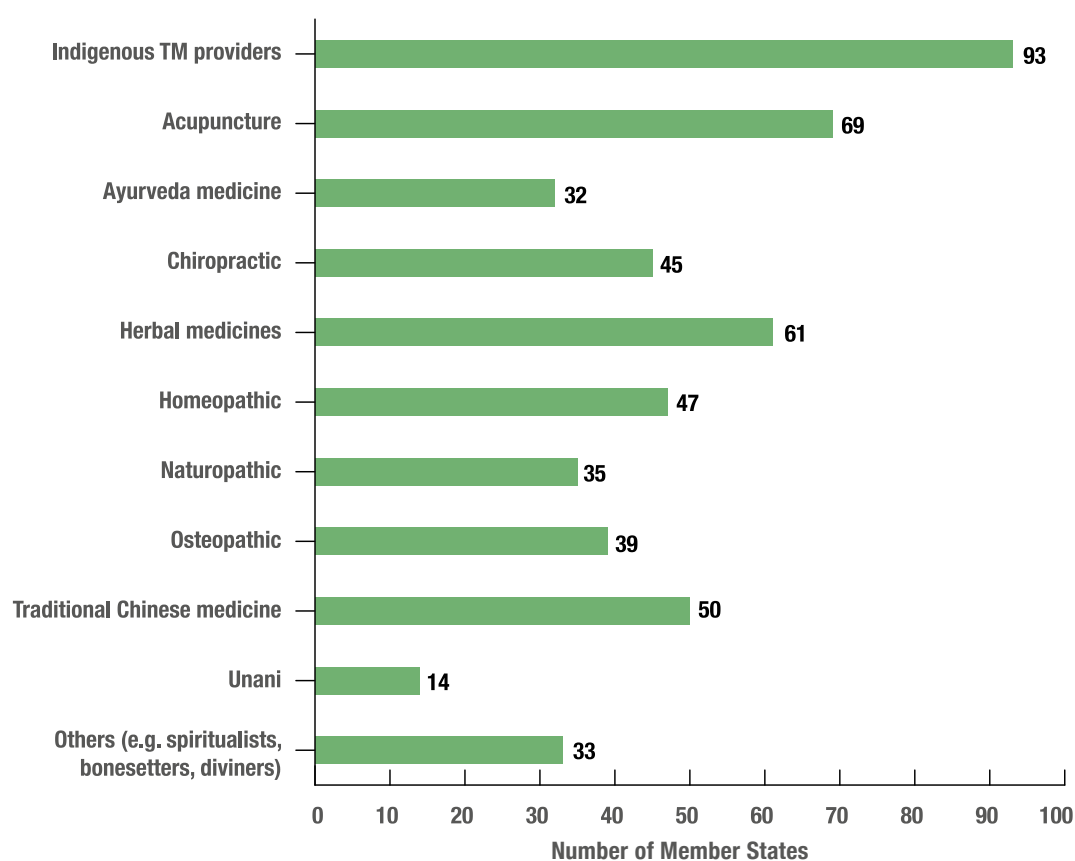
Some Member States reported official involvement in T&CM education of other countries. For example, since 2010, the Department of Traditional Medicine in Mali has participated in the supervision and examination of doctoral theses of African PhD students from Benin, Burkina Faso, Congo, Côte d'Ivoire, Guinea and Mali.

The WHO Regional Office for Africa provided an update that 21 Member States in the region have included TM in university health sciences curricula by 2016. Additional information and updates indicate that as at 2018, a further four Member States –Hungary, Lao People’s Democratic Republic, Mozambique and Portugal – also provide some form of T&CM education at university level. The relevant country summaries in Section 5 provide details. In Hungary, health training curricula include T&CM topics (theoretically), and some universities provide optional continuing professional education courses in T&CM (e.g. Pécs University, Health Science Faculty).

3.5 Types of T&CM providers

Member States were asked about the types of T&CM providers practising in their country. The statistics are shared in individual country summaries, and Fig. 3.10 shows the number of Member States reporting each type of T&CM providers. Providers of indigenous TM were the most common, followed closely by providers of acupuncture and herbal medicines, then chiropractic and homeopathy. “Other” types of T&CM provider were reported by 33 Member States.

Fig. 3.10. Types of T&CM providers practising in Member States, 2012



Based on the second WHO global survey respondents only, 2012 (N=133)

TM: traditional medicine

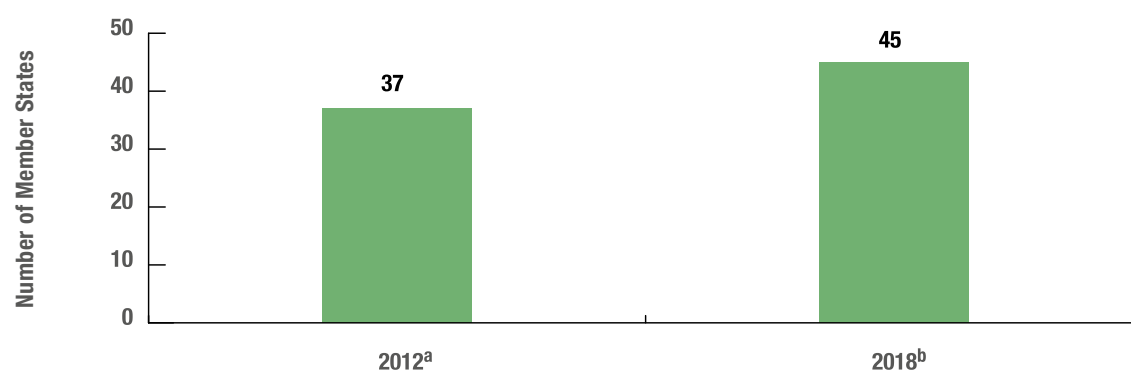
3.6 Health insurance and T&CM

Health insurance was broadly defined in the surveys to include both public and private payers that cover medical expenditures incurred by a defined population in a variety of settings.

Member States were asked whether indigenous TM and T&CM were covered by health insurance, and if so, whether the coverage was full or partial. The next question asked Member States to indicate, for each of the nine T&CM practices listed plus an option to include “other” practices, whether the health insurance was government or private.

As at 2018, 45 Member States reported the coverage of T&CM by health insurance, with the majority indicating this coverage was partial rather than full (see Fig. 3.11).

Fig. 3.11. Number of Member States with health insurance cover for T&CM, 2012–2018



T&CM: traditional and complementary medicine (which here includes indigenous traditional medicine).

Sources:

^a Based on the second WHO global survey respondents only (N=133).

^b Includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016-2018).

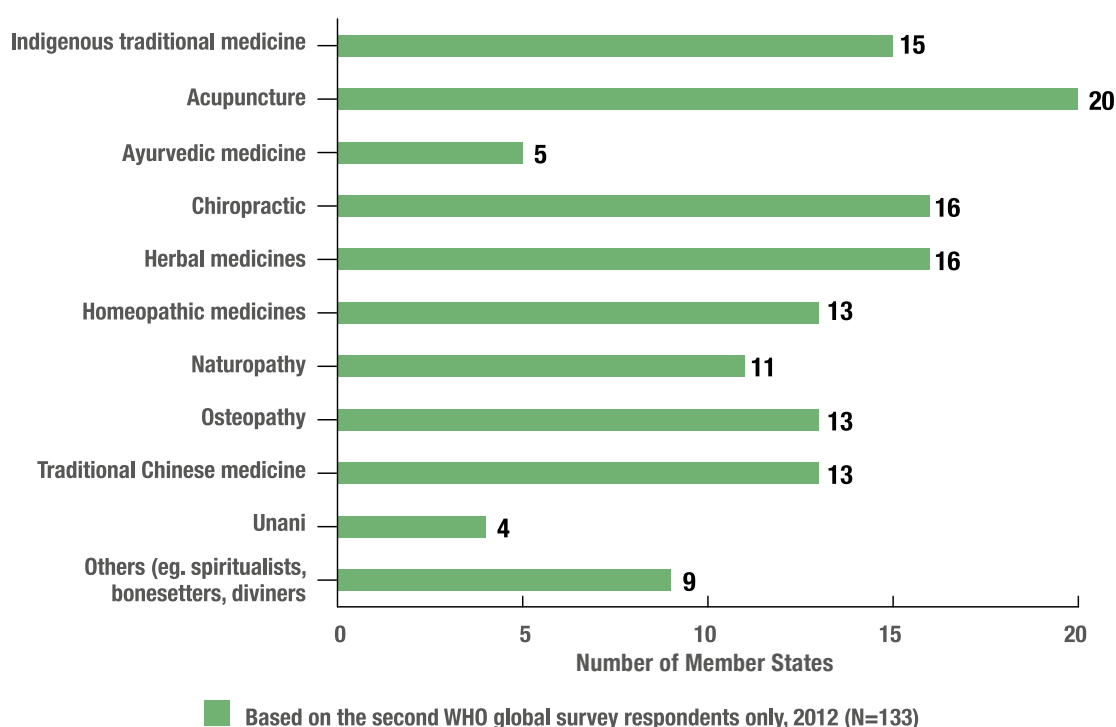
Fig. 3.12. Health insurance coverage of T&CM practices, 2012

Fig. 3.12 shows that as of 2012, the T&CM practice with the highest number of Member States reporting availability of health insurance was acupuncture (20), followed by chiropractic and herbal medicines (both 16), and then indigenous TM (15).

The type of coverage (private or government) and level of cover for different T&CM practices varied widely among Member States. Examples of full government cover include Bhutan, where full government insurance is available for gSo-ba Rig-pa (traditional Bhutanese medicine) as an integrated part of formal health care, and Cuba, where the health care system is universal, accessible, regionalized and free of charge, and thus no payment or insurance is needed for any health service provided.

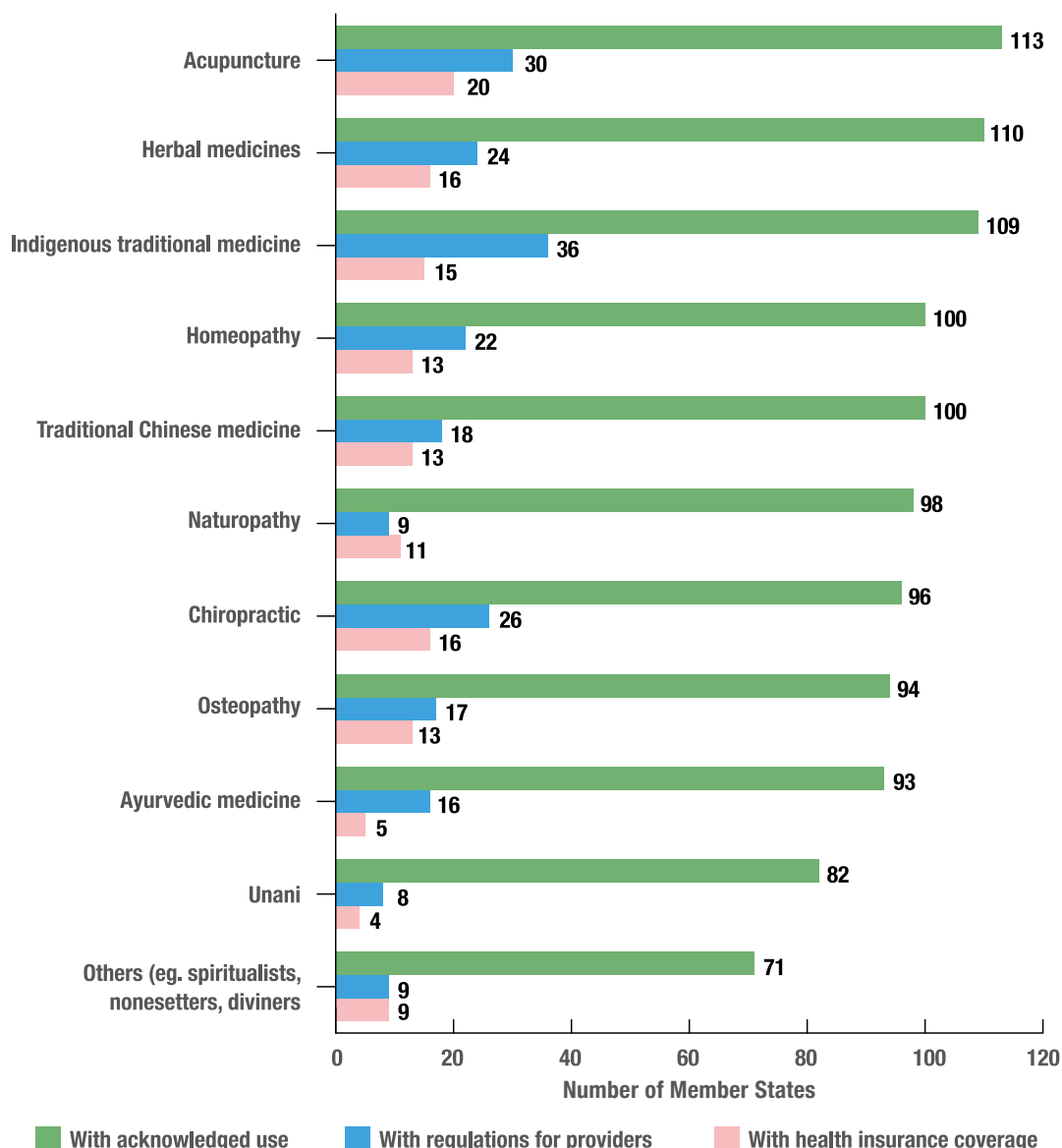
In Switzerland, T&CM is only covered under compulsory “basic” health insurance if the practice is recognized as mainstream medicine (e.g. chiropractic) and it is delivered by accredited physicians. Some coverage is also available if the T&CM practice has an “evidence development scheme”, such as homeopathy, phytotherapy, traditional Chinese medicine, anthroposophical medicine or neural therapy (which are being evaluated).

In Norway, there is full reimbursement for T&CM practices if the service is included in hospital treatment. For polyclinic treatment at hospitals, partial coverage is given. Chiropractic is regarded as mainstream health treatment and is fully covered.

In China, both government and commercial insurance (including both state-owned and private insurance companies) cover indigenous TM and part-cover the T&CM practices of acupuncture, herbal medicines, osteopathy and traditional Chinese medicine.

The number of Member States where a T&CM practice is used (Fig. 3.4), the number with regulations for providers of that practice (Fig. 3.6) and the number providing health insurance for that practice (Fig. 3.12) are shown together in Fig. 3.13.

Fig. 3.13. T&CM practices by number of Member States where the practice is used, its providers are regulated, and health insurance is available, 2012



Source: Based on the second WHO global survey respondents only (N=133).

3.7 Consumer education project or programme for self-health care using T&CM

The update survey asked Member States whether there is a consumer education project or programme for self-health care using T&CM.

Of the 61 respondents to the update survey, 16 Member States responded affirmatively; that is, Brazil, Cambodia, Chile, Cuba, Democratic People's Republic of Korea, Ghana, India, Mongolia, Morocco, Nicaragua, Oman, Peru, Philippines, Thailand, the United States and Viet Nam. In Peru, EsSalud (the contributory public social health insurance system) has a Complementary Medicine Directorate that, in 2013, developed a health education programme for people with metabolic syndrome. In the United States, consumer education projects and programmes for self-health care using T&CM form part of the National Center for Complementary and Integrative Health (NCCIH). In Saudi Arabia, a national consumer education plan is under development, and will be implemented in partnership with the National Committee through the Saudi Health Services Council.

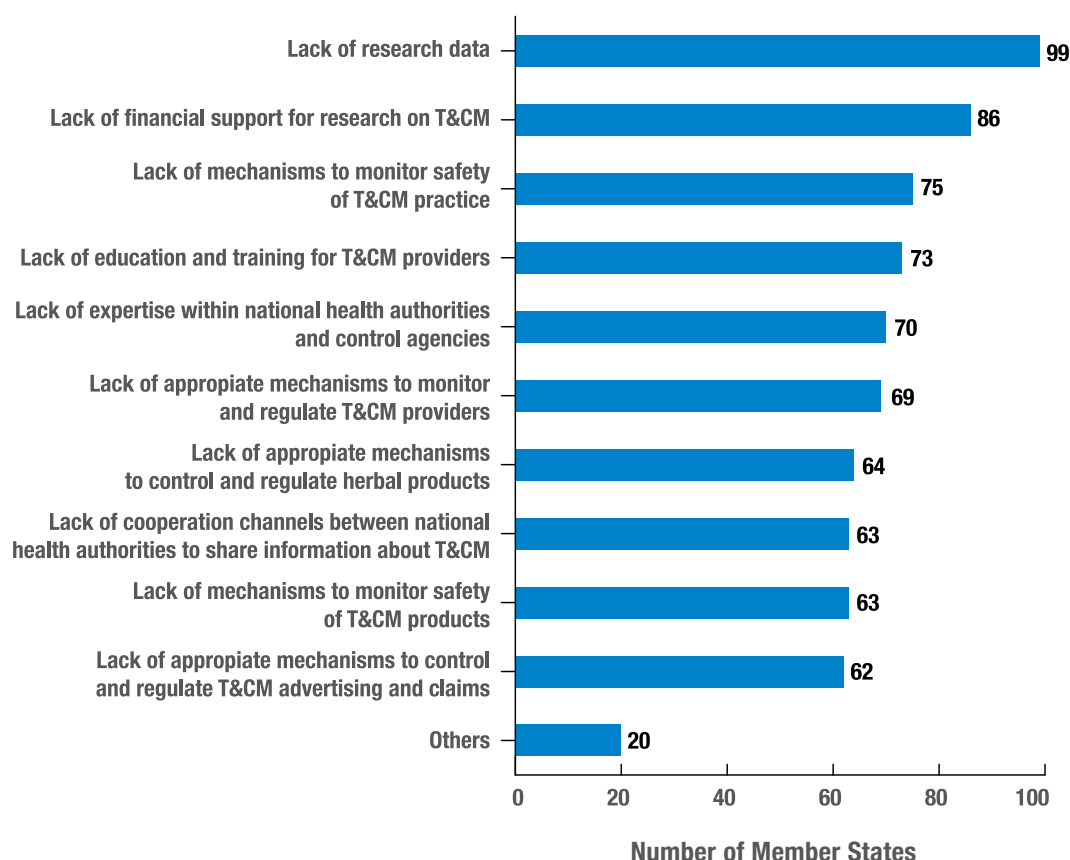
4. CHALLENGES AND THE NEED FOR WHO SUPPORT

This section covers information from the second survey, but not the first or the update survey.

4.1 Main difficulties faced by Member States

In this section, Member States were asked to share the difficulties they face with regard to regulatory issues related to the practice of T&CM. Of the 133 respondent Member States, a total of 113 answered this question (Fig. 4.1).

Fig. 4.1. Difficulties faced by Member States



Source: Based on the second WHO global survey respondents only (N=133).

Note: This graph differs from the equivalent graph in the WHO Traditional Medicine Strategy 2014–2023. Upon verification, some discrepancies were found in the interim data of the strategy and those data have been corrected here.

Lack of research data was reported by 99 Member States to be their top difficulty. The next two top difficulties were lack of financial support for research on T&CM (reported by 86 Member States) and lack of mechanisms to monitor safety of T&CM products, including herbal medicines (reported by 75 Member States).

Under “other” difficulties, Member States mentioned the lack of such things as political will, a legal framework, capacity to monitor safety of T&CM practice, capacity to monitor safety of T&CM products, referral mechanisms between T&CM and conventional medical practitioners, information systems and analysis of T&CM, and integration of T&CM into health systems.

The difficulties varied from region to region, as shown in Table 4.1, which presents the three most highly ranked difficulties reported by each WHO region (noting that for some regions there are more than three difficulties because of equivalent rankings).

Table 4.1. The top difficulties faced by Member States in each WHO region, with regard to regulatory issues related to the practice of T&CM, 2012

WHO region	Top difficulties
African Region (N=28)	1. Lack of research data & lack of financial support for research on T&CM: stated by 86% of the respondent African MS. 2. Lack of education and training for T&CM providers (79%). 3. Lack of appropriate mechanisms to control and regulate herbal products (68%); lack of mechanisms to monitor safety of T&CM practice (68%).
Region of the Americas (N=18)	1. Lack of research data: stated by 83% of the respondent Americas MS. 2. Lack of expertise within national health authorities and control agencies (67%); lack of cooperation channels between national health authorities to share information about T&CM (67%). 3. Lack of appropriate mechanisms to monitor and regulate T&CM providers (61%); lack of education and training for T&CM providers (61%); lack of mechanisms to monitor safety of T&CM practice and safety of T&CM products (61%); lack of financial support for research on T&CM (61%).
Eastern Mediterranean Region (N=17)	1. Lack of research data: stated by 76% of the respondent Eastern Mediterranean MS. 2. Lack of appropriate mechanisms to monitor and regulate T&CM providers (71%); lack of financial support for research on T&CM (71%); lack of education and training for T&CM providers (71%). 3. Lack of appropriate mechanisms to control and regulate T&CM advertising and claims (59%); lack of mechanisms to monitor safety of T&CM practice (59%).
European Region (N=36)	1. Lack of research data: stated by 47% of the respondent European MS. 2. Lack of expertise within national health authorities and control agencies (44%). 3. Lack of mechanisms to monitor safety of T&CM practice (39%); lack of financial support for research on T&CM (39%).
South-East Asia Region (N=10)	1. Lack of research data: stated by 90% of the respondent South-East Asia MS. 2. Lack of financial support for research on T&CM (70%). 3. Lack of expertise within national health authorities and control agencies (50%); lack of appropriate mechanisms to control and regulate herbal products (50%).
Western Pacific Region (N=23)	1. Lack of research data: stated by 87% of the respondent Western Pacific MS. 2. Lack of financial support for research on T&CM (74%). 3. Lack of appropriate mechanisms to control and regulate herbal products (70%); lack of mechanisms to monitor safety of T&CM practice and safety of T&CM products (70%).

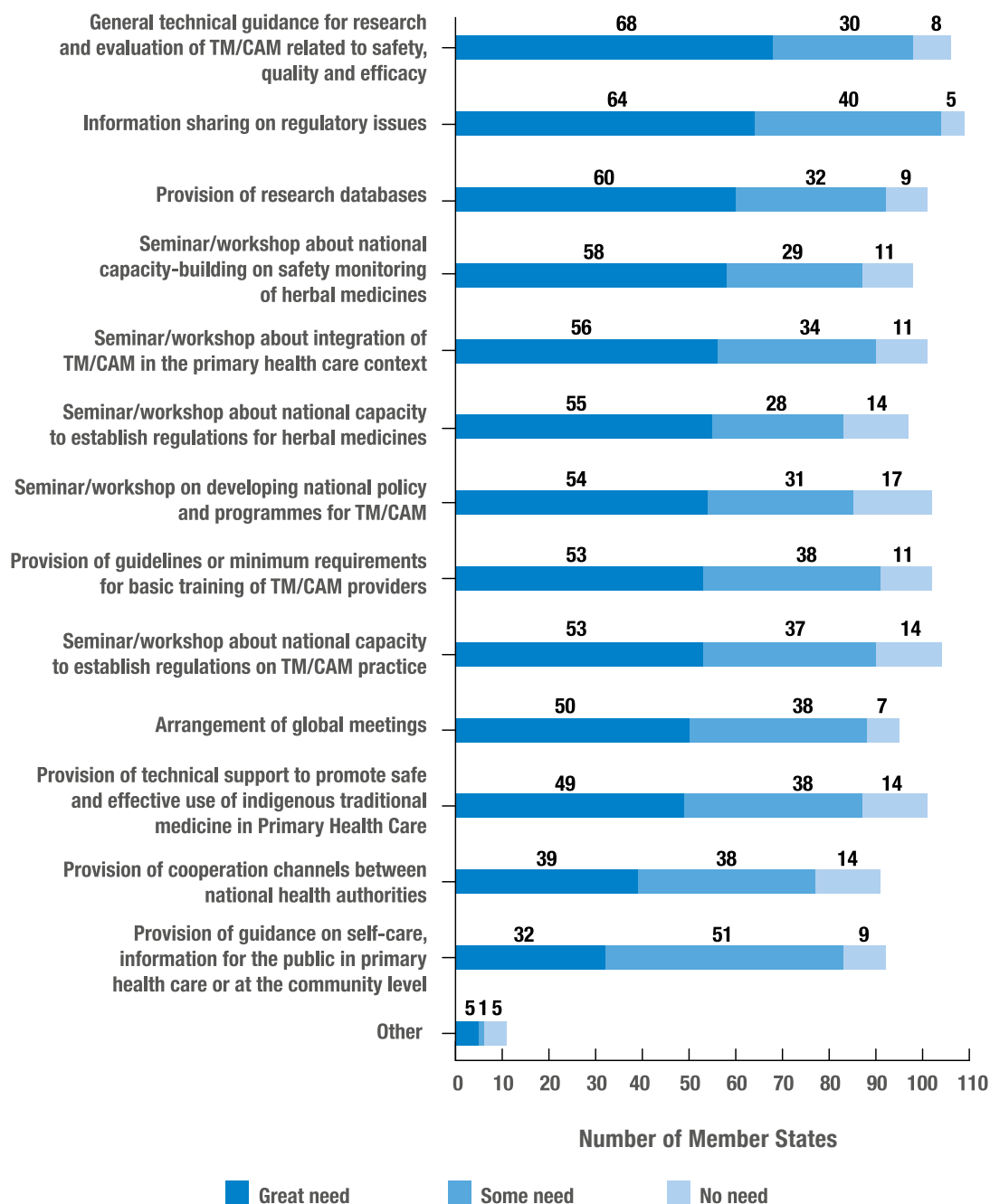
MS: Member States

Source: Based on the second WHO global survey respondents only (N=133).

4.2 Where WHO support is needed

Fig. 4.2 provides a detailed breakdown of the rating of each category of WHO support, as the number of Member States ranking each category differed in each case. While a majority of Member States ranked every category as “great need”, the category cited by most and the one most often ranked “great need” was that of general technical guidance for research and evaluation of T&CM related to safety, quality and efficacy.

Fig. 4.2. Type of support for T&CM issues that Member States are interested in receiving from WHO, 2012



TM/CAM: traditional medicine/complementary and alternative medicine

Source: Based on the second WHO global survey respondents only (N=133).

5. COUNTRY SUMMARIES

The country summaries included in this chapter follow a generalized template that includes the status of the following:

- national policy on T&CM (national policy, laws, regulations, national programme, national office, and national research institutes);
- the regulation of herbal medicines (laws, regulations, regulatory categories, claim types, pharmacopoeias and monographs used, manufacturing requirements and control mechanisms, safety requirements and control mechanisms, registration system, essential drug list, market surveillance, marketing and sales); and
- T&CM practices, providers and health insurance (use of T&CM, regulation of providers, education of providers, statistics and health insurance).

These summaries are provided for countries that responded to the second survey or the update survey (or both); that is, for 148 Member States across the six WHO regions and three other territories. The information shared from the update survey and additional sources during 2016–2018 is dated accordingly. In some cases, complete information was never provided; thus, data are incomplete for some countries. In other cases, relevant health focal points provided additional information at some point during the working procedure. Where the information was directly relevant to the subjects listed above, it was incorporated into the summary.

5.1 WHO African Region

Table 5.1 summarizes the development of national policy, regulation of T&CM and herbal medicines, along with use of T&CM in the WHO African Region, and compares the percentage of Member States in the region with the global percentage for each indicator.

In the period between 2005 and 2018 (in particular, 2001–2010), Member States in the region took steps to develop national policies and regulatory frameworks for T&CM practice, practitioners and products, and to implement some priority interventions (1).

While the region surpassed the global scenario in almost all indicators as at 2018, regulation and registration of herbal medicines were the two areas where the percentage of Member States in the region was not as high as the percentage of all Member States. 41 of the 47 Member States in the WHO African Region (87%) formally acknowledged the use of T&CM by their populations, similar to the global percentage.

Table 5.1. WHO African Region, development of T&CM, 2005–2018

Category	Regional number of Member States with affirmative responses in 2005	Regional number of Member States with affirmative responses as at 2018	Regional % of Member States with affirmative responses as at 2018 (N=47)	Global % of Member States with affirmative responses as at 2018 (N=194)
National policy on T&CM	12	40	85%	51%
Laws or regulations on T&CM	10	39	83%	56%
National programme on T&CM	15	34	72%	41%
National office for T&CM	25	39	83%	55%
Expert committee on T&CM	16	34	72%	48%
National research institute for T&CM or herbal medicines	18	29	62%	39%
Regulation of herbal medicines	12	20	43%	64%
Registration of herbal medicines	8	23	49%	64%
Population using T&CM	–	41	87%	88%

Note: The 2018 data set includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018). There may be Member States in which the T&CM situation has changed, not accounted for here.

1. Benin

National policy on T&CM

Benin has a national policy for T&CM: National Policy of Benin Pharmacopoeia and Traditional Medicine (*Politique Nationale de la Pharmacopée et de la Médecine Traditionnelles du Bénin*).

The most recent update of the national policy and laws on T&CM was done in 2016, and the regulations on T&CM practice in 2013.

Annual Government or public research funding for T&CM (in US\$) in Benin, 2010–2016						
2010	2011	2012	2013	2014	2015	2016
160 000	100 000	160 000	200 000	200 000	300 000	200 000

A national plan for integrating T&CM into the National Health Service delivery was established in 1996.

Regulatory status of herbal medicines

The national regulation on herbal medicines was last updated in 2013. The West African Pharmacopoeia (developed by the West African Health Organization [WAHO] in 2013) is now in use. The list of registered herbal medicines was last updated in 2016.

Herbal medicines are sold with claims that are unregulated. National monographs on herbal medicines are used, but are not legally binding. Examples include two 2009 monographs on plants used in TM in Benin for the prevention and treatment of malaria, and of sexually transmitted diseases (STDs) and HIV/AIDS.

The regulations on manufacturing of herbal medicines used to ensure the quality of such medicines require adherence to manufacturing information in pharmacopoeias and monographs. The mechanisms to ensure compliance are periodic inspections by authorities at the manufacturing plants or laboratories; manufacturers are required to submit samples of their medicines to a government-approved laboratory for

testing, and to assign a person to the role of ensuring compliance with manufacturing requirements and reporting back to the Government.

To meet regulatory requirements for the safety assessment of herbal medicines, either exclusive or traditional use without demonstrated harmful effects is considered sufficient. The NEML does not include herbal medicines. The market surveillance system for safety of medicines has included herbal medicines since 2007. Herbal medicines are sold in pharmacies and in other outlets, and by licensed providers. Regulatory categories for herbal medicines are prescription medicines, non-prescription medicines, self-medication and OTC medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Benin, with estimated use by 80–99% of the population (11). Other T&CM practices are also used.

Providers of herbal medicines, naturopathy and osteopathy have been regulated at the national level since 2004. These regulations were updated in 2013.

T&CM providers practise only in private sector clinics and hospitals. A T&CM licence or certificate, issued by the national Government, is required for practice.

Data from the Benin Registry of Traditional Medicine Practitioners, 1999 (*Répertoire des Praticiens de la Médecine Traditionnelle du Bénin, 1999*) showed that about 7500 indigenous TM providers were practising in Benin in 1999. Data for 2007 from the Benin MoH showed that about 1650 chiropractic, 4500 herbal medicine, 2200 homeopathic medicine, 1500 naturopathic medicine and 450 traditional Chinese medicine providers were practising in Benin.

2. Burkina Faso

National policy on T&CM

Burkina Faso's national policy is titled National Policy Framework on Document Traditional Medicine and Pharmacopoeia (*Document Cadre de Politique Nationale en Matière de Médecine et Pharmacopée Traditionnelles*). The national laws regulating T&CM are part of the Public Health Code (No. 23/94/ADP du 19 Mai 1994 portant Code de la Santé Publique).

Regulatory status of herbal medicines

Herbal medicines are regulated under the *Decree on authorisation of marketing medicines from Burkina Faso traditional pharmacopoeia* (Décret No. 2004/569/PRES/PM/MS du 13/10/2004 portant autorisation de mise sur le marché des médicaments issus de la pharmacopée traditionnelle au Burkina Faso).

Herbal medicines are sold with medical and health claims. Pharmacopoeias, such as the African Union's pharmacopoeia (*Pharmacopée de l'Union Africaine*, 1ère éd., vol. 1., 1985), are used but are not legally binding.

Manufacturers of herbal medicines must comply with the GMP for medicines of categories 1 and 2 (*Module de formule des tradipraticiens: bonne pratique de fabrication des médicaments des deux premières catégories*). The regulation on manufacturing of herbal medicines to ensure their quality requires adherence to manufacturing information in pharmacopoeias and monographs. There are periodic inspections by authorities at the manufacturing plants or laboratories. Regulatory requirements for the safety assessment of herbal medicines are the same as those for conventional pharmaceuticals.

As at 2012, 13 herbal medicines were registered in Burkina Faso and the NEML included four herbal medicines. The selection criteria for inclusion in the NEML are based on the traditional use of the herbal medicine, clinical data and long-term historical use. Herbal medicines are sold in pharmacies and other outlets as non-prescription medicines, self-medication or OTC medicines, and in special outlets such as herbal stores.

Practices, providers, education and health insurance

Indigenous TM is considered important in Burkina Faso, with use by an estimated 60–79% of the population, according to the Directorate of Traditional Medicine and Pharmacopoeia. Other T&CM practices are also used, such as acupuncture, chiropractic, herbal medicines, homeopathy and naturopathy. Herbal medicines and naturopathy are used by 40–59% of the population.

Regulations at the national level apply to indigenous TM providers. T&CM providers practise only in the private sector. A T&CM licence or certificate is required for practice. The Government does not officially recognize any T&CM training programmes.

There were about 30 000 practising indigenous TM providers as of 2012.

3. Burundi

National policy on T&CM

In 2012, Burundi had a policy and national strategy for T&CM. In November 2014, a new decree (policy and regulation) was endorsed by the Government and signed by the Président of the Republic.

There has been a national office in charge of T&CM issues since 2002. There is no formalized national expert committee as such, although there have long been individual researchers and experts in T&CM working in a private capacity or at the University of Burundi. The University Centre for Research on Pharmacopoeia & Traditional Medicine (*Centre Universitaire de Recherche sur la Pharmacopée & la Médecine Traditionnelle*) of the University of Burundi undertakes research in T&CM.

Regulatory status of herbal medicines

Herbal medicines are regulated by Decree No. 100/253, which commenced on 11 November 2014, under the provision “traditional medicine and the art of the traditional therapist”. Conventional medicines are regulated by a different decree, dated 30 September 1980. There is no mandatory reference pharmacopoeia.

Herbal medicines are sold with claims that are unregulated. There is no regulation of the manufacturing of herbal medicines to ensure their quality, and no safety requirements for herbal medicines. The NEML does not include herbal medicines. Herbal medicines are sold in outlets other than pharmacies as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Burundi. T&CM practices used by the population include acupuncture, ayurvedic medicine, chiropractic, herbal medicine, homeopathy, naturopathy, osteopathy and traditional Chinese medicine. Providers of these types of T&CM practise in Burundi.

T&CM providers practise in the private sector and home-based settings. The Government does not officially recognize any T&CM training programmes.

T&CM in Burundi is not covered by public or private health insurance.

4. Cameroon

National policy on T&CM

Cameroon’s national policy on T&CM is integrated into other national policies such as the Healthcare Sector Strategy 2001–2015 and the Health Framework Law (*Stratégie Sectorielle de Santé 2001–2015 et Loi Cadre Santé*). The national programme for T&CM is the Traditional Medicine Strategic Development Plan 2006–2010 (*Plan Stratégique de Développement de la MTR 2006–2010*).

The national office for T&CM is the Traditional Health and Social Services unit (*Service des Prestations Socio Sanitaires Traditionnelles, DOST/MINSANTE, Yaoundé, Cameroun*), which is administered by the MoH.

The Institute for Medical Research and the Study of Medicinal Plants (*Institut des Recherches Médicales et d’Etude des Plantes Médicinales*) conducts research on T&CM at the national level.

Regulatory status of herbal medicines

National regulation of herbal medicines is within an approval procedures framework for medicines, which is set out in the standard for homologation procedures for medications from traditional pharmacopoeias (*Référentiel pour des Procédures d'Homologation des Médicaments Issus de la Pharmacopée Traditionnelle*). Cameroon does not have yet its own traditional pharmacopoeia. For approval of imported herbal medicine-based products, the pharmacopoeia used is the one of the country of origin.

Herbal medicines are regulated under the category “herbal medicines” and are sold with medical, health and nutrient content claims, which are unregulated. National monographs on herbal medicines are used, but are not legally binding. A monograph on plants is used to treat some priority conditions: diabetes, diarrhoea, drepanocytose, hypertension, malaria and tuberculosis. Other monographs on herbal medicines used are the *WHO monographs of selected medicinal plants*, vol. 3 (2007) and vol. 4 (2009).

There are exclusive regulatory requirements for the safety assessment of herbal medicines from categories 2, 3 and 4, and toxicity assessments for category 1 herbal medicines. To ensure compliance with GMP for the manufacture of herbal medicines, manufacturers must file an approval request that includes an expert report on GMP as well as the results of the final product quality control.

As at 2012, 41 herbal medicines were listed and three were registered in Cameroon. The NEML included three herbal medicines that are locally produced. The selection criteria for inclusion in the NEML are based on the traditional use of the herbal medicines, clinical data, long-term historical use and laboratory testing. Herbal medicines categorized as prescription medicines are sold in pharmacies. Other categories – non-prescription medicines, self-medication and OTC medicines – are sold in pharmacies and other outlets (including special outlets), and by licensed providers.

Practices, providers, education and health insurance

Indigenous TM is considered important in Cameroon, although only an estimated 1–19% of the population uses it, according to 2004 data from a study titled *Déterminants of recourse to care (Déterminants de recours aux soins)*. Other T&CM practices in use include acupuncture, ayurvedic medicine, chiropractic, herbal medicine, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine, along with practices such as prayer.

Indigenous TM providers are regulated under the African Organization for Intellectual Property (OAPI) framework for identification of traditional therapists, developed in 2004. T&CM providers practise in the private sector only. In universities, training is provided to medical students to build their awareness of T&CM. Indigenous TM providers and acupuncture providers are known to practise within Cameroon but data on their numbers are not available.

5. Central African Republic

National policy on T&CM

The Central African Republic has an exclusive national policy titled Central African Republic National Policy on Traditional Medicine (*Politique Nationale de la Médecine Traditionnelle en République Centrafricaine*).

There has been a Federation of Traditional Healers in Bangui since 1984. There is also a non-permanent expert committee on T&CM that is formed (through a ministerial order) whenever the need arises. Otherwise, the Central African Republic usually relies on the expertise of the WHO's expert committee of the WHO African Region.

The African Pharmacopoeia and Traditional Medical Research Centre (*Centre de Recherches en Pharmacopée et Médecine Traditionnelle Africaines*) undertakes research in T&CM as part of the Faculty of Health Sciences at the University of Bangui.

There are a number of national laws and regulations for T&CM, including:

- Ordinance No. 85.025 of 16 August 1985, on the legal recognition of the traditional pharmacopoeia and medicine in the Central African Republic;

- Decree No. 85.250 of 16 August 1985, establishing the national committee to popularize, coordinate and develop pharmacopoeias and traditional medicine in the Central African Republic;
- Decree No. 85.059 of 5 March 1985, on the organization and functioning of the Ministry of Public Health and Population and Social Affairs and setting the powers of the minister; this decree provides, within the Central Inspectorate of Health Services and Social Affairs, an Inspection of Pharmaceutical Services that includes the organization of traditional medicine in its responsibilities;
- Order No. O91/MSPP/CAB/SG/DGSA/DES of 8 March 1997, setting out the powers and duties of the various departments of the Department of Health Care Establishments, including the Department of Traditional Medicine, which is responsible for:
 - promoting collaboration with traditional healers in the development of care;
 - designing and participating in sociocultural and sociomedical studies to identify the number of traditional healers, to define their profile, to assess their attitudes and behaviour, and to regulate their professional activity; and
 - providing guidance to the health regions to develop programmes for the insertion of traditional healers into primary health care activities.

Regulatory status of herbal medicines

There is no regulation of the manufacturing of herbal medicines to ensure their quality. The safety requirements are the same as those for conventional pharmaceuticals; traditional use without demonstrated harmful effects is sufficient for the safety assessment of herbal medicines. The NEML does not include herbal medicines. Herbal medicines in the categories of non-prescription medicines, self-medication or OTC medicines are sold in outlets other than pharmacies, and there are no restrictions on selling herbal products.

Practices, providers, education and health insurance

Indigenous TM is considered important in Central African Republic. T&CM practices such as acupuncture, herbal medicine, naturopathy and traditional Chinese medicine are also used by the population.

Herbal medicine providers are regulated. T&CM providers practise in the private sector only. The Government does not officially recognize any T&CM training programmes.

6. Chad

National policy on T&CM

The national office for T&CM is located in N'Djamena and is administered under the Chad MoH. According to a 2008 report by the African Union Commission on Traditional Medicine (12), a national expert committee on T&CM was constituted in Chad in 2005. The Study and Research Unit in Pharmacopoeia and Traditional Medicine – a research facility for traditional health care practices within the Health Department of the University of N'Djamena – is affiliated with the central African traditional medicine and pharmacopoeia network.

Regulatory status of herbal medicines

The NEML does not include herbal medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Chad, with the Pharmacopoeia and Traditional Medicine Division estimating that it is used by 60–79% of the population. Other T&CM practices are also used; for example, acupuncture is used by 1–19% of the population.

Indigenous TM providers are regulated at the national level. T&CM providers practise in both private and public sectors.

7. Comoros

National policy on T&CM

Comoros has had a national policy and laws on T&CM since 2011. *Law No. 11-001/AU of 26 March 2011 on the Public Health Code in its Title III: Exercise and Organization of Traditional Medicine*, particularly in Articles 262–279, covers the general conditions and practice of TM, including the creation of a unit responsible for TM in the Comoros MoH.

A national research institute on traditional medicine, the National Documentation and Scientific Research Centre (*Centre National de Documentation et de Recherche Scientifique*), was founded in 1979.

Regulatory status of herbal medicines

There is no regulation of the manufacturing of herbal medicines to ensure their quality, nor is there any regulatory requirements for the safety assessment of herbal medicines. The NEML does not include herbal medicines. Herbal medicines are categorized as non-prescription medicines, self-medication or OTC medicines, and are sold in pharmacies and other outlets.

Practices, providers, education and health insurance

T&CM practices such as acupuncture, ayurvedic medicine, chiropractic, herbal medicine, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine are used by the population of Comoros.

T&CM providers, including indigenous TM providers, practise in the private sector only.

8. Congo

National policy on T&CM

The Congo has had a national policy exclusively for T&CM (*Politique Nationale de Médecine Traditionnelle*) since 2006. The national office is the traditional medicine unit within the Ministry of Health and Population (*Service de la Médecine Traditionnelle, Ministère de la Santé et de la Population, BP78 Brazzaville Congo*).

Regulatory status of herbal medicines

Herbal medicines are sold in outlets other than pharmacies, including special outlets. They are categorized as non-prescription medicines, self-medication or OTC medicines. The NEML does not include herbal medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in the Congo, and is used by an estimated 80–99% of the population. It is estimated that 1–19% of the population uses acupuncture, based on a sampling of patients attending Chinese and Congolese practices in Brazzaville and Pointe-Noire carried out by the National Traditional Medicine Unit. Ayurvedic medicine, chiropractic and herbal medicines are each used by an estimated 80–99% of the population, according to the 2006 national policy document. Traditional Chinese medicine is used by 1–19% of the population, based on data from outlets selling traditional Chinese medicine products. Homeopathy, naturopathy, osteopathy and Unani medicine are also used by the population.

Indigenous TM providers are regulated at the national level. T&CM providers practise in the private sector, public hospitals and in traditional health care practices and centres. A T&CM licence or certificate, issued by the national Government, is required for practice. The Government officially recognizes T&CM training programmes such as apprenticeship with a T&CM provider (without certificate or licensing); certified programmes; and training programmes for indigenous TM practitioners, T&CM technicians or equivalent.

According to the 2006 national policy document, there were 2084 indigenous TM providers and, based on a countrywide census of traditional practitioners (year unspecified), an estimated 2000 herbal medicine providers practising in the Congo.

9. Côte d'Ivoire

National policy on T&CM

In Côte d'Ivoire there has been a national policy exclusively for T&CM since 2007, the National Policy Framework Document on Traditional Medicine and African Pharmacopoeia (*Document Cadre de Politique Nationale en Matière de Médecine Traditionnelle et de Pharmacopée Africaine*).

The national laws and regulations on traditional medicine are Law No. 2015–536 of 20 July 2015 (on the exercise and organization of medicine and traditional pharmacopoeia) and Decree No. 2016–24 of 27 January 2016 (on the code of ethics and professional conduct of practitioners of traditional medicine and pharmacopoeia).

Regulatory status of herbal medicines

There are pharmacopoeias, such as the *Nigerian herbal pharmacopoeia* (1st ed., 2008), and monographs, such as the *Ghanaian monographs of medicinal plants* (2009; Pharmacopée Européenne), but they are not legally binding.

The regulation of manufacturing of herbal medicines to ensure their quality is the same as that for conventional pharmaceuticals. Compliance mechanisms include periodic inspections by government authorities at manufacturing plants and laboratories, the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing, and the requirement for manufacturers to assign a person to be responsible for ensuring compliance with manufacturing requirements and reporting back to the Government authorities. The regulatory requirements for the safety assessment of herbal medicines are also the same as that for conventional pharmaceuticals.

As at 2012, two herbal medicines were registered. The NEML does not include herbal medicines. There is a market surveillance system for the safety of herbal medicines. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets, including special outlets.

Practices, providers, education and health insurance

Indigenous TM is considered important in Côte d'Ivoire, being used by an estimated 80–99% of the population. Estimates of population use, obtained from the 2009 data from the Coordination Centre for the National Programme for Promoting Traditional Medicine (*La Direction de Coordination du Programme National de Promotion de la Médecine Traditionnelle* [DC PNPM]), for various T&CM practices are as follows: 60–79% for acupuncture, ayurvedic medicine, chiropractic, herbal medicine and naturopathy; and 20–39% for homeopathy, osteopathy and traditional Chinese medicine. Unani medicine is also used. Other practices, such as spiritualism, are used by 40–59% of the population.

T&CM providers practise in private clinics, health care centres and herbal stores. The Government officially recognizes training programmes, such as an apprenticeship with a T&CM provider (without certificate or licensing); it also recognizes programmes provided by the DC PNPM, such as training in conventional hygiene, anatomy, sustainable use and conservation of medicinal plants, and data collection and management.

According to the DC PNPM, there are an estimated 20 000 indigenous TM providers practising within Côte d'Ivoire, including those practising in acupuncture (100), herbal medicine (7000), naturopathy (12 000), traditional Chinese medicine (3500), and other practices such as spiritualism (2500).

10. Democratic Republic of the Congo

National policy on T&CM

The Democratic Republic of the Congo has had a national policy exclusively for T&CM since 2006 – National Policy on Traditional Medicine in DRC.

The national research institute is the Institute for Health Sciences Research (*Institut de Recherche en Sciences de Santé*), founded in 1976, which conducts research on TM (13) and herbal medicines. There is also a national expert committee for T&CM (14).

Regulatory status of herbal medicines

There is a national-level regulation governing herbal medicines (12). Herbal medicines are sold with medical, health and nutrient content claims, although these claims are unregulated. The pharmacopoeia used is the *Pharmacopée traditionnelle de la RDC: répertoire de 120 plantes médicinales* (1st ed., 2009).

There is no regulation of the manufacturing of herbal medicines to ensure their quality. Regulatory requirements for the safety assessment of herbal medicines are the same as that for conventional pharmaceuticals. Herbal medicines are registered and the NEML includes three herbal medicines (as of 2012). The selection criteria for inclusion in the NEML are based on traditional use of the herbal medicines, clinical data and laboratory testing. Herbal medicines categorized as non-prescription medicines, self-medication or OTC medicines are sold in outlets other than pharmacies.

Based on estimates from herbal medicines importers, the annual market sales of herbal medicines in 2007, 2008 and 2009 were US\$ 200 000, US\$ 600 000 and US\$ 1 300 000, respectively.

Practices, providers, education and health insurance

Indigenous TM is considered important in the Democratic Republic of the Congo. T&CM practices also used by the population include acupuncture, herbal medicines, osteopathy and traditional Chinese medicine.

Regulation of indigenous TM providers is enforced at provincial and local levels. T&CM providers practise in private clinics and public hospitals. A T&CM licence or certificate, issued by the national Government, is required to practise. The Government officially recognizes training programmes on TM for health care sciences students.

According to the Traditional Practitioners Associations, there are between 10 000 and 20 000 indigenous TM providers practising within the Democratic Republic of the Congo. T&CM providers of acupuncture, herbal medicine, osteopathy and traditional Chinese medicine, as well as traditional birth attendants, are also found in the country.

12. Equatorial Guinea

National policy on T&CM

Equatorial Guinea has had a national policy exclusively for T&CM since 1985: Law 4/1985, which provided for the creation of a National Service for Traditional Medicine (*Servicio Nacional de Medicina Tradicional*).

The national office for T&CM has been administered under the MoH since 1990. There is also a national research institute for T&CM (12).

Regulatory status of herbal medicines

National regulation of herbal medicines is the same as that for conventional pharmaceuticals. The monograph used is *Medicinal plants of Equatorial Guinea, 1996* (*Plantas medicinales de Guinea Ecuatorial, 1996*). There is a registration system for herbal medicines. Herbal medicines categorized as non-prescription medicines, self-medication or OTC medicines are sold in outlets other than pharmacies and by licensed practitioners.

Practices, providers, education and health insurance

Indigenous TM is considered important in Equatorial Guinea, being used by an estimated 60–79% of the population. A T&CM licence or certificate, issued by the national Government, is required for practice. The Government officially recognizes training programmes such as an apprenticeship with a T&CM provider.

11. Eritrea

National policy on T&CM

In 2012, the MoH established a Traditional Medicine Unit under the National Medicines and Food Administration, with the responsibilities of formulating policy guidelines on the practice of T&CM, registering T&CM practitioners, monitoring safety of T&CM practices, and heightening public education about and research into T&CM.

The Medicinal Plants and Drug Discovery Research Centre of the University of Asmara has been advancing research on T&CM in Eritrea (15).

Regulatory status of herbal medicines

In Eritrea, no regulatory status is given to herbal medicines and they are sold without any type of medical, health or other claims. No regulations apply to the manufacturing of herbal medicines and no safety requirements currently exist for the assessment of herbal medicines. Eritrea does have an NEML (the fifth edition was published in June 2010) and a market surveillance system for the safety of medicines, but neither includes herbal medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Eritrea, and T&CM practices are used by the population, but no data on percentages of population use are available.

T&CM providers practise in both the public and private sector, and a licence issued by the national government is required for practice.

13. Ethiopia

National policy on T&CM

Ethiopia has an integrated policy, titled National Drug Policy of Ethiopia, which covers both herbal medicines and conventional pharmaceuticals. The national office for T&CM is the Food, Medicine and Health Care Administration and the Control Authority of Ethiopia in Addis Ababa, under the MoH.

The Ethiopian Health and Nutrition Research Institute serves as the national research institute for T&CM.

Regulatory status of herbal medicines

There is a regulation exclusively for herbal medicines, which also covers TM practice, defined as “any plant, animal or mineral product that can be used independently or in combination for the treatment of human or animal diseases”. Herbal medicines are sold with claims, but these claims are unregulated.

No regulations apply to the manufacturing of herbal medicines and there are currently no safety requirements. Neither Ethiopia’s NEML nor its market surveillance system for safety of medicines, in place since 1999, include herbal medicines. Herbal medicines categorized as non-prescription medicines, self-medication or OTC medicines are sold in outlets other than pharmacies.

Practices, providers, education and health insurance

According to the New Partnership for Africa’s Development, the use of indigenous TM by the population in Ethiopia is estimated between 60% and 79%, but data are not available for the use of other T&CM practices.

Draft regulations exist on indigenous TM providers since 2009, at a national and state level. There are regulations on herbal medicine providers and T&CM, enforced at national and state level. T&CM providers practise only in private sector clinics. A licence or certificate, issued by the national or state Government, is required for practice.

The Government does not officially recognize any T&CM training programmes. According to the Office of Food, Medicine and Health Care Administration and Control Authority of Ethiopia, citing publications and proceedings, there are an estimated 600 herbal medicine providers (as at 2012) and other T&CM providers such as bonesetters, spiritual healers and traditional birth attendants practising in Ethiopia.

14. Gabon

National policy on T&CM

In Gabon, the national office for T&CM (*Service de médecine traditionnelle*) has been administered under the MoH since 2000. The National Research Institute for Pharmacopoeia and TM (*Institut de Pharmacopée et de Médecine Traditionnelle*) was established in 1992.

Regulatory status of herbal medicines

Herbal medicines are sold in the marketplace by T&CM practitioners, with no quality or safety regulation.

Practices, providers, education and health insurance

Indigenous TM is considered important in Gabon, with 80–99% of the population using it. T&CM practices in use include acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine, as well as other practices such as initiatory and spiritual medicine (Mbiri or Bwiti).

T&CM providers practise in home-based settings. Providers self-regulate by a delegated special technical association. A licence or certificate issued by the association is required to practise.

It is estimated that over 3000 indigenous TM providers practise within the country (as at 2012).

15. Gambia

National policy on T&CM

Gambia has had a national policy exclusively on T&CM since 2005, titled National Traditional Medicine Policy of Gambia.

The National Traditional Medicine Programme, under the MoH in Banjul, serves as the national office for T&CM; there is also an expert committee for T&CM. Both have been in place since 2002.

Regulatory status of herbal medicines

Herbal medicines are not given regulatory status in Gambia. Medical, health and nutrient content claims are made, but are unregulated.

There is no pharmacopoeia for herbal medicines; however, during critical times, reference is made to the WAHO's West African pharmacopoeia. No safety requirements currently exist for herbal medicines. Herbal medicines are sold without restrictions as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM and other forms of T&CM – acupuncture, ayurvedic medicine, herbal medicines, homeopathy and Unani medicine – are used in Gambia, but usage data are not available. T&CM providers practise in the private sector. T&CM education is provided at the university level but the Government officially recognizes other T&CM training programmes such as an apprenticeship with a T&CM provider. About 3000 indigenous TM providers practise in Gambia (as at 2012).

16. Ghana

National policy on T&CM

In Ghana, there is a national policy on T&CM, titled Policy of Traditional Medicine Development in Ghana, which is also integrated into the Policy on Protection of Genetic Resources. The *Traditional Medicine Practice Act of 2000* (TMP Act) constitutes the national regulation on T&CM. This Act established the Traditional Medicine Practice Council (TMPC) as a regulatory body.

The Traditional and Alternative Medicine Directorate under the MoH serves as the national office for T&CM. A national expert committee exists and comprises stakeholders from the MoH, academia, civil society, the Noguchi Memorial Institute for Medical Research, the Centre for Scientific Research into Plant Medicine and the Ghana Federation of Traditional Medicine Practitioners Association.

The Centre for Scientific Research into Plant Medicine in Ghana functions as the national research institute for T&CM. National laws and regulations on T&CM include the *Food and Drugs Law of 1992*, the *Pharmacy Act of 1995* and the TMP Act. There are also policy guidelines on intellectual property rights related to plant genetic resources.

As at end 2016, there is no government or public research funding for T&CM. In 2011, a national plan for integrating T&CM into national health service delivery was formulated. A consumer education programme for self-health care using T&CM was introduced in 2000.

Regulatory status of herbal medicines

Herbal medicines are regulated partly in the same way as conventional pharmaceuticals, in the category of herbal medicines. Regulations were updated in 2012. The new *Pharmacy Act* and the *Food and Drugs Law* are yet to classify medicines and provide definitions.

Herbal medicines are sold with medical, health and nutrient content claims that are regulated by laws, but those laws are weakly enforced.

The *Ghana herbal pharmacopoeia* (2nd ed., 2007) is the national pharmacopoeia and the *Ethnobotanical and Floristic Studies* is also used; these publications are authoritative and respected but not legally binding. The *Nigerian herbal pharmacopoeia* (2008), the *African herbal pharmacopoeia* (1995) and the WAHO's West African pharmacopoeia are also referred to. As of 2012, 120 national monographs were issued as part of the series, *Monographs on medicinal plants of Ghana*. The *Training manual for traditional medicine practitioners* was issued in 2002.

The GMP regulations that apply to herbal medicines are the same as that for conventional pharmaceuticals. Manufacturers of herbal medicines are required to adhere to the manufacturing information in pharmacopoeias and monographs, to ensure their quality. To ensure compliance, pre-registration inspections and testing, usually executed by the Food and Drugs Board of Ghana, are statutory requirements. Chronic, sub chronic and organ-specific toxicity profiling is part of the safety assessment of herbal medicines.

Herbal medicines are registered with the Food and Drugs Board; 375 out of 500 herbal medicines still maintain their registration. These were last updated in 2016. Ghana has kept a national list of 190 herbal medicines since 2008 and these are selected based on traditional use of the herbal medicines, clinical data, long-term historical use, laboratory testing and registration. Two herbal medicines were selected for the NEML (as at end 2016).

The market surveillance system for safety of medicines has included herbal medicines since 2000. Herbal medicines are sold in pharmacies as prescription and non-prescription medicines, in shops that sell chemicals, in special outlets such as herbal medicine shops and by licensed practitioners in small clinics.

Practices, providers, education and health insurance

According to an MoH study in 1998 and WHO data from 2009, 60–79% of the population in Ghana uses indigenous TM. Data obtained from the Tracking Adaptation and Measuring Development (TAMD) issues from 2004 to 2006 provide estimates of population use for T&CM practices of 1–19% for each of the

following practices: acupuncture, ayurvedic medicine, chiropractic, homeopathy, naturopathy, osteopathy, therapeutic massage, traditional Chinese medicine and Unani medicine. Herbal medicines are used by 80–99% of the population.

Indigenous TM providers are regulated under the national laws, which are enforced at the level of the TMPC, zonal offices, city councils and community-level associations. Providers of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy and traditional Chinese medicine are regulated at the national level. Regulations for T&CM practitioners were updated in 2016.

T&CM providers practise in private clinics. Agencies of the MoH, such as the Food and Drugs Board and the TMPC, issue the relevant T&CM licence or certificate that providers require to practise.

The Kwame Nkrumah University of Science and Technology (KNUST) offers a 4-year bachelor's of science programme in herbal medicines. The programme started in 2001, and the first batch of “medical herbalists” graduated in 2005. Other T&CM training programmes that the Government officially recognizes include apprenticeships with T&CM providers; a specialized training programme for acupuncture where, after completion, the student receives a certificate or licence; and a training programme for indigenous TM practitioners.

According to a report from the MoH, based on a census of TMPs, 20 000 indigenous TM providers practise within Ghana. The TMPC's national register of T&CM providers for 2009 included 12 acupuncture providers, six ayurvedic medicine providers, six chiropractic providers, 25 000 herbal medicine providers, 40 homeopathic medicine providers, 10 naturopathic medicine providers, four osteopathic providers and 12 traditional Chinese medicine providers.

Private organizations provide the health insurance under which indigenous TM is covered. As of 2012, other T&CM practices were partially covered by both Government agency and private organizations. Partial private coverage is available for chiropractic, herbal medicines, naturopathy and traditional Chinese medicine. As at end 2016, T&CM services are not reimbursed by public health insurance.

17. Guinea-Bissau

National policy on T&CM

Guinea-Bissau's national policy on T&CM is the National Policy and Regulation of Guinea-Bissau Traditional Medicine (*Politique Nationale et Reglementation de la Medicine Traditionnelle de la Guinée-Bissau*), in place since 2010. The national office is the Directorate of Community Health Care Services and Promotion of Traditional Medicine (*Direction des Services de Santé Communautaire et Promotion de la Medicine Traditionnelle*), which is administered under the MoH.

Regulatory status of herbal medicines

Herbal medicines are sold with medical, health and nutrient content claims; these claims are unregulated. The NEML does not include herbal medicines. Herbal medicines categorized as non-prescription medicines, self-medication or OTM medicines are sold in outlets other than pharmacies, in special outlets and in CARITAS herbal medicines outlets.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in Guinea-Bissau. Other T&CM practices in use are acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine.

Regulation of T&CM providers has been in place since 2010, and it is enforced at national, province, city and community levels. T&CM providers practise in private clinics and home-based settings.

18. Liberia

National policy on T&CM

Liberia has a national office for T&CM, located in the Ministry of Health and Social Welfare, Monrovia, established formally in April 1998.

National laws and regulations are in place for T&CM (12); there is also a national programme for T&CM (1).

Regulatory status of herbal medicines

No regulations apply to the manufacturing of herbal medicines to ensure their quality. The market surveillance system for safety of medicines does not include herbal medicines. About 55 herbal medicines are registered (as of 2012). There are no restrictions on selling herbal products that are categorized as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

According to the MoH, in 2010, 60–79% of the population used indigenous TM in Liberia. The same percentage applied to the population's use of acupuncture, herbal medicines and other unspecified forms of T&CM practices. A much lower proportion, 1–19%, uses ayurvedic medicine, naturopathy, traditional Chinese medicine and Unani medicine.

There are about 1500 indigenous TM providers in Liberia, as per the Ministry of Health and Social Welfare (2010), and providers of acupuncture, ayurvedic medicine, herbal medicines, homeopathy, traditional Chinese medicine and osteopathy practise in the country.

T&CM providers practise in the private sector in a hospital setting. The national Government (Ministry of Health and Social Welfare) issues the licence required to practise. Indigenous TM and other T&CM practices are not covered by health insurance.

19. Madagascar

National policy on T&CM

In Madagascar, the national policy for T&CM is integrated into the National Pharmaceutical Policy (*Politique Pharmaceutique Nationale*). The national office is located at the Traditional Pharmacopoeia and Medicine Unit (*Service de la Pharmacopée et de la Médecine Traditionnelle*), which is administered by the MoH.

Regulatory status of herbal medicines

Herbal medicines are specifically regulated under a law governing the sale of medicinal plants and the manufacture of plant-based medicines (*Décret réglementant la vente des plantes médicinales, la fabrication et la vente des médicaments à base de plantes*). The regulations cover herbal medicines that are classified as prescription medicines and sold with medical, health or nutrient content claims.

The monograph used is *Towards a Malagasy pharmacopoeia (Vers une pharmacopée Malagasy)*, Pt 1 (2008).

Manufacturers of herbal medicines are required to adhere to the manufacturing information in the monograph, to ensure their quality. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. There are specific regulatory requirements for the safety assessment of herbal medicines; reference to safety data in documented scientific research on similar products is sufficient.

The NEML includes 26 herbal medicines (as at 2012). Criteria for selection are based on traditional use of the herbal medicines, clinical data, long-term historical use and laboratory testing. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in outlets other than pharmacies, in special outlets and by licensed practitioners.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in Madagascar. Other T&CM practices used by the population include acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine.

Indigenous TM providers have been regulated, with enforcement at the national level, since 2005. T&CM providers practise in the private sector and in public sector clinics and hospitals. T&CM providers require a relevant licence or certificate, issued by the national Government or relevant academic institution, to practise. T&CM education is provided at university level as a master's degree. There are also other T&CM training programmes that the Government officially recognizes.

According to the National Association of Traditional Practitioners in Madagascar (*Association Nationale des Tradipraticiens de Madagascar*), in 2010 there were an estimated 2000 indigenous TM providers practising in the country.

20. Mali

National policy on T&CM

In Mali, the national policy on T&CM – *Politique Nationale de Médecine Traditionnelle* – and a national plan for integrating T&CM into national health service delivery, have been in place since 2005. The national office is located in the department for TM, the *Département Médecine Traditionnelle* (DMT), administered under the MoH.

Annual Government or public research funding for T&CM (in US\$) in Mali, 2010-2016						
2010	2011	2012	2013	2014	2015	2016
48 414	53 474	5 000	5 000	5 000	43 296	10 000

Regulatory status of herbal medicines

Some herbal medicines are subject to specific regulations, while others are subject to the same regulations as conventional pharmaceuticals. The regulations are Decree No. 95–009/P-RM, modified by Decree No. 04–557/P-RM, authorizing the marketing of medicines for human and veterinarian usage; and Order No. 95–2084/MSS-PA-MFC-MDRE, modified by Order No. 05–2203, defining the modalities of medicines marketing authorization requests.

The most recent update of the national regulations on herbal medicines and registered herbal medicines was in 2016.

Herbal medicines are classified as prescription, non-prescription and herbal medicines. Traditional herbal medicines are defined as improved traditional medicines based on traditional pharmacopoeia. Herbal medicines are sold with medical and health claims.

The pharmacopoeias used are the African pharmacopoeia vol. 1 (1985) and vol. 2 (1988) and the WAHO's West African pharmacopoeia. WHO monographs are also used (2-4).

The GMP for herbal medicines are based on a 1994 decree for the creation of an improved TM production unit, implemented in 1995 (*Décret Portant Création d'une Unité de Production des Médicaments Traditionnels Améliorés et son Arrêté d'Application*).

The regulations on manufacturing of herbal medicines to ensure their quality require adherence to manufacturing information in pharmacopoeias and monographs. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing, and testing of samples by the National Health Laboratory (*Laboratoire National de la Santé*). Six new herbal medicines were developed between 2005 and 2016.

There are specific regulatory requirements for the safety assessment of herbal medicines. The rules vary according to whether a medicine is plant-based, a standardized extract or molecules obtained from a plant, and whether there is ethnomedical evidence. Reference to safety data in documented scientific research on similar products is sufficient.

Herbal medicines are registered and the NEML includes all seven registered herbal medicines (as at 2012). The criteria for selection are based on traditional use, clinical data, long-term historical use, laboratory testing and cost. Herbal medicines categorized as prescription medicines are sold in pharmacies, and those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and by licensed practitioners.

Estimates shared by the DMT show that the annual market sales of herbal medicines in 2007, 2008 and 2009 were US\$ 97 200, US\$ 106 920 and US\$ 117 612, respectively.

Practices, providers, education and health insurance

Indigenous TM is considered important in Mali and, according to 2009 data from the DMT, is used by 80–99% of the population.

Data from the Malian Federation of Traditional Therapists and Herbalists Associations (*Fédération Malienne des Associations de Thérapeutes Traditionnels et Herboristes* [FEMATH]) from 2010 shows that T&CM practices such as acupuncture, ayurvedic medicine, chiropractic and herbal medicines were used by 60–79% of the population. Other T&CM practices in use include homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine.

Indigenous TM providers have been regulated at national level since 1994. Herbal medicine providers are regulated at national and community or village level. T&CM providers practise in private clinics, health care practices and herbal stores. A licence or certificate, issued by the national Government, is required to practise. The Government officially recognizes training programmes such as an apprenticeship with a T&CM provider, training with licensed T&CM practitioners, programmes in herbal medicines and TM. Since 2010, the DMT has participated in the supervision and examination of doctoral theses of African PhD students from Mali and other countries, including the Congo, Burkina Faso, Côte d'Ivoire, Benin and Guinea, and receives trainees from Guinea, Niger and Togo, for training in herbal medicine.

FEMATH data from 2010 indicates that there are about 5000 indigenous TM providers practising in the country, and there are also providers of acupuncture, herbal medicines, homeopathic medicine, osteopathic, TM and traditional Chinese medicine in Mali. FEMATH collaborates with the Department of Traditional Medicine; it also has an agreement with the MoH and is actively involved in all activities of public health. It played a large role in the care of Ebola virus disease and was involved in organizing the International Week of Traditional African Medicine from 2002 to 2012.

Some complementary health insurance companies reimburse prescription herbal medicines. As of 2016, T&CM services are reimbursed by compulsory health insurance (*assurance maladie obligatoire*).

21. Mozambique

Mozambique's national policy on T&CM, titled Traditional Medicine Policy and Strategy to be Implemented (*Política da Medicina Tradicional e Estratégia para ser Implementados*), was issued in 2009.

In 1977, the Traditional Medicine Studies office was established, and in 1990, the Traditional Medicine and Medicinal Plants Studies Department was formed. The MoH opened the Traditional Medicine Institute in 2009. Topics related to TM are dealt with by both the MoH and the Ministry of Science and Technology. The expert committee for T&CM was established in 2012 for the purpose of legislation and regulations; it is referred to as a multisectoral group.

Two national institutes undertake research in T&CM: the Centre of Ethnobotanics Investigation under the Ministry of Science and Technology (established in 2008) and the Traditional Medicine Institute under the MoH.

As at end 2017, national laws and regulations on T&CM are in process of being established. Most annual plan activities are financed by the Government and are part of the MoH's 5-year strategic plan and the Government's 5-year plan. Future plans are to work on regulation of TM through legislation that is already in the Ministerial Council for approval.

Regulatory status of herbal medicines

In 1999, regulation of herbal medicines was introduced and in 2008 a Ministerial Diploma of the Regulation was adopted. The regulation for herbal medicines is exclusive but is the same as that for conventional pharmaceuticals.

Herbal medicines are categorized as non-prescription medicines, herbal medicines and dietary supplements. They are sold with medical, health and nutrient content claims, but these claims are unregulated.

The *United States pharmacopeia*, *Brazilian pharmacopoeia*, *Portuguese pharmacopoeia* and *European pharmacopoeia* are used and are legally binding. The national monographs on herbal medicines are also legally binding, and include:

- *Medicinal plants of traditional use in Mozambique (Plantas Medicinais sao uso Tradicional em Moçambique)* comprising five monographs published in 1983, 1984, 1990, 1991 and 2001;
- *Ethnobotanical research on medicinal plants in the province of Manica and Zambezia (Pesquisa Ethnobotanica sobre Plantas medicinas na provineia de Manica e Zambezia)* comprising two monographs issued in 2001 and 2004; and
- *Medicinal plants used in the treatment of diseases (Plantas medicinais utilizadas no tratamento de doen mentais)*, a single monograph issued in 2009.

As at end 2016, there is no GMP document but the WHO standard is used to evaluate the quality of manufacturing of herbal medicines. Regulations for the manufacturing of herbal medicines are the same as that for conventional pharmaceuticals; they also follow Southern African Development Community and WHO guidelines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories and the requirement for manufacturers to assign a person to the role of ensuring compliance with manufacturing requirements. Regulatory requirements for the safety assessment of herbal medicines are the same as that for conventional pharmaceuticals.

As of 2012, 43 herbal medicines and 18 nutrient supplements were registered. The market surveillance system for safety of medicines has included herbal medicines since 2008. As at end 2016, herbal medicines (final product) are licensed at the National Directorate of Pharmacy in the MoH, but are not included in the NEML.

Herbal medicines categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies, in other outlets, in special outlets and by licensed practitioners.

Practices, providers, education and health insurance

Indigenous TM is used by 60–79% of the population, according to 2004 data contained in the Mozambique Traditional Medicine Policy. T&CM practices such as acupuncture, ayurvedic medicine, chiropractic, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine are each estimated to be used by 1–19% of the population according to a report from August 2010. The use of herbal medicines is estimated to be higher, at 60–79%. Other practices such as aromatherapy, hands-on healing, hypnotherapy, reflexology and reiki are used by 1–19% of the population.

T&CM providers practise in private sector clinics. City and community governments issue the licence required for T&CM practice. As at end 2016, a master's degree in natural products is offered by the Universidade Pedagogica in collaboration with Lisbon Pharmacy University. The Government officially recognizes a training programme for indigenous TM practitioners and for T&CM technicians or equivalent (but these programmes are not at university level).

According to the 2010 report, about 70 000 indigenous TM providers practise in Mozambique. T&CM providers in practice (approximate numbers) include acupuncture (50), ayurvedic medicine (50), chiropractic

(50), herbal medicines (20 000), homeopathy (80), naturopathy (40), osteopathy (20), traditional Chinese medicine (60) and Unani medicine (20). There are about 100 providers of other practices such as aromatherapy, hands-on healing, hypnotherapy, reflexology and reiki.

22. Namibia

National policy on T&CM

In Namibia, the University of Namibia in Windhoek serves as the national research institute for T&CM. The Medicine and Related Substances Control Act of 2003 is the national law on herbal medicines.

Regulatory status of herbal medicines

Herbal medicines are regulated under the category “herbal medicines”. No safety requirements currently exist for the safety assessment of herbal medicines. The market surveillance system for safety of medicines has included herbal medicines since 2007.

Practices, providers, education and health insurance

Indigenous TM and other forms of T&CM such as acupuncture, ayurvedic medicine and traditional Chinese medicine are used in Namibia, but the percentage of use by the population is unknown.

23. Niger

National policy on T&CM

Niger has had an exclusive national strategy on T&CM – *Stratégie Nationale de Médecine Traditionnelle* – since 2002. The national programme is under development within the logical framework of the integration strategy of T&CM into Niger’s health system.

The national office for T&CM (*Division Médecine Traditionnelle*) is administered by the MoH.

Regulatory status of herbal medicines

Regulation of herbal medicines is partly the same as that for conventional pharmaceuticals, both coming under national pharmaceutical legislation. Under these laws and regulations, herbal medicines are categorized as non-prescription medicines, herbal medicines and dietary supplements. Herbal medicines are sold with medical, health and nutrient content claims.

Niger has a registration system for herbal medicines; in 2000, one TM product was included in the NEML (12).

24. Sao Tome and Principe

National policy on T&CM

Sao Tome and Principe has a national policy and programme for T&CM (1), and a national office.

Regulatory status of herbal medicines

Herbal medicines are sold with claims, but these are unregulated. There are no regulations on manufacturing of herbal medicines to ensure their quality, nor safety requirements for herbal medicines. There are no restrictions on selling herbal products.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in Sao Tome and Principe. T&CM practices also in use are acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy and traditional Chinese medicine.

T&CM providers practise in private clinics only.

25. Senegal

National policy on T&CM

In Senegal, the national policy for T&CM is integrated into the Strategic Plan for Promotion of Traditional Medicine in the Health Care System (*Plan Stratégique pour la Promotion de la M.T dans le Système de Santé*).

A national programme for T&CM has been in existence since 1995, but there was a traditional pharmacopoeia office well before that date.

The national office for T&CM is the Private, Occupational and Traditional Medicine Division of the Health Directorate, administered under the MoH.

As at end 2016 there has been no government or public research funding for T&CM.

Regulatory status of herbal medicines

The national regulation on herbal medicines is the same as that for conventional pharmaceuticals: “Law 65–33 modifying the provisions of the public health code on manufacturing, sale and advertisement of pharmaceutical specialties (*Loi 65–33 du 19 mai 1965 portant modification des dispositions du code de la santé publique relatives à la préparation, à la vente et à la publicité des spécialités pharmaceutiques*).

At the commission level, the mix of experts (technical committee and national commission) used for registration of herbal medicines is different from that for conventional medicines. Expertise files requested during registration are also different. The procedure for plants is simpler and the repositories used are also different (e.g. pharmacopoeia).

Herbal medicines are regulated as conventional medicines and sold with medical, health and nutrient content claims, unregulated. The regulation on manufacturing of herbal medicines to ensure their quality requires adherence to manufacturing information in pharmacopoeias and monographs, and regulations for GMP are the same as that for conventional pharmaceuticals. The mechanism to ensure compliance is by periodic inspections by authorities at the laboratories. The regulatory requirements for the safety assessment of herbal medicines are the same as that for conventional pharmaceuticals.

Herbal medicines are sold in pharmacies and other outlets as non-prescription medicines, self-medication or OTC medicines, and by traditional practitioners.

As at end 2016 there is a technical committee and a national commission for registering medicinal plants.

Practices, providers, education and health insurance

According to a 2003 census by Ministry of Health and Prevention, there are 1000 indigenous TM providers practising in the country. According to same source, T&CM providers of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathic medicine, naturopathic medicine, osteopathic and traditional Chinese medicine practise in the country.

T&CM providers practise in the private and public sectors.

26. South Africa

National policy on T&CM

In South Africa, the national policy on T&CM was issued in 1996 as part of the national drug policy. There is a national law and regulation on complementary medicine titled *Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act of 1982*. There is no national law or regulation for TM.

The national office for T&CM is the Directorate of Traditional Medicine, established in 2006. The South African Medical Research Council, which has a unit on TM, receives some funding from the Government.

Regulatory status of herbal medicines

There is no national regulation of herbal medicines; however, under draft regulations, herbal medicines will at least in part be regulated in the same way as conventional pharmaceuticals. Herbal medicines are not given regulatory categories.

In 2010, the South African Pharmacopoeia Monograph Project was underway, with 63 pharmacopoeias and monographs listed. Depending on the discipline of the product, the following are used for herbal medicines: *WHO monographs on selected medicinal plants*, the *German pharmacopoeia*, the *Chinese pharmacopoeia*, the *Ayurveda pharmacopoeia of India*, the *Unani pharmacopoeia of India*, and the EU's *European pharmacopoeia*.

The GMP regulations and safety requirements for conventional pharmaceuticals also apply to herbal medicines. South Africa is currently drafting guidance documents to ensure compliance with the manufacturing requirements. Herbal medicines are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies, in other outlets and in special outlets (e.g. in herbal medicines stores and in T&CM supply stores); they are also sold by licensed practitioners.

Practices, providers, education and health insurance

According to 2010 estimates from the Allied Health Professions Council of South Africa (AHPSCA), 1–19% of the population uses T&CM practices, including acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine, Unani medicine and other practices such as therapeutic aromatherapy, therapeutic massage therapy and therapeutic reflexology.

Providers of the above T&CM practices are regulated under the national Allied Health Service Professions legislation.

T&CM providers practise in the private sector. The AHPSCA, a statutory body, issues the T&CM licence required to practise. Students of T&CM can obtain both bachelor's and master's degrees at university level. The Government also officially recognizes a training programme for T&CM technicians or equivalent (not at university level).

The AHPSCA database for 2010 included a total of 3289 practising T&CM providers, distributed as follows: 130 acupuncture providers, 60 ayurveda medicine providers, 612 chiropractors, 34 herbal medicine providers, 574 homeopaths, 97 naturopaths, 49 osteopaths, 160 traditional Chinese medicine providers, 81 Unani medicine providers and 1492 "other" kinds of providers.

T&CM practices such as acupuncture, chiropractic, homeopathic medicines, naturopathy and osteopathy are partially covered by private health insurance.

27. Uganda

National policy on T&CM

In Uganda, the policy on T&CM is integrated into the National Policy on Public-Private Partnership Policy for Health (final draft 2009). Regulation of T&CM has been part of the law since 1957.

The Natural Chemotherapeutics Research Institute, created by the Uganda National Health Research Organisation, is the national research institute for T&CM. Also, for over 40 years, the Natural Chemotherapeutics Research Laboratory has been acting as a technical arm on issues related to T&CM for the MoH.

Regulatory status of herbal medicines

The regulation for herbal medicines is partly the same as that for conventional pharmaceuticals. The *National Drug Policy and Authority Act* (1993) constitutes the national law on herbal medicines and is in the process of being repealed for certain adjustments. Regulatory categories are not given to herbal medicines.

Herbal medicines are sold with medical, health and nutrient content claims but these claims are unregulated.

The same regulations apply to the manufacturing of herbal medicines as to conventional pharmaceuticals, to ensure their quality. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing.

Regulatory requirements for the safety assessment of herbal medicines are the same as that for conventional pharmaceuticals; traditional use without demonstrated harmful effects is sufficient. The market surveillance system for safety of medicines includes herbal medicines.

Herbal medicines are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies and other outlets, and in special outlets (e.g. in herbal medicines stores and T&CM supply stores).

Practices, providers, education and health insurance

The use of indigenous TM is estimated to be between 60–79% of the population in Uganda (11). According to practitioner data from 2010, between 1% and 19% of the population use acupuncture, chiropractic, homeopathy, osteopathy or traditional Chinese medicine. Informal estimates put the use of ayurvedic medicine, hydrotherapy and naturopathy at 1–19%.

Over 200 000 indigenous TM providers were practising in Uganda as at 2012. The number of herbal medicine providers is similarly estimated to be over 200 000. Also practising in Uganda are providers of acupuncture, ayurvedic medicine, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and other practices, such as spiritual therapy (estimated to be >100 000) and hydrotherapy. T&CM providers practise in private sector clinics and home-based settings.

28. United Republic of Tanzania

National policy on T&CM

In the United Republic of Tanzania, the national policy on T&CM is integrated into the national health policy of 1990. The national office for T&CM is administered under the Ministry of Health and Social Welfare. The Institute of Traditional Medicine and the National Institute for Medical Research are the two national research institutes for T&CM.

Regulatory status of herbal medicines

The United Republic of Tanzania has a regulation exclusively for herbal medicines, titled *Materia Medica Regulations*, under which herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines. Herbal medicines are sold with medical claims.

WHO monographs on selected medicinal plants, vol. 4 (2007) is used. Manufacturers of herbal medicines are required to submit samples of their medicines to the Tanzania Food and Drugs Authority (TFDA), to ensure compliance with manufacturing requirements. The same safety requirements apply to herbal medicines as that for conventional pharmaceuticals; traditional use without demonstrated harmful effects and reference to safety data in documented scientific research on similar products is sufficient.

As at 2012, nine herbal medicines were registered, all of which are imported. The NEML and the market surveillance system for safety of medicines do not include herbal medicines. Herbal medicines categorized as prescription medicines are sold in pharmacies, non-prescription medicines, self-medication or OTC medicines and by licensed practitioners.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in the United Republic of Tanzania, with use by 60–79% of the population; the same percentage is estimated for the population's use of herbal medicines.

Regulation of indigenous TM and T&CM providers is enforced at national, state, city and community level. Since 2002, there have been regulations governing providers of acupuncture, ayurvedic medicine, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine.

T&CM providers practice in the private sector, in both clinic and hospital settings. The national Government issues the T&CM licence required to practise. A T&CM master's degree is available at university level and is officially recognized.

According to Ministry of Health and Social Welfare statistics from 1989, about 75 000 indigenous TM providers practise in the United Republic of Tanzania. Providers of other T&CM practices are also found, including acupuncture, ayurvedic medicine, chiropractic, herbal medicines (75 000), homeopathy, naturopathy, osteopathy and traditional Chinese medicine.

5.2 WHO Region of the Americas

Table 5.2 summarizes the development of national policy for T&CM, regulation of T&CM and herbal medicines, and use of T&CM among populations of Member States in the WHO Region of the Americas. The table also compares the percentage of Member States in the region with the global percentage for each indicator.

In the period between 2005 and 2018, Member States in the region demonstrated a strong commitment to the development of national policies, laws and a regulatory system for T&CM. A significant increase was seen in the number of Member States establishing a national programme and office for T&CM.

As at 2018, although most of the T&CM indicators were not on a par with global percentages, the progress made from 2005 indicates that Member States in the region realize the importance and are making efforts to develop this sector. A majority – 28 out of 35 (80%) – of Member States in the region acknowledged the use of T&CM among their populations.

Table 5.2. WHO Region of the Americas, development of T&CM, 2005–2018

Category	Regional number of Member States with affirmative responses in 2005	Regional number of Member States with affirmative responses as at 2018	Regional % of Member States with affirmative responses as at 2018 (N=35)	Global % of Member States with affirmative responses as at 2018 (N=194)
National policy on T&CM	3	11	31%	51%
Laws or regulations on T&CM	6	15	43%	56%
National programme on T&CM	4	13	37%	41%
National office for T&CM	8	17	49%	55%
Expert committee on T&CM	9	12	34%	48%
National research institute for T&CM or herbal medicines	7	9	26%	39%
Regulation of herbal medicines	13	18	51%	64%
Registration of herbal medicines	13	19	54%	64%
Population using T&CM	–	28	80%	88%

Note: The 2018 data set includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018). There may be Member States in which the T&CM situation has changed, not accounted for here.

29. Argentina

National policy on T&CM

No data are available on national policy for T&CM.

Regulatory status of herbal medicines

There is national legislation exclusive to herbal medicines (Resolution 144/1998 and Provisions 2673/99, 2671/99 and 1788/00). The most recent update of these laws was in 2013.

The regulations categorize herbal medicines as prescription, non-prescription and herbal medicines, dietary supplements and functional foods. They are sold with medical and health claims.

The pharmacopoeias used are the legally binding Argentinian medicines codex (*Codex Medicamentario Argentino*, 6th ed., 1978) and the *United States pharmacopeia* (2010). The monographs used, though not legally binding, are the American Botanical Council monographs and the EU monographs.

Regulation of the manufacturing of herbal medicines to ensure their quality requires adherence to manufacturing information in the above pharmacopoeias and monographs, and there are regulations for GMP for herbal medicines, separate from those for conventional pharmaceuticals. The mechanism to ensure compliance is by periodic inspections by authorities at the manufacturing plants or laboratories. The regulatory requirements for the safety assessment of herbal medicines include reference to safety data in documented scientific research on similar products and toxicity studies. Herbal medicines have been registered since 1999.

Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets.

Practices, providers, education and health insurance

T&CM practices are used in Argentina. As at end 2016, only acupuncture is regulated by way of the following resolutions:

- Resolution 997 of 2001 (Health Ministry), which restricts the use of acupuncture to physicians; and
- Resolution 859 of 2008 (Health Ministry), which modifies the previous resolution, allowing kinesiologists and physical therapists to legally practise acupuncture.

30. Bahamas

The Bahamas did not reply to the second survey but volunteered that, as at end 2016, there is no T&CM policy or regulatory system and no other significant information.

31. Barbados

National policy on T&CM

There is no national policy on T&CM in Barbados, and legislation on T&CM is lacking; thus, T&CM is not fully regulated.

Regulatory status of herbal medicines

Herbal medicines are sold with medical and nutrient content claims. No regulations apply to the manufacturing of herbal medicines and there are currently no safety requirements.

The market surveillance system established in 1980 for the safety of medicines does not include herbal medicines. Herbal medicines are sold in outlets other than pharmacies as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

T&CM practices are found in Barbados, but the percentage of the population using them is not known. T&CM providers practise in the private sector. Providers of acupuncture, chiropractic and naturopathy are known to practise in Barbados but there is no registration system, so no data on their numbers are available.

32. Belize

Belize did not reply to the second survey but provided a voluntary update of the situation as at end 2016.

There is no national policy on T&CM and no regulation of herbal medicines. However, the MoH acknowledged that it is cognizant of the role T&CM plays in today's medical field.

33. Bolivia (Plurinational State of)

National policy on T&CM

In the Plurinational State of Bolivia, the national policy for T&CM is integrated into the health sectoral plan. The most recent update of the national policy and legislation for T&CM was in 2013. The new legislation comprises an Act and Regulation covering Bolivian traditional ancestral medicine.

The national office for T&CM is located in the General Directorate on Traditional Medicine and Interculturality, administered under the MoH.

As of 2014, there is a national programme for T&CM. The national plan for integrating T&CM into national health service delivery was established in 2010.

Regulatory status of herbal medicines

The regulation of herbal medicines is the same as that for conventional pharmaceuticals. Herbal medicines are sold with medical, health and nutrient content claims, although these claims are unregulated. The regulation on herbal medicines was most recently updated in 2014.

Regulation of the manufacturing of herbal medicines to ensure their quality requires adherence to manufacturing information in pharmacopoeias and monographs. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing, the requirement for manufacturers to assign a person to the role of compliance officer, and the requirement for the compliance officer to ensure the manufacturer complies with manufacturing requirements and to report back to the Government authorities.

The regulatory requirements for the safety assessment of herbal medicines are the same as that for conventional pharmaceuticals. Traditional use without demonstrated harmful effects is also sufficient.

The NEML includes herbal medicines and the criteria for selection are based on the traditional use of the herbal medicines, clinical data and long-term historical use.

Herbal medicines are sold in outlets other than pharmacies, including special outlets, as non-prescription medicines, self-medication or OTC medicines. There are no restrictions on selling herbal products.

There is a list of registered herbal medicines, which was updated in 2015.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in the Plurinational State of Bolivia, with an estimated 60–79% of the population using it. Other T&CM practices are also used, and the percentages of the population using each practice are as follows: acupuncture 1–19%, ayurvedic medicine 1–19%, chiropractic 40–59%, herbal medicines 80–99%, homeopathy 20–39%, naturopathy 1–19%, osteopathy 60–79% and traditional Chinese medicine 1–19%.

The regulation of T&CM providers, including indigenous TM providers, chiropractors, herbal medicine providers and osteopaths is enforced at national, province and city levels.

The regulation on T&CM practice was updated in 2015.

T&CM providers practise in private clinics only. A T&CM licence or certificate – issued by the national, provincial, city or community government – is required to practise. Training programmes that the Government officially recognizes include apprenticeships with T&CM providers (without certification or licensing), certified training programmes, a training programme for indigenous TM practitioners, and training programmes for T&CM technicians or equivalent (not at university level).

According to 2010 data from the national office, there are an estimated 2500 indigenous TM providers practising within the Plurinational State of Bolivia. Indigenous TM is covered by private health insurance organizations.

As at end 2016, T&CM services are reimbursed by health insurance in 60 public establishments.

34. Brazil

National policy on T&CM

In Brazil, the national policy for T&CM called integrative and complementary practices (*Política Nacional de Práticas Integrativas y Complementarias*) is part of the unified health system (*Sistema Unico de Saúde [SUS]*). It covers five practices grouped as homeopathy, traditional Chinese medicine and acupuncture, medicinal plants and herbal medicines, anthroposophic medicine and social thermalism. In 2017, the national policy for T&CM was expanded to include 14 practices additional to the original five.

The national office for T&CM follows directives from SUS and implements a range of policies on primary health care. Two of these additional policies are:

- National Policy on Medicinal Plants and Herbal Medicines (*Política Nacional de Plantas Medicinales y Fitoterápicos*)
- National Policy on Indigenous Populations Health Care (*Política Nacional de Atención a la Salud de los Pueblos Indígenas*).

The national office is the National Coordination Office on Integrative and Complementary Practices (*Coordinación Nacional de Prácticas Integrativas y Complementarias*), administered under the MoH.

The most recent update of the legislation on T&CM practices was in 2016.

Government or public research funding for T&CM totalled US\$ 1 million in 2013. A national plan for integrating T&CM into national health service delivery was established in 1988.

Regulatory status of herbal medicines

There is an exclusive regulation for herbal medicines, called the Directors' Collegiate Resolution (*Resolución de Directoría Colegiada*, DRC-Resolution No 14), which provides for the registration of herbal medicines. Herbal medicines are categorized as prescription and non-prescription medicines, and sold with medical and health claims.

The legally binding pharmacopoeia used is the *Brazilian pharmacopoeia*. Other pharmacopoeias permitted under RDC 37/2009 are the pharmacopoeias of Argentina, the EU, France, Germany, Japan, Mexico, Portugal, United Kingdom, the United States and the *WHO monographs on selected medicinal plants*.

GMP for herbal medicines is regulated under Resolution RDC No. 17 of 19/04/2010, which also covers GMP for conventional pharmaceuticals. The provisions on manufacturing of herbal medicines to ensure their quality require adherence to manufacturing information in the specified pharmacopoeias and monographs, as for conventional pharmaceuticals. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, the requirement for manufacturers to assign a person to the role of compliance officer, and the requirement for the compliance officer to ensure manufacturing complies with requirements and to report back to the Government authorities. There are exclusive safety requirements for herbal medicines, with preclinical and clinical testing required when there is no available information on the safety of the extract in the literature. Testing must be verified and approved by the national health surveillance agency (*Agencia Nacional de Vigilancia Sanitaria [ANVISA]*), which was established in 1999.

As of 2009, 5 19 herbal medicines were registered. The register of herbal medicines was updated in 2016. Herbal medicines are included in NEML, with the most recent update in 2014.

Herbal medicines are sold in pharmacies as prescription and non-prescription medicines, self-medication or OTC medicines. In 2001, ANVISA established a process of drug monitoring that includes medicines based on medicinal plants.

Practices, providers, education and health insurance

2007 data from the National Health Foundation (*Fundação Nacional de Saúde* [FUNASA]) indicates that 1–19% of the population uses indigenous TM practices.

Other T&CM practices are also used. The MoH estimates that 1–19% of the population uses acupuncture and the same percentage use homeopathy. ayurvedic medicine, chiropractic, herbal medicines, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine are also used by the Brazilian population, but percentage data are not available.

Regulation of T&CM providers is enforced at the national level for providers of acupuncture, chiropractic, herbal medicines, homeopathy, naturopathy and osteopathy. The most recent update of the regulations governing T&CM practitioners was in 2016.

T&CM providers practise in both private and public sector clinics and hospitals. A T&CM licence or certificate is required for practice, with self-regulation by delegated special technical associations.

T&CM education is provided at a university level, and students can undertake the following programmes: clinical doctorate; pharmaceutical specialist (in either homeopathy, herbal medicines or acupuncture); physiotherapist specialist in acupuncture; biomedical specialist in acupuncture; doctor specialist in homeopathy; doctor specialist in acupuncture; nurse specialist in acupuncture; physical educator specialist in acupuncture; occupational therapist specialist in acupuncture; and psychologist specialist in acupuncture. The Government also officially recognizes certified T&CM training programmes.

FUNASA data for 2007 puts the number of T&CM providers practising in the unified health system at 1 100 for acupuncture providers and 560 for homeopathic medicine providers.

T&CM services are partially insured by both government and private organizations. For example, acupuncture is fully covered by government and private insurance, herbal medicines are partially covered by government, and homeopathic medicines are fully covered by government and partially by private insurance. As at end 2016, T&CM services are reimbursed by both public and private health insurance.

A consumer education project or programme for self-health care using T&CM started in 2006.

35. Canada

National policy on T&CM

In 1999, the Canadian Minister for Health announced the creation of the Office of Natural Health Products (now the Natural Health Products Directorate) to deal with herbal medicines (see below).

The policy Ethical Conduct for Research Involving Humans is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council; it promotes the ethical conduct of research involving humans. Chapter 9 of the policy is designed to guide research involving First Nations, Inuit and Métis Peoples of Canada. It affirms respect for community customs and codes of research practice to better ensure balance in the relationship between researchers and participants, and mutual benefit in researcher–community relations. The policy includes the ethical aspects of research with Aboriginal populations, respect for confidentiality, dissemination of research outcomes, etc.

Regulatory status of herbal medicines

Herbal medicines are classified as natural health products, regulated under the Natural Health Products Regulations (NHPR), which came into force on 1 January 2004. The regulation of T&CM products (including

herbal medicines) is integrated into the policy Pathway to Licensing, which itself is a result of amendments to the Evidence for Safety and Efficacy of Finished Natural Health Products Guidance Document.

The Natural and Non-Prescription Health Products Directorate (NNHPD), under Health Canada, looks after regulation of natural health products.

Under the NHPR, the definition of “natural health product” includes homeopathic medicines and traditional medicines that make medical or health claims if the medicine is a substance or includes a substance that is listed in Schedule 1 (inclusion list) to the NHPR. Homeopathic medicines and traditional medicines that are or that include a substance set out in Schedule 2 (exclusion list) are not considered to be natural health products.

Herbal medicines are sold with health claims. The *British pharmacopoeia*, the *United States pharmacopeia* and the *European pharmacopoeia* are used, but none is legally binding. Monographs that are used, but that are not legally binding, are the NNHPD Compendium of Monographs (herbals, vitamins, minerals, etc.).

The NHPR was updated in 2008 to require individuals to obtain a product licence before they can sell a natural health product in Canada. To obtain a product licence, individuals must submit a product license application to the NNHPD. The application must include sufficient data to allow the NNHPD to assess the safety, quality and efficacy of the natural health product when used under its recommended conditions of use. Various evidence types are accepted, from human clinical trials to traditional use claims. Also, a product must also be manufactured according to GMP. The difference between GMP requirements for conventional pharmaceuticals and those for natural health products is validation of processes and procedures, in that validation is not required under the NHPR. A paper-based review process is used for ensuring compliance. Manufacturers of natural health products are required to submit an extensive quality assurance report (QAR) describing how all GMP requirements outlined in Part 3 of the NHPR are met. In addition, records (logs) must be provided as evidence that the described procedures have been followed. The QAR must include the following parameters: premises, quality assurance, personnel, operations, equipment, sanitation programme, samples, records, recall reporting, specifications, stability and sterile products.

More than 56 000 natural health products are available for sale in Canada (not all are herbal medicines), and are registered in the Licensed Natural Health Products Database (as at 2012). Since 2004, there has been a market surveillance system for safety of medicines, including natural health products.

Practices, providers, education and health insurance

The Canadian Community Health Survey (2005) indicates that 1–19% of the population uses acupuncture, chiropractic, herbal medicines, homeopathy and naturopathy. Ayurvedic medicine, osteopathy, traditional Chinese medicine and Unani medicine are also used, but data on their percentage use are not available. Other T&CM practices, such as Feldenkrais method and Alexander technique, biofeedback, rolfing, reflexology, religious healing and spiritual healing, are also used by 1–19% of the population in Canada.

Regulation of T&CM practices is within the provincial rather than national jurisdiction.

As at end 2016 regulation for T&CM practitioners is a provincial or territorial responsibility.

In Canada, some Government agencies provide health insurance under which indigenous TM services are covered. Examples include the National Native Alcohol and Drug Abuse Program (NNADAP) and the Indian Residential Schools Resolution Health Support Program (IRSRHSP).

36. Chile

National policy on T&CM

In Chile, the most recent update of the national policy and law on T&CM was in 2006. There is an Indigenous Peoples Health Policy that includes TM, and Administrative Rule No. 16 on interculturality in Health Services (both from 2006). Article 7 of law 20.584 (regulating the rights and duties of people with respect to actions related to their health care), 2012, specifically covers the indigenous population; however, a policy on complementary medicine has yet to be developed.

Within the MoH, there is a technical area in CM, in the Department of Pharmaceutical Policies and Regulations, Health Providers and Complementary Medicines. There is also a Special Program on Health and Indigenous Peoples, created in 2000, which is installed in 26 of 29 Health Services at national level, with allocated resources and specific workplans to develop in the field.

There are advisory commissions for the three regulated therapies – acupuncture, homeopathy and naturopathy – created after the publication of the decrees that regulate them (beginning in 2009).

Between 2006 and 2013, the MoH allocated resources for the elaboration of basic epidemiological profiles by indigenous peoples, and areas of coverage of the health services. There are currently 11 epidemiological profiles. No resources are allocated for complementary medicine.

The MoH has been working (since 2015) on the development of a regulation that establishes the right of indigenous peoples to receive health care with cultural relevance (Article 7 of Law 20,584). The intention is to regulate health care provided in the public sector, and in no way to regulate the health systems of indigenous or native peoples; rather, the regulation recognizes, protects and respects ancestral systems of healing, religious practices, and cultural and spiritual beliefs of these peoples. The proposed regulation was developed in consultation with indigenous peoples and is currently in administrative proceedings to be implemented.

Regulatory status of herbal medicines

There are two categories of medicines based on medicinal plants: phytopharmaceuticals and traditional herbal medicines. Both are part of the Regulation of the National System for the Control of Pharmaceutical Products for Human Use (Decree No. 3 of 2010).

Herbal medicines are regulated as prescription, non-prescription and traditional herbal medicines, and are sold with medical claims (for phytopharmaceuticals) and health claims (for traditional herbal medicines).

The pharmacopoeia used that is legally binding is the *Chilean pharmacopeia*; other pharmacopoeias used are from the EU, France, Germany, United Kingdom and the United States, and *Dr Willmar Schwab's Homeopathic Pharmacopeia*. The GMP for herbal medicines is the same as that for other registered medicines. The regulations on manufacturing of herbal medicines to ensure their quality require adherence to manufacturing information in pharmacopoeias and monographs, and are the same as that for conventional pharmaceuticals. The mechanism to ensure compliance is by periodic inspections by authorities at the manufacturing plants or laboratories. The safety requirements for herbal medicines are the same as that for conventional pharmaceuticals. In addition, there is a list containing 103 traditional herbal medicines (vegetal species), as of 2012, labelled with health claims, interactions and warnings.

About 300 herbal medicines are registered (as at 2012).

Phytopharmaceuticals are registered with the Public Health Institute of Chile. As at end 2016, traditional herbal medicines are understood to be registered for the purposes of their free sale and distribution, for the sole reason that the competent regional health authority (SEREMI) has authorized the establishment where they are stored, processed, fractionated or bottled, or undergo other processing activities, but must meet the following conditions:

- be part of a list contained in a technical standard approved by decree of the MoH, which indicates the denomination, therapeutic properties and uses of each of them, and must be used as symptomatic auxiliaries;
- be handcrafted as isolated, unmixed plant species; and
- include in their labels only those properties recognized in the respective technical standard (Article 27 of Decree No. 3 of 2010).

The NEML does not include herbal medicines. Herbal medicines categorized as prescription medicines are sold in pharmacies, and in other and special outlets as non-prescription medicines, self-medication or OTC medicines.

Market surveillance of herbal medicines is a part of the national pharmacovigilance system, which was last updated in 2010.

Practices, providers, education and health insurance

Health surveys estimate that 1–19% of the population uses indigenous TM. Other T&CM practices used by the same percentage of the population include acupuncture, herbal medicines, homeopathy and naturopathy. An unknown percentage use ayurvedic medicine, chiropractic, osteopathy and traditional Chinese medicine.

The regulation on T&CM practice (Decree No. 42 of 2004), issued by the MoH, governs the “exercise of alternative medical practices as auxiliary health professions and the facilities in which these are carried out”.

Three T&CM practices – acupuncture, homeopathy and naturopathy – are recognized as therapies and are governed under the following regulations:

- Decree No. 123 of 2006, which grants recognition to acupuncture and regulates acupuncturists as Assistant Health Professionals;
- Decree No. 19 of 2009, which grants recognition to and regulates homeopathy as an Auxiliary Profession of Health; and
- Decree No. 5 of 2012, which grants recognition to naturism and regulates naturopathy as an Auxiliary Profession of Health.

These regulations are enforced at national level. The most recent update of the regulations for T&CM practitioners was in 2012. There is no regulation recognizing indigenous TM practice or regulating its providers.

T&CM providers practise in private and public clinics. A T&CM licence or certificate, issued by the MoH via the regional health authorities, is required to practise the recognized therapies. A bachelor's degree is available at university level. The numbers of T&CM providers in practice in Chile (as at 2012) are acupuncture (500), herbal medicines (10), homeopathic medicine (200) and naturopathic medicine (500).

A consumer education project or programme for self-health care using T&CM started in 2016. There is an ongoing project on complementary practices for self-care and well-being. The most recent study available in relation to T&CM is the 2015 documentation of good field practices in phytotherapy in the health delivery network.

37. Colombia

National policy on T&CM

As at 2017, there is no specific policy or law document for T&CM; however, Colombia has a regulatory framework that covers T&CM practice by health care professionals; the inclusion of services in the health system; the provision of services, homeopathic medicines and phytotherapeutic products; and health food stores.

Since 2015, the Ministry of Health and Social Protection (MSPS) has been building the guidelines for harmonizing (integrating) medicine and alternative therapies and complementary medicine with the health system, as a first step for the construction of the policy (16). Since 2010, the indigenous peoples of the country, in coordination with the ministry, has been building the Indigenous System of Personal and Intercultural Health (SISPI).

Resolution 2003 of 2014 regulates all health care services, including T&CM. It defines the minimum requirements for physical spaces where services are to be provided, equipment and training of professionals.

In January 2013, the MSPS formed a working group that leads the institutional efforts and advances in the construction of public policy on T&CM in Colombia; delegates from 14 MSPS units participated in this group. For the development of TM, the MSPS has the Ethnic Affairs Group of the Office of Social Promotion, from which issues of traditional Colombian medicine are handled.

National expert committees exist for both TM and CM (since 2013 and 2015, respectively):

- TM: within the framework of the construction of SISPI, through Decree 1973, the Health Subcommittee of the Permanent Bureau of Concertation with the Indigenous Peoples and Organizations, as “an advisory and technical working body for the collective construction of public health policies for the indigenous peoples of Colombia”; this subcommittee comprises governmental institutions and indigenous authorities of indigenous peoples as experts on the subject.
- CM: in July 2015, through agreement number 002 of the National Council of Human Talent in Health, the Committee of Support to the National Council of Human Talent in Health for Alternative Medicine and Alternative Therapies, comprising a delegate from each of the six component Committees of Alternative Medicines, corresponding to: Naturopathic Medicine, Neural Therapeutic Medicine, Osteopathic Medicine, Traditional Chinese Medicine, Homeopathic Medicine and ayurvedic Medicine, which in turn, by virtue of the same administrative Act, are made up of experts from each of these medical systems, representing the associations, the academy and the service providers.

Regulatory status of herbal medicines

Decree 2266, issued in 2004 (modified by Decree 3553 in 2004), regulates health registers, health surveillance and control, and advertising of herbal medicines.

There is a regulation exclusively for herbal medicines (*productos fitoterapéuticos*), which are regulated as non-prescription medicines, and are sold with medical claims.

The legally binding pharmacopoeias used are the *British herbal pharmacopoeia* (4th ed., 1996), the *British pharmacopoeia* (2010), the *Spanish pharmacopoeia* (3rd ed., 2005), the combined *United States pharmacopoeia* and *National formulary* (USP–NF) (USP34/NF29, 2010), the *Brazilian pharmacopoeia* (4th ed.), the *Pharmacopoeia of the united Mexican states* (9th ed., 2008) and the *Codex Français* (2004).

The monographs used, also legally binding, are the *Colombian vademecum of medicinal plants* (2008) (119 monographs published), the *WHO monographs on selected medicinal plants*, and *Plantas medicinales iberoamericanas*, Gupta (243 monographs).

The GMP for herbal medicines is covered in *GMP for pharmaceuticals based on natural products* (Resolution 3131 of 1998; the GMP compliance instrument was adopted by Resolution 5107 of 2005). The regulations for manufacturing of herbal medicines to ensure their quality require adherence to manufacturing information in pharmacopoeias and monographs. The mechanisms to ensure compliance include periodic inspections by authorities at the manufacturing plants or laboratories; also, laboratories must obtain a certificate in GMP for herbal medicines before manufacturing products, and manufacturers must have a technical director in chemical pharmaceuticals in charge of products quality and reporting to health authorities. The safety requirements for herbal medicines are exclusive, as determined by a specialized panel on natural products of the reviewing commission of the National Surveillance Institute of Medicines and Foods (*Instituto Nacional de Vigilancia de Medicamentos y Alimentos* [INVIMA]).

As of 2019, 913 herbal medicines were registered. The NEML does not include herbal medicines. Herbal medicines categorized as prescription medicines are sold in pharmacies. They are also sold in pharmacies, other and special outlets as non-prescription medicines, self-medication or OTC medicines; by licensed practitioners; and via other unregulated media such as the Internet and telesales.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in Colombia, with use by 1–19% of the population in 2005, according to the National Administrative Department of Statistics. Other practices used include T&CM practices such as acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine; and other practices such as electromagnetic polar balance, neural therapy and sintergetics. However, data on percentage of use by the population are not available.

Law 1164 of 2007 dictates provisions on the practice of T&CM; these provisions are taken up by Resolution 2003 of 2014, which regulates all health care services, including CM. It defines the minimum requirements

for physical spaces where services are to be provided, equipment and training of professionals; also, it includes the standards for health professionals in T&CM. Decree 2753 of 1997 (Article 4) limits CM practice to physicians. It mandates that health care providers consult with indigenous communities when setting up services. Resolution 2927 of 1998 defines and regulates different types of CM practices.

The regulations on T&CM providers, enforced at national level, are for acupuncture (2006), ayurvedic medicine (2006), herbal medicines (2006) and homeopathic medicine (1962 and 2006).

T&CM providers practise in private and public clinics. A T&CM licence or certificate, issued by a relevant academic institution, is required to practise. A master's degree and clinical doctorate degree in T&CM are available at university level.

T&CM services such as acupuncture, chiropractic, homeopathy, osteopathy and traditional Chinese medicine are partially covered by private health insurance.

As a result of participatory work with the expert committees for TM and CM, there is a proposal to define the profile and professional competencies of health professionals, to guide the formation and performance in each of the recognized systems.

38. Costa Rica

National policy on T&CM

In Costa Rica, the Government sector has only recently been paying attention to T&CM, but planning for activities to advance T&CM is underway.

Regulatory status of herbal medicines

There is a regulation exclusively for herbal medicines that deals with the registration, importation, marketing and advertising of natural and manufactured resources “with medicinal properties” (*Reglamentado para la inscripción, importación, comercialización y publicidad de recursos naturales industrializados y con cualidades medicinales*). Herbal medicines are sold with medical claims.

The most recent update of the regulation was in 2014. The regulation sets the requirements for inclusion in the register of herbal medicines. The list of registered herbal medicines was updated in 2014.

Since Costa Rica is a country member of the Central-American Economic Integration, the suite of Central-American technical regulations for pharmaceutical products applies to herbal medicines in Costa Rica. The relevant regulations are three regulations covering natural medical products for human use, specifically:

- health registration requirements (since 2013);
- quality control (since 2012); and
- labelling requirement (since 2012).

The monographs used are the *WHO monographs on selected medicinal plants*, vol. 1 (1999), vol. 2 (2002) and vol. 3 (2007).

The regulation on manufacturing of herbal medicines to ensure their quality is the same as that for conventional pharmaceuticals. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories; the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing; the requirement for manufacturers to assign a person to the role of compliance officer; and the requirement for the compliance officer to ensure the manufacturer complies with manufacturing requirements and to report back to the Government authorities. There are specific safety requirements specifically for herbal medicines that include the manufacturing laboratory obtaining a certificate of analysis.

Herbal medicines are sold in pharmacies, other outlets and special outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

T&CM practices of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy and traditional Chinese medicine are used; however, data on the percentage of use by the population are not available. T&CM providers practise in the private sector.

39. Cuba

National policy on T&CM

In Cuba, T&CM is called “natural and traditional medicine” (NTM). The national policy for NTM is integrated within the national policy for public health, as set out in Ministerial Council Accord No. 4282. Since 1995, there has also been a national plan for integrating NTM into national health service delivery. The most recent update of the national policy and law on T&CM was in 2015, supported by a ministerial council accord from 2014.

The national office for T&CM and the national research institute for T&CM are in the same location in Havana and are administered under the MoH.

Annual government research funding for NTM (in US\$) in Cuba 2010–2016						
2010	2011	2012	2013	2014	2015	2016
82 241	82 960	125 000	128 936	132 204	151 691	152 972

Regulatory status of herbal medicines

There is a regulation exclusively for herbal medicines, which was updated in 2016. Herbal medicines are categorized as prescription, non-prescription and herbal medicines, dietary supplements and functional foods. Herbal medicines are sold with medical, health and nutrient content claims.

The Central Pharmacology Laboratory is the centre that coordinates the national program in NTM research, which is within the Medical Sciences University of Havana. When referring to herbal medications, other products of animal origin are included, such as bee products and homeopathic medicines, which are registered as medicines or as dietary supplements.

The State Center for the Control of Medicines, Equipment, and Medical Devices (CECMED) issues the administrative resolutions that approve the regulations governing herbal medicines and other NTM products. These include the following regulations:

- M85–16, which sets requirements for issuing licences for the production and commercialization of medicines of herbal and animal origin in local producing centres (approved by Resolution CECMED No. 50/2016);
- M28–13, which sets requirements for the health register of natural medications for human use (approved by Resolution CECMED No. 186/2013);
- M53–2011, which sets requirements for the register of homeopathic medicines for human use (approved by Resolution CECMED No. 36/2011); and
- M54–2012, which specifies GMP for the local production of natural products (approved by Resolution CECMED No. 183/2012).

The legally binding pharmacopoeias used are the national pharmacopoeias of China (2004), Japan (2001), Philippines (2004), Spain (*Real Farmacopea Espanola*, 1997), Thailand (1998), the United Kingdom (2004), and the United States (2009). The legally binding monographs used are the *Cuban therapeutic guide to plant pharmaceuticals and honey pharmaceuticals* (*Guia Terapeutica Dispensarial de Fitofarmacos y Apifarmacos*, 1992) and the surveys of medicinal plants known as serial *FITOMED* (vols. I–II, 1998).

The 2006 GMP for herbal medicines (*Buenas Prácticas de Fabricación de Medicamentos Herbarios*) and for pharmaceutical products (*Directrices sobre Buenas Prácticas de Fabricación de Productos Farmacéuticos*) are equivalent.

The regulation on manufacturing of herbal medicines to ensure their quality requires adherence to manufacturing information in the legally binding pharmacopoeias and monographs. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. The safety requirements for herbal medicines are the same as that for conventional pharmaceuticals; reference to safety data in documented scientific research on similar products is sufficient.

As of 2012, 44 herbal medicines were registered. The list of registered herbal medicines was updated in 2016. Herbal medicines are included in the NEML, with the most recent update in 2016.

Herbal medicines in all categories – prescription medicines, non-prescription medicines, self-medication and OTC medicines – are sold only in pharmacies.

Practices, providers, education and health insurance

NTM is practised within the national health system by health professionals and technicians, according to their specialty and area of practice. Since 1995, there has been training for physicians in NTM specialties. As at 2017, there were 215 NTM specialists and 122 residents in training.

The regulations governing the practice of NTM were most recently updated in 2015.

There is no separate register for NTM practitioners because it is practised by health professionals and technicians, including specialist physicians, and so these practitioners are included on the practitioner register under the National Health System.

According to a 2010 report on use of NTM within Cuba (17), indigenous TM is used by 80–99% of the population, acupuncture by 60–79%, herbal medicines by 80–99% and homeopathy by 40–59%.

NTM providers practise in public¹ clinics, hospitals, integrated rehabilitation services, and municipal and provincial centres of NTM. A licence or certificate issued by a relevant academic institution is required for NTM practice. Universities offer higher education degrees such as a master's, a PhD in medicine or a clinical doctorate. The Government also officially recognizes training programmes for herbalists, health care workers and agricultural technicians.

The types of NTM practices approved for use in the national health care system are phytotherapy, apitherapy, traditional Asian medicine (acupuncture, catgut implantation, acupuncture points stimulation using medicines, light, temperature, mechanical, ultrasonic, electrical, magnetic and traditional Asian medicine microsystems), ozone therapy, homeopathy, floral therapy (Bach floral therapeutic system), medical hydrology (medicinal mineral waters, minerals, peloids and climate), helium thalassotherapy, traditional therapeutic exercises and naturalistic nutritional counselling.

The number of patients who received NTM treatment in 2009, according to statistics from the Ministry of Public Health (MoPH) is set out in the table below.

Care received by NTM patients in Cuba, 2009	Total no. of NTM patients	Percentage of all patients
Outpatients in primary health care	12 343 095	25.24
Integrated system of medical emergencies	4 220 788	19.06
Major surgical interventions with surgical analgesia by means of acupuncture	35 810	9.67
Inpatients	294 998	25.92
Stomatology consultations	7 367 398	41.45
Extractions	45 854	4.12

¹ The Cuban system is universal, accessible, regionalized, and free of charge, so there are no private health services, providers or insurance.

40. Ecuador

Ecuador did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2017.

National policy on T&CM

The national policy and law on T&CM was most recently updated in 2016. There is a general regulatory framework that starts with Ecuador's constitution and organic law of health (Ley Orgánica de Salud [LOS]), which recognizes traditional (indigenous) and complementary medicines (in Ecuador these are divided into two categories: alternative medicines and alternative therapies). Based on this, and as part of the country's public policies, the Model of Integral Health, Family, Community and Intercultural Care (MAIS-FCI) was established, along with the National Plan for Good Living 2013–2017, which guides the implementation of the public policy on T&CM in the country.

The regulation on T&CM practice, last updated in 2016, comprises Ministerial Agreements 000037 (Alternative Therapies) and 5001 (Alternative Medicines), which regulate, monitor and control the practice of alternative therapies and alternative medicine, respectively. As for indigenous TM, public policy provides for its strengthening, self-determination and recognition. Regarding TM, there is a standardized manual (published in 2016) that guides the articulation of health teams with traditional midwives based on the intercultural approach and knowledge dialogue exchange. Also, regulation 00031, issued in 2016, regulates the practices of alternative therapies.

The MoPH (Ministerio de Salud Pública [MSP]) reformed its internal structure in 2013, creating the National Directorate of Intercultural Health. The directorate has two divisions: the Division for the Promotion of Intercultural Health Coordination (in charge of working towards implementing the intercultural approach within the national health system) and the Division of Cosmovision, Indigenous Traditional Ancestral Medicine, and Alternative Medicine. The aim of both divisions is to implement public policy actions related to T&CM, guided by the competencies defined in the LOS.

Within the MSP there is no institution specifically in charge of research in T&CM, nor is there a committee of experts; however, there is the National Institute of Public Health Research (INSPI) that can develop research related to T&CM. Moreover, in the Ministry of Culture there is a Research Department of Traditional and Alternative Medicine.

The MSP has no specific budget allocated for T&CM research, but in 2015 the Ecuadorian State, through the PROMETEO Project (of scientific research), developed a research study called Interdisciplinary Program for the Use of Native Medicinal Plants of Ecuador as Valid, Safe, and Effective Therapeutic Alternatives in Primary Health Care.

There is no explicit national plan for T&CM but there is a law that provides for implementing alternative medicine in health services and for articulating with traditional (indigenous) medicines. There is also the normative framework related to regulation of the exercise of alternative therapies (2016). The National Plan for Good Living 2013–2017 contemplated aspects related to the integration of T&CM as part of other objectives and strategic lines of the plan.

Regulatory status of herbal medicines

The Health Control Registry regulates the registration, manufacture, distribution and marketing of both herbal medicines and homeopathic medicines (under the regulation for health registration and control of processed natural products for medicinal use, and establishments where such products are manufactured, stored, distributed and marketed). There are registered herbal medicines, but the NEML does not include herbal medicines.

Practices, providers, education and health insurance

The most recent update for regulations on T&CM practitioners was in 2014. T&CM practices and providers are regulated under the alternative therapies and alternative medicines laws mentioned above. As for indigenous TM, public policy provides for its strengthening, self-determination and recognition (under the

mandate of the constitution), which means that communities themselves identify legitimate indigenous TM practices and providers. In the case of traditional midwives, there is a manual (issued in 2016) that defines the mechanisms for integrating them with health teams (at primary care level), sets out the process of community legitimation, and establishes parameters for the certification given by the ministry to midwives based on a methodology of dialogue of knowledge.

41. El Salvador

National policy on T&CM

No data for national approaches to T&CM were available for El Salvador.

Regulatory status of herbal medicines

Both herbal medicines and conventional pharmaceuticals are regulated as pharmaceutical specialties (*Reglamento de especialidades farmaceuticas*, 1970).

Herbal medicines are categorized as non-prescription medicines, herbal medicines and dietary supplements; they are sold with nutrient content claims. The pharmacopoeias used, although not legally binding, are the *United States pharmacopeia* (2009), the *Royal Spanish pharmacopoeia* (2002) and the *British pharmacopoeia* (2009). The monographs used, also not legally binding, are the *WHO monographs on selected medicinal plants*.

The regulation of GMP of herbal medicines to ensure their quality is the same as that used for conventional pharmaceuticals. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing, the requirement for manufacturers to assign a person to the role of compliance officer, and the requirement for the compliance officer to ensure that the manufacturer complies with manufacturing requirements and to report back to the Government authorities. The safety requirements for herbal medicines are the same as that for conventional pharmaceuticals; reference to safety data in documented scientific research on similar products is sufficient.

The registration system for herbal medicines follows the suite of Central American technical regulations for pharmaceutical products. The two regulations approved in El Salvador are the technical regulations covering natural medical products for human use, for labelling and for quality control.

Herbal medicines categorized as prescription medicines are sold in pharmacies; herbal medicines categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies, other outlets and special outlets, and by licensed practitioners.

Practices, providers, education and health insurance

Indigenous TM is considered important in El Salvador. T&CM practices such as acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine are also used. T&CM providers practise only in the private sector.

42. Grenada

National policy on T&CM

No data for national approaches to T&CM were available for Grenada.

Regulatory status of herbal medicines

Herbal medicines are not regulated and are not sold with any type of health or other claims. The *British pharmacopoeia* and the *United States pharmacopeia* are used and are legally binding. Currently, no regulations apply to the manufacturing of herbal medicines and there are no safety requirements. Neither the NEML (kept since 2010) nor the market surveillance system for safety of medicines (operating since 1995) include herbal medicines.

There are no restrictions on selling herbal products. Herbal medicines are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies, in other outlets and in special outlets.

Practices, providers, education and health insurance

Indigenous TM is considered important in Grenada, and T&CM practices are also used by the population; however, data on the percentages of use by the population are not available. T&CM providers practise mainly in the private sector.

43. Guatemala

Guatemala did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2017.

Within the framework of the Peace Accords, Guatemala put effort into building national unity based on the respect and exercise of political, cultural, economic and spiritual rights of the Guatemalan population (1995). The Ministry of Public Health and Social Assistance was responsible for the creation of the Traditional and Alternative Medicine Program in 2004.

A national plan for integrating T&CM into national health service delivery was established in 2016.

44. Guyana

Guyana did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2017.

There is no national policy or regulatory system for T&CM in Guyana. However, the Government recognizes the important role played by T&CM.

45. Haiti

Haiti did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2017.

National policy for T&CM

T&CM is managed by the Department of Pharmacy, Medicine, and Traditional Medicine (Direction de la Pharmacie du Médicament et de la Médecine Traditionnelle) within the Ministry of Public Health and Population.¹ There is a national programme, expert committee and research institute for T&CM.

As at 2017, there is no government or public research funding for T&CM. There is, however, a national plan for integrating T&CM into national health service delivery.

Regulatory status of herbal medicines

There is regulation for herbal medicine, but herbal medicines are not currently registered, and they are not included in the NEML.

Practices, providers, education and health insurance

There are no regulations for T&CM practitioners, and T&CM services are not covered by insurance.

¹ See http://mspp.gouv.ht/newsite/?page_id=503

46. Honduras

National policy on T&CM

No data for national approaches to T&CM were available for Honduras.

Regulatory status of herbal medicines

Herbal medicines are known as “natural products”, and are defined as “Products without defined pharmaceutical form, whose formulation is defined by synthetic ingredients and/or natural origin. These products have a food form”. They are sold without prescription and with medical, health, nutrient content claims that are unregulated.

There are no regulations for GMP for herbal medicines but there are specific regulatory requirements for the safety assessment of herbal medicines. It is compulsory to present the methodology of physical, chemical and microbiological analyses of the product.

There are 425 herbal medicines registered (and a further 147 in process as of 2011). There are no restrictions on selling herbal products, and they are sold in pharmacies, other special outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

T&CM providers practise only in the private sector. A T&CM licence or certificate, issued by the national Government, is required to practise.

47. Mexico

National policy on T&CM

The national policy is integrated into the National Health Programme 2007–2012, For a Healthy Mexico: Building Alliances for Better Health (*Programa Nacional de Salud 2007–2012, Por un México sano: construyendo alianzas para una mejor salud*).

There is a national law on T&CM, in that a decree issued in 2006 under the General Law of Health recognizes TM (*El decreto que reconoce la Medicina Tradicional en la Ley General de Salud*).

The national programme is the Programme of Specific Action 2007–2012: Traditional Medicine and Complementary Systems for Health Care (*Programa de Acción Específico 2007–2012. Medicina Tradicional y Sistemas Complementarios de Atención a la Salud. Publicado el 31 de Julio de 2008*).

The national office for T&CM is the Directorate of Traditional Medicine and Intercultural Development Directorate (*Dirección de Medicina Tradicional y Desarrollo Intercultural*), which is administered under the MoH. The directorate was officially installed in August 2002, with the mandate of articulating matters related to indigenous TM; in August 2003, that mandate was expanded to include CM.

Expert committees were established in 2002 for indigenous TM and in 2007 for the CM practices of herbalism, homeopathy and acupuncture.

Regulatory status of herbal medicines

The official Government document *Towards an integral pharmaceutical policy for Mexico* (2005) included a chapter on herbal medicines. Herbal medicines are regulated as “health products”, alongside conventional pharmaceuticals, allopathic medicines and homeopathic medicines. The national regulation on herbal medicines was most recently updated in 2013 to reference the Mexican herbal pharmacopoeia (*Farmacopea herbolaria de los Estados Unidos Mexicanos*).

Herbal medicines are categorized as prescription, non-prescription and herbal medicines; dietary supplements; health foods; functional foods; and general food products. Herbal medicines are sold with medical, health and nutrient content claims.

The pharmacopoeias used, legally binding, are the three Mexican pharmacopoeias: the herbal pharmacopoeia of 2001 (*Farmacopea herbolaria de los Estados Unidos Mexicanos*), the homeopathic pharmacopoeia of 2007 (*Farmacopea homeopática de los Estados Unidos Mexicanos*), and the general pharmacopoeia of 2005 (*Farmacopea de los Estados Unidos Mexicanos*).

The regulation of GMP of herbal medicines to ensure their quality is, like conventional pharmaceuticals, under the Regulation of Health Products (*Reglamento de Insumos para la Salud*), with specific provisions for herbal medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing, the requirement for manufacturers to assign a person to the role of compliance officer, and the requirement for the compliance officer to ensure the manufacturer complies with manufacturing requirements and to report back to the Government authorities. The safety requirements for herbal medicines are the same as that for conventional pharmaceuticals (specifically, microbiological analysis, and absence of toxic residuals, heavy metals, pesticides and foreign materials) and as indicated in the legally binding pharmacopoeias.

The Federal Commission for Protection against Health Risks sets the criteria for inclusion in the register of herbal medicines and in the NEML. In 2009, 154 herbal medicines (79 from parts of plants or extracts and 75 presented in pharmaceutical form) were registered (18). One herbal medicine was included in the NEML in 2003; however, as at 2017, there are no herbal medicines in the NEML.

Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other special outlets.

Practices, providers, education and health insurance

According to the results of a survey by the national office published in 2009–2010, indigenous TM practices and herbal medicines are used by 20–39% of the population, while 1–19% of the population uses acupuncture, aromatherapy, Bach floral therapy, chiropractic, homeopathy and naturopathy (19). Osteopathy, traditional Chinese medicine and Unani medicine are also used.

The regulation of acupuncture providers was issued in 2002, enforced at national level. T&CM providers practise in private clinics and in public clinics and hospitals. A T&CM licence or certificate issued by a relevant academic institution is required to practise.

As per the 2011 data from Authorisation and Professional Registry Directorate, the following degrees are provided at university level: bachelor (6585 graduates in 2009); Master (6 graduates in 2009); PhD (1 graduate in 2009); clinical doctorate (1005 graduates in 2009); and technicians (in acupuncture and homeopathy: 101 graduates in 2009). Certified training programmes are also officially recognized by the Government. According to the Registry data, the T&CM providers in practice included 379 in acupuncture, 148 in chiropractic, 37 in herbal medicines and 7 171 in homeopathic medicine.

As of 2009, 27 852 indigenous TM providers were practising in Mexico, according to data from the National Centre for Gender Equity and Reproductive Health.

In addition, Mexico reports that as at 2017 it has:

- developed a proposed basic table of homeopathic medicines and herbal remedies;
- introduced a regulation for health supplies that includes herbal medicines and remedies;
- published guidelines for structuring and evaluating homeopathic medicine teaching programmes, university undergraduate acupuncture and chiropractic degrees and herbal medicine diplomas, to strengthen medical practice, as elaborated by the interinstitutional committee for the training of human resources in health;
- recognized an official Mexican standard on acupuncture that regulates its practice; and
- published guidelines for the implementation of TM, and the “clinical-therapeutic and health-strengthening models” (CM) in the health system.

48. Nicaragua

Nicaragua did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2017.

National policy on T&CM

National laws for T&CM are Law 774 of 2011 (Ley de medicina natural, terapias, complementarias y productos naturales en Nicaragua), which regulates natural medicine, therapies, and complementary and natural products, and Law 759 of 2011, which regulates indigenous TM, or “traditional ancestral medicine” (Ley de medicina tradicional ancestral).

The national office for T&CM is also the national institute for research into T&CM: the Institute of Natural Medicine and Complementary Therapies, inaugurated in 2014 in Silais-Managua, as part of the MoH. The institute is also responsible for the national programme for T&CM.

There is no Government or public research funding for T&CM as at 2017, although a national plan for integrating T&CM into national health service delivery was formulated in 2014.

Regulatory status of herbal medicines

Herbal medicines are not regulated in Nicaragua, but a registration system for herbal medicines was started in 2016.

Practices, providers, education and health insurance

T&CM practitioners are not yet regulated. In 2015, a consumer education programme was initiated for self-health care using T&CM. As at 2017, T&CM services are covered by the public health system.

49. Panama

National policy on T&CM

Law 17 of 2016 establishes the protection of indigenous TM knowledge (Que establece la protección de los conocimientos de la Medicina Tradicional Indígena). The Directorate of Indigenous Health (*Dirección de Asuntos Sanitarios Indígenas*) of the MoH is in charge of T&CM issues.

An advisory committee on indigenous TM – the Consultative Commission of Traditional Indigenous Medicine (Comisión Consultiva de Medicina Tradicional Indígena) – attached to the Directorate of Indigenous Affairs of the MoH, was created in 2017, and tasked with guiding the implementation and regulation of the TM law. At the moment, the committee is in its initial organizing stage. It is in the process of identifying and recognizing TM agents, and engaging the traditional authorities and communities of the indigenous regions of the country.

There is no national institute for T&CM research as at 2017.

Regulatory status of herbal medicines

Herbal medicines are regulated as non-prescription medicines and dietary supplements, and sold with health claims. There is no regulation on manufacturing of herbal medicines to ensure their quality, nor are there any safety requirements for herbal medicines. Herbal medicines are sold in pharmacies, other and special outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Panama. Other T&CM practices are also in use. A T&CM licence or certificate is required to practise, with self-regulation by delegated special technical associations.

50. Paraguay

National policy on T&CM

Paraguay does not yet have a national policy or law for T&CM. The draft National Policy on Medicinal Plants is a structured document that was reviewed by experts and discussed in topic-related conferences. The document update continued in the 2nd Congress of Medicinal Plants, held in November 2017, in the city of Hernandarias.

Several research institutes undertake scientific research into medicinal plants; for example, the Facultad de Ciencias Químicas (FCQ–UNA), the Facultad de Ciencias Exactas y Naturales (FACEN–UNA) and the Health Sciences Research Institute (IICS).

Regulatory status of herbal medicines

There is a regulation specific to herbal medicines (although the same regulation includes homeopathic products). Herbal medicines are categorized as non-prescription phytopharmaceuticals, and are sold with claims based on popular use.

The pharmacopoeias used are the national pharmacopoeias of Paraguay (1938), Argentina and Brazil. The monographs used are the *WHO monographs on selected medicinal plants*. These publications are not legally binding.

There is no regulation on manufacturing of herbal medicines to ensure their quality. The safety requirements are the same as that for conventional pharmaceuticals; traditional use without demonstrated harmful effects and reference to safety data in documented scientific research on similar products are sufficient.

The NEML does not include herbal medicines. Herbal medicines are sold in pharmacies, other outlets and special outlets as non-prescription medicines, self-medication or OTC medicines. The list of registered herbal medicines was most recently updated in 2017.

Practices, providers, education and health insurance

Indigenous TM is considered important in Paraguay. T&CM practices such as acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine are used.

T&CM providers practise in private clinics only. As at 2017, there is a draft regulation for T&CM providers that is being reviewed by the MoH's legal advisory office.

51. Peru

National policy on T&CM

Peru's national policy for T&CM is integrated into the General Health Law (*Ley General de Salud* No. 26842), which states that the promotion of TM is of special interest and attention for Peru (*Título XVII: "La promoción de la Medicina Tradicional es de interés y atención preferente del estado"*).

In 2016, the National Policy of Intercultural Health (*Política Nacional de Salud Intercultural*) was issued.

The national office for T&CM is the National Institute of Traditional Medicine (*Instituto Nacional de Medicina Tradicional*), established in 1990 and administered by the MoH. The National Centre of Intercultural Health (*Centro Nacional de Salud Intercultural* [CENSI]), located in the National Institute of Health (*Instituto Nacional de Salud*) as part of the MoH, serves as the national research institute. There is also the Traditional Medicine Institute (*Instituto de Medicina Tradicional*), which is part of the public health care provider EsSalud, and was established by government resolution in 1992.

A national programme on T&CM was established in 1998 in the social health insurance division of EsSalud (*Seguro Social de Salud del Perú, EsSalud*) under the Ministry of Labor; in 2009, this programme became the national Complementary Medicine Directorate.

Annual government research funding for NTM (in US\$) in Peru, 2010–2016						
2010	2011	2012	2013	2014	2015	2016
300 000	310 000	320 000	320 000	330 000	310 000	310 000

CENSI is currently working on a technical service provision guideline as part of a national plan for integrating T&CM into national health service delivery.

Regulatory status of herbal medicines

Regulation of herbal medicines comes under the regulation for registration, control and health surveillance of pharmaceutical and related products, approved by Supreme Decree No. 010, and the law on pharmaceutical products, medical devices and health care products (*Ley de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios* No. 29459), which is in the process of being implemented. Under this legislation, herbal medicines are categorized as herbal medicines, dietary supplements and functional foods.

The monographs used are not legally binding; they include a medicinal plants formulary (*Formulario de Plantas Medicinales del Seguro Social de Salud*) comprising 54 monographs (2002), a phytotherapy manual (*Manual de Fitoterapia*) comprising 73 monographs (2000) and a database of medicinal plants of the Peruvian Amazon (*Banco de Datos de Plantas Medicinales de la Amazonía Peruana*) comprising 80 monographs (2007).

The GMP for herbal medicines are specified in the manual of GMP for all pharmaceutical products (*Manual de Buenas Prácticas de Manufactura de Productos Galénicos y Recursos Terapéuticos Naturales*), issued in 2000. There are specific regulations on manufacturing of herbal medicines to ensure their quality. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, the requirement for manufacturers to assign a person to the role of compliance officer, and the requirement for the compliance officer to ensure the manufacturer's compliance with manufacturing requirements and to report back to the Government authorities. There are specific safety requirements for herbal medicines according to their classification: norms of medicines for herbal medicines, certificate of traditional use and toxicity studies for herbal products, and certificate of traditional use and botanical certificate for herbal resources.

Between 2002 and 2007, 962 herbal medicines were registered (435 natural products from Peru and 527 foreign ones). The most recent update of the register of herbal medicines was in 2017. Herbal medicines are included in the NEML, most recently updated in 2016.

Herbal medicines are sold in pharmacies and other special outlets as non-prescription medicines, self-medication or OTC medicines.

A consumer education programme for self-health care using T&CM was established in 2011. In 2013, EsSalud's Complementary Medicine Directorate developed a health education programme for people with metabolic syndrome, titled "Life Reform Program", and a programme to train peer educators (former patients) as health promoters using T&CM-related interventions.

Practices, providers, education and health insurance

Indigenous TM is considered important in Peru. Other T&CM practices are also in use.

T&CM providers practise in private and public clinics and hospitals. Education provided at the university level includes a diploma in alternative therapies (48, 54 and 60 graduates in 2007, 2008 and 2009, respectively). The Government also officially recognizes a certified training programme.

Providers of indigenous TM and other T&CM practices such as acupuncture, chiropractic, floral therapy, herbal medicines, homeopathic medicines, mind–body medicine, naturopathic medicine, neural therapy, osteopathic and traditional Chinese medicine are all found in Peru.

With regard to health insurance, the MoH, through the integrated health system (serving the poor population of the country), covers some acupuncture services. Government social security insurance (EsSalud), which provides care to about 30% of the population, provides T&CM services for those it insures.

52. Saint Lucia

National policy on T&CM

As at 2017, there is no national policy or law for T&CM in Saint Lucia.

The Health Practitioners Act (2006) established the Allied Health Council to be responsible for registering, licensing and regulating T&CM providers as “allied health practitioners”.

Regulatory status of herbal medicines

There is no national regulation on herbal medicines and Saint Lucia does not have any mechanism to register medicines. Herbal medicines are sold with medical, health and nutrient content claims but these claims are unregulated. No regulations apply to the manufacturing of herbal medicines. The NEML (established in 2009) does not include herbal medicines and there is no market surveillance system for safety of medicines.

There are no restrictions on selling herbal products, which are sold in pharmacies, other outlets and special outlets (e.g. in herbal medicines stores) as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Saint Lucia. Other T&CM practices, such as acupuncture and herbal medicines, are also used.

T&CM providers practise in the private sector. Data on their numbers are not available.

T&CM practices are regulated via the Allied Health Council, which registers, licenses and regulates allied health practitioners. As at 2017, some services from certain naturopaths are honoured by certain private health insurance companies, but most are not. The public National Insurance Corporation St Lucia does not cover T&CM services.

53. Saint Vincent and the Grenadines

National policy on T&CM

No data for national approaches to T&CM were available for Saint Vincent and the Grenadines.

Regulatory status of herbal medicines

Herbal medicines are not regulated. They are sold with medical, health and nutrient content claims but these claims are unregulated. No regulations apply to the manufacturing of herbal medicines. Traditional use without demonstrated harmful effects is sufficient for meeting regulatory requirements for safety assessment of herbal medicines.

There are no restrictions on selling herbal products, which are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies and other outlets, in special outlets (e.g. in herbal medicine stores), by licensed practitioners and even on the street.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in Saint Vincent and the Grenadines. Other T&CM practices – such as chiropractic, herbal medicines and homeopathy – are also used by the population. Providers of all these practices practise in the country. The Government does not officially recognize any T&CM training programmes.

54. Trinidad and Tobago

National policy on T&CM

The national drug policy from 1998 mentions “complementary medicine” (20). The Food and Drug Division under the MoH, established in 1960, serves as the national office for T&CM. An expert committee was established in 2000.

Regulatory status of herbal medicines

There are no regulations specific to herbal medicines, but the Food and Drugs Act and Regulations (Chapter 30:01) cover all drugs, including herbal medicines.

Herbal medicines are categorized as prescription and non-prescription medicines. They are sold with medical, health and nutrient content claims, but these claims are unregulated. There is no national pharmacopoeia but other pharmacopoeias, such as the *British herbal pharmacopoeia* (1983) and the *Ayurveda pharmacopoeia of India* (10th ed., 1990), are used. These pharmacopoeias are not legally binding. Monographs in use are also not legally binding.

There is a registration system for herbal medicines. There are no restrictions on selling herbal products and they are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies and other outlets, in special outlets (e.g. in herbal medicines stores) and by licensed practitioners.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in Trinidad and Tobago. The use T&CM practices by the population is also acknowledged. The Government does not officially recognize any T&CM training programmes. There is no regulation on T&CM practice or practitioners and the T&CM services are not reimbursed by insurance. T&CM providers mainly practise in the private sector.

55. United States of America

The United States did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2017.

National policy for T&CM

An Office of Alternative Medicine was formed within the National Institutes of Health (NIH) Office of the Director in 1992. In 1999, the National Center for Complementary and Integrative Health (NCCIH) was established.

Government or public research funding for T&CM (categorised as “Complementary and Alternative Medicine” for the NIH by fiscal year (1 October through 30 September) is as follows:

Annual government or public research funding for T&CM (in US\$) in the United States, 2013–2016			
2013	2014	2015	2016
380 million	360 million	337 million	366 million

There is no national plan for integrating T&CM into mainstream health service delivery.

Regulatory status of herbal medicines

The Dietary Supplement Health and Education Act of 1994 forms the national regulation on herbal medicines. There is no registration of herbal medicines and they are not included in the NEML.

Practices, providers, education and health insurance

T&CM practices and providers are regulated at the state level. Regulations for T&CM providers are delegated to each of the 50 states.

Consumer education projects and programmes for self-health care using T&CM form part of the NCCIH.

As at 2017, T&CM services are reimbursed in some cases by private health insurance, as determined by individual insurance providers.

56. Uruguay

Uruguay did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2017.

There is no national policy, law or regulatory system for T&CM. In 2016, regulation and registration of herbal medicines was established through Decree 403 (Phytotherapeutics) and Decree 404. T&CM practitioners are not yet regulated.

The Integrated Health Care Plan – a benefits package of the National Integrated Health System for universal health coverage by public and private providers – includes a limited number of herbal medicines. Other T&CM services are not included. This has contributed to the low cultural usage of T&CM services and the fact that health professionals and users of the system have not explicitly demanded their incorporation.

5.3 WHO Eastern Mediterranean Region

Table 5.3 summarizes the development of national policy for T&CM, regulation of T&CM and herbal medicines, and use of T&CM among populations of Member States in the WHO Eastern Mediterranean Region. The table also compares the percentage of Member States in the region with the global percentage for each indicator.

In the period between 2005 and 2018, Member States in the region demonstrated a strong commitment to the regulation and registration of herbal medicines. The use of T&CM among the population is also strong, being acknowledged by over 90% of Member States in the region. However, there are fewer national policies and programmes on T&CM than in other regions.

Table 5.3. WHO Eastern Mediterranean Region, development of T&CM, 2005–2018

Category	Regional number of Member States with affirmative responses in 2005	Regional number of Member States with affirmative responses as at 2018	Regional % of Member States with affirmative responses as at 2018 (N=21)	Global % of Member States with affirmative responses as at 2018 (N=194)
National policy on T&CM	5	9	43%	51%
Laws or regulations on T&CM	8	12	57%	56%
National programme on T&CM	2	4	19%	41%
National office for T&CM	10	13	62%	55%
Expert committee on T&CM	8	11	52%	48%
National research institute for T&CM or herbal medicines	8	10	48%	39%
Regulation of herbal medicines	12	18	86%	64%
Registration of herbal medicines	12	17	81%	64%
Population using T&CM	–	19	90%	88%

Note: The 2018 data set includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018). There may be Member States in which the T&CM situation has changed, not accounted for here.

57. Afghanistan

National policy on T&CM

Previously, the MoPH's General Directorate for Pharmaceutical Affairs (GDPA) dealt with T&CM topics. In 2007, an expert committee for TM (only) was formed.

Under the structure of a newly established National Medicine and Health Products Regulatory Authority (NMHRA), there is a unit responsible for T&CM that has started working in the area but it is not yet fully functional.

As at end 2016, there is no national policy, law or regulation for T&CM practice in Afghanistan, and no Government or public research funding available for T&CM.

Regulatory status of herbal medicines

Herbal medicines are mentioned in the general medicine law, but they are not well defined or illustrated in other regulations. The NMHRA's herbal committee reviews licence applications for factories manufacturing herbal medicines. The NEML (revised in 2013) does not include herbal medicines, and there is no market surveillance system for the safety of herbal medicines. There is scant regulation to restrict the selling of herbal products in the market.

As at 2016, herbal and traditional medicines are not registered properly, and there is no specific guideline for registration; they are also imported illegally by T&CM practitioners. The MoPH has recently opened a department under the Curative Medicine Directorate for the regulation of homeopathic medicine, but it is not yet fully functional. Currently, an international consultant has been deployed by WHO Afghanistan for the NMHRA, to develop guidelines for the registration of traditional and herbal medicine products, and for the licensing of traditional and herbal medicine establishments.

Practices, providers, education and health insurance

Indigenous TM is important in Afghanistan. Other T&CM practices are used by the population but the percentages are not available. T&CM providers mainly practise in private sector clinics. There are no T&CM training programmes that the Government officially recognizes.

Indigenous TM providers practise in Afghanistan, but there are no data available on their numbers or on the use of the different types of T&CM practices among the population.

There are no regulations on T&CM providers as at end 2016, but during recent years, the expert committee in the NMHRA has examined TM practitioners and issued licences for their practice accordingly. T&CM services are currently not reimbursed by health insurance.

58. Bahrain

National policy on T&CM

In Bahrain, the Directorate of Pharmacy and Drug Control (under the MoH) and the National Health Regulatory Authority established in 2009 look after topics related to T&CM.

Regulatory status of herbal medicines

Regulation of herbal medicines is partly the same as that for conventional pharmaceuticals. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines, dietary supplements and health foods. They are sold with health and nutrient content claims.

Regulations for the manufacturing of herbal medicines are the same as that for conventional pharmaceuticals. To ensure compliance, manufacturers are required to submit samples of their medicines to a government-approved laboratory for testing and to submit the latest GMP from their local authority. Safety requirements similar to those for conventional pharmaceuticals apply to herbal medicines.

Since 2016, all complementary and alternative medicine products (not herbal medicines specifically) must be registered in Bahrain.

Herbal medicines are sold as prescription medicines, non-prescription medicines or OTC medicines in pharmacies and other outlets, in special outlets (e.g. in herbal medicines stores) and by licensed practitioners.

Practices, providers, education and health insurance

Indigenous TM is considered important in Bahrain, with 60–79% of the population using it. Other T&CM practices are also used as follows: acupuncture is used by 60–79% of the population, ayurvedic medicine by 20–39%, herbal medicines by 80–99% and homeopathy by 20–39%.

T&CM was practised in Bahrain but was not well regulated until 2016, when a decree was issued regulating the licensing and practice of complementary and alternative medicine.

59. Iran (Islamic Republic of)

National policy on T&CM

The Islamic Republic of Iran has an integrated national policy on T&CM – the “doctrines of revival and indication” for Iranian TM, issued in 1996 and revised in 2010. This also serves as the national programme on T&CM. The process is being extended to develop policies for other T&CM practices. A law on T&CM relates to responsibility and administrative structure in the Ministry of Health and Medical Education.

Since 1981, all tasks related to T&CM have been conducted by an office in the Department of Pharmaceuticals Affairs. In 2004, the Secretariat for the Educational Council of Iranian Traditional and Complementary Medicine was established under the Ministry of Health and Medical Education to look after T&CM.

There are two national research institutes: the Institute for Research on Medical History, Islamic and Complementary Medicine, located in Tehran and established in 1997, and the Traditional Medicine and Materia Medica Research Centre, founded in 1999.

Regulatory status of herbal medicines

Regulations and orders governing the issue of licences for packaging and producing herbal products were issued in 1981 and revised in 2006. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines and dietary supplements, and are sold with medical and health claims.

The *Iranian herbal pharmacopoeia*, vol. 1, is the national pharmacopoeia. It includes herbal medicines in use and is legally binding. The *British pharmacopoeia*, *European pharmacopoeia* and the *United States pharmacopoeia* are also used but they are not legally binding. Monographs in use include the *National formulary of Iran* (the latest, third, edition contains 168 monographs) and the *WHO monographs on selected medicinal plants*. These monographs are not legally binding.

GMP principles on production of herbal products (revised in 2006) contains regulations that apply to the manufacturing of herbal medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing and to assign a person to the role of ensuring compliance. The safety requirements that apply to herbal medicines are the same as those for conventional pharmaceuticals. Traditional use without demonstrated harmful effects and reference to safety data in documented scientific research on similar products are sufficient to meet these requirements.

A register of herbal medicines, the Licensed Natural Medicines List, is regularly published on the Iran Food and Drug Administration (IFDA) site. Selection criteria for inclusion are based on the herbal medicine's traditional use, clinical data, long-term historical use and laboratory testing. There are 549 registered herbal medicines. As at end 2016, 56 herbal drugs are national drugs (i.e. they are included in the NEML) separate from the list of IFDA, and are covered by public health insurance. More than 300 are in process of being evaluated.

Since 1998, adverse drug reaction (ADR) data for both conventional pharmaceuticals and herbal medicines are collected by the same office. Market quality controls are done by Food and Drug Control Laboratories (FDCL) regularly. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets, and in special outlets.

Practices, providers, education and health insurance

Indigenous TM is considered important in Iran. Other T&CM practices are used but the percentage of use is not known. T&CM providers practise in public and private sector clinics.

A PhD in T&CM has been available at university level since 2007. A national regulation on the activities of graduates in the field of Traditional Persian Medicine (TPM) was established in August 2013, and a similar national regulation of the activities of practitioners in the field of complementary medicine came in November 2012. A licence to practise is required, issued only to MDs or PhDs in TPM or trained physicians.

Iranian TM and complementary medicine have been practised by physicians based on their own expertise and interest. Iranian TM has also been continued by a small number of traditional practitioners and “attaries” (medicinal plant shops that meet public demand for herbs). More than 10 000 herbal medicine providers work in attaries. For other types of T&CM practices, the numbers of providers are as follows: 55 acupuncturists, 100 chiropractors, five homeopathic medicine providers, two naturopaths and more than 1000 Iranian TM providers, according to 2010 data from the Deputy for Education.

As at end 2016, 56 herbal drugs are covered by public health insurance but visits and services of T&CM practitioners are not covered by any health insurance.

60. Iraq

National policy on T&CM

The national policy for T&CM is the Herbal Medicines Policy issued in 2010. Since 1989, a national office under the MoH has looked after issues related to T&CM. A research unit exists in the National Center for Drug Control and Research.

Regulatory status of herbal medicines

There is a regulation exclusively for herbal medicines, and it is partly the same as that for conventional pharmaceuticals. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines and dietary supplements. Herbal medicines are sold with medical, health and nutrient content claims, but these are unregulated.

The *British herbal pharmacopoeia* is used as the national pharmacopoeia for herbal medicines and is legally binding. The *WHO monographs on selected medicinal plants* are used as national monographs on herbal medicines. There are specific safety requirements for herbal medicines, which are the same as those for conventional pharmaceuticals.

As of 2012, seven herbal medicines were registered. Herbal medicines are included in the NEML; criteria for inclusion are based on herbal medicine’s traditional use, clinical data, long-term historical use and reference books. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets, in special outlets and by licensed practitioners.

Practices, providers, education and health insurance

The use of indigenous TM is considered important in Iraq. Other T&CM practices are also used by the population, but the percentages are not known. The T&CM licence required to practise is issued by the national Government.

Bachelor’s, master’s and PhD degrees are available at university level. The Government also recognizes a training programme for T&CM technicians or equivalent (not at university level).

Herbalists and herbal medicine providers are found to practise in Iraq.

61. Jordan

National policy on T&CM

Herbal and other traditional remedies were introduced as a key component of the National Medicine Policy published in 2014. The national office on T&CM is part of the Drug Directorate of the MoH, established in 1999. A special unit was established in 2007 as part of the Drug Directorate at Jordan Food & Drug Administration (JFDA), in which the JFDA became a separate and independent entity from the MoH in 2003.

No independent national research institutes on T&CM or herbal medicines have been established, although research on quality, safety and efficacy of herbal medicines are conducted by local universities and research centres. There is no government or public research funding for T&CM as at end 2016.

Regulatory status of herbal medicines

National regulations on herbal medicines and herbal products were established in 2001 and updated in 2007. In 2017 “natural products” were added to the latter regulation in order to have a comprehensive definition of T&CM. In 2016, the regulations were also updated to specify the documents required to support quality, safety and efficacy of herbal medicines, under the national Drug and Pharmacy Law.

There are separate provisions for herbal medicines and herbal preparations. *Herbal medicines* are regulated as prescription herbal medicines and sold with medical claims. *Herbal preparations* are treated as general health products, and are sold with health and nutrient content claims.

Official monographs referred to include WHO monographs, international monographs and pharmacopoeias, the EU’s herbal monograph and assessment reports. Scientific published literature is used for safety and toxicological information.

The regulations that apply to the manufacturing of herbal medicines are the same as those for conventional pharmaceuticals. GMP requirements are specified in current GMP (cGMP) guidelines, including the Arab, US Food and Drug Administration (FDA) and EU guidelines on cGMP. To ensure compliance, internal periodic inspections are carried by authorities at the manufacturing plants, and manufacturers are required to submit samples of their medicines to a government-approved laboratory for testing. There is external inspection for accreditation of manufacturing sites and lines. Recent published literature and clinical assessment reports or periodic safety update reports are regulatory requirements for the safety assessment of herbal medicines.

There are 76 herbal medicines registered. Herbal medicines categorized as prescription medicines are sold in pharmacies. Herbal preparations are sold in pharmacies and other specialized stores as non-prescription products, self-medication or OTC products.

Practices, providers, education and health insurance

Under Article 12 of each of the national regulations on herbal medicines and herbal and natural products (as updated in 2017), practitioners and specialized stores selling natural products must be certified according to a regulation yet to be issued, indicating an intent to have practitioners for T&CM regulated.

62. Kuwait

National policy on T&CM

No data for national approaches to T&CM were available for Kuwait.

Regulatory status of herbal medicines

There has been a regulation exclusively for herbal medicines since 1997. Herbal medicines are regulated as non-prescription medicines and dietary supplements; they are sold with medical, health and nutrient content claims, but these claims are unregulated. There is adherence to manufacturing information in pharmacopoeias and monographs.

There are no restrictions on selling herbal products and they are sold in pharmacies, other outlets and special outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Kuwait. Other T&CM practices are used by the population, but the percentage of use is not known. T&CM providers practise in the public sector.

The types of T&CM providers found in practice include those of acupuncture, chiropractic, herbal medicines, osteopathy, traditional Chinese medicine and Unani medicine. Indigenous TM is covered by government health insurance.

63. Lebanon

Lebanon did not reply to the second survey but provided a voluntary update of the T&CM situation as at end 2016.

National policy for T&CM

There is no national policy and law on T&CM in Lebanon. Since 2010, there has been regulation of T&CM practice. There is currently no national office, programme, expert committee or research institute for T&CM.

Regulatory status of herbal medicines

There is a national regulation on herbal medicines but details are not provided. Herbal medicines are registered but are not included in the NEML.

Practices, providers, education and health insurance

Promotion of T&CM providers and products on media is not regulated. There are no regulations for T&CM practitioners and, currently, there is no consumer education project or programme for self-health care using T&CM. As at end 2016, T&CM services are not reimbursed by health insurance.

64. Morocco

National policy on T&CM

As at end 2016, Morocco does not have a national policy on T&CM.

Regulatory status of herbal medicines

The practice of the profession of herbalist is regulated under Dahir No. 1–59–367. No update of this law has been made since its introduction in 1960.

The safety of herbal medicines is monitored by the National Pharmacovigilance Centre within the Poison Control and Pharmacovigilance Centre of Morocco (CAPM). A unit of phytovigilance was created in 2000 to ensure the surveillance of safe use of herbal medicines and to minimize harm from their misuse.

The same monitoring as conventional drugs is used for herbal medicines. It involves detecting and collecting data on side-effects, analysing cases, signal detection and looking at all contributing factors leading to risk occurrence in order to minimize the risk through regulatory action or communication about the risk with population, health care providers or media.

Up to December 2017, there were a total of 4300 cases of ADRs in the CAPM database, with an average of 9% of all individual case study reports unregistered in the Moroccan database.

The CAPM database is an important source of information for most of the vegetable species existing in Morocco (where, what, which parts used, how it is used and for what indication) and the side-effects occurring with plants or drug–herbals interactions.

Herbal medicines that are or contain plants registered in the national pharmacopoeia are governed by the Code of Medicine and Pharmacy of 2006. If the plants are not registered in the pharmacopoeia and do not present a health claim, the herbal products are considered as food supplements and are governed by a joint circular between the MoH and the Ministry of Agriculture. They are registered at the MoH (Directorate of Medicine and Pharmacy) and receive a registration certificate allowing them to be marketed in the national territory.

The regulation on manufacturing of herbal medicines to ensure their quality requires adherence to manufacturing information in pharmacopoeias and monographs. The mechanism to ensure compliance is periodic inspections by authorities at the manufacturing plants or laboratories. The safety requirements are the same as those for conventional pharmaceuticals; traditional use without demonstrated harmful effects is sufficient.

The NEML does not include herbal medicines. Herbal medicines are sold in pharmacies and by licensed practitioners as prescription and non-prescription medicines, self-medication or OTC medicines.

To regulate the use of herbal medicines, CAPM has proposed a new law, currently in draft stage and ongoing. The former National Institute of Aromatic Medicinal Plants became the National Agency of Medicinal Aromatic Plants in 2016.

CAPM's phytovigilance unit undertakes to educate the general population about the misuse of herbal medicines via the mass media, to reinforce to government members the importance of TM, and to publish safety alerts.

Practices, providers, education and health insurance

Indigenous TM providers practise within Morocco (number unknown). T&CM providers also practise (numbers unknown).

65. Oman

National policy on T&CM

In Oman, guidelines for regulation of TM preparations are integrated into the National Medicine Policy of 2008. There is a national office for T&CM under the MoH, Directorate General of Pharmaceutical Affairs & Drug Control in Muscat.

The Oman Animal and Plant Genetic Resources Center (OAPGRC) was established by the Research Council in 2012, with a mission to promote recognition, sustainable exploitation and valuation of genetic diversity inherent in Oman's animals, plants and microorganisms as a natural heritage resource. From 2016 onwards, a focus area for OAPGRC is organizing grants, and collaboration in research and training.

Regulatory status of herbal medicines

Herbal regulation in Oman began in 1998, and the laws were updated in 2008. The regulation for herbal medicines is partly the same as that for conventional pharmaceuticals. Herbal medicines are regulated as herbal medicines and are sold with medical claims. The *Ayurveda pharmacopoeia of India* (2010), the *Indian herbal pharmacopoeia* (2002) and the *British herbal pharmacopoeia* (1996) are used, and they are legally binding. The *WHO monographs on selected medicinal plants*, the EU herbal monographs (2005) and the European Scientific Cooperative on Phytotherapy (ESCOP) herbal monographs (2003), comprising 80 monographs, are used and these are legally binding.

The WHO guidelines on GMP for herbal medicines (2007) are used, and the same regulations apply for manufacturing of herbal medicines as for conventional pharmaceuticals, including adherence to manufacturing information in the pharmacopoeias and monographs. Compliance is ensured by periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. The safety requirements for conventional pharmaceuticals also apply to herbal medicines; reference to safety data in documented scientific research on similar products is sufficient to meet these requirements.

Herbal medicines are sold in pharmacies by licensed practitioners as prescription medicines, non-prescription medicines, self-medication or OTC medicines.

The herbal medicines registration system was updated in 2016. Sixty herbal medicines are registered. In 2016, a herbovigilance system was established.

Practices, providers, education and health insurance

Indigenous TM is considered important in Oman, with acknowledged use by 80–99% of the population. Data on types of T&CM practices used by the population were not available.

National-level regulations apply to indigenous TM providers. T&CM providers of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy and traditional Chinese medicine practise in Oman; they are regulated by national-level regulations, but their numbers are not known.

T&CM providers practise in the private sector clinics. The national Government issues the licence required for T&CM practice. Bachelor's and master's degrees are available at university level. The Government also recognizes training programmes for indigenous TM practitioners and for T&CM technicians or equivalent (not at university level).

There is partial health insurance coverage of some T&CM services such as acupuncture, herbal medicines and traditional Chinese medicine by government agencies, and of homeopathic medicine by private organizations.

In 2016, a TV programme called “Tadawi”, which covered consumer awareness on herbal drug interactions and other relevant issues, was aired as an initiative of the Department of Health Education and Awareness Programs in the MoH. The programme featured the services of health professionals – a physician, a pharmacist, a physiotherapist and a nutritionist – as a general health-related programme, not intended for any particular system of medicine. The programme addressed issues with drugs (e.g. how to use them, the side-effects and other pertinent points). Topics that have been covered include diabetes, renal diseases, cardiac diseases, hypertension, breast cancer, osteoporosis, smoking and medication in the holy month of Ramadhan. One of the topics also related to slimming or weight loss products, especially those products that claimed to be of herbal origin and were found to be adulterated with chemical agents.

66. Pakistan

National policy on T&CM

In Pakistan, the policy on T&CM is integrated into the national health policy of 2001. The law relating to T&CM is the Unani, Ayurvedic, Homeopathic Act of 1965 (updated in 1982 and 2003). T&CM is administered under the MoH. The Drug Control Organization (DCO) in the Traditional Medicine Division of the National Institute of Health serves as the national research institute on T&CM.

Regulatory status of herbal medicines

A draft regulation on herbal medicines was approved by cabinet in 2001. In November 2014, the Alternate Medicine Health Products Enlistment Rules with exemption period was introduced.

An online ADR reporting form covering T&CM products has been available on the official website¹ since January 2018, to gather ADR data. Herbal medicines are sold with medical, health and nutrient content claims but these are unregulated. The *American herbal pharmacopeia*, WHO monographs and EU monographs are used. Information in the pharmacopoeias is not legally binding. Monographs of Unani medicine are used nationally, but these are not legally binding. Malaysian monographs and the *Indian pharmacopoeia* are also used.

¹ See <http://www.dra.gov.pk/>

GMP for traditional herbal medicines, published by the DCO, are followed. There are exclusive regulations for GMP, separate from those for conventional pharmaceuticals. Mechanisms are in place to ensure compliance and the regulatory Act to control manufacturing is yet to be enacted. Traditional use without demonstrated harmful effects is considered sufficient for the safety assessment of herbal medicines. There are no restrictions on selling herbal products.

The annual market sales for herbal medicines in Pakistan in the years 2007, 2008 and 2009 were estimated by the Pakistan Tibbi and Homeopathic Manufacturers Association data to be US\$ 5.5 million, US\$ 6.5 million and US\$ 7 million, respectively.

Practices, providers, education and health insurance

Indigenous TM is considered important in Pakistan, with acknowledged use by 40–59% of the population (21).

The percentage of the population using different types of T&CM practices are as follows: acupuncture 1–19%, herbal medicines 40–59%, homeopathy 20–39%, naturopathy 1–19%, traditional Chinese medicine 1–19% and Unani medicine 40–59%.

National-level regulations under the Unani, Ayurvedic and Homeopathic Practitioners Act apply to indigenous TM providers and T&CM providers of ayurvedic medicine, chiropractic, herbal medicines, homeopathy and Unani medicine; these regulations are fully enforced.

T&CM providers practise in both public and private sector clinics and hospitals. The National Council for Tibb and Homeopathy issues the T&CM licence that is required to practise. Bachelor's, master's, PhDs and clinical doctorate degrees in T&CM are available at university level.

About 120 000 homeopaths and 40 000 hakims (indigenous TM practitioners) practise in Pakistan. T&CM providers of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine also practise in Pakistan but their numbers are not known.

67. Qatar

National policy on T&CM

Currently, there is no national law in Qatar on T&CM. T&CM is known as complementary and alternative medicine (CAM) in Qatar. A draft law is in the revision phase. The Qatar Council of Healthcare Practitioners (QHCP), established in 2013, is the sole regulatory authority, and is responsible for regulation of all health care practitioners including CAM practitioners.

The CAM regulatory framework was prepared by the QHCP and approved by the QHCP Board and (as of 2012) was undergoing the final formalities and approvals. The regulatory framework defines five scopes of CAM practice (the most common, most proven to be safe and scientifically sound, and most regulated worldwide). The concept of CAM, rather than alternative medicine, was adopted by QHCP to ensure that it will not be used as a substitute for modern medicine.

Apart from the QHCP, there is no national office for T&CM (e.g. for herbal medicines). The CAM specialized expert committee was formed in 2016 to deal with issues related to registration and licensing of CAM practitioners.

Currently, Qatar is in the implementation stage for the legislation on the practice of CAM. The QHCP is working with the legal department in the MoPH towards the approvals of regulatory standards and framework.

Regulatory status of herbal medicines

Herbal medicines are regulated under the "Regulation for herbal medicines, dietary supplements and medicated cosmetics", issued in 2009. Herbal medicines are categorized as herbal medicines or dietary supplements, and are sold with health and nutrient content claims.

The pharmacopoeias in use are *Martindale: the complete drug reference* (33rd ed., 2003) and the *Physician's desk reference for herbal medicines* (3rd ed., 2005).

The WHO good agriculture and collection practice (GACP) guidelines apply to the manufacture of herbal medicines, and the GMP for conventional pharmaceuticals also applies to herbal medicines. Compliance is ensured through periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. The same safety requirements apply as for conventional pharmaceuticals.

As of 2012, 2980 herbal medicines including dietary supplements were registered. Herbal medicines are sold in pharmacies as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

T&CM practices are used in Qatar. The percentage of the population using acupuncture was 1–19% in 2012.

68. Saudi Arabia

National policy on T&CM

In 2008, the National Center for Complementary and Alternative Medicine (NCCAM) was established in the MoH. It took its role as a national reference for all activities of CAM in Saudi Arabia.

The Medicinal Aromatic and Poisonous Plants Research Center (MAPPRC) was established in 1985 in the college of pharmacy in King Saud University.

Regulatory status of herbal medicines

Herbal medicines have been regulated since 1989 as reported in *WHO legal status of traditional medicine and complementary/alternative medicine: a worldwide review*, but not as a separate law.

The “Regulation for registration of herbal preparations, health and supplementary food, cosmetics and antiseptics that have medical claims” is a specific regulation for herbal medicines that commenced in 1991. The Saudi Food and Drug Administration (Saudi FDA), established in 2004, is responsible for registering and regulating T&CM products, particularly medicinal herbs and devices.

Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines, dietary supplements and health foods. They are sold with medical, health and nutrient content claims. The pharmacopoeias in use include the *United States pharmacopeia*, the *British pharmacopoeia* and the *European pharmacopoeia*. Monographs in use include the *WHO monographs on selected medicinal plants*, ESCOP monographs and the *Complete German Commission E monographs: therapeutic guide to herbal medicines* (comprising 81 monographs). The pharmacopoeias and monographs are not legally binding.

The regulations for GMP for conventional pharmaceuticals also apply to herbal medicines. Compliance is ensured through periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. Reference to safety data in documented scientific research on similar products is considered sufficient for the safety assessment of herbal medicines. Herbal medicines are sold in pharmacies and in other outlets as prescription and non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Saudi Arabia, with reported use by 40–59% of the population, based on 2010 data from the NCCAM.

The reported percentages of use by the population of the different types of T&CM are as follows: acupuncture 1–19%, chiropractic 1–19%, herbal medicines 40–59%, naturopathy 1–19% and traditional Chinese medicine 1–19%. Other practices, such as Prophetic medicine, Islamic medicine, Hijama, and honey and bee products are reportedly used by 60–79% of the population. National-level regulations on acupuncture providers commenced in 1997, and those on naturopathic medicine providers in 2007.

T&CM practices and practitioners are the responsibility of NCCAM in the MoH; a joint committee between the NCCAM and Saudi FDA is responsible for coordinating the work.

As of 2017, providers of acupuncture, osteopathy, chiropractic, naturopathy and cupping therapy must be licensed in Saudi Arabia. Two years ago, NCCAM started to implement a new regulation for cupping (AlHijamah) practice, which is one of the most common TM practices in Saudi Arabia.

Courses were developed by NCCAM for the training of cupping providers as a prerequisite for licensing. By January 2017, more than 400 cupping practitioners and more than 20 cupping clinics were licensed. A T&CM educational course for undergraduate medical students was developed and introduced in three universities, with written mission, objectives, academic policies, measurable education outcome and quality management according to international standards. As a part of health care transformation in Saudi Arabia, there is a need to ensure the quality of T&CM services that are integrated into the health care transformation model.

T&CM providers practise in both public and private sector hospitals and clinics. The national Government issues the licence required for T&CM practice. The Government recognizes T&CM training programmes at a postgraduate level (e.g. pharmacognosy at pharmacy colleges). In some medical schools, integrated lectures are given.

The number of indigenous TM providers in the country is not known. Based on 2010 data from the Saudi Commission for Health Specialities, the number of T&CM providers in practice includes providers of acupuncture, chiropractic and naturopathy.

As of 2017, NCCAM has launched a consumer campaign (@aware_cam) on social media to increase awareness and to promote the rational use of T&CM in Saudi Arabia. Also in progress is the development of a national consumer education plan and implementation in partnership with the National Committee through the Saudi Health Services Council. The future plan for NCCAM includes building integration models to integrate T&CM therapies into the new health care transformation model.

69. Somalia

As per the official response received, there is a national medicine policy document that was developed in 2014 in Somalia and the National Medicines Regulatory Authority was established in 2016 but is yet not functional. As at end 2016, there is no expert committee or research institute on T&CM and no government funding is available for T&CM research. T&CM practitioners are not regulated, and services are not covered by insurance.

70. Sudan

National policy on T&CM

In Sudan, the national policy on T&CM is integrated with the primary health care programme of the National Drugs Policy 2005–2009. Three national institutes conduct T&CM research: the Medicinal and Aromatic Plants Research Institute (established in 1974), the Traditional Medicine Research Institute (established in 1983) and the WHO Collaborating Centre in Traditional Medicine (established in 1984).

Regulatory status of herbal medicines

All regulations for conventional pharmaceuticals are applied to herbal medicines in addition to specific requirements. The main piece of legislation is the Medicines and Poisons Act 2009. Herbal medicines are categorized as prescription medicines and herbal medicines, and are sold with medical claims. The pharmacopoeias in use include the *United States pharmacopeia* and the *British pharmacopoeia* (2010), and these are legally binding.

WHO guidelines on GMP for herbal medicines are followed and compliance is ensured through periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing.

For safety assessment, manufacturers are required to submit samples and do microbial limit testing for all herbal products, as well as a limit test for pesticide and insecticide and aflatoxin and adulterant by synthetic products and others. Forty herbal medicines are registered. Herbal medicines categorized as prescription medicines are sold in pharmacies.

Practices, providers, education and health insurance

Indigenous TM and many types of T&CM are used by Sudan's population, but the percentages of use are not known. National-level regulations apply to indigenous TM providers. T&CM providers practise in both the public and private sector hospitals and clinics, and independently as traditional healers.

Permission to practise is given at different levels (national, state, city and community) but permits are not proper licences, which are required for medical practitioners (doctors, pharmacists and dentists). T&CM education is not available at university level, but any T&CM certificate or licence approved by an international body is recognized by the Sudan Medical Council. The numbers of indigenous TM providers and T&CM providers practising in the country are not known. Traditional healers, religious healers, spiritualists, bonesetters, eye couchers, zar practitioners and diviners are also found in practice in Sudan.

71. Syrian Arab Republic

National policy on T&CM

In the Syrian Arab Republic, the national policy on T&CM is integrated into the national policy on pharmaceutical products of 1998, updated in 2017. The Office of Pharmaceutical Affairs under the MoH looks after issues related to T&CM.

Regulatory status of herbal medicines

Regulation of herbal medicines is the same as that for conventional pharmaceuticals. Herbal medicines are categorized as herbal medicines and are sold with medical claims.

Herbs are categorized as follows:

- Dietary herbs (spices), such as saffron, pepper, mint, thyme, cumin and black seed, are sold at al-attarin shops, and the use of these herbs is not accompanied by medical claims (e.g. they might be used as flavours for foods). Dietary herbs are not registered with the MoH; however, they are monitored by the Department of the Laboratory of Food at the MoH to ensure that they do not include pesticides, radioactive elements, aflatoxins, bacteria or fungi.
- Medicinal herbs with medical claims are categorized as pharmaceutical products, according to the relevant regulation (Decision No.10/T issued by the MoH). These herbs are produced in different pharmaceutical forms (e.g. tisanes, tea bags, powders, oils, creams and shampoos). They should be produced at pharmaceutical facilities that are monitored by the MoH.
- Botanical drugs include standardized herbal extracts and dietary supplements. These drugs are produced in different pharmaceutical forms, such as capsules (soft and hard), syrups, elixirs, drops, suppositories, creams and ointments; they should be produced at pharmaceutical factories. The same regulations that apply to the registration of medicinal drugs apply to the registration of botanical drugs.

The *United States pharmacopeia*, the *British pharmacopoeia*, the *Indian pharmacopoeia* and the *Chinese herbal pharmacopoeia* are used. The Herbal Physician Desk Reference monographs are used and they are legally binding.

GMP guidelines for herbal medicines were issued in 2004, and adherence to manufacturing information in pharmacopoeias and monographs is regulated to ensure quality. Compliance is ensured through periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. Traditional use without demonstrated harmful effects and reference to safety data in documented scientific

research on similar products are considered sufficient for the safety assessment of herbal medicines. As of 2012, over 200 herbal medicines were registered. Herbal medicines categorized as prescription medicines are sold in pharmacies. The Office of Pharmaceutical Affairs at MoH carries out surveillance for poisoning effects resulting from all pharmaceuticals, including herbal medicines, but there is no surveillance for traditional medicines in particular.

As of 2017, shops called attaries (العطاريون) are licensed by the Ministry of Commerce and not the MoH. These shops sell herbs and are used by a lot of people for their medical indications. Herbs are used in some pharmaceutical products such as “evening primrose” or “garlic extract”, which are filled in capsules and produced by some of the pharmaceutical manufacturers that are licensed by the MoH. There is currently no distinction between the two terms “traditional medicines” and “complementary medicines” and the term “herbs” is used widely instead.

Practices, providers, education and health insurance

T&CM practices are used, but the percentages of the population using acupuncture, herbal medicines, homeopathy, naturopathy, traditional Chinese medicine and Unani medicine are not known.

T&CM providers practise in private sector clinics. The numbers of indigenous TM providers and T&CM providers practising in the country are not known.

Attarins (traditional practitioners) sell dietary herbs only. The MoH, in cooperation with the Syrian Scientific Society for the Medicinal Herbs & Complementary Medicine & Nutrition, plans to provide relevant trainings to attarins to build their professional capacity.

Pharmacists licensed by the MoH can sell all the herbal products that are authorized for use by the MoH. There are several physicians in Syria who practise complementary medicine in their private clinics.

The subject “practical pharmacognosy” covers T&CM topics, and is offered at the faculties of pharmacy in the different universities in Syria. There are also postgraduate courses in alternative medicine and nutrition open to pharmacy students.

Dedicated T&CM specialization is one of the ministry’s potential approaches to improve the practice of T&CM in Syria.

Indigenous TM services are covered by private and government health insurance, and there is partial coverage of some T&CM services (e.g. herbal medicines) by government agencies and private organizations.

72. Tunisia

National policy on T&CM

In Tunisia, the national policy is integrated into the law on medicines (*Loi sur le médicament* No. 85–91 of 1985) and related regulations.

Regulatory status of herbal medicines

The national regulation on herbal medicines is the same as that for conventional pharmaceuticals. Herbal medicines are categorized as prescription and non-prescription medicines, and are sold without claims.

The pharmacopoeias used, although not legally binding, are the *European pharmacopoeia*, the *United States pharmacopoeia* and the *British pharmacopoeia*. The monographs used, also not legally binding, are the publications of the Laboratoire d'Essayage.

The GMP for herbal medicines are fixed by Decree No. 90–1400 of 1990. They are the same as that for other registered medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing, and the requirement for manufacturers to assign a person to the role of ensuring compliance with manufacturing requirements and reporting back to the Government. The regulatory requirements for the safety assessment of herbal medicines are the same as that for conventional pharmaceuticals.

Herbal medicines categorized as prescription medicines are sold in pharmacies.

As at 2018, herbal medicines are included in the NEML, with the most recent update in 2015. The regulation governing the registration system for herbal medicines is currently being revised. The regulation governing local manufacture and distribution of dietary supplements is under development.

Practices, providers, education and health insurance

T&CM practices such as acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine are used by the population of Tunisia, but the percentages of use are not known.

Regulation of T&CM providers of acupuncture, chiropractic, herbal medicines, homeopathic medicine and osteopathy is enforced at the city or county level.

T&CM providers practise in the private and public sectors. A licence or certificate, issued by the national Government, is required to practise T&CM. Education is provided at university level, such as a PhD in Pharmacy.

As of 2012, there were 300 indigenous TM providers practising within the country.

73. United Arab Emirates

National policy on T&CM

In the United Arab Emirates, the Traditional Complementary and Alternative Medicine Unit, established in 2002 under the MoH, serves as the national office for T&CM. Zayed Complex for Herbal Research and Traditional Medicine, located in Abu Dhabi, is the national research institute for T&CM.

Regulatory status of herbal medicines

Federal law No. 20 of 1995 for “Medicines and products derived from natural sources” forms the national legislation specific to herbal medicines. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines and dietary supplements; they are sold with health and nutrient content claims.

The MoH code for GMP is followed for herbal medicines. Regulations for GMP are the same as that for conventional pharmaceuticals. To ensure compliance, manufacturers are required to submit the latest GMP from their local authority and samples of their medicines to a government-approved laboratory for testing. Safety requirements are the same as that for conventional pharmaceuticals.

As of 2010, 224 herbal medicines were registered. Herbal medicines are sold as prescription medicines, non-prescription medicines, self-medication or OTC medicines, in pharmacies and other outlets, in special outlets (e.g. in herbal medicines stores) and by licensed practitioners.

Practices, providers, education and health insurance

Indigenous TM is considered important in the United Arab Emirates. As of 2012, indigenous TM practices are reported to be used by 20–39% of the population. Percentages of use by the population of other T&CM practices are as follows: acupuncture 20–39%; ayurvedic medicine, chiropractic, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine all 1–19%; and other T&CM practices, such as cupping therapy, 40–59%.

National-level regulations have applied to indigenous TM providers since 2010, and to T&CM providers of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy and Unani medicine since 2002. Cupping therapy has been regulated since 2010 and ozone therapy since 2004. T&CM providers practise in private sector clinics and hospitals. State or provincial government issues the relevant licence required for T&CM practice.

At present, the Government recognizes qualifications in T&CM from foreign universities recognized in their own countries and universities recognized by the Ministry of Higher Education and Scientific Research.

About 200–300 indigenous TM providers were practising in the United Arab Emirates as at 2012. Approximate numbers of licensed T&CM providers in practice were as follows: 26 acupuncture providers, 60 ayurvedic medicine providers, 24 chiropractors, 120 homeopaths, 12 naturopaths, nine osteopaths, 16 traditional Chinese medicine providers, 25 Unani medicine providers, 13 cupping therapists and four ozone therapists.

There is partial private health insurance coverage of T&CM services such as acupuncture, ayurvedic medicine, chiropractic, homeopathy, naturopathy, osteopathy, Unani medicine and other practices such as ozone therapy.

74. Yemen

National policy on T&CM

In Yemen, a CM programme was instituted in 2004 under the ministry for the planning sector. As at end 2016, this programme remains temporarily discontinued, although the practice of T&CM is recognized by the ministry to be widespread in Yemen, especially in rural areas. Before the programme was discontinued, there were ongoing activities for surveying and assessment, production of documentation (a book on herbalism in Yemen) and the aim of eventually registering and regulating practices.

Regulatory status of herbal medicines

There is an exclusive regulation for manufactured herbal products titled “Regulation of Herbal Drugs, Food Supplements and Medicinal Cosmetics”, activated in 2010. Herbal medicines are categorized as prescription medicines, non-prescription medicines, health food and herbal drugs under control; they are sold with medical, health and nutrient content claims.

The *British pharmacopoeia* and the *United States pharmacopeia* are used. The *Atlas of medicinal plants in Yemen* (2008) comprises 126 monographs that are legally binding. *WHO monographs on selected medicinal plants* is also used. WHO GMP regulations are applied, but there are no mechanisms in place to ensure compliance. Safety requirements are the same as those for conventional pharmaceuticals.

As at 2012, 55 herbal products were registered. Herbal medicines are sold in pharmacies and in other outlets as prescription and non-prescription medicines, self-medication or OTC medicines. The 2009 annual report of the Supreme Board for Drugs and Medical Appliances reported the total market sales of herbal medicines in 2009 to be 1 287 630 958 Yemeni rials.

Practices, providers, education and health insurance

According to the database of TM/CAM, in 2009, about 73% of the population used indigenous TM practices. T&CM practices are used, but the percentages of use by the population are not known. Other practices such as faith healing, Islamic medicine, cupping, traditional cautery, herbalism (herbal remedies) and home remedies are practised in Yemen.

T&CM providers practise in the private and public sector. The database of traditional and complementary medicine (2009) reported that there were 1000–1500 indigenous TM providers in the country, 668 of whom were registered as at 2010. The numbers of the different types of T&CM providers were not available.

5.4 WHO European Region

Table 5.4 summarizes the development of national policy for T&CM, regulation of T&CM and herbal medicines, along with use of T&CM among populations of Member States in the WHO European Region. The table also compares the percentage of Member States in the region with the global percentage for each indicator.

In the period between 2005 and 2018, Member States in the region demonstrated a strong commitment to regulation and registration of herbal medicines. However, only 11 Member States had developed a national policy for T&CM by 2018.

Table 5.4. WHO European Region, development of T&CM, 2005–2018

Category	Regional number of Member States with affirmative responses in 2005	Regional number of Member States with affirmative responses as at 2018	Regional % of Member States with affirmative responses as at 2018 (N=53)	Global % of Member States with affirmative responses as at 2018 (N=194)
National policy on T&CM	7	11	21%	51%
Laws or regulations on T&CM	14	21	40%	56%
National programme on T&CM	3	7	13%	41%
National office for T&CM	9	15	28%	55%
Expert committee on T&CM	10	15	28%	48%
National research institute for T&CM or herbal medicines	10	11	21%	39%
Regulation of herbal medicines	36	45	85%	64%
Registration of herbal medicines	32	45	85%	64%
Population using T&CM	–	47	89%	88%

Note: The 2018 data set includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018). There may be Member States in which the T&CM situation has changed, not accounted for here.

75. Albania

National policy on T&CM

No information is available on national policy for T&CM in Albania.

Regulatory status of herbal medicines

Albania’s regulation on drug registration, issued in 2009, includes herbal medicines (categorized as “herbal medicines”).

The *European pharmacopoeia*, the *British pharmacopoeia* (vol. 11, 2007) and the *United States pharmacopoeia* are used, and these are legally binding. Regulations require manufacturers of herbal medicines to adhere to manufacturing information in pharmacopoeias to ensure quality; GMP requirements are the same as those for conventional pharmaceuticals.

Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. Regulatory requirements for the safety assessment of herbal medicines are the same as those for conventional pharmaceuticals; traditional use without demonstrated harmful effects is considered sufficient for herbal medicines. Herbal medicines are sold in pharmacies as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

No data are available on T&CM practices, providers, education or health insurance in Albania.

76. Andorra

National policy on T&CM

No information is available on national policy for T&CM in Andorra.

Regulatory status of herbal medicines

Herbal medicines are normally sold as dietary supplements. Andorra does not have a pharmaceutical industry, and medicines are imported from other countries, mainly France or Spain. A herbal medicine sold as medicine in its origin country can be sold as a medicine in Andorra without any labelling or claim change.

Most herbal medicines are found with medical, health and nutrient content claims. Those categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and in special outlets.

Practices, providers, education and health insurance

T&CM practices are used but information on the percentages of use by the population is not available. T&CM providers practise in the private sector.

77. Armenia

National policy on T&CM

No information is available on national policy for T&CM in Armenia.

Regulatory status of herbal medicines

The legislation governing herbal medicines is the same as that for conventional pharmaceuticals – namely, the law on medicines, issued in 1998. Herbal medicines are categorized as non-prescription medicines, herbal medicines and dietary supplements; they are sold with medical and health claims.

The *European pharmacopoeia*, the *State pharmacopoeia of the Union of Soviet Socialist Republics* (Russian pharmacopoeia) and the *United States pharmacopoeia* are used and are legally binding. The *Armenian national formulary for herbal medicines* (2001) contains 46 monographs that are legally binding. The *WHO monographs on selected medicinal plants* and the *WHO monographs on medicinal plants commonly used in the newly independent states* (NIS) (2010) are also used and are legally binding.

The Rules of Good Manufacturing Practice, issued in November 2010, constitutes the regulations for GMP for both herbal medicines and conventional pharmaceuticals. Manufacturers of herbal medicines must adhere to manufacturing information in the pharmacopoeias to ensure quality. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing and to assign a person to the role of compliance officer. Regulatory requirements for the safety assessment of herbal medicines are the same as that for conventional pharmaceuticals.

As of 2012, 64 herbal medicines were registered. The NEML has included herbal medicines since 2008, selected based on the traditional use of the herbal medicines and clinical data. There are currently two herbal medicines on the NEML. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets.

Practices, providers, education and health insurance

T&CM practices are used by the population of Armenia but percentages of use are not known. National-level regulations apply to indigenous TM providers.

T&CM providers of acupuncture, chiropractic, herbal medicines and homeopathy have been regulated since 2001; providers of osteopathy and traditional Chinese medicine are now also regulated. Data on the actual numbers of providers practising in the country are not available. T&CM providers practise in public and private sector clinics and hospitals. The national Government issues the T&CM licence required to practise.

There is no T&CM education available at university level but the Government recognizes certified training programmes.

78. Austria

National policy on T&CM

The Department III/2, under the federal MoH, looks after all T&CM-related issues.

Regulatory status of herbal medicines

The *Medicine Act* (updated in 2006) applies to herbal medicines as well as to conventional pharmaceuticals. Herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines; they are sold with medical claims. The *Austrian pharmacopoeia*, which includes 74 monographs, is used and is legally binding. The *European pharmacopoeia* is also referred to and is legally binding. The 90 monographs of the European Medicines Agency's (EMA) Committee on Herbal Medicinal Products (HMPC) are referred to, but these are not legally binding.

Manufacturing of herbal medicines is regulated under the *Rules governing medicinal products in the European Union* (vol. 4) and the *EU guidelines to GMP medicinal products for human and veterinary use*, issued in 2009. Manufacturers must adhere to manufacturing information in the pharmacopoeias to ensure quality. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing and to assign a person to the role of compliance officer. Safety requirements for herbal medicines are in line with EU legislation.

As at 2012, 85 herbal medicines were registered. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets.

Practices, providers, education and health insurance

T&CM practices are used in Austria, but data on percentages of use by the population are not available. There are national-level regulations on providers of ayurvedic medicine and traditional Chinese medicine. T&CM providers practise in the public and private sector.

T&CM education is not available at the university level but the Government recognizes certified training programmes. Providers of acupuncture, chiropractic, herbal medicines, homeopathy and traditional Chinese medicine practise in Austria. There is partial insurance coverage for T&CM services.

79. Azerbaijan

National policy on T&CM

No information is available on national policy for T&CM in Azerbaijan.

Regulatory status of herbal medicines

The regulations governing herbal medicines comprise two instruments relating to the registration of herbal medicines. Herbal medicines are categorized as herbal medicines and dietary supplements; they are sold with medical and health claims.

The main pharmacopoeia in use is the Russian pharmacopoeia (vols. 10 and 11). The *European pharmacopoeia*, the German *Homeopathic pharmacopoeia*, the *American herbal pharmacopoeia* and the *British herbal pharmacopoeia* are also used. The pharmacopoeias are not legally binding. Monographs include those in the *British pharmacopoeia* and the *WHO monographs on selected medicinal plants*, but these are not legally binding.

The WHO GMP guidelines are used for manufacturing of herbal medicines. Manufacturers are required to adhere to manufacturing information in the pharmacopoeias to ensure quality. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. The same safety requirements apply to herbal medicines as for conventional pharmaceuticals.

As at 2012, 144 herbal medicines were registered. Herbal medicines are sold in pharmacies as prescription medicines, non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

No data are available on T&CM practices, providers, education or health insurance in Azerbaijan.

80. Belarus

National policy on T&CM

No information is available on national policy for T&CM in Belarus.

Regulatory status of herbal medicines

The national legislation on medicinal products applies to both conventional pharmaceuticals and herbal medicines. Herbal medicines are categorized as prescription medicines, non-prescription medicines, dietary supplements and health foods; they are sold with medical, health and nutrient content claims.

The *State pharmacopoeia of the Republic of Belarus* is used and is legally binding. Safety requirements for herbal medicines are the same as that for conventional pharmaceuticals; reference to safety data in documented scientific research on similar products is sufficient to meet regulatory requirements for the safety assessment of herbal medicines.

As at 2012, 408 herbal medicines were registered. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies, other outlets and special outlets.

Practices, providers, education and health insurance

No data are available on T&CM practices, providers, education or health insurance in Belarus.

81. Belgium

National policy on T&CM

No information is available on national policy for T&CM in Belgium.

Regulatory status of herbal medicines

The Federal Agency for Medicines and Health Products (FAMHP) is the national competent authority for medicines. The term “herbal preparations” is used instead of “herbal medicines”; herbal preparations are categorized into either “food supplements” or “medicinal products”. EU provisions apply to herbal medicinal products in Belgium through being embedded in Belgian legislation on medicinal products.

Herbal preparations in predosed forms (tablets, capsules) are readily available on the Belgian market. These can be marketed as food supplements or medicinal products, depending on whether they fall under the EU provisions for food supplements or medicinal products. To determine their category, products are evaluated on a case-by-case basis, taking into account all their characteristics. The Mixed Commission (established within the FAMHP to this extent) can be consulted in cases of doubt.

Food supplement legislation is one of the tasks of the Federal Public Service for Public Health, Security of the Food Chain and Environment. Herbal preparations are considered traditional herbal medicinal products when they comply with the requirements of the EU Directive 2004/24/EC, as embedded in Belgian

legislation. When not considered traditional, these herbal medicinal products may be authorized using procedures that are the same as those for conventional medicines.

The minister responsible for public health decides whether a registration or authorization is granted. The minister is advised by the Belgian Commission for Herbal Medicinal Products for Human Use, which was established in 2007 within the FAMHP.

Herbal preparations that are food supplements can use health claims in accordance with applicable EU provisions. Herbal medicinal products can bear therapeutic indications provided that a product's label contains the official "summary of product characteristics" set out in EU pharmaceutical legislation, as evaluated for that product.

Herbal medicinal products can only be sold in pharmacies, whereas herbal food supplements can be sold in pharmacies and other outlets (e.g. supermarkets and health stores).

As at 2012, 84 registered herbal medicinal products were authorized for release into the Belgian market, with numerous applications pending.

Homeopathic medicines have been marketed for many years. The legislative body has taken steps to control this market, taking into account the developments at the European level. In Belgium, as a first step, all homeopathic medicines that were on the market became subject to notification. The notification period ended in 2003, and all homeopathic medicines that had not been notified were withdrawn from the market. The next step was to implement the registration of homeopathic medicines, to develop an accurate inventory of homeopathic medicines available for sale in Belgium and to plan the work of the Commission for Homeopathic Medicines for Human and Veterinary Use.

About 18 000 homeopathic medicines have been notified. From 2006, the European provisions on homeopathic medicines have applied to homeopathic medicinal products in Belgium. In practice, this means that homeopathic medicinal products can only be sold in pharmacies; it also means that there is an authorization procedure and a simplified registration procedure. An application for registration and authorization of a homeopathic medicine must comply with the applicable EU provisions. The registration and authorization of notified homeopathic medicinal products in Belgium is currently ongoing.

There is no specific legislation for herbal products used in other T&CM practices such as ayurvedic medicine and traditional Chinese medicine.

Practices, providers, education and health insurance

The FAMHP does not have data about the percentage of the Belgian population using T&CM practices.

Legislation to allow the certification of practitioners of nonconventional therapeutic approaches (relating to medicine, the preparation of medicines, manual therapy, nursing and paramedical professions) was drafted in 1999. However, before this law commences, in-depth studies into each practice are being undertaken; the most recent study (on homeopathy) was published in 2011.

T&CM services are not covered by health insurance; however, as part of Belgium's social security scheme, the National Institute for Health provides each citizen mandatory sickness and disability insurance.

Partial government insurance covers some phytotherapy as a solid or fluid extract, and magistral preparations (i.e. medicines made by a pharmacist in a pharmacy) in ambulatory pharmacy care.

82. Bosnia and Herzegovina

National policy on T&CM

No information is available on national policy for T&CM in Bosnia and Herzegovina.

Regulatory status of herbal medicines

The *Medicinal Products and Medical Devices Act* (2008) and the *Book of Rules on Procedure and Method for Issuing Marketing Authorization Approval* (2011) comprise the national legislation on both herbal

medicines and conventional pharmaceuticals. Herbal medicines are categorized as “herbal medicines” and are sold with medical and health claims.

The *European pharmacopoeia* is used and is legally binding. Regulations for GMP for herbal medicines are the same as those for conventional pharmaceuticals. To ensure compliance, there are periodic inspections by authorities at the manufacturing plants. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals. Herbal medicines are sold in pharmacies as prescription medicines, non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM and T&CM practices are used, but the percentages of use by the population and the numbers of providers practising in the Bosnia and Herzegovina are not known. T&CM providers practise in the private sector.

83. Croatia

National policy on T&CM

No information is available on national policy for T&CM in Croatia.

Regulatory status of herbal medicines

Herbal medicines and traditional herbal medicines are covered by the *Medicinal Products Act*, as are conventional pharmaceuticals. However, traditional herbal medicines are also subject to an instrument that has specific provisions for the marketing, labelling and advertising of traditional herbal medicinal products.

Herbal products are categorized as medicines (mostly non-prescription), dietary supplements or general food products, depending on their presentation. General food products include spices and herbal teas without medical or health claims. Herbal medicines and dietary supplements are sold with medical and health claims.

The *Croatian pharmacopoeia* and the *European pharmacopoeia* (including its 241 monographs) are used and are legally binding.

Regulations for GMP for herbal medicines are the same as that for conventional pharmaceuticals. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples of their medicines to government-approved laboratory for testing and to assign a person to the role of compliance officer. Safety requirements for herbal medicines are the same as that for conventional pharmaceuticals; reference to safety data in documented scientific research on similar products and traditional use without demonstrated harmful effects are sufficient to meet regulatory requirements for the safety assessment of herbal medicines.

As at 2012, 60 herbal medicines are registered. Herbal medicines are sold in pharmacies and other outlets as non-prescription medicines, self-medication or OTC medicines.

The Agency for Medicinal Products and Medical Devices (HALMED) estimates that total market sales of herbal medicines in Croatia for 2007, 2008 and 2009 were € 3.1 million, € 2.95 million and € 4.01 million, respectively.

Practices, providers, education and health insurance

No data are available on T&CM practices, providers, education or health insurance in Croatia.

84. Cyprus

National policy on T&CM

In Cyprus, the national policy on T&CM is integrated into National Policy 70(I) / 2001. The pharmaceutical services division of the MoH looks after all T&CM-related issues.

Regulatory status of herbal medicines

The regulation for herbal medicines is the same as that for conventional pharmaceuticals, issued in 2005. Herbal medicines are regulated as prescription medicines, non-prescription medicines, herbal medicines and dietary supplements. They are sold with medical claims.

The *European pharmacopoeia* (and its monographs) and the *British pharmacopoeia* are used and are legally binding. Volume IV of the EU's *Eudralex* contains the GMP for herbal medicines used in Cyprus. The manufacturing regulations are the same for conventional pharmaceuticals and herbal medicines, and require adherence to the manufacturing information in the pharmacopoeias and monographs to ensure quality. To ensure compliance, there are periodic inspections by authorities at the manufacturing plants. The safety requirements that apply to herbal medicines are the same as those for conventional pharmaceuticals.

As at 2012, one herbal medicine is registered. Herbal medicines are sold in pharmacies as prescription medicines, non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Providers of herbal medicines and homeopathy have been regulated at a national level since 2006. T&CM providers practise in the private sector, and the national Government issues the T&CM licence required to practise.

85. Czech Republic

National policy on T&CM

No information is available on national policy for T&CM in the Czech Republic.

Regulatory status of herbal medicines

Regulation of herbal medicines is the same as that for conventional pharmaceuticals under the national law on pharmaceuticals. Herbal medicines are categorized as non-prescription medicines and herbal medicines; they are sold with medical claims.

The *Czech pharmacopoeia* is used and is legally binding. Also used are the *European pharmacopoeia* and pharmacopoeias of other EU Member States. The *Czech pharmaceutical codex* contains 88 monographs that are used but are not legally binding. Community monographs (e.g. the HMPC monographs) are also used, and these are legally binding.

Regulations for GMP apply to herbal medicines: Guidelines No. VYR-32 on GMP for both conventional pharmaceuticals and herbal medicines, and Annex No. 7 on GMP specifically for herbal medicinal products, issued in 2003. To ensure compliance, there are periodic inspections by authorities at the manufacturing plants. EU directives apply to the safety assessment of herbal medicines.

As of 2012, 47 traditional medicines were registered. Herbal medicines are sold in pharmacies and in special outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

As per qualified estimates from health experts (T&CM practices are not covered by the public health insurance; hence, there is no obligation for statistical reporting), 1–19% of the Czech population uses indigenous TM and acupuncture practices.

National-level regulations have applied to providers of indigenous TM and acupuncture since 2004.

T&CM providers practise in public and private sector hospitals and clinics. A T&CM licence, issued by the national Government, is required to practise. A certified training programme for T&CM (open to medical school graduates only) is recognized by the Government.

The Czech Medical Acupuncture Society (*Česká lékařská akupunkturistická společnost*) estimates there are 34 indigenous TM providers and 7000 acupuncture providers practising in the Czech Republic, as at 2012.

86. Denmark

National policy on T&CM

No information is available on national policy for T&CM in Denmark.

Regulatory status of herbal medicines

The Executive Order on Herbal Medicinal Products and Traditional Herbal Medicinal Products forms the national regulation for herbal medicines. Quality requirements follow EMA and HMPC guidelines. Herbal medicinal products follow requirements for bibliographic applications¹ and traditional herbal medicinal products follow Directive 2004/24.

Herbal medicines are categorized as non-prescription medicines and herbal medicines. Herbal medicines are considered medicinal products if they fulfil the definition of a medicinal product, which means that (unless they are homeopathic medicinal products) they have a medical indication; thus, medical claims are made for herbal medicinal products.

The *European pharmacopoeia* is used and is legally binding. HMPC monographs are also used but are not legally binding.

Manufacturing of herbal medicines is regulated under the *Rules governing medicinal products in the European Union* (vol. 4), which sets out the applicable GMP for both herbal medicines and conventional pharmaceuticals. Manufacturers are required to adhere to the manufacturing information in pharmacopoeias and monographs to ensure the quality of herbal medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples to a government-approved laboratory for testing. Safety requirements for herbal medicinal products follow the EU requirements for well-established use.

As at 2012, 90 herbal medicines were registered. There are no restrictions on selling herbal medicines, and they are sold in pharmacies and other outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM and other T&CM practices are used by Denmark's population, but the percentages of use are not available. Regulation of chiropractic providers has been in place since 1991, at a national level. T&CM providers practise in public and private sector hospitals and clinics.

Indigenous TM providers and T&CM providers of acupuncture, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy and traditional Chinese medicine practise in Denmark, but their numbers are not known.

Indigenous TM services are covered by private health insurance and there is partial coverage of chiropractic services by government and private health insurance.

¹ Refers to the EU requirements that need to be met for marketing of a herbal medicine in the region, which require submission of a full application (form) or a bibliographic one to obtain a marketing authorisation. A bibliographic application allows for results of pre-clinical tests and clinical trials to be replaced by scientific literature, provided that the active substance of the medicinal product has been in well-established medicinal use within the community for at least 10 years.

87. Estonia

National policy on T&CM

No information is available on national policy for T&CM in Estonia.

Regulatory status of herbal medicines

Herbal medicines are specifically regulated under the Estonian Medicinal Products Act (2004) which sets out the application conditions and procedures for market authorization of “herbal medicinal products” and “traditional herbal medicinal products”. The requirements for quality are the same as those for conventional pharmaceuticals.

Herbal medicines are categorized as prescription medicines, OTC medicines and herbal medicines; they are sold with medical and health claims. The *European pharmacopoeia* is used and is legally binding. Also in use but not legally binding are the *British pharmacopoeia* and the *United States pharmacopoeia*, as well as the HPMC monographs and the *WHO monographs on selected medicinal plants*.

The GMP rules and regulations for manufacturing that apply to herbal medicines are the same as those for conventional medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples to a government-approved laboratory for testing. Safety requirements are also the same as that for conventional pharmaceuticals; traditional use without harmful effects and reference to safety data in documented scientific research are sufficient to meet regulatory requirements for the safety assessment of herbal medicines.

As at 2012, 31 herbal medicines are registered. Herbal medicines are sold in pharmacies as prescription medicines, non-prescription medicines, self-medication or OTC medicines.

Figures from the State Agency of Medicine for 2011 indicate that the total market sales of herbal medicines in Estonia, in the years 2007, 2008 and 2009, were € 1.9 million, € 1.8 million and € 1.6 million, respectively. (For comparison, the total market sales of prescription medicines in the years 2007, 2008 and 2009 were € 141.06 million, € 162.74 million and € 161.20 million, respectively.)

Practices, providers, education and health insurance

The Estonian Health Interview Survey of 2006, published by the National Institute for Health Development in 2009, estimates that 1–19% of the population uses indigenous TM practices. Other T&CM practices are also used but the percentages are not known.

National-level regulations apply to acupuncture providers (since 2002), herbal medicine providers (since 2004) and homeopathic medicine providers (since 2005). T&CM providers practise in public and private sector hospitals and clinics. A T&CM licence, issued by the national Government, is required for practice.

Estimates for 2011 from the Estonian Qualification Authority give T&CM provider numbers as follows: 14 homeopathic medicine providers, 17 traditional Chinese medicine providers, 28 aromatherapists, eight Nuad Bo-Rarn natural therapists and 24 reflexologists. Acupuncture and chiropractic providers (numbers unknown) also practise in Estonia.

88. Finland

National policy on T&CM

No information is available on national policy for T&CM in Finland.

Regulatory status of herbal medicines

Valid EU legislation relating to medical products for human use has been embedded into the national legislation in Finland. The *Medicines Act* includes regulations for herbal medicines.

Herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines; they are sold with medical claims. The *European pharmacopoeia* and official national pharmacopoeias of other EU Member States are used and are legally binding.

Volume IV of the EU's *Eudralex* contains the GMP used for herbal medicines. The manufacturing regulations for herbal medicines are the same for conventional pharmaceuticals and herbal medicines. Manufacturers are required to adhere to the manufacturing information in the pharmacopoeias and monographs to ensure the quality of herbal medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to assign a person to the role of compliance officer.

Valid EU regulations, community monographs and community lists are safety requirements for herbal medicines. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets.

Practices, providers, education and health insurance

T&CM practices are used by the population in Finland, but the percentages of use are not available. Regulation of T&CM providers of chiropractic and osteopathic medicine has been in place since 1994, at a national level. T&CM providers practise as independent private service providers.

Health care professionals need authorization to practise. Indigenous TM providers practise in Finland but the numbers are not known. As at 2012, there were an estimated 77 chiropractic providers, 1600 homeopathic medicine providers, 245 osteopathic providers, 750 TM providers and 125 naprapaths practising in Finland.

There is partial insurance coverage provided by the Patient Insurance Centre for patients who suffer a personal injury during health care treatment by health care professionals, including chiropractic, osteopathy and naprapathy providers.

89. Germany

National policy on T&CM

In Germany, the national policy for T&CM is integrated into Social Code V and laws for pharmaceuticals (drugs).

Regulatory status of herbal medicines

The German drugs law includes provision for the registration of traditional herbal medicinal products. Herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines; they are sold with medical and health claims.

The German national pharmacopoeia (*Deutsches Arzneibuch*), the *European pharmacopoeia* and the EU's *Homeopathic pharmacopoeia* are used and are legally binding. Some 380 monographs in the *Complete German Commission E monographs: therapeutic guide to herbal medicines* are used along with standard approvals, and these are legally binding.

GMP are required for manufacturing pharmaceutical products. The manufacturing regulations for herbal medicines are the same as those for conventional pharmaceuticals; they require adherence to the manufacturing information in the pharmacopoeias and monographs to ensure product quality. To ensure compliance, there are periodic inspections by authorities at the manufacturing plants. The same safety requirements that apply to herbal medicines are the same as those for conventional pharmaceuticals.

Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets.

Practices, providers, education and health insurance

According to 2000 data, 60–79% of the German population uses indigenous TM practices (9). A 2004 study estimated that 1–19% of the population uses acupuncture, ayurvedic medicine, chiropractic, homeopathy and traditional Chinese medicine; herbal medicines are used by 20–39%; and naturopathy is used by 80–99% (22).

90. Hungary

At the time of the second survey, the response received from Hungary was that there has been no change in the situation since 2005. However, the summary was reviewed, updated and officially cleared, most recently in 2018.

National policy on T&CM

A national policy on T&CM was introduced in 1997 as part of the *Law on Public Health*, Ch. IV, s. 104. Laws and regulations were issued on naturopathic activities in 1987 and 1997. There is no national programme on T&CM. The National Institute of Pharmacy, which was established in 1962 under the MoH, has dealt with the evaluation and registration of traditional herbal medicines since about 1982. Two scientific societies and an association on T&CM have been established. The Research Institute for Medicinal Plants was founded in 1915.

An expert committee for T&CM was established in 1997, later becoming the “CAM advisory board” for the health minister. Since 2011 there has been a Complementary Medicine Chamber (acting as de facto advisory board for the health minister) among other nominated professional chambers.

Regulatory status of herbal medicines

Herbal medicinal products may be sold as traditional herbal products, called “healing products or paramedicine” (having therapeutic effects but not considered to be medications), or as herbal medicines, which are considered to be conventional pharmaceutical products. Both are regulated as OTC medicines for self-medication purposes; by law, medical claims and health claims may be made.

The regulation for traditional herbal products (“healing products or paramedicine”) was issued in 1987. According to this decree, a traditional herbal product may be approved if it meets each of the following requirements: its composition or components are known; the quality of the product, and of its components, is determined and constantly ensured; its safety in the doses to be administered is proven; the conditions of its production meet the public health regulations; the prescribed technology for its production can be ensured; and its established effect is proven through evaluation or is based on scientific knowledge.

The legislation governing herbal medicines (conventional pharmaceutical products that contain herbal drugs or herbal drug preparations) were laid down in a law of 1998, and in regulations in 2000 and 2001, which refer to medicines in general. This legislation includes some special quality requirements for herbal medicines.

The *Pharmacopoea Hungarica* (7th ed., 1986) is the national pharmacopoeia in force. However, Hungary has signed the Convention on the Elaboration of a European Pharmacopoeia, so the standards of the *European pharmacopoeia*, which are included in the forthcoming eighth edition of the Hungarian pharmacopoeia, are also legally binding.

The GMP rules used for conventional pharmaceuticals also apply to the manufacture of herbal medicines; compliance is ensured through regular GMP inspections of herbal preparation manufacturers. The safety and efficacy of a herbal medicinal product may be proved using the same requirements as those for conventional pharmaceuticals, including preclinical and clinical trials, or by referring to documented scientific research on similar products. Safety and efficacy requirements are ensured through the controlled production of the product and quality assurance data.

There are authorized herbal medicinal products and registered traditional herbal medicinal products (healing products) in Hungary. Although none of these is included on the NEML, there is also a traditional herbal drugs list containing drugs without medical indication. A market surveillance system including ADR monitoring was established in 1970. Herbal medicines are sold in pharmacies as OTC medicines; traditional herbal medicines are sold in pharmacies and in special shops for healing products.

Practices, providers, education and health insurance

In February 1997, the Hungarian legislature passed two pieces of comprehensive legislation on natural medicine and on some aspects of the practice of natural medicine. These two decrees clearly and officially integrate physicians who practise T&CM into the national health care system.

All health care providers, including those who practise T&CM, must be authorized to practise and be included on the register of providers (since 2004).

The training of health professionals has been regulated since 2011. The health care activities of a person with a diploma in traditional Chinese medicine obtained in China were made subject to regulation, including the requirement for authorization, in 2017.

As at 2018, there is no special national programme for T&CM, but health training curricula include T&CM topics (theoretically), and some universities provide optional continuing professional education courses in T&CM (e.g. Pécs University, Health Science Faculty).

Only physicians (i.e. medical doctors) are allowed to practise the following T&CM practices: acupuncture, chiropractic, herbal medicines, homeopathy, osteopathy, traditional Chinese medicine, neural therapy, anthroposophic medicine and detoxification therapies. Non-physicians can provide reflexology, acupressure, lifestyle advice, kinesiology and bioenergetics services. There is a national programme for MDs for neural therapy, manual therapy, T&CM and acupuncture courses at university, with exams. After these exams, the doctor can apply to the state for a licence to practise.

There is partial insurance coverage for acupuncture in public hospitals and in public outpatient consulting rooms, if the providing doctor has a licence.

91. Iceland

National policy on T&CM

In Iceland, the national policy for T&CM is the Report of the Minister of Health about Healers and their Activities in Iceland (*Skýrsla heilbrigðisráðherra um græðara og starfsemi þeirra á Íslandi*), presented to the parliament at the 131st Legislative Assembly 2004–2005.

Regulatory status of herbal medicines

There is a regulation exclusively for herbal medicines titled Regulation on the Marketing Authorization for Herbal Remedies and the Listing of Traditional Herbal Medicinal Products (*Um markaðsleyfi náttúrulyfja og skráningu jurtalyfja sem hefð er fyrir*). Herbal medicines are categorized as non-prescription medicines, herbal medicines, dietary supplements and health foods. They are sold with health and nutrient content claims.

The European pharmacopoeia is used and is legally binding. The latest EU GMP rules are valid in Iceland under s. 6 of the Icelandic Pharmaceutical Act, which applies to both herbal medicines and conventional pharmaceuticals. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to assign a person to the role. For safety assessment of herbal medicines, traditional use without demonstrated harmful effects is sufficient. Herbal medicines are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies and other outlets, and in special outlets.

Practices, providers, education and health insurance

T&CM practices are used by the population of Iceland, but the percentages of use are not available. National-level regulations have been in place for indigenous TM providers since 2005. Chiropractic and osteopathic providers have been regulated since 1990 and 2005, respectively. T&CM providers practise in private sector clinics. A T&CM licence, issued by the national Government, is required to practise.

92. Ireland

National policy on T&CM

No information is available on national policy for T&CM in Ireland.

Regulatory status of herbal medicines

In Ireland, the EU Directive on Traditional Herbal Medicinal Products (THMPD) is followed; for products that do not fall into this category, conventional rules apply. The regulation is titled Control of Placing on Market Regulations, SI540 of 2007. Herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines. They are sold with medical claims.

The *European pharmacopoeia* and the *British pharmacopoeia* are used and are legally binding. Some 360 monographs from the *European pharmacopoeia* are used and the GMP guide *EudraLex*, vol. 4, is used for herbal medicines. There are specific GMP requirements for herbal medicines over and above the requirements for all medicines. The EMA quality guidelines apply to herbal medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples for testing and to assign a person to the role of ensuring compliance. For safety assessment of herbal medicines, traditional use without demonstrated harmful effects and reference to safety data in documented scientific research are sufficient.

As at 2012, five herbal medicines were registered. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets, in special outlets and by licensed practitioners.

Practices, providers, education and health insurance

Indigenous TM and other T&CM practices are used by the population in Ireland, but the percentages of use are not available.

T&CM providers of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine, aromatherapy, reiki and reflexology practise in Ireland.

There is partial health insurance coverage by the Government of some T&CM services such as acupuncture, chiropractic, homeopathic medicines and osteopathy.

93. Israel

National policy on T&CM

No information is available on national policy for T&CM in Israel.

Regulatory status of herbal medicines

Herbal medicines are sold with nutrient content claims.

Practices, providers, education and health insurance

T&CM practices are used by the population in Israel, but percentages of use are not available. T&CM providers practise in public and private sector clinics. The practices are self-regulated by delegated special technical associations.

University-level education in T&CM is not available, but the Government officially recognizes apprenticeships with T&CM providers, certified training programmes, and training programmes for indigenous TM practitioners and T&CM technicians.

Indigenous TM providers and T&CM providers of acupuncture, chiropractic, herbal medicines, homeopathy, naturopathy and osteopathy practise in Israel.

There is partial coverage of T&CM practices by private health insurance.

94. Lithuania

National policy on T&CM

No information is available on national policy for T&CM in Lithuania.

Regulatory status of herbal medicines

In general, the regulations that apply to herbal medicinal products are the same as those for conventional pharmaceuticals. However, EU Directive 2004/24/EC sets out a simplified registration procedure for traditional herbal medicinal products and a definition of such medicinal products, which was adopted under Lithuanian legislation in 2007.

Herbal medicines are defined as any product containing herbal constituents, which means that a herbal medicine may be categorized as a herbal medicinal product, a traditional herbal medicinal product or a food supplement, depending on the content of product and instructions for use. The claims may only be made according to the product's classification (e.g. medical claims are only made for medicinal products).

The *European pharmacopoeia*, the *British pharmacopoeia*, the French pharmacopoeia (*Pharmacopée française*), the official Italian pharmacopoeia (*Farmacopea ufficiale del Repubblica Italiana*) and the German pharmacopoeia are used. In cases where the *European pharmacopoeia* does not contain the necessary monographs, pharmacopoeias of other EU Member States apply. If none of these contains the necessary monograph, compliance with the monograph of a third country pharmacopoeia can be accepted. In such cases, the applicant shall submit a copy of the monograph accompanied by the validation of the analytical procedures contained in the monograph and by a translation where appropriate.

The pharmaceutical laws contain provisions on GMP for medicinal products and investigational medicinal products. GMP requirements are applicable to medicinal products only.

Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples for testing and to assign a person to the role of ensuring compliance. Safety requirements for herbal medicines are the same as that for conventional pharmaceuticals; traditional use without demonstrated harmful effects is considered sufficient.

As at 2012, 213 herbal medicines were registered. Herbal medicines categorized as prescription medicines, non-prescription medicines, self-medication or OTC medicines are sold in pharmacies.

Practices, providers, education and health insurance

Indigenous TM and other T&CM practices are used by the population of Lithuania, but the percentages of use are not available. TM providers practise in public and private sector hospitals and clinics. A TM licence, issued by the national Government, is required to practise. The Government officially recognizes certified training programmes. Acupuncture providers and providers of manual therapy practise in Lithuania.

The mandatory public health insurance fund covers expenses of health care services provided by a general practitioner or by specialists, who are allowed to use both conventional and alternative medical practices, according to the professional competence of the specialist. Contracts with the fund are signed with both private or government health care providers.

95. Malta

National policy on T&CM

No information is available on national policy for T&CM in Malta.

Regulatory status of herbal medicines

Regulation of traditional herbal medicines is under the Herbal Medicinal Products Regulation, which commenced in 2005. Conventional pharmaceuticals are under a different regulatory regime. The registration of traditional herbal medicinal products is a simplified procedure compared with the procedure

for registration of conventional pharmaceuticals, in terms of needing to prove efficacy and safety. Quality standards are the same as those for conventional methods. The procedure and standards that apply depend on the legal basis of the application – whether it is for a traditional herbal medicinal product or a full registration.

Traditional herbal medicinal products are regulated as medicines, depending on whether they satisfy the definition of “medicinal product” in the legislation (content and presentation to treat or prevent disease). If they are not medicinal, then they can be placed on the market as, for example, dietary supplements, health foods, functional foods or cosmetics. However, those considered medicinal may only be sold as prescription or non-prescription medicines.

Traditional herbal medicinal products that are considered medicinal may make medical claims, provided that these are substantiated by evidence (traditional from literature or through clinical trials – this depends on the legal basis of the application to apply for registration as a medicinal product). The *European pharmacopoeia* and the EMA’s monographs are used but are not legally binding.

The EU GMP guidelines apply, and regulations for GMP are the same as those for conventional pharmaceuticals. To ensure compliance, there are periodic inspections by authorities at the manufacturing plants.

Safety requirements depend on the legal basis of the application. If the registration procedure is the conventional marketing authorization procedure (as for allopathic medicines), the safety criteria are the same. If the application is for a traditional herbal medicinal product, safety can be proven by literature covering 30 years of traditional use of the herbal product or preparation.

Any applicants seeking registration may submit their applications to the Medicines Authority. Currently, there are no products authorized as traditional herbal medicinal products. Classification of products already on the market as foods supplements is ongoing and, at the end of the process, those products that fall under the definition of herbal medicinal products (and traditional herbal medicinal products) will require registration if they are to continue to be placed on the market. Herbal medicines are sold in pharmacies as prescription medicines, non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

T&CM practices are used by the population of Malta. National regulations on providers of acupuncture, chiropractic, herbal medicines, osteopathy and traditional Chinese medicine commenced in 2004. T&CM providers practise in private clinics and in public hospitals. A T&CM licence, issued by the national Government, is required to practise.

According to data from the Superintendent of Public Health, as at 2012 there were 16 acupuncture providers, eight chiropractic providers, 207 herbal medicine providers, three osteopathic providers and 16 traditional Chinese medicine providers practising in Malta.

There is full coverage of acupuncture provided by government health insurance.

96. Montenegro

National policy on T&CM

The MoH of Montenegro is in the process of preparing legislation for “traditional alternative medicine” (TAM), which will define the types of TAM practices that will be allowed in Montenegro. The MoH, in cooperation with the Technical Assistance Information Exchange instrument of the European Commission (TAIEX), also organized a workshop on TAM in September 2010. A memorandum of cooperation signed by the MoH with China contains a topic on cooperation in TAM; the MoH plans to invite TAM experts from China to train their health professionals. TAM practices are not yet regulated in Montenegro; therefore, expenditures are not defined.

Regulatory status of herbal medicines

The law on medicines includes provisions for herbal medicines, defined as traditional medicines and herbal medicines. Under this law, the procedures for market authorization for herbal medicines are the same as that for conventional medicines. Herbal medicines are sold with medical claims.

The *European pharmacopoeia* and its monographs are used. Regulations for GMP and safety assessments are the same as those for conventional pharmaceuticals. There are no domestic manufacturers of herbal or traditional medicines in Montenegro. Foreign manufacturers are obliged to have a GMP certificate issued by a competent authority from the EU or a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S), if they wish to apply for market authorization or import in Montenegro.

As at 2012, four herbal medicines were registered. Herbal medicines are sold in pharmacies as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

No data are available on T&CM practices, providers, education or health insurance in Montenegro.

97. Netherlands

National policy on T&CM

No information is available on national policy for T&CM in the Netherlands.

Regulatory status of herbal medicines

The Medicine Law (*Geneesmiddelenwet*), issued in 2007, includes provisions for the regulation for herbal medicines. For well-established herbal medicines, the requirements of the dossier (i.e. the application file for registration and marketing authorization in EU) are similar to those for conventional pharmaceuticals; for herbal medicines based on traditional use, specific European legislation applies. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines and dietary supplements. They are sold with health claims.

The *European pharmacopoeia* and the HMPC monographs are used, and are legally binding.

Regulations for GMP and safety assessments of herbal medicines are the same as those for conventional pharmaceuticals; the pharmacopoeias and monographs must be followed. To ensure compliance, there are periodic inspections by authorities at the manufacturing plants.

Herbal medicines are sold in pharmacies and other outlets as prescription medicines, non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM and other T&CM practices, including anthroposophic medicine, are used in the Netherlands. T&CM providers practise in the private sector.

There is partial health insurance coverage by private insurance companies for some T&CM practices such as acupuncture, chiropractic, herbal medicines, homeopathic medicines, naturopathy, osteopathy and traditional Chinese medicine.

98. Norway

National policy on T&CM

Norway has legislation specific to CAM (“complementary and alternative treatments”) comprising the law “on alternative treatment of disease etc” (*Om lov om alternativ behandling av sykdom mv*) of 2002 and two regulations of 2003 on marketing of alternative treatments, and registration of providers of alternative treatment.

The Norwegian Directorate of Health, functioning as the national office for CAM, is a specialist directorate and an administrative body under the Ministry of Health and Care Services (MoHCS) and the Ministry of Labour and Social Inclusion. The directorate is administered by the MoHCS.

The national programme for T&CM is the MoHCS's annual budgetary discussion to set priorities for the three organizations that work on CAM, namely:

- the National Research Center in Complementary and Alternative Medicine (NAFKAM), which also serves as the national research institute for T&CM;
- the National Information Center in Complementary and Alternative Medicine, Norway (NIFAB); and
- the Bronnoysund Register Center, which is a government body under the Norwegian Ministry of Trade and Industry that develops and operates many of the nation's most important registers, such as registers for alternative treatment providers) and electronic solutions.

Regulatory status of herbal medicines

A market authorization can be given for herbal medicinal products according to the same regulation as is used for conventional medicine, provided that the requirements are fulfilled. In addition, EC directives on traditional and herbal medicines have been adopted under Norwegian regulations.

Herbal medicines are categorized as non-prescription medicines, herbal medicines and dietary supplements. They are sold with medical and health claims. The *European pharmacopoeia* and the HMPC monographs are used and are legally binding.

The EU GMP and GACP guidelines apply to the manufacture of herbal medicines. Regulations for GMP and safety assessments of herbal medicines are the same as those for conventional pharmaceuticals. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples for testing and to assign a person to the role of ensuring compliance.

Herbal medicines are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies and other outlets, and in special outlets.

Practices, providers, education and health insurance

Indigenous TM practices are used by the population of Norway. According to data from a NIFAB user survey of 2007, 1–19% of Norway's population uses acupuncture, homeopathy and naturopathy. Other T&CM practices (e.g. massage) are used by 20–39% population.

Chiropractic is a health profession in Norway; hence, chiropractors are regulated under the legislation governing health professionals. T&CM providers practise in public and private sector hospitals and clinics.

The Norwegian Health College (*Norges Helsehøyskole Campus Kristiania*) is now the owner of the acupuncture college, and it offers an accredited bachelor's degree in acupuncture; the college has applied to the national authorities for accreditation of a bachelor's degree in osteopathy. The Government also recognizes certified training programmes in CAM.

T&CM providers of acupuncture, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and others are found in Norway but their numbers are not known.

Full reimbursement of CAM practices is given if treatment is included in hospital treatment. For polyclinic treatment at hospitals, partial coverage is given. Chiropractic is regarded as a conventional health treatment and is fully covered.

99. Poland

National policy on T&CM

The national legislation for T&CM only covers herbal medicines. Similarly, the national office is the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (for herbal and homeopathic medicinal products) in Żabkowska, and the national research institute is the National Medicines Institute, Chelmska, in Warsaw.

Regulatory status of herbal medicines

Articles 20a and 20b of the Pharmaceutical Law concern herbal medicinal products. The definition of herbal medicinal product in the European Directive 2001/83/UE, which has been adopted under these articles, is based on the content of active substances. Traditional herbal medicinal products can be used without supervision by professional medical personnel. Herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines; they are sold with medical claims.

The Polish pharmacopoeia (*Farmakopea Polska*) is legally binding and contains 19 monographs. The *European pharmacopoeia* is also used, along with 234 of its monographs. In 2008, the MoH issued requirements for GMP, which include adherence to the manufacturing information in the pharmacopoeias and monographs; the same GMP regulations apply to both herbal medicines and conventional pharmaceuticals. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples for testing and to assign a person to the role of ensuring compliance. The safety requirements are regulated by the European Directive 2001/83/EC (Community code relating to medicinal products for human use).

Herbal medicines are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies and other outlets, and in special outlets.

Practices, providers, education and health insurance

No data are available on T&CM practices, providers, education or health insurance in Poland.

100. Portugal

National policy on T&CM

T&CM legislation in Portugal started in 2003, to cover six “nonconventional therapies” (NCT): acupuncture, chiropractic, homeopathy, naturopathy, osteopathy and phytotherapy (herbal medicines).

In 2013, the law was expanded to include traditional Chinese medicine and to regulate practitioners in these NCTs as health professionals. Specific measures included:

- assigning the process of regulation to the MoH and the Ministry of Higher Education (e.g. a bachelor's degree in an NCT is a 4-year degree course, with different content for each of the seven NCTs);
- establishing the functional content for each of the seven NCT professions;
- establishing the content of the 4-year higher education courses for each of the seven NCTs;
- requiring NCT professionals to hold a licence issued by the MoH;
- requiring professionals to hold civil liability insurance;
- developing legislation for NCTs similar to that already available for regular health professions' private clinics; and
- establishing the National Council of NCT, comprising 23 members, to serve the role of the national advisory office for T&CM.

There is no national research institute as such, although individual universities have independent ongoing projects. It is also possible that the law may be expanded further to include other NCT practices such as ayurveda medicine.

Regulatory status of herbal medicines

The regulation of herbal medicines is the same as that for conventional pharmaceuticals, under Articles 141–147 of Law 176/2006.

The National Authority of Medicines and Health (INFARMED) is a government agency accountable to the MoH that evaluates, authorizes, regulates and controls human medicines as well as health products such as medical devices and cosmetics. INFARMED follows the EU directives strictly, and the *European pharmacopoeia*.

Homeopathic and herbal medicines are licensed by INFARMED. Food supplements are licensed by the Nutrition and Agricultural Ministry, with a simplified registration. Many products (e.g. some of those used in traditional Chinese medicine) are licensed as food supplements, and any person can buy them without prescription.

The Portuguese pharmacopoeia (*Farmacopeia Portuguesa*) is used, including its annual supplements. It is legally binding. The *European pharmacopoeia* is also used and is legally binding.

GMP apply to the manufacture of herbal medicines and conventional pharmaceuticals. Manufacturers are required to adhere to the manufacturing information in the pharmacopoeias and monographs. EC regulation No. 852/2004 defines mechanisms to ensure compliance. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals.

As at 2017, 35 homeopathic products with approved therapeutic indications and 800 homeopathic medicinal products with simplified registrations were registered in Portugal.

Practices, providers, education and health insurance

T&CM practices are used by Portugal's population, but the percentages of use are not available. Indigenous TM providers and T&CM providers of acupuncture, chiropractic, herbal medicines (phytotherapy), homeopathy, naturopathy, osteopathy, traditional Chinese medicine and ayurvedic medicine all practise in Portugal, but their numbers are not known.

The Portuguese Accreditation Agency for University and Polytechnics Studies authorized 4-year degrees in osteopathy (as of 2016) and acupuncture (as of 2017). The Central Administration of the Health System (ACSS) is the MoH body responsible for issuing professional licences for Diagnostic and Therapeutic Technicians, Nonconventional Therapeutic Technicians and Podiatrists.

Under the 2013 changes to the law, only those who hold a professional licence in one of the seven NCTs can practise that NCT and use the appropriate professional title. Future applications for a professional licence will require the applicant to hold a bachelor's degree in an NCT. However, for professionals already practising in an NCT, a special transition system applies. A specific health department will organize a record of professionals and keep it updated, turning it into a public list online so that the public can have access to it. The ACSS created a working group that will evaluate all candidates applying for licences under the transition system and decide whether the candidate should have a full licence, a provisional licence or neither.

Acupuncture, chiropractic, herbal medicines, homeopathic medicines, naturopathy and osteopathy are partially covered by some private health insurance. Some insurances have NCT practitioners in their health staff and the users of these insurances can use their services. But the services of external practitioners of NCT are not reimbursed.

101. Republic of Moldova

National policy on T&CM

No information is available on national policy for T&CM in the Republic of Moldova.

Regulatory status of herbal medicines

The national regulation that provides for registration of medicines includes herbal medicines. Herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines; they are sold with medical, health and nutrient content claims.

The *European pharmacopoeia*, the Romanian pharmacopoeia (*Farmacopeea Romana*) and the Russian pharmacopoeia are used, and these are all legally binding. A 2009 publication contains 1000 monographs (23), and these are legally binding. The regulations and safety requirements that apply to GMP for herbal medicines as those that apply to conventional pharmaceuticals, including adherence to the manufacturing information in the pharmacopoeias and monographs.

Herbal medicines are registered under four classifications: (a) antimicrobial, antifungal, antiseptic; (b) enteric sorbents; (c) cytoprotective, regenerating, antioxidants; and (d) etymological. Herbal medicines have been included in the NEML since 2007, based on their traditional use, clinical data and laboratory testing. There are no restrictions on selling herbal medicines and they are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies and other outlets, and in special outlets.

Practices, providers, education and health insurance

Indigenous TM practices are used in the Republic of Moldova, but the percentages of use by the population and number of providers in the country are not available. However, estimates from homeopathy private clinics data are that 20–39% of the population uses acupuncture, 60–79% uses herbal medicines and 20–39% uses homeopathy.

National regulation of providers of acupuncture has been in place since 1994, of homeopathic providers since 2000, and of chiropractic and osteopathy providers since 2011. T&CM providers practise in public and private sector hospitals and clinics. The national Government, relevant academic institution or licensing authority issues the T&CM licence that practitioners require to practise.

A student can obtain a PhD after obtaining a degree in the field of traditional medicine. Students are licensed after completion of a residency (3 years), such as a clinical residency in the field of manual therapy (e.g. osteopathy). Postgraduate education in the field of manual therapy and 3-month internships and modules in specialties are available to students. Training programmes for T&CM technicians and postgraduate training in phytotherapy, homeotherapy and acupuncture are also available.

The number of T&CM providers of acupuncture, homeopathy, chiropractic and osteopathy in 2010 were 96, 37, 48 and 37, respectively.

T&CM practices of acupuncture, chiropractic and osteopathy are partially covered by government health insurance.

102. Romania

National policy on T&CM

No information is available on national policy for T&CM in Romania.

Regulatory status of herbal medicines

As of 2006, Romania's laws on medicinal products adopted European Directive 2001/83/EC to provide for regulation of herbal medicines. There are additional specific provisions applicable to traditional herbal medicinal products. Herbal medicines are categorized as prescription medicines and non-prescription medicines, and are sold with medical claims.

The Romanian pharmacopoeia is legally binding. It contains 16 monographs, although the information in the monographs is not legally binding. The *European pharmacopoeia* and other national pharmacopoeias are also used and are legally binding.

The GMP guidelines in *EudraLex* vol. 4 of 2010 are used; they apply to both herbal medicines and conventional pharmaceuticals. Manufacturers must adhere to the manufacturing information in the pharmacopoeias and monographs. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to assign a person to the role of ensuring compliance. Traditional herbal medicinal products require a bibliographic review of safety data together with an expert report and, upon request, data necessary for assessing the safety of the medicinal product.

As at 2012, 68 herbal medicines were registered. Herbal medicines are sold in pharmacies and other outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

No data are available on T&CM practices, providers, education or health insurance in Romania.

103. Serbia

National policy on T&CM

Serbia has health care laws that include provisions on T&CM, with a by-law on suitable T&CM practices (methods), introduced in 2007.

Regulatory status of herbal medicines

The regulation of herbal medicines is partly the same as that for conventional pharmaceuticals, under the law on medicines and medical devices of 2010. Traditional herbal medicines have separate regulations. Herbal medicines are categorized as herbal medicines and are sold with medical claims.

The Yugoslavian pharmacopoeia (*Pharmacopoea Jugoslavica*) (vols. 3–5) is used and is legally binding. The *British pharmacopoeia*, the *European pharmacopoeia* and the *United States pharmacopoeia* are also used, along with their monographs, and are legally binding.

The law on medicines and medical devices prescribes the same GMP for herbal medicines and conventional pharmaceuticals. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples for testing to an approved laboratory and to assign a person to the role of compliance officer. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals.

As at 2012, 20 traditional herbal medicines and 30 herbal medicines were registered. Herbal medicines are sold in pharmacies as non-prescription medicines, self-medication or OTC medicines.

Data from the Medicines and Medical Devices Agency of Serbia estimate the total market sales of herbal medicines (in Serbian dinar) were 163.15 million, 250.07 million and 283.10 million in 2007, 2008 and 2009, respectively. The total market sales of prescription medicines were 65.59 billion dinar in 2009.

Practices, providers, education and health insurance

Indigenous TM and T&CM practices are used in Serbia. National-level regulation commenced in 2007 for indigenous TM providers and providers of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy and traditional Chinese medicine.

T&CM providers practise in public and private sector hospitals and clinics.

The national Government issues the T&CM licence required to practise. A certificate or diploma from an accredited school (from abroad) confirming successful completion of training enables an entry in the register of practitioners for each regulated T&CM practice managed by the Serbian Medical Society or the registry of a corresponding association. The Experts Commission on TM of the MoH of Serbia reviews T&CM work permit applications. The work permit is signed by the Minister of Health. On the basis of this permission, the Medical Chamber issues a licence that allows the TM practice over the next 7 years.

Currently, education is provided through various types of courses within continuing medical education for doctors, dentists and pharmacists, according to licensed educational programmes of various T&CM areas (e.g. quantum medicine, acupuncture and homeopathy). Those programmes are approved by the Healthcare Council of Serbia, which is the highest accrediting body for the programmes of continuing medical education. College diplomas from countries where those colleges have a legal status are also recognized.

The number of indigenous TM providers in Serbia is not known because no licences have been issued so far. As per 2012 data from the MoH, there are 133 acupuncture providers, two ayurvedic medicine providers, two chiropractic providers, 60 homeopathic medicine providers, two traditional Chinese medicine providers and 65 providers of other practices such as macrobiotics (two), quantum medicine (52), reiki/shiatsu (six), apitherapy (two) and yoga (three). These numbers represent numbers of licences issued so far, including licences for health care facilities (private or public) to provide T&CM practices. Some doctors hold licences for practising more than one method of T&CM (e.g. acupuncture, homeopathy and quantum medicine); thus, the total number of T&CM providers is estimated at 220, which is less than 1% of the total number of licensed doctors in Serbia (30 000).

T&CM services are paid mainly by patients (users) and are not covered by health insurance.

104. Slovakia

National policy on T&CM

The national legislation on T&CM in Slovakia is under regulation 296/2010, which applies to professional qualifications for health care practice. The national office on T&CM is included under the MoH.

Regulatory status of herbal medicines

European regulations apply to herbal medicines in the same way as they apply to conventional medicines. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines, dietary supplements, health foods, functional foods and general food products. They are sold with medical, health and nutrient content claims.

The *European pharmacopoeia* is used. In assessing documentation for the registration of (traditional) herbal medicines, there is a comparison of data with HMPC monographs. For herbal components in the role of excipients, monographs from the *European pharmacopoeia* are applied.

For herbal medicines, it is necessary to have permission for production under GMP 1.4.1.1. Herbal products. In addition, when assessing herbal medicines, it is necessary to review GACP.

Once a (traditional) herbal medicine has been approved, its registration is uploaded to the database of national medicines, which is updated every Monday on the MoH website. The criterion for inclusion is recognized efficacy (well-established use and bibliography), and the standard pharmacovigilance requirements since 2012 are applied. Once traditional herbal medicines have been put on the market, safety monitoring is not usually carried out.

Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in outlets other than pharmacies, in special outlets and by licensed practitioners.

Practices, providers, education and health insurance

Herbal medicines and traditional medicines are not considered as a specialized field of health care in Slovakia. TM healers are not considered as part of the health workforce according to Act No. 578/2004 on health care providers, health workers and professional organizations in health.

T&CM practices are used in Slovakia, but the percentages of use by the population are not available. Regulation of homeopathic medicine providers commenced in 2004, and regulation of acupuncture providers and traditional Chinese medicine providers in 2010; these regulations are enforced at national level.

T&CM providers practise in private sector clinics and hospitals. The national Government issues the T&CM licence required to practise. A specialist degree in acupuncture is available at university level. The Government also recognizes certified training programmes. According to 2011 data from Slovak Medical University, there are an estimated 300 acupuncture providers, 350 homeopathic providers and 20 providers of traditional Chinese medicine in Slovakia.

105. Slovenia

National policy on T&CM

No information is available on national policy for T&CM in Slovenia.

Regulatory status of herbal medicines

Herbal medicines with well-established medicinal use are regulated in the same way as conventional pharmaceuticals. For traditional herbal medicines, a simplified procedure for marketing authorization was introduced in 2006, when Directive 2004/24/ES (Rules on traditional herbal medicinal products) was adopted in the national legislation. Herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines. They are sold with medical and health claims.

The national formulary (*Formularium Slovenicum*) is used; it contains 240 monographs and is legally binding. The *European pharmacopoeia* is also used. Monographs from pharmacopoeias of other EU Member States may be used but are not legally binding.

EU guidelines on GMP are used. The regulations for manufacturing of herbal medicines are the same as that for conventional medicines plus some specific requirements for herbal medicinal products. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to submit samples for testing to an approved laboratory. Directive 2004/24/ES prescribes the regulatory requirements for safety assessment of herbal medicines.

As at 2012, 69 herbal medicines are registered. Herbal medicines categorized as prescription medicines, non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and in specialized shops licensed for selling OTC medicinal products.

Practices, providers, education and health insurance

T&CM practices are used in Slovenia. Regulation of providers of ayurvedic medicine, chiropractic, homeopathic medicine, osteopathy, traditional Chinese medicine and Unani medicine has been in place since 2007. Data on the numbers of each type of provider are not available. The national Government issues the T&CM licence required to practise.

106. Spain

National policy on T&CM

No information is available on national policy for T&CM in Spain.

Regulatory status of herbal medicines

The regulation of herbal medicines is partly the same as that for conventional pharmaceuticals, under the Directive 2001/83/EC, as amended by Directive 2004/24/EC. Herbal medicines are categorized as prescription medicines and non-prescription medicines; they are sold with health and nutrient content claims. Registered herbal food products with health claims from other EU countries are also received, owing to the free movement of goods.

The Royal Spanish pharmacopoeia (*Real Farmacopea Española*) and the *European pharmacopoeia*, including its monographs, are used and are legally binding.

The GMP guidelines in *EudraLex*, vol. 4, form the GMP for herbal medicines and conventional pharmaceuticals. Manufacturers of herbal medicines must adhere to the manufacturing information in the pharmacopoeias and monographs. To ensure compliance, there are periodic inspections by authorities at the manufacturing plants and laboratories.

As at 2012, 52 herbal medicines were registered. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and in special outlets.

Practices, providers, education and health insurance

T&CM practices are used in Spain. Providers practise in the private sector. The state Government issues the T&CM licence required to practise.

107. Sweden

National policy on T&CM

Sweden's patient safety laws include provisions for T&CM.

Regulatory status of herbal medicines

The same medical products legislation applies to both conventional pharmaceuticals and herbal medicines. Herbal medicines are categorized as prescription medicines and non-prescription medicines, and are sold with medical claims. The *European pharmacopoeia* is used and is legally binding. The EC monographs on (traditional) herbal substances/preparations, issued in 2012, contain 100 monographs that are used, but these are not legally binding.

Commission Directive 2003/94/EC, which lays down the principles and guidelines of GMP in respect of medicinal products for human use and investigational medicinal, was adopted in Sweden in 2003. It applies to both herbal medicines and conventional pharmaceuticals. Manufacturers of herbal medicines must adhere to the manufacturing information in the pharmacopoeias and monographs. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants and laboratories, and the requirement for manufacturers to assign a person to the role of ensuring compliance. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals; traditional use without demonstrated harmful effects is sufficient and reference is made to safety data in documented scientific research.

As at 2012, 100 herbal medicines were registered. Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication, or OTC medicines are sold in pharmacies, in other outlets and in specialized shops.

Practices, providers, education and health insurance

T&CM practices are used in Sweden. T&CM providers practise in public and private sector hospitals and clinics. Providers of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy and traditional Chinese medicine practise within Sweden, but their numbers are not known.

Regulation of chiropractic providers has been in place since 1989, enforced at the national level. The National Board of Health and Welfare (Chiropractor) issues the T&CM licence required to practise. The Government recognizes certain certified training programmes for T&CM, in the absence of T&CM education at university level.

Chiropractic services are partially covered by government health insurance.

108. Switzerland

National policy on T&CM

In Switzerland, the national policy for T&CM is embedded in the Swiss Federal Constitution, in Article 118a: "Complementary medicine: The Confederation and the Cantons shall within the scope of their powers ensure that consideration is given to complementary medicine", issued in 2009.

Regulatory status of herbal medicines

For herbal medicines (including homeopathic, anthroposophic and Asian medicines in complementary medicines), a premarket approval is necessary. Quality, safety and efficacy must be proven. The regulations (*Ordonnance sur les médicaments complémentaires et les phytomédicaments* and *Instructions sur les phytomédicaments*) foresee a simplified premarket approval process for herbal medicines. If appropriate, clinical trials to demonstrate efficacy and safety may be replaced by bibliographic documentation, treatment records, or proof of pharmaceutical or therapeutic equivalence with an already authorized product. Homeopathic, anthroposophic and traditional Asian medicines can be marketed with or without

an indication. In cases where medicines are registered without an indication (and without a tradename), only a reduced documentation needs to be submitted (no proof of efficacy). Some established homeopathic, anthroposophic and traditional Asian medicines may also be registered using a notification procedure (if they are part of the lists published by the registration agency).

Herbal medicines are categorized as prescription, non-prescription and herbal medicines. Herbal medicines are sold with medical claims. Health or nutrient content claims are possible for herbal products that are classified as food products, dietary supplements or functional foods. These claims are not allowed for herbal medicines (only medical claims are allowed for herbal medicines). Herbal products include herbal medicines as well as dietary supplements, health foods, functional foods and general food products – the common element being that these products contain herbs. In Switzerland, medicines and food products are regulated in different legal acts; therefore, this distinction is important.

The pharmacopoeias used, which are legally binding, are the Swiss pharmacopoeia (*Pharmacopoea Helvetica*), the *European pharmacopoeia*, the German pharmacopoeia, the *British pharmacopoeia*, the *Pharmacopée française* and the *Homeopathic pharmacopoeia* of the United States.

Switzerland uses the GMP guides of PIC/S, which are the same for both conventional pharmaceuticals and herbal medicines. The regulation on manufacturing of herbal medicines to ensure their quality requires adherence to manufacturing information in pharmacopoeias and monographs. The compliance mechanism is periodic inspections by authorities at the laboratories; in some instances, samples for laboratory testing are required (e.g. application for marketing authorization and market surveillance).

The regulatory requirements for the safety assessment of herbal medicines are the same as those for conventional pharmaceuticals. Either traditional use without demonstrated harmful effects or reference to safety data in documented scientific research on similar products is sufficient.

Herbal, homeopathic, anthroposophic and Asian medicines with indications are registered in the same system as conventional pharmaceuticals; homeopathic, anthroposophic and Asian medicines without indication are registered separately. As of October 2011, the following were registered: 649 phytotherapeutics; 778 homeopathic, anthroposophic or Asian medicines with indication; and 6100 homeopathic, anthroposophic or Asian medicines without indication.

Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets, and by licensed practitioners.

Practices, providers, education and health insurance

In 2007, the percentage of the Swiss population using T&CM practices was found to be less than 1% for ayurvedic medicine, traditional Chinese medicine, neural therapy and anthroposophic medicine; 1–19% for acupuncture, chiropractic, herbal medicines, homeopathy and osteopathy; and an unknown percentage for naturopathy (24).

There is regulation of osteopathic providers, and a nationwide examination is used as the basis for granting permission to practise in cantons (provinces). Other regulations apply only at canton level. Chiropractic is covered under mainstream medicine regulations.

T&CM providers practise in both private and public clinics and hospitals, although private practices are the most important. Education is provided at university level for chiropractic only, with a bachelor's degree (first awarded in 2011) and a master's degree (first awarded in 2014).

Indigenous TM providers practise within Switzerland. According to the data from the Swiss Institute for Postgraduate Medical Education, shared in 2012, the number and types of T&CM providers practising in the country are as follows: acupuncture (655), ayurvedic medicine (unknown), chiropractic (250), herbal medicines (unknown), homeopathic (255), naturopathic (unknown), osteopathic (unknown), traditional Chinese medicine (unknown), neural therapy (118) and anthroposophic (95). All providers are mainstream practitioners with an extra postgraduate certificate, with the exception of chiropractic providers who are members of ChiroSuisse (Swiss Association of chiropractors) with practice permission.

T&CM services are partially covered by health insurance that is provided by private insurance companies that assume compulsory health insurance defined by federal legislation (referred to as “government” below).

Health insurance coverage in Switzerland, as of 2012				
T&MC practices	Government		Private	
	Full	Partial	Full	Partial
Acupuncture		X		X
Ayurvedic medicine				X
Chiropractic	X			
Herbal medicines		X		X
Homeopathic medicines		X		X
Naturopathy				X
Osteopathy				X
Traditional Chinese medicine		X		X
Anthroposophic medicine	X			X
Neural therapy	X			X

Chiropractic is considered mainstream medicine in Switzerland. It is delivered by chiropractors trained in the United States or Canada, and is fully covered by compulsory health insurance. With the new legislation on medical professions, effective since 2007, training of chiropractic is also offered by Swiss medical schools, so in the near future chiropractors trained in Switzerland will provide treatments.

Compulsory (“basic”) health insurance covers T&CM services other than chiropractic only if delivered by physicians accredited as “western” physicians and (apart from acupuncture) in a “coverage with evidence development scheme” (i.e. homeopathy, phytotherapy, traditional Chinese medicine, anthroposophical medicine and neural therapy); this is the case until 2017 – a trial period during which the effectiveness, adequacy and economicity of these five T&CMs will be evaluated. Reimbursement after 2017 will depend on the results of the evaluation projects and of international health technology assessments.

Acupuncture, herbal medicines, homeopathy and traditional Chinese medicine services that are delivered by non-physicians (or in the case of acupuncture and traditional Chinese medicine, by physicians trained in China), as well as many other T&CM methods, are covered by private health insurance. Many insurance companies offer contracts for coverage to various degrees (lists of therapists, methods and limited sum per year).

109. Turkey

National policy on T&CM

The 2013–2017 Strategic Plan published by the MoH aims at adoption of evidence-based T&CM practices through legislation, definition of practices and practitioners, rules and procedures of certification of practitioners, authorization process and supervision mechanisms of practice centres and units.

The Department of Traditional and Complementary Medicine was established under the Directorate General of Health Services, MoH in 2012. Scientific study groups were created after the establishment of the department.

The main regulatory body for T&CM practice is the MoH. The Directorate General of Health Services is the responsible directorate for certification, authorization and supervision. The Turkish Medicine and Medical Devices Agency affiliated with the MoH is responsible for certification and supervision of all kinds of medical devices and products.

T&CM practice centres and units in the public and private sector are established, with their own equity (resources). Many research fields, including T&CM practices, are funded with private and public sector grants and funds.

Regulatory status of herbal medicines

The regulation on traditional herbal medicinal products was issued in 2010. Herbal medicines are categorized as herbal medicines or traditional herbal medicinal products, based on indication and pharmaceutical formulation; both categories are authorized by the MoH.

For traditional use registration, the product itself or the active ingredients should have been in medicinal use for 30 years, including at least 15 years within Turkey or the EC, and should be designed for self-medication. Products that do not fulfil these criteria are treated as medicines. Herbal medicines are sold with medical, health and nutrient content claims. Dietary supplements are authorized by the Ministry of Food, Agriculture and Animal Husbandry. There must not be any claims on the label of dietary supplements.

The *European pharmacopoeia* is regarded as the national pharmacopoeia, but it is not legally binding. Other national pharmacopoeias may be used if the *European pharmacopoeia* does not have the required monograph. Other monographs are used, but are not legally binding: *Plants used in treatment* (88 monographs) and *Crops used in treatment* (43 monographs).

Guidance on GMP for pharmaceutical products and the regulation on manufacturing of medicinal products for human use are used for GMP for herbal medicines. The GMP regulations for conventional medicines also apply to herbal medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to assign a person to the role of ensuring compliance. Safety requirements are the same as those for conventional pharmaceuticals.

Herbal medicines are sold in pharmacies as traditional herbal medicinal products for self-medication. Legislation came into force on 6 September 2010, under which market authorization holders are given a 2-year period to translate products whose official categorization is unclear according to the classification list published on the website of the Turkish Drug Regulatory Authority. The transition period is still ongoing, so the market authorization for this type of product has not been given yet.

Practices, providers, education and health insurance

Indigenous TM and other T&CM practices are used by the population in Turkey, but the percentages of use are not available. Indigenous TM providers have been regulated at the national level since 2011 and acupuncture providers since 2002.

Following legislation commencing in 2014, T&CM practices are regulated by the MoH within the new legal framework. This framework covers 15 T&CM practices: acupuncture, phytotherapy, apitherapy, homeopathy, hypnosis, leech therapy, cupping therapy, osteopathy, chiropractic, reflexology, musicotherapy, prolotherapy, maggot therapy and ozone therapy.

Training programmes on T&CM practice can be organized, but only under the university hospitals and training and research hospitals affiliated with the MoH, and with MoH authorization. Doctors and dentists may attend these courses, but can practise only in their working areas. Pharmacists can attend homeopathy training in order to increase their knowledge of products. Pharmacists are entitled to prepare phytotherapy and homeopathy products after they are prescribed, and to inform patients about these products.

Integrative training programmes are provided by doctors who received conventional medical education and by health professionals. The training is designed as a combination of distance learning, formal education and clinical practices. Certificates approved by the MoH are given to doctors and dentists who undertake regular training and perform successfully in the exam at the end of the training.

As at end 2016, 378 T&CM practice units have been certified by the MoH. These units operate in public hospitals, private hospitals, medical centres, polyclinics and clinics, and are entitled to perform treatments only on patients with specific and restricted indications.

T&CM providers practise in public and private sector hospitals and clinics. The national Government issues the T&CM licence required to practise.

T&CM practices are not covered by (public) general health insurance. However, it is expected that private insurance companies are planning work on this issue. Some T&CM practices that are similar to conventional medicine – such as physical medicine, rehabilitation practices and thermal spa practices – are partially or fully covered by insurance. However, for reimbursement, these practices must be prescribed by a specialist doctor.

110. Ukraine

National policy on T&CM

Ukraine has a national law for T&CM, Decree No. 823 of 1998: “On measures pertinent to folk and alternative medicine regulation”. The Ukrainian Association of Folk Medicine under the Kyiv Medical University is the national research institute for T&CM.

Regulatory status of herbal medicines

The same regulation (Order No. 426 of 2005) applies to both herbal medicines and conventional pharmaceuticals. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines, dietary supplements, health foods and functional foods. They are sold with medical and health claims.

The State pharmacopoeia of the Ukraine is used and is legally binding. GMP and safety requirements for herbal medicines are the same as those for conventional pharmaceuticals.

There are 957 herbal medicines registered. Since 2009, herbal medicines have been included in the NEML; currently, only one herbal medicine is listed. Selection is based on long-term historical use. Herbal medicines categorized as prescription medicines, non-prescription medicines, self-medication or OTC medicines are sold in pharmacies.

Practices, providers, education and health insurance

No data are available on T&CM practices, providers, education or health insurance in Ukraine.

111. United Kingdom of Great Britain and Northern Ireland

National policy on T&CM

In the United Kingdom, the T&CM policy is integrated into the national health policy. There is regulation of OTC herbal medicines under the Traditional Herbal Medicines Regulation (THMR) scheme, but there is limited regulation of herbal practitioners or the herbal remedies that they supply to patients following a one-to-one consultation.

The Medicines and Healthcare Products Regulatory Agency and the Department of Health in England have several teams to develop policy on the safe use and practice of T&CM. The Professional Standards section under the Department of Health, in Leeds, is responsible for the professional regulation of practitioners. The Public Health Strategy and Social Marketing section, under the Department of Health, in London, is responsible for policy on CM.

In the United Kingdom, the voluntary sector plays an important facilitating role, and for T&CM this is done by the Prince of Wales' Foundation for Integrated Health. The Department of Health has a programme to develop research expertise in T&CM and to strengthen the evidence base. It also commissions periodic surveys of the use of T&CM in the United Kingdom.

Regulatory status of herbal medicines

There are three regulatory routes for herbal medicines in the United Kingdom: unlicensed herbal remedies (covered by s. 12 of the *Medicines Act 1968*), registered herbal remedies and licensed herbal medicines. The licensed herbal medicines are licensed in the same way as conventional pharmaceuticals; the s. 12 provisions are exclusive to herbal medicines; and the THMR scheme is partly the same as that for conventional pharmaceuticals, but the requirement for efficacy is replaced by proof of traditional use.

Herbal medicines are categorized as prescription medicines, non-prescription medicines and an exclusive regulatory category. They are sold with medical claims. Herbal products not classified as medicines fall within a range of other categories (e.g. foods, food supplements and cosmetics).

The *British pharmacopoeia* and the *European pharmacopoeia* are used and are legally binding. The *British herbal pharmacopoeia* is also used but is not legally binding. Monographs from the *British pharmacopoeia* (85 British monographs, 244 European monographs) and the *European pharmacopoeia* (248 monographs) are used and are legally binding. Monographs from the *British herbal pharmacopoeia* (169 monographs) are not legally binding.

Directive 2003/94/EC covers GMP for herbal medicines, and the regulations that apply for conventional pharmaceuticals also apply for herbal medicines. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants, and the requirement for manufacturers to assign a person to the role of ensuring compliance. Safety requirements are the same as those for conventional pharmaceuticals.

There are 46 traditional herbal registrations, as of 2012. In addition, there are several hundred herbal medicines with a market authorization. These products are currently being reviewed to assess whether some would more appropriately come within the traditional category. Herbal medicines are sold in pharmacies and other outlets as non-prescription medicines, self-medication or OTC medicines, and in special outlets.

Practices, providers, education and health insurance

T&CM practices of acupuncture, ayurvedic medicine, chiropractic, herbal medicines, homeopathy, naturopathy, osteopathy, traditional Chinese medicine and Unani medicine are used by the population in the United Kingdom. An estimated 20–39% of the population uses herbal medicines. T&CM providers practise in public and private clinics and hospitals.

The regulation of T&CM providers is handled by the Department of Health, but there are two groups that are statutorily regulated (chiropractors and osteopaths). Data on education of T&CM providers and information on coverage of private health insurance are not readily available.

Based on the information shared by the Medicines and Healthcare Products Regulatory Agency, as at 2012, there are an estimated 12 900 acupuncture providers, 3200 herbal medicine providers and 2800 traditional Chinese medicine providers in the United Kingdom.

5.5 WHO South-East Asia Region

Table 5.5 summarizes the development of national policy for T&CM, regulation of T&CM and herbal medicines, along with use of T&CM among populations of Member States in the WHO South-East Asia Region. The table also compares the percentage of Member States in the region with the global percentage for each indicator.

From 2005 till 2018, Member States in the region demonstrated a continued strong commitment to policy, law, regulation and national infrastructure for T&CM. Of the 11 Member States in the region, 10 reported having a national policy, programme, office and expert committee for T&CM. The use of T&CM among populations is also strongly acknowledged in the region.

The most growth was seen in regulation for herbal medicines, from seven Member States in 2005 to 10 by 2018. However, the number of Member States with national research institutes for herbal medicines and T&CM remained static and is one area with scope for further improvement in the region.

Table 5.5. WHO South-East Asia Region, development of T&CM, 2005–2018

Category	Regional number of Member States with affirmative responses in 2005	Regional number of Member States with affirmative responses as at 2018	Regional % of Member States with affirmative responses as at 2018 (N= 11)	Global % of Member States with affirmative responses as at 2018 (N= 194)
National policy on T&CM	8	10	91%	51%
Laws or regulations on T&CM	7	9	82%	56%
National programme on T&CM	9	10	91%	41%
National office for T&CM	10	10	91%	55%
Expert committee on T&CM	9	10	91%	48%
National research institute for T&CM or herbal medicines	7	7	64%	39%
Regulation of herbal medicines	7	10	91%	64%
Registration of herbal medicines	9	10	91%	64%
Population using T&CM	–	10	91%	88%

Note: The 2018 data set includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018). There may be Member States in which the T&CM situation has changed, not accounted for here.

112. Bangladesh

National policy on T&CM

In Bangladesh, the national policy on T&CM is integrated into the national drug policy of 2005. The national law for T&CM was issued in 1982 and amended in 2006. The national policy, law and regulation on T&CM was updated in 2016.

An office of the Director, Homeo & Traditional Medicine (DHTM) was established in 1991, as part of the Directorate General of Health Services (DGHS) in Mohakhali, Dhaka.

Regulatory status of herbal medicines

Regulation of herbal medicines is the same as that for conventional pharmaceuticals; both are under the Registration Guidelines of Herbal Medicine, issued in 2006.

Herbal medicines are categorized as non-prescription medicines and herbal medicines. They are sold with medical claims. The *British herbal pharmacopoeia*, the *American herbal pharmacopeia* and the *Therapeutic compendium* are used, although they are not legally binding. The *WHO monographs on selected medicinal plants* is used, but is not legally binding.

Bangladesh follows the WHO GMP guidelines for herbal medicines, and the regulations for GMP are the same as that for conventional pharmaceuticals, to ensure their quality. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, and manufacturers are required to submit samples of their medicines to a government-approved laboratory for testing and to assign a person to the role of ensuring compliance. There are no current regulatory requirements for the safety assessment of herbal medicines.

As at 2012, 55 *brands* of herbal medicines were registered, according to the herbal drug database of the Directorate General Of Drug Administration.¹ There are no restrictions on selling herbal products. Herbal medicines are sold in pharmacies, in special outlets and by licensed practitioners, as prescription medicines, non-prescription medicines, self-medication or OTC medicines. The regulation on herbal medicines, list of registered herbal medicines and regulations on practitioners were also updated in 2016.

According to the information shared from the 2010 records of the Unani Ayurvedic Herbal Homeopathic Manufacturers Association, the total market sales of herbal medicines were US\$ 43 million, US\$ 64 million and US\$ 86 million in 2007, 2008 and 2009, respectively.

Practices, providers, education and health insurance

According to the DHTM in 2007, 20–39% of the population reported use of indigenous TM. The data for 2008 show that between 20–39% of the population use ayurvedic medicine, while 1–19% reported the use of herbal medicines, homeopathy and Unani medicine.

National-level regulations on indigenous TM providers have been in place since 2005, and on providers of ayurvedic medicine, herbal medicines, homeopathy and Unani medicine providers since 1983.

T&CM providers practise in clinic settings in the private sector and in hospitals in the public sector.

The national Government issues the T&CM licence required to practise. A student can obtain a bachelor's degree in T&CM at the university level.

According to 2012 information from the DGHS, there are an estimated 469 indigenous TM providers (i.e. Unani and ayurvedic medicines) in Bangladesh. In 2009, there were 297 graduate and 491 diploma holders in ayurvedic medicine, 616 graduate and 16 222 diploma holders in homeopathic medicine, and 364 graduate and 1025 diploma holders in Unani medicine.

As at end 2016, T&CM services are not covered by health insurance in Bangladesh.

113. Bhutan

National policy on T&CM

Bhutan's national health policy of 2011 includes T&CM. The national law is the Medicines Act of 2003, which governs all kinds of medicines and medicinal products in the country, including medicines for animal health. The Drug Regulatory Authority (DRA) enforces the Act and carries out regular monitoring of medicine and medicinal products in the country.

All traditional medicine and medicinal products produced in Bhutan or imported from other countries must be registered with the DRA to ensure patient safety. TM is dealt with by the Drug Technical Advisory Committee and other committees formed under the Medicines Act. The Institute of Traditional Medicine Services, established in 1993 under the MoH, serves as the national office for T&CM.

Regulatory status of herbal medicines

The Bhutan Medicines Rules and Regulation 2012 is the national regulation governing herbal medicines. Herbal medicines are categorized as prescription medicines.

The *Traditional medicine formulary* 1st edition (1983) and 2nd edition (2007) are both used as national pharmacopoeias and are legally binding. *Monographs on medicinal plants* (both editions comprising 20 monographs) are also used. A national monograph on TM was developed in 2015.

GMP are carried out according to the Bhutan Medicines Rules and Regulation 2012; the WHO guidelines are also followed. Regulations for GMP are the same as those for conventional pharmaceuticals; to ensure compliance, there are periodic inspections by authorities at the manufacturing plants or laboratories.

¹ See <http://dgda.gov.bd/>

Traditional use without demonstrated harmful effects is the regulatory requirement for safety of herbal medicines.

As of 2017, 128 herbal medicines were registered and these 128 are included in the NEML, based on traditional use of the herbal medicines. Herbal medicines are sold as prescription medicine in pharmacies and by licensed practitioners.

As per the Revolving Fund Annual Report from 2009, the total market sales of herbal medicines in 2007, 2008 and 2009 were (in Bhutanese ngultrum) 10.53 million, 5.54 million and 12.94 million, respectively.

Practices, providers, education and health insurance

Indigenous TM practices are used in the country, but the percentage of the population using such practices is not known. The National Institute of Traditional Medicine reports that 20–39% of the population uses herbal medicines. According to hospital morbidity reports, 10–20% of outpatients use gSo-BA Rig-PA (traditional Bhutanese medicine).

There are national-level regulations on indigenous TM providers. T&CM providers practise in hospitals in the public sector. The national Government issues the T&CM licence required to practise. Bachelor's and master's degrees in T&CM are available at the university level. According to the Graduate Register (2012), there are about 78 bachelor and 114 diploma TM providers in Bhutan.

Full government insurance coverage is available for the practice of gSo-BA Rig-PA.

114. Democratic People's Republic of Korea

National policy on T&CM

In the Democratic People's Republic of Korea, the national policy on T&CM – Developing Koryo Traditional Medicine – was issued in 1979.

The Department of Koryo Traditional Medicine under the MoPH in Pyongyang serves as the national office for T&CM. The national programme for T&CM was established in 1948.

The national research institute for T&CM is the Academy of Koryo Traditional Medicine, established in 1961 in Pyongyang. The national plan for integrating T&CM into the national health service delivery began in 1979.

Regulatory status of herbal medicines

The regulation for herbal medicines is the same as that for conventional pharmaceuticals. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines, dietary supplements, health foods and general food products. They are sold with medical, health and nutrient content claims.

The latest editions of the *Pharmacopoeia of DPR Korea* constitute the national pharmacopoeia and they are legally binding. The national monographs include *Herbal plants in Korea* (1981), *Herbal plants and their use in Koryo traditional medicine* (2005) and *Collection of Korean herbs* (2010). These are all legally binding. Other monographs in use are the *Encyclopaedia of Koryo traditional medicine* (2009), *Collection of folk remedies* (2010) and *Clinical acupuncture, moxibustion and manual therapy* (2010); these are also legally binding.

Regulations for GMP are the same as those for conventional pharmaceuticals; they require adherence to manufacturing information in the pharmacopoeias and monographs. Compliance mechanism include periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing and to assign a person to the role of ensuring compliance. Safety requirements are the same as that for conventional pharmaceuticals; traditional use without demonstrated harmful effects is considered sufficient for the safety assessment of herbal medicines.

In 2010, 671 herbal medicines were registered. Herbal medicines are included in the NEML, with 19 first included in 1972 and 28 in 2006. They are selected based on the herbal medicine's traditional use, clinical data, long-term historical use and laboratory testing.

Herbal medicines are sold as prescription medicines, non-prescription medicines, self-medication or OTC medicines, in pharmacies and by licensed practitioners.

Practices, providers, education and health insurance

The Department of Koryo Traditional Medicine estimates that, in 2010, 40–59% of the population used indigenous (Koryo) TM practices; 20–39% used acupuncture, chiropractic and naturopathy; and 40–59% used herbal medicines.

National-level regulations apply to indigenous TM providers and to providers of acupuncture, chiropractic, herbal medicines and naturopathic medicine. T&CM providers practise in public sector clinics and hospitals. The national Government issues the licence required for T&CM practice. Bachelor's and master's degrees in T&CM are offered at the university level.

As of 2013, 5249 Koryo TM doctors (2.3 per 10 000 population) and 1869 Koryo pharmacists were registered. In addition, the system includes technician and assistants with diploma degrees in Koryo TM, such as manual therapist and natural therapists.

Indigenous TM is covered by government health insurance, and full government insurance coverage is available for the T&CM practices of acupuncture, chiropractic, herbal medicines and naturopathy.

A consumer education programme for self-health care using T&CM has been in place since 1980.

115. India

National policy on T&CM

In India, the national policy on T&CM is the National Policy on Indian Systems of Medicine and Homeopathy, issued in 2002. National legislation on T&CM includes the Indian Medicines Central Council Act 1970, the Homeopathy Central Council Act 1973 and the Drugs and Cosmetics Act of 1940 (amended in 2009).

The Government of India created a separate department known as the Department of Indian Systems of Medicine and Homeopathy in 1995, later renamed as the Department of ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH), to serve as the national office for T&CM, which is administered under the MoH. The independent Ministry of AYUSH was formed in 2014.

There are a number of expert committees for T&CM in the country, the important ones being the pharmacopoeia committee, the Drug Control Cell, and the ayurveda Siddha and Unani Technical Advisory Board.

There are four separate councils for research under AYUSH: the Central Council for Research in ayurveda and Siddha, the Central Council for Research in Unani Medicine, the Central Council for Research in Yoga and Naturopathy, and the Central Council for Research in Homeopathy.

A national plan for integrating T&CM into national health delivery began in 2014. Government and public research funding is allocated towards T&CM.

Regulatory status of herbal medicines

Herbal medicines are regulated under ayurveda, Siddha and Unani drugs provision in the Drugs and Cosmetics Act. They are categorized as prescription medicines and non-prescription medicines, and are sold with medical claims, health claims and nutrient content claims. Regulations for herbal medicines were updated in 2006 and 2017, and the list of registered herbal medicines was updated in 2016. The herbal medicines included in the NEML were updated in 2013.

The *Ayurveda pharmacopoeia of India*, the *Unani pharmacopoeia of India* and the *Siddha pharmacopoeia of India* are used and are legally binding. There are also monographs on single herbs and formularies. The *Indian herbal pharmacopoeia* is also used but is not legally binding.

GMP exist for ayurveda, Unani and Siddha drugs, which include herbal medicines. There are exclusive regulations for GMP, separate from those for conventional pharmaceuticals, that apply to the manufacturing of herbal medicines to ensure their quality. Adherence to manufacturing information in pharmacopoeias and monographs is required. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing and to assign a person to the role of ensuring compliance. Licences given to manufacturing units are renewed every 3 years, to ensure compliance with GMP. Traditional use without demonstrated harmful effects is considered sufficient for safety assessment of herbal medicines.

Herbal medicines are also included under Schedule E of the Drugs and Cosmetics Rules. There is a separate essential drug list for ayurveda and Unani medicines; inclusion of a herbal medicine is based on its traditional use and long-term historical use, as well as disease-wise classification.

Herbal medicines categorized as prescription medicines are sold in pharmacies; herbal medicines categorized as non-prescription medicines, self-medication or OTC medicines are sold in pharmacies and other outlets, and by licensed practitioners.

Practices, providers, education and health insurance

There are national and state level regulations that apply to providers of ayurvedic medicine, homeopathic medicine and Unani medicine.

T&CM providers practise in both public and private sector clinics and hospitals. The national Government issues the T&CM licence required to practise. Licences and certificates are both issued after graduation and subsequent completion of compulsory rotating internship. Bachelor's, master's, PhDs and clinical doctorate degrees in T&CM are available at the university level.

Regulations for homeopathy practitioners were updated in 2014 and the list of registered TM practitioners was updated in 2016. A consumer education programme for self-help care using T&CM has been in place since 1997. T&CM services are reimbursed by both public and private health insurance as at end 2016. Numbers of T&CM practitioners registered (as at 1 January 2016) under each practice are: ayurveda, 419 217; Unani, 48 196; Siddha, 8528; naturopathy, 2220; and homeopathy, 293 307. The total number is 771 468 (6.4 per 10 000 population).

116. Indonesia

National policy on T&CM

Indonesia's national policy on T&CM is the National Traditional Medicine Policy (*Kebijakan Obat Tradisional Nasional*), issued in 2007.

The national legislation on T&CM comprises provisions of the Health Law (No. 36/2009) and T&CM regulations on the role of TM practitioners (No. 1076/2003) and the role of CAM practitioners (No. 1109/2007). There is also a draft national policy on the practice of T&CM.

Under the national programme for T&CM, the Center of Traditional Medicine Development (SP3T), is responsible for TM practice. CM practices were introduced in 12 pilot hospitals in 2010. The development of a standard for quality of herbal medicines (*Indonesian herbal pharmacopoeia*) took place in 2008. National research and development in herbal medicines started in 1980.

The Deputy of Traditional Medicines, Cosmetics and Complementary Product Control, National Agency of Drug and Food Control Indonesia, 2001 serves as the point of contact for T&CM. The Directorate of Traditional, Complementary and Alternative Medicine, MoH, was established in 2011. (In the past, the activities of T&CM were conducted under a number of directorates within the MoH.)

A national working group on Indonesian medicinal plants was established in 1991. An expert team for TM product evaluation and a working group for CAM practices were established in 2001 and 2007, respectively. In 1977, the National Institute of Health Research and Development – a research and development institute for medicinal plants, including herbal medicines – was set up.

Regulatory status of herbal medicines

There is a regulation exclusively for herbal medicines, titled Criteria and Procedure on Registration of Traditional Medicines, Standardized Herbal Medicines and Phytopharmaca (*Kriteria dan Tata Laksana Pendaftaran Obat Tradisional, Obat Herbal Terstandar dan Fitofarmaka*) that was issued in 1976 and revised in 2005.

Herbal medicines are categorized as non-prescription medicines and herbal medicines; they are sold with medical claims and health claims.

The *Indonesian herbal pharmacopoeia* (4th ed., 1995) and its supplement (2009) are used and are legally binding. Monographs are used from *Materia medica Indonesia* (comprising 237 monographs) and *Vademekum Bahan Obat Alam* (comprising 100 monographs) and these are legally binding. *WHO monographs on selected medicinal plants* is also used and is legally binding.

The GMP on Traditional Medicines Products, issued in 1991 and revised in 2005, is followed. There are exclusive regulations for GMP, separate from those for conventional pharmaceuticals, that apply to the manufacturing of herbal medicines to ensure their quality. Adherence to manufacturing information in the pharmacopoeias and monographs is required. To ensure compliance there are periodic inspections by authorities at the manufacturing plants or laboratories and sampling of products in the market.

Safety requirements for herbal medicines are the same as that for conventional pharmaceuticals; traditional use without demonstrated harmful effects is considered sufficient for safety assessment of herbal medicines. There is a market surveillance system for herbal medicines.

In 2010, 13 000 herbal medicines were registered. Herbal medicines are sold as non-prescription medicines, self-medication or OTC medicines, in pharmacies and other outlets, in special outlets and by licensed practitioners.

Practices, providers, education and health insurance

As per 2010 data from the National Basic Health Survey, 40–59% of the population uses indigenous TM practices and herbal medicines. T&CM practices of acupuncture, ayurvedic medicine and chiropractic are used, but data on percentages used by the population are not available.

Regulations apply to indigenous TM providers, four types of traditional medicine practices and providers of acupuncture, chiropractic and herbal medicines. These are enforced at national, state and local (city) government level. Regulations for hypnotherapy are in the process of being established. T&CM providers practise in public and private sector clinics and hospitals. The state or city Government issues the relevant T&CM licence required to practise; there is also self-regulation by a delegated special technical association.

A student of T&CM can obtain a bachelor's and master's degree at the university level. The Government also recognizes certified training programmes, a training programme for indigenous TM practitioners and for T&CM technicians or equivalent (not at university level).

117. Maldives

National policy on T&CM

In Maldives, there is a policy framework exclusively on T&CM. The legislation comprises various laws and regulations on traditional medicine practice, import and dispensing of medicines and medical products, traditional and alternative medicine service provision, criteria for granting licences to practice to TM practitioners, and a general regulation on traditional and alternative medicine.

The Medicines Act (in draft) also addresses T&CM, and an alternative medicine regulation is being drafted. As at end 2016, the national policy and law for T&CM has been updated. Currently, there is no government or public research funding for T&CM.

The Maldives Food and Drug Authority, under the Ministry of Health and Family (MoHF), is mandated to regulate all medicine and medical products, and the import and dispensing of traditional and alternative medicine. The Quality Assurance and Improvement Division of the MoHF is mandated to regulate traditional and alternative medicine services, practitioners and facilities.

Regulatory status of herbal medicines

The regulations on herbal medicines and list of registered herbal medicines have been updated as at end 2016.

All herbal and alternative medicines are dispensed as OTC products. Herbal medicines are sold with medical, health and nutrient content claims, but these are unregulated. Currently, no regulations apply to the manufacturing of herbal medicines to ensure their quality, and there are no safety requirements.

In 2010, 241 herbal medicines were registered. There are no restrictions on selling herbal products. Herbal medicines are sold as non-prescription medicines, self-medication or OTC medicines in pharmacies, in special outlets and by licensed practitioners.

Practices, providers, education and health insurance

Indigenous TM and T&CM practices are used in Maldives, but the data on percentages of use by the population are not available.

National-level regulations have applied to indigenous TM providers since 2001. Previously, T&CM practitioners were regulated under the MoHF, Dhivehi beys committee. These regulations have been updated. T&CM clinics are regulated by the MoHF while services are monitored by the ministry's Quality Assurance and Regulation Division (QARD).

T&CM providers practise in private sector clinics; there are also individual practitioners who practise in home-based settings. The national Government issues the licence required to practise.

In the absence of university level T&CM education, students can obtain an advanced certificate in TM taught by faculties of health sciences and colleges of higher education. There is also an officially recognized training programme for indigenous TM practitioners.

As per 2010 data from QARD, there were four acupuncture providers, seven ayurvedic medicine providers, three traditional Chinese medicine providers and one Unani medicine providers practising in Maldives. Other practitioners include 51 Dhivehi beys verin providers (the indigenous TM of the Maldives), and one Qigong therapist.

118. Myanmar

National policy on T&CM

In Myanmar, the national policy on T&CM is integrated into the national health policy of 1993. The national office for T&CM, located in Naypyidaw, was established in 1989 under the MoH.

A research and development division in the Department of Traditional Medicine (DTM) was established in 1998. Research works and scientific analysis involves botanical, chemical, pharmaceutical, pharmacological and clinical investigations on traditional drug samples. Scientific analysis works usually aim to distribute safe and effective traditional medicines among the people by investigating quality assurance, and to improve traditional medicine clinical practice. The DTM also conducts research works in collaboration with the Department of Medical Research and Department of Medical Care under the Ministry of Health and Sports.

Regulatory status of herbal medicines

The regulation for herbal medicines is the Myanmar Traditional Medicine Drug Law. Issued in 1996, this law was followed by a series of notifications concerning registration and licensing, labelling and advertising. The objective of the law is to enable the public to consume genuine quality, safe and efficacious traditional drugs. The law requires all traditional medicine drugs produced in Myanmar to be registered, and manufacturers to have licences to produce their products. There are 13 343 registered items of drugs and 2878 manufacturers with licences for production.

Herbal medicines are categorized as "herbal medicines" and are sold with medical claims and health claims. The *WHO monographs on selected medicinal plants* is used.

The DTM also developed GMP guidelines based on guidelines from WHO and the Association of Southeast Asian Nations (ASEAN) countries. Traditional use without demonstrated scientific research on similar products is considered sufficient for the safety assessment of herbal medicines.

There are no restrictions on selling herbal products. In 2010, 10 150 herbal medicines were registered.

Practices, providers, education and health insurance

According to a knowledge, attitudes and practices (KAP) survey conducted in 2009, indigenous TM is used by 80–99% of the population. T&CM is used, but the percentage of usage is known only for acupuncture and herbal medicines (both 80–99%), according to the survey.

Regulations enforced at national, state and city level have applied to indigenous TM providers and herbal medicine providers since 2000. T&CM providers practise in public and private sector clinics and hospitals. The national Government issues the T&CM licence required to practise.

Bachelor's degrees in T&CM are offered at the university level.

119. Nepal

National policy on T&CM

In Nepal, the national policy on T&CM is integrated into the National Drug Policy, which was issued in 1995. There is no separate national law or regulation on T&CM. The Drug Act 1978 controls and regulates T&CM as well as allopathic and veterinary medicines; related legislation includes the Drug Registration Regulation (1981), the Code on Drug Manufacturing (1984, revised in 2015), the Drug Standard Regulation (1986) and the Drug Investigation and Inspection Rules (1983).

The Ayurveda and Alternative Medicine Unit under the Ministry of Health and Population in Kathmandu has been the T&CM national office since 2001. The national programme for T&CM is integrated into the Second Long-Term Health Plan, 1997–2017. The National Ayurveda Research Training Centre, Implementation Unit under the Ministry of Health and Population is in the process of being established in Kathmandu, to conduct T&CM research.

Regulatory status of herbal medicines

Regulation of herbal medicines is partly the same as that for conventional pharmaceuticals, under the Drug Registration Regulation. Herbal medicines are categorized as prescription medicines and herbal medicines. Claims are made, but these are unregulated.

The volumes of the *Ayurveda pharmacopoeia of India* are used along with classical texts such as *Bhaisajya Ratnawali*, *Siddhayaog sangrah* and *Rasshastra*, but these are not legally binding.

GMP for herbal medicines are in draft stage. Regulations for GMP are the same as those for conventional pharmaceuticals, and they require adherence to manufacturing information in pharmacopoeias and monographs. There are currently no mechanisms to ensure compliance. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals.

Herbal medicines categorized as such are sold in pharmacies as prescription medicines, non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM and T&CM practices are used in Nepal, but data on percentages of use by the population are not available. A national-level regulation on indigenous TM providers and ayurvedic medicine providers has been in place since 2001.

T&CM providers practise in public and private sector clinics and hospitals. The national Government issues the T&CM licence required to practise.

Bachelor's and master's degrees in T&CM are offered at university level. The Government also recognizes certain training programmes for T&CM technicians or equivalent (although not at university level).

The Nepal Ayurveda Medical Council estimates that about 1200 indigenous TM providers were practising in Nepal in 2010.

120. Sri Lanka

National policy on T&CM

Sri Lanka has different indigenous TM systems, such as ayurveda, Siddha, Unani and traditional medicine. All systems are controlled by the Ayurveda Act, issued in 1961. As at end 2016, the Sri Lankan policy on indigenous medical systems was in draft stage.

In 1997, as part of the President Task Force, a national programme for T&CM was introduced. The Ministry of Indigenous Medicine serves as the national office for T&CM. The Bandaranayake Memorial Ayurvedic Research Institute, established in 1961, serves as the national research institute for T&CM.

Regulatory status of herbal medicines

Herbal medicines are included in the system of ayurveda, and all T&CM herbal medicines are categorized as "Indigenous Medicines". Under the ayurvedic code (established in 1929 and renewed in 2012), indigenous medicines are further categorized as prescription medicines, non-prescription medicines and herbal medicines, and are sold with medical claims.

The *Ayurvedic pharmacopoeia* (1975) is used and is legally binding. Under certain circumstances, references are made to the *Indian pharmacopoeia*. The *Thalpathe pilium* contains the national monographs on herbal medicines but is not legally binding.

GMP are followed, and manufacturing information in pharmacopoeias and monographs is applied to the manufacturing of herbal medicines to ensure their quality. Manufacturers are required to assign a person to the role of ensuring compliance with manufacturing requirements and to report back to government authorities. Requirements for safety are the same as those for conventional pharmaceuticals; traditional use without demonstrated harmful effects is considered sufficient for the safety assessment of herbal medicines.

About 960 herbal medicines were registered in 2010. There are no restrictions on selling herbal medicinal products, and they are sold as prescription medicines, non-prescription medicines, self-medication or OTC medicines in pharmacies and other outlets, in special outlets (e.g. in herbal medicines stores and in T&CM supply stores) and by licensed practitioners.

According to data from the Department of Ayurveda, market sales of herbal medicines totalled US\$ 500 million, US\$ 500 million and US\$ 550 million in 2007, 2008 and 2009, respectively.

Practices, providers, education and health insurance

The Medicine Statistics Section of the Department of Ayurveda estimated that, in 2007, 40–59% of the population used indigenous TM. Acupuncture, homeopathy and Unani medicine practices were used by 1–19% of the population and ayurvedic medicine by 40–59%. Data for chiropractic, herbal medicines, osteopathy and naturopathy are not available.

National-level regulation has applied to indigenous TM providers and ayurvedic medicine providers since 1962 and to homeopathic providers since 1972.

T&CM providers practise in public and private sector clinics and hospitals, and in hotels. The national Government issues the licence required for T&CM practice.

University level degrees in T&CM include postgraduate diplomas, bachelor's, master's, MPhil and PhD degrees. The Government also recognizes certified training programmes, and a training programme for indigenous TM practitioners.

Ayurvedic Medical Council data from 2009 indicate that there were about 16 650 indigenous TM providers practising in Sri Lanka; data from 2007 indicate there were 500 acupuncture providers, 15 000 ayurveda medicine providers, 350 homeopathic medicine providers, 300 Unani medicine providers and 500 Siddha providers.

Full government health insurance coverage is available for ayurvedic medicine and Unani medicine. Partial private insurance coverage is also available for ayurvedic medicine. As at 2018, some insurance schemes do cover other T&CM practices, but none covers indigenous TM practice.

121. Thailand

National policy on T&CM

In Thailand, the policy on T&CM is integrated into the National Health Act (B.E.2550) of 2007. There is also a national policy exclusively on traditional Thai medicine (TTM), which is included in the 10th National Health Development Plan, 2007–2011. Legislation related to T&CM includes laws and regulations on the “practice of the art of healing” (B.E.2542), pharmaceuticals (B.E.2510) and the protection and promotion of TTM (B.E.2542). The national policy and law on T&CM was updated in 2016, and regulations were updated in 2013.

The national programme for T&CM is part of the 2010 Health Promotion Hospital initiative for the sub-district community. The Department for Development of Thai Traditional and Alternative Medicine, established in October 2002 under the MoPH in Nonthaburi, serves as the national office for T&CM.

There is no single committee in Thailand that looks over all the aspects of T&CM. However, there are expert committees, subcommittees and groups in different areas of TTM, such as the committee on the protection and promotion of TTM, the profession commissions in the branches of TTM and applied TTM, the network of graduate schools (comprising deans from each school), and the national expert working group on selection of herbal medicinal products.

The Thai Traditional Medicine Research Institute (under the Institute of Thai Traditional Medicine) was established in 2010 in Bangkok.

As at end 2016, US\$ 30.85 million in government research funding has been allocated towards T&CM. A national plan for integrating T&CM into national health delivery has been in place since 1992.

Regulatory status of herbal medicines

There is a regulation exclusively for herbal medicines, issued in 1967 (B.E.2510) under the Drug Act and its amendments. Herbal medicines are regulated as non-prescription medicines and are sold with medical and health claims.

The *Thai pharmacopoeia* and its supplements are used. Other traditional pharmacopoeia that are legally binding include *Wetchasuksa of Phraya Phitsanuprasatwet* (The medical study of Phraya Phitsanuprasatwet), *A treatise on traditional medicine* by Khun Sophitbunnalak, the *Phaetthayasatsongkhro* and the *Thai herbal pharmacopoeia* (containing 11, 10 and 11 monographs, respectively, in its three volumes). The *Pharmacopoeia of the People's Republic of China*, the *Japanese pharmacopoeia* and the *British herbal pharmacopoeia* are also used but are not legally binding. The *Complete German Commission E monographs: therapeutic guide to herbal medicines* (comprising 81 monographs) and *Monographs of selected Thai materia medica*, vol. I (54 monographs) are also used.

The GMP of herbal medicinal products, issued in 2005 (by the Thai calendar, Thai B.E. 2548), are followed. Regulations for GMP of herbal medicines are different from those for conventional pharmaceuticals on certain aspects because of the difference in the source of raw materials; the quality assurance processes for herbal medicines are also different. In 2010, a new regulation applying to the manufacturing of herbal medicines was under consideration by the Office of the Council of State. Compliance mechanisms include periodic inspections by authorities at the manufacturing plants or laboratories, and the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing. Traditional use without demonstrated harmful effects and reference to safety data in documented scientific

research on similar products are considered sufficient for the safety assessment of herbal medicines. Tests for microbial contamination limits and heavy metals limits are carried out.

In 2010, 12 625 herbal medicines were registered. The 2006 List of Herbal Medicinal Products contained 21 single herbs and 50 formulae of combined herbs, based on the traditional use of the herbal medicines, clinical data, long-term historical use and laboratory testing. Herbal medicines are sold as prescription medicines, non-prescription medicines, self-medication or OTC medicines, in pharmacies and other outlets, in special outlets and by licensed practitioners. The regulation on herbal medicines and list of registered herbal medicines was updated in 2017. The list of herbal medicines in the NEML was updated in 2016.

As at 2018, the registration of traditional medicines or herbal medicines is under the Drug Act. However, it is considered that the current Drug Act and Food Act are not suitable for the registration of traditional or herbal medicines and herbal dietary supplements. A new Act called the Herbal Product Act has therefore been drafted since 2016. As of April 2017, the draft Act was under the final round of consideration by the Office of Juridical Council and was expected to be enacted later the same year.

As per 2010 data from the Drug Control Division of the Thai Food and Drug Authority, the total manufacturing of herbal medicines (for both human and animals) in Thai baht was 2188.12 million, 2547.30 million and 2804.15 million in 2007, 2008 and 2009, respectively.

Practices, providers, education and health insurance

According to the Institute of Thai Traditional Medicine, in 2010, an estimated 1–19% of the population used indigenous TM practices, and a similar percentage used herbal medicines. Data from the Southeast Asian Institute of Thai-Chinese Medicine show that, in 2010, less than 1% of the population used acupuncture and 1–19% used traditional Chinese medicine. The Division of Complementary and Alternative Medicine reported that, in 2010, ayurvedic medicine, chiropractic, homeopathy, naturopathy, osteopathy and Unani medicines were used by less than 1% of the population.

National-level legislation to regulate indigenous TM providers comprises the Practice of the Art of Healing Act (1999), the Code of Ethics for Thai Traditional Medicine Providers (2002) and the Code of Ethics for Applied Thai Traditional Medicine Providers (2002). Also, national-level legislation applies to T&CM providers such as chiropractic providers (2006 Code of Ethics) and traditional Chinese medicine providers (2000 Code of Ethics, revised in 2009).

T&CM providers practise in public and private sector clinics and hospitals. The national Government issues the T&CM licence or certificate required to practise. Bachelor's, master's and PhD degrees in T&CM are offered at university level. The PhD is available in Public Health Sciences (Thai Traditional and Alternative Medicines) from Chulalongkorn University. The Government also recognizes apprenticeships with T&CM providers, certified training programmes and a training programme for indigenous TM practitioners and T&CM technicians.

Regulations on T&CM practitioners were updated in 2013, and the list of registered practitioners was also updated. The Medical Regulation Division, Department of Health Service Support, provided cumulative numbers of practitioners who have passed the licensing examination, registered and received the licences from 1929 to 2017 (excluding those who have passed away). The number of practitioners in different branches are as follows:

- Thai traditional medicine practitioners: 21 495;
- Thai traditional pharmacy practitioners: 29 165;
- Thai traditional midwifery practitioners: 9851;
- Nuad Thai (Thai traditional massage) practitioners: 4737; and
- applied Thai traditional medicine practitioners: 2860.

Thai pharmacists are also referred to as herbal medicine providers. There are also providers of chiropractic and traditional Chinese medicine practising in the country.

A consumer education programme for self-help care using T&CM has been in place since 1996. As at 2018, T&CM services are reimbursed by public insurance.

122. Timor-Leste

National policy on T&CM

Timor-Leste did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2018, as below.

There is no significant update. There is not yet a national policy, law or regulation on T&CM or regulation on herbal medicines in Timor-Leste. There are no regulations for T&CM practitioners yet.

5.6 WHO Western Pacific Region

Table 5.6 summarizes the development of national policy for T&CM, regulation of T&CM and herbal medicines, along with use of T&CM in the WHO Western Pacific Region. The table also compares the percentage of Member States in the region, with the global percentage for each indicator.

From 2005 to 2018, Member States in the region showed a strong acknowledgement of T&CM, with 93% reporting use of T&CM by their populations. However, the development of laws, regulations and registration of herbal medicines did not quite match global percentages.

Table 5.6. WHO Western Pacific Region, development of T&CM, 2005–2018

Category	Regional number of Member States with affirmative responses in 2005	Regional number of Member States with affirmative responses as at 2018	Regional % of Member States with affirmative responses as at 2018 (N=27)	Global % of Member States with affirmative responses as at 2018 (N=194)
National policy on T&CM	10	17	63%	51%
Laws or regulations on T&CM	9	13	48%	56%
National programme on T&CM	7	11	41%	41%
National office for T&CM	13	13	48%	55%
Expert committee on T&CM	9	11	41%	48%
National research institute for T&CM or herbal medicines	8	9	33%	39%
Regulation of herbal medicines	12	13	48%	64%
Registration of herbal medicines	11	11	41%	64%
Population using T&CM	—	25	93%	88%

Note: The 2018 data set includes 1) 2012 data and 2) additional Member States who responded “Yes” to the update survey, but either replied “No” or did not reply to the first and second surveys or responded “Yes” through additional data sources (e.g. regional reports and data verification during 2016–2018). There may be Member States in which the T&CM situation has changed, not accounted for here.

123. Australia

National policy on T&CM

In Australia, the national policy for T&CM is integrated into the National Medicines Policy of 2000. The term “medicine” includes prescription and non-prescription medicines, including complementary health care products.

Therapeutic goods for human use are regulated under the Therapeutic Goods Act 1989. This Act is administered by the Australian Government’s Therapeutic Goods Administration (TGA), and sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods in Australia, along

with the related Therapeutic Goods Regulation 1990.

Therapeutic goods are divided broadly into two classes: medicines and medical devices. Unless exempt, all products presented as therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) before being imported into, supplied in or exported from Australia.

A key component of the Australian National Medicines Policy is the appropriate use of medicines. The National Prescribing Service (NPS), established in 1998, is the Australian Government's major implementation body for quality use of medicines programmes. The NPS is independent of government and industry, and it provides medicines information and resources for health practitioners and consumers in improving quality use of medicines.

The scope of the work of the NPS covers all prescription, non-prescription and complementary medicines, with many of these programmes targeted directly towards areas of specified need.

The NPS recently undertook a study to determine the availability of complementary medicines information for consumers, and the information and skills needs of health care professionals. The study was undertaken in response to the *Complementary medicines in the Australian health system* report.

The TGA is responsible for the regulation of OTC medicines as well as complementary medicines (which include traditional and herbal medicines, vitamin and mineral supplements) that are supplied in Australia, to provide assurance that these medicines meet appropriate standards of quality, safety and efficacy consistent with their risk. The TGA does not regulate raw materials or the conduct or qualifications for practitioners and retail trading practices. There are certain exemptions under the Therapeutic Goods Act relating to medicines prepared by a practitioner where the health practitioner prepares a medicine for an individual patient, either following consultation with that particular patient, or to fill a prescription for that particular patient.

The national expert committee for T&CM in Australia is the Advisory Committee on Complementary Medicines (ACCM). The ACCM advises and makes recommendations to the TGA on the inclusion, variation or retention of a complementary medicine product in the ARTG. A major role for ACCM is to provide scientific and policy advice relating to controls on the supply and use of complementary medicines in Australia. The ACCM provides this advice with particular reference to the safety and quality of products and, where appropriate, efficacy relating to the claims made for products.

The ACCM may also provide advice to the TGA on any other matters concerning complementary medicines, and any other matters referred to it by the TGA (whether or not related to a complementary medicine). The ACCM supersedes the Complementary Medicines Evaluation Committee (CMEC), which was established in 1997. The National Medicines Policy Committee, established in 2009, provides advice on broader medicines policy in Australia. (This Committee supersedes the Pharmaceutical Health and Rational Use of Medicines Committee, which was established in 1992.)

The Australian National Institute of Complementary Medicine (NICM) is a nongovernmental organization that is hosted by the University of Western Sydney. However, T&CM research is undertaken at other Australian research institutes.

Regulatory status of herbal medicines

National regulation on herbal medicines began in 1989 and 1990; however, a formal regulatory system commenced in 1999. The TGA regulates herbal medicines in Australia.

Products are only regulated by the TGA if they come within the definition of "therapeutic goods" under the Therapeutic Goods Act. The determination that something is or is not a therapeutic good is based on several factors, including the overall presentation and the types of claims being made for the product. Foods (including many that make health claims) are regulated by state and territory food regulatory bodies through their enforcement of the Food Standards Code. The Food Standards Code is developed by Food Standards Australia and New Zealand, which is a statutory authority in the Australian Government health portfolio.

Australia has a two-tiered system for the regulation of medicines. Within the regulatory framework, medicines are classified as either “registered” or “listed”. Medicines considered to have a higher level of risk, such as prescription medicines, are “registered” on the ARTG. Registered medicines can also include non-prescription medicines such as OTC medicines, including common analgesics (e.g. aspirin, paracetamol and some complementary medicines that carry higher risk indications and health claims). Before registration, registered medicines are required to undergo comprehensive evaluations of safety, quality and efficacy by the TGA.

Medicines considered to have a lower risk are “listed” on the ARTG. Most medicines listed on the ARTG are complementary medicines, including products such as herbs, vitamins, minerals, nutritional supplements and traditional Chinese medicines, as well as homeopathic and certain aromatherapy preparations. However, complementary medicines are just a subset of listed medicines, with products such as sunscreens and dental products also listed in the ARTG.

Although “listed” medicines are required to meet certain criteria in relation to safety and quality of manufacture, the TGA does not evaluate their effectiveness before market approval. Therefore, they may not refer to serious forms of disease, disorders or conditions and, generally, they must not indicate that they are for the treatment, cure, management or prevention of any disease, disorder or condition. However, sponsors of such medicines are required to hold evidence to support the claims made for their product, and to make such evidence available to the TGA if requested.

In general, products making therapeutic claims must be manufactured by TGA-licensed manufacturers in accordance with the principles of GMP, and must be included in the ARTG before being supplied in Australia. To have a product included in the ARTG, a sponsor must submit an application to the TGA, together with relevant supporting data. The sponsor of a therapeutic good included in the ARTG must be an Australian resident or carrying on business in Australia.

General, medium and high level claims are based on evidence of traditional use of a substance or product, or on scientific evidence. Listed medicines may not refer to serious forms of disease, disorders or conditions and, generally, must not indicate that they are for the treatment, cure, management or prevention of any disease, disorder or condition. Sponsors of such medicines are required to hold evidence to support the claims made for their product, and to make such evidence available to the TGA if requested.

The TGA has developed guidelines for levels and kinds of evidence to support indications and claims, to assist sponsors in determining the level of evidence required to support indications and claims made for complementary medicines. The *British pharmacopoeia*, the *European pharmacopoeia* and the *United States pharmacopoeia* and *National formulary* (USP–NF) are used and these are legally binding.

The guide to GMP for medicinal products published by PIC/S was adopted in Australia in July 2010. The same regulations for GMP apply to all therapeutic goods, with the regulations interpreted through appropriate guidelines. Compliance is ensured by periodic inspections by authorities at the manufacturing plants or laboratories, the requirement for manufacturers to submit samples of their medicines to a government-approved laboratory for testing and to assign a person to the role of compliance officer, and the requirement for the compliance officer to ensure compliance with manufacturing requirements and to report back to government authorities.

For registered complementary medicines only, the same safety requirements as for conventional pharmaceuticals apply. For listed medicines, safety is assessed on a case-by-case basis. Traditional and scientific data on the product is taken into account.

There are 128 registered and 11 493 listed medicines in Australia as at June 2018.

Herbal medicines are sold in pharmacies and other outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

There is lack of data on the use of indigenous TM in Australia. The Australian and New Zealand Standard Classification of Occupations includes acupuncturist, massage therapist, homeopath, natural remedy consultant, naturopath and traditional Chinese medicine practitioner. Osteopathy and chiropractic are often considered mainstream allied health rather than complementary therapies. The percentages of the population using these types of T&CM practices are not known.

Australia is a federation, governed by a national government (the Australian, or Commonwealth, Government) and eight state and territory governments. Both these levels of government play roles in the regulation of health care. With regard to the regulation of T&CM providers, each state has its own legislation. The practice of various forms of T&CM is regulated to varying extents in different state and territory jurisdictions. Currently, the practices of osteopathy and chiropractic are regulated in every state and territory jurisdiction, but the practice of traditional Chinese medicine is regulated only in the State of Victoria. The practices of naturopathy and homeopathy remain unregulated in all jurisdictions.

Recently, Australia has implemented a National Registration and Accreditation Scheme (NRAS) for health professions that operate under the Health Practitioner Regulation National Law Act 2009. The sole purpose of national regulation of a health profession is to protect the public interest. An occupation must meet the requirements of six criteria to be considered for registration. The guiding principles and the criteria are outlined in an Intergovernmental Agreement.

The NRAS commenced on 1 July 2010 and presently covers 10 professions: medicine, nursing and midwifery, pharmacy, physiotherapy, psychology, osteopathy, chiropractic, optometry, dental care (including dentists, dental hygienists, dental therapists and dental prosthetists) and podiatry.

Four partially regulated professions will also be regulated from 1 July 2012 under the NRAS. These are traditional Chinese medicine practitioners, Aboriginal and Torres Strait Islander health practitioners, medical radiation practitioners and occupational therapists. Aboriginal and Torres Strait Islander clinical health work as defined under the NRAS does not refer to the practice of indigenous TM.

The national board for each profession is responsible for setting standards for the registration of practitioners and the accreditation of training institutions, in addition to registering health practitioners. It is anticipated that a national board for each of these partially regulated professions will be established by 1 July 2012. For example, the Chinese Medicine Board of Australia will oversee the registration of traditional Chinese medicine practitioners, the development of professional standards, the handling of notifications and complaints in relation to the profession, and the assessment of overseas trained practitioners who wish to practise in Australia. The national boards are assisted in their work by the Australian Health Practitioner Regulation Agency.

T&CM providers practise in private sector clinics. Practice of some forms of CM is currently regulated. Osteopathy and chiropractic are currently regulated under the NRAS for health practitioners.

Bachelor's and master's degrees in T&CM are available to students, in addition to a range of training options and courses in traditional Chinese medicine, osteopathy, chiropractic, naturopathy, homeopathy, massage and others.

According to data from the Australian Institute of Health and Welfare (25), the following numbers of T&CM providers practise in Australia: acupuncture (950), chiropractic (2486), homeopathy (235), naturopathy (2982), osteopathy (776), traditional Chinese medicine (481), massage therapists (8199) and natural remedy consultants (2631). The numbers practising ayurvedic medicine, herbal medicines and Unani medicine are not known.

In Australia, there are currently 35 different private health insurance organizations providing over 22 000 different private health insurance products. Health insurers are free to determine the services that attract general treatment benefits and that T&CM practices fall under. Health insurers can place limitations on entitlements, to impose quality and accreditation requirements that must be met by individual T&CM practices in order to receive insurance benefits.

124. Brunei Darussalam

National policy on T&CM

Currently, Brunei Darussalam has no national policy on T&CM, but a related integrated health care approach to achieve the wellness and well-being of the participating community is endorsed in the policy titled Vision 2035 – Together towards a Healthy Nation. There is a regulatory system on T&CM. The MoH established a Traditional/Complementary & Alternative Medicine Unit in the Department of Medical Services in May 2008.

In December 2015, the name of the unit was changed to Traditional and Complementary Medicine (T&CM) Unit, in line with nomenclature used by WHO and the ASEAN Task Force on Traditional Medicine.

Regulatory status of herbal medicines

Herbal medicines are categorized as traditional medicines and health supplements (TMHS), which are controlled administratively under the Department of Pharmaceutical Services, MoH, in accordance to the Guidelines for Dealing with Traditional Medicines & Health Supplements. Responsibility for the safety and quality of TMHS products rests with importers, manufacturers and wholesale dealers. It is the obligation of the seller to ensure that their products are not harmful or unsafe, and that they conform to the safety and quality requirements standard. TMHS products have to be approved by the Department of Pharmaceutical Services before they are imported into and marketed in Brunei Darussalam. The public can access TMHS products at retail pharmacies and outlets.

A market surveillance system exists for monitoring the safety and quality of TMHS products in the market; surveillance measures include random collection of product samples from the market for laboratory analysis, to ensure that they conform to quality and safety specifications. The public will be informed through mass media if TMHS products are unsafe to be used or consumed. In ASEAN, there is an exchange and sharing of information among member states on drug regulatory matters, including a post-market alert system for pharmaceuticals, cosmetics and TMHS.

Practices, providers, education and health insurance

Brunei Darussalam has a T&CM system similar to that of Malaysia and Singapore. Data on percentages of use by the population are not available at the moment. The use of indigenous TM and T&CM practices are considered important, but has reduced due to modernization and paradigm shift.

Since 2016, three new guidelines have been issued:

- Guidelines for registration of traditional and complementary medicine practitioners in Brunei Darussalam;
- Standard of practice for acupuncture; and
- Guidelines on infection control related to traditional and complementary medicine practices.

The Guidelines for Registration of Traditional and Complementary Medicine Practitioners in Brunei Darussalam was prepared based on qualification requirements set by WHO and regulatory authorities in other countries. This guide will be a useful reference for the public, for existing and future practitioners, as well as T&CM business owners, as to the processes and basic requirement to practise T&CM.

Since 2009, there are regulations in progress for providers of acupuncture, ayurvedic medicine, chiropractic, homeopathy, naturopathy, traditional Chinese medicine, Unani medicine and other practices such as spa, massage, beauty care and health practices.

Currently the T&CM Unit only registers (administratively) practitioners of traditional Chinese medicine, traditional Chinese medicine herbal dispensing, traditional Malay medicine, traditional Indian medicine, acupuncture, chiropractic, homeopathy, osteopath, massage, reflexology and cupping.

Practitioners are either registered with their practitioner bodies from the country of origin or through trade certification. Local practitioners are normally trained in China, Malaysia and Singapore, and set up their practices in medical halls, dispensaries and some home-based settings. T&CM providers practise only in the private sector. The T&CM Unit is required to submit a support letter to the Labour Department for foreign T&CM providers to be granted a work quota and subsequently a working visa by the Immigration Department, before they can practise in the private sector.

125. Cambodia

National policy on T&CM

Cambodia has a specific national policy for T&CM, the Policy on Traditional Medicine of the Kingdom of Cambodia, issued in 2010. There are also national regulations for T&CM in relation to herbal medicines (see below). There is a national programme for T&CM; as part of this programme, the Phnom Penh Municipal Health Department has mobilized traditional Khmer healers to be trained and to provide T&CM services at public health facilities since 1982.

In 1982, during the communist regime, the Center of Traditional Medicine (CTM) was established as the national office for T&CM. In 1997, the office was re-established and renamed as the National Center for Traditional Medicine (NCTM), under the MoH.

The Traditional Medicine Strategic Plan, 2012–2020 was issued in 2012. Research on T&CM is conducted in universities.

Regulatory status of herbal medicines

Legislation for herbal medicines has been in place since 1998; it includes regulations on the manufacture, import and export of “traditional medicine”, and on establishments that sell pharmaceuticals. Herbal medicines are categorized as herbal medicines and they are made with claims for health and nutrient content.

The monographs in use include *Plants used in Cambodia*, which contains 645 monographs and *Medicinal plants of Cambodia*, which contains 763 monographs.

The regulation for herbal medicines requires manufacturing of herbal medicines to follow any declaration issued by the MoH, but no such declaration has yet been issued.

TM products must be registered before being sold in the market. Registration criteria includes a certificate of analysis (to search for heavy metals, microorganisms, chemical substances, total ash and pesticides). However, many traditional medicines are currently sold in the market without registration.

As at end 2017, there were 474 registered herbal medicines; with one exception (Yang Chun), all of these medicines are imported from neighbouring countries. The MoH considers this to be a problem because local TM products do not meet registration requirements and local TM drug makers lack knowledge of how to prepare the documents required by the MoH.

Selling of TM or herbal products is regulated under Declaration No. 570 (Articles 3, 4, 9, 13 and 15). However, the implementation has not completely complied with the declaration. There are not enough restrictions on selling herbal products, and they are sold as non-prescription medicines, self-medication or OTC medicines in outlets other than pharmacies, in special outlets and by licensed practitioners.

Practices, providers, education and health insurance

Indigenous TM is considered important in Cambodia. Indigenous TM and other T&CM practices are used by the population, but the percentages of use are not known. Through the 1998 regulations, T&CM providers of herbal medicines are regulated at national level, but enforcement lacks the involvement of relevant bodies.

T&CM providers practise in private sector clinics. State or province level government issues the T&CM licence required to practise. The Government officially recognizes training programmes for indigenous TM

practitioners (not at university level). Many indigenous TM providers and providers of T&CM practices such as acupuncture, ayurvedic medicine, chiropractic, naturopathy and traditional Chinese medicine practise within Cambodia, but data to quantify numbers are not available.

There are regulations on herbal medicine providers (dispensers and producers). Based on the recently revised Law on Regulation of Health Practitioners (2016), the MoH established a working group, chaired by a secretary of state for health and comprising members from relevant institutions under the MoH, and from TM and pharmacist associations. The group is currently developing an instrument under this law to regulate T&CM practitioners. Short-term training (lower than university level) for T&CM practitioners is provided by the NCTM.

There is no health insurance for T&CM services.

126. China

National policy on T&CM

The State Council issued two documents – the Regulations of the People's Republic of China on Traditional Chinese Medicine, in 2003, and the Opinions on Supporting and Promoting the Development of Traditional Chinese Medicine, in 2009 – gradually forming a relatively complete policy system on traditional Chinese medicine. In 2016, the Communist Party of China Central Committee and the State Council issued the Outline of a Healthy China 2030 Plan, a guide to improving the health of the Chinese people in the coming 15 years. The plan sets out a series of tasks and measures to implement a programme for developing traditional Chinese medicine. The State Council issued the Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016–2030), which made development of traditional Chinese medicine a national strategy.

The Law on Licensed Doctors of the People's Republic of China, which regulates all physicians including traditional Chinese medicine doctors, commenced in 1998. The Law on Traditional Chinese Medicine came into force on 1 July 2017.

In 1986, the State Council set up a relatively independent administration of traditional Chinese medicine, the State Administration of Traditional Chinese Medicine. The China Academy of Chinese Medical Sciences, established in Beijing in 1955, constitutes the national research institute for T&CM.

Sixteen national traditional Chinese medicine clinical research bases have been built as part of the clinical research system for preventing and treating infectious diseases and chronic non-infectious diseases with traditional Chinese medicine. Organizational work has been done for collation of literature and screening of appropriate skills of ethnic minority medicine, involving 150 works on ethnic minority medicine and 140 appropriate skills.

In total, 130 traditional Chinese medicine elements have been incorporated into the Representative List of National Intangible Cultural Heritage, with the traditional Chinese medicine practices of acupuncture and moxibustion being included in the Representative List of the Intangible Cultural Heritage of Humanity by UNESCO, and the Yellow Emperor's Inner Canon (*Huang Di Nei Jing*) and the Compendium of Materia Medica (*Ben Cao Gang Mu*) being listed in the Memory of the World Register.

Regulatory status of herbal medicines

The drug administration law (revised in 2001) provides the national regulatory system on traditional Chinese medicines and natural medicines (herbal medicines). There are also regulations that govern how the drug administration law is implemented, the protection of traditional Chinese medicines, the administration of toxic drugs for medical use, and the protection of "wild medicinal resources".

Herbal products are categorized as prescription medicines, non-prescription medicines, health foods and general food products. Traditional Chinese medicines are sold with medical claims.

The Pharmacopoeia of the People's Republic of China (vol. 1) is used and it is legally binding. The Chinese materia medica and Standards for imported crude drugs are also used and are legally binding.

In September 2003, the Good Agricultural Practice for Chinese Crude Drugs (for Trial) was issued (“crude drugs” here means raw pharmaceutical materials). Manufacturers are required to assign a specific person to ensure compliance with relevant manufacturing requirements; this person must report on manufacturing compliance to the Government authorities.

For safety assessment, the GLP compliance programme for drug safety studies applies to both traditional Chinese medicines and conventional pharmaceuticals. Herbal medicines are included in the NEML, with selection criteria based on traditional use, clinical data and long-term historical use. Since 2009, 102 herbal medicines have been listed in the NEML. Since 2001, in accordance with Article 71 of the Drug Administration Law, traditional Chinese medicines have been included in the market surveillance system. There are no restrictions on selling herbal products. Herbal products categorized as prescription medicines or non-prescription medicines are sold in pharmacies and by licensed pharmacists; those categorized as food and health food are sold in supermarkets and other outlets.

As at end 2017, more than 60 000 traditional Chinese medicines and ethnic minority medicines have been approved (based on the number of Approval Letters), and 4424 pharmaceutical enterprises (including active pharmaceutical ingredient and finished dosage forms) have been granted manufacturing licences and passed the GMP inspection. In addition, 177 sites for crude drugs (raw pharmaceutical materials) have been certified for good agricultural practices (GAP). Chinese drug regulatory authorities are also exploring the revision of GAP and the implementation of a record system for Chinese crude drugs. A modern Chinese pharmaceutical industry, held together by commerce, has been established. In 2015, the total output value of the traditional Chinese medicine pharmaceutical industry was RMB 786.6 billion, accounting for 28.55% of the total generated by the country’s pharmaceutical industry.

Practices, providers, education and health insurance

An urban traditional Chinese medicine medical care network has been formed. This network mainly comprises hospitals for traditional Chinese medicine (including ethnic minority medicine and integrated Chinese and Western medicine), traditional Chinese medicine clinics and general hospitals’ traditional Chinese medicine clinical departments, and community health centres. A rural traditional Chinese medicine medical care network has also been established, mainly comprising county-level traditional Chinese medicine hospitals, traditional Chinese medicine clinical departments of general hospitals (specialized hospitals and centres for maternal and child health), traditional Chinese medicine departments of township-level health centres, and village health clinics that provide basic traditional Chinese medicine health care services.

At the end of 2015, there were 3966 traditional Chinese medicine hospitals across the country, including 253 hospitals of ethnic minority medicine and 446 hospitals of integrated Chinese and Western medicine; there were 452 000 practitioners and assistant practitioners of traditional Chinese medicine (including practitioners of ethnic minority medicine and integrated Chinese and Western medicine); there were 42 528 traditional Chinese medicine clinics, including 550 for ethnic minority medicine and 7706 for integrated medicine; there were 910 million visits that year to traditional Chinese medicine medical and health service units across the country and 26 915 000 in-patients treated.

Bachelor’s, master’s and PhD degrees are available to students at university level. At the end of 2015, there were throughout the country 42 institutions of higher learning in traditional Chinese medicine (including 25 traditional Chinese medicine colleges), and more than 200 Western medicine or nonmedical institutions of higher learning offering programmes in traditional Chinese medicine, enrolling a combined total of 752 000 students.

The state encourages exchanges between traditional Chinese medicine and Western medicine, and creates opportunities for Western medical practitioners to learn from their traditional Chinese medicine counterparts. Modern medicine courses are offered at traditional Chinese medicine colleges and universities to strengthen the cultivation of doctors who have a good knowledge of both traditional Chinese medicine and Western medicine. Traditional Chinese medicine hospitals have been encouraged to open specialized departments for specific diseases, in addition to general departments. General hospitals and community-level medical care organizations have been encouraged to set up traditional Chinese medicine departments, and traditional Chinese medicine has been made available to patients in the basic medical care system and efforts have been made to make it play a more important role in basic medical care.

Government and commercial insurance (including both state-owned and private insurance companies) cover indigenous TM (i.e. traditional Chinese medicine) and partially cover T&CM practices of acupuncture, herbal medicines and osteopathy.

It is envisioned that by 2020 every Chinese citizen will have access to basic traditional Chinese medicine services, and by 2030 traditional Chinese medicine services will cover all areas of medical care.

127. Cook Islands

The Cook Islands did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2018.

There was no significant update from the Cook Islands. There is not yet a national policy on T&CM or regulation on herbal medicines or T&CM practitioners.

128. Fiji

National policy on T&CM

As at 2018, there is no separate national policy or strategy on T&CM, but it is included in the National Medicine Products Policy 2013 and the Pharmaceutical Sector Strategic Plan for implementing the Fiji National Medicinal Products Policy 2013–2018. The MoH will be developing the first draft of a national T&CM policy by end of 2018, with the aim of recognizing T&CM in Fiji as part of mainstream health care services.

Currently, the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC), where the Chief Pharmacist is based, is referred to as the national office for T&CM programme management. The Chief Pharmacist's office oversees the Medicines Regulatory Authority, which deals with the administration and enforcement of regulations applying to medicinal products including T&CM products. (The FPBS was formerly known as the Fiji Government Pharmacy, established in 1895.)

A National Taskforce on T&CM was formed in 2012; however, the frequency of meetings was inconsistent until 2017, when the Deputy Secretary of Public Health convened the committee again to progress some policy instructions for the MoH. There is no formal national programme on T&CM, and no national research institute for T&CM, as at 2018.

Regulatory status of herbal medicines

Herbal medicines are categorized as non-prescription medicines and are sold with health claims. There are no regulations applying to the manufacturing of herbal medicines in Fiji. Traditional use without demonstrated harmful effects is considered sufficient for the safety assessment of herbal medicines.

Herbal medicines are sold in outlets as general sales products for self-medication or OTC medicines.

As at 2018, the FPBSC is trying to develop regulations on imported natural health products, including herbal medicines.

Herbal medicines are not registered in Fiji.

Practices, providers, education and health insurance

Indigenous TM is considered important in Fiji. As at end 2017, indigenous TM practices are used by many communities in the periurban and rural community sector, because people still use indigenous TM providers as their primary health care contact before they seek conventional health services.

T&CM providers that have been regulated since 1976 are acupuncturists, chiropractors and chiropodists. These T&CM providers practise in the private sector. The national Government issues the T&CM licence required to practise.

Indigenous TM providers and providers of other T&CM practices, such as acupuncture and chiropractic, practise within Fiji, but data on numbers are not available. There are new Asian business investors in Fiji that have set up alternative (traditional Chinese medicine) health services.

As at 2018, there is no health insurance coverage for T&CM services in general.

129. Japan

National policy on T&CM

Although there is no one national law or regulation that covers the entire area of T&CM, some areas are regulated by relevant laws (e.g. the Law on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices regulates marketing approvals for drugs including herbal medicines). There is no official office in charge of T&CM and no expert committee – issues regarding specific areas of T&CM are handled by existing offices and committees. Some research projects on T&CM are funded by the Government.

Regulatory status of herbal medicines

The Pharmaceutical Affairs Law issued in 1960 forms the national regulation on herbal medicine (including traditional Japanese Kampo medicines). Herbal medicines are regulated as prescription and non-prescription medicines and sold with medical claims. The Japanese pharmacopoeia (17th ed., 2016) is used and it is legally binding.

A guidebook on approval standards for OTC Kampo products was issued in 2008 and later revised. It contains 294 monographs as of 2014, though these are not legally binding. A regulation on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs, issued in 2004, sets out the GMP for both herbal medicines and conventional pharmaceuticals. Periodic inspections by authorities at the manufacturing plants or laboratories are carried out to ensure compliance. Safety requirements for herbal medicines are also the same as that for conventional pharmaceuticals.

Herbal medicines are sold in pharmacies as prescription medicines or non-prescription medicines (OTC medicines) for self-medication. The total quantity of shipments of herbal medicines were ¥ 146.4 billion and ¥ 154.7 billion in 2014 and 2015, respectively. (Here, herbal medicine refers to natural medicine and traditional Kampo medicine.)

Practices, providers, education and health insurance

Indigenous TM practices are considered important in Japan. Indigenous TM and other T&CM practices are used by the population, but the percentages of use are not known. Indigenous TM providers and acupuncture providers have been regulated at the national level since 1947, and providers of herbal medicines and traditional Chinese medicine since 1960.

The Medical Professions Division, Health Policy Bureau (MHLW), indicates that the number of practising acupuncture providers is about 86 000; the number of practising providers of herbal medicines and traditional Chinese medicine is not known.

T&CM providers practise in public and private sector hospitals and clinics. The national government issues the T&CM licence required to practise.

Bachelor's, master's and PhD degrees (in acupuncture and moxibustion) are available at university level. There is partial coverage of Indigenous TM and the T&CM practices of acupuncture and herbal medicines by government health insurance.

130. Kiribati

National policy on T&CM

As at 2018, Kiribati does not have a national office or research institute for T&CM. A national expert committee on T&CM was established in 1995 but is no longer active.

Regulatory status of herbal medicines

There is one private pharmacy or chemist in Kiribati that sells both non-prescriptions and prescription medicines. There is no local manufacturing of herbal medicines, apart from Noni juice, and there are no mechanisms in place to ensure compliance and safety. The Government issues prescription medicines via health facilities for free.

As at 2018, there is still no regulation on herbal medicines, and herbal medicines are not registered.

Practices, providers, education and health insurance

Indigenous TM is considered important in Kiribati. Indigenous TM providers and T&CM providers practise within Kiribati, but the number of providers is not known. T&CM providers practise in the private sector.

As at 2018, there are no regulations on T&CM practitioners and there is no health insurance coverage for T&CM services.

131. Lao People's Democratic Republic

National policy on T&CM

In Lao People's Democratic Republic, the national policy on T&CM is the Policy on the Promotion of Traditional Medicine, issued in 1996, which is also integrated into the national drug policy.

National legislation related to T&CM includes the law on drugs and medical products, issued in 2000, which applies to herbal medicines and T&CM products, and the decree on medicinal natural resources.

The Institute of Traditional Medicines (ITM), previously the Traditional Medicine Research Center, established in 1976, conducts research into medicinal plants and Lao TM. The ITM also served as the national office for T&CM until 2004, when the Traditional Medicine Division of the Food and Drug Department became the national office. Since 2013, the Traditional Medicine Management Division of the Health Care Department has functioned as the national office for T&CM.

TM is included in the revised National Medicine Policy 2003 as one of 13 components. This policy has been implemented through the 5-year National Health Sector Plan (programme no. 4 related to food and drug sector). This plan has been translated into a yearly operational plan with funding from the Government budget. The Lao National Strategy on Traditional Medicine, 2012–2015 is in the process of being revised (as at 2018). The 8th 5-year National Health Plan 2016–2020 forms the national programme.

Regulatory status of herbal medicines

The decree on medicinal natural resources also serves as the exclusive regulation for herbal medicines. No special regulatory category is given to herbal medicines. Many are sold with medical and health claims by some pharmacies and licensed practitioners.

The *Pharmacopoeia of the People's Republic of China* (English edition, 1992), the *Pharmacopoeia of Japan* (11th ed., 1986) and the *Vietnamese pharmacopoeia* (3rd ed., 2005) are used but are not legally binding.

There are no specific national monographs on herbal medicines. Lao People's Democratic Republic submitted 15 herbal monographs to be included in the Database on ASEAN Herbal and Medicinal Plants (10 monographs in vol. I, 2003 and five in vol. II). The *WHO monographs on selected medicinal plants* is used and is also not legally binding.

There are no specific GMP requirements for herbal medicines; however, to regulate the manufacturing of herbal medicines in terms of ensuring their quality, the GMP regulations for conventional pharmaceuticals are currently being applied under the law on drugs and medical products that covers both conventional pharmaceuticals and herbal medicines. Manufacturers are required to submit samples of their medicines to a government-approved laboratory for testing. Reference to safety data in documented scientific research on similar products is sufficient for safety assessment of herbal medicines.

The regulations governing drug registration cover both conventional pharmaceuticals and herbal medicines. The number of registered TM products is 288.

Herbal medicines have been included in the NEML since 2004. Selection criteria are based on traditional use of the herbal medicines, clinical data, long-term historical use and laboratory testing. Currently there are herbal medicines included, but the number has not been provided. The regulation for registration of herbal medicines and inclusion in the NEML was updated in 2015.

Herbal medicines are sold in pharmacies and other outlets as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Lao People's Democratic Republic, but the number of practising providers is not known. T&CM practices are used by the Lao population, including acupuncture, ayurvedic medicine, chiropractic, herbal medicines and traditional Chinese medicine, but the numbers of practising providers in each area are not available. The Government recognizes a training programme for indigenous TM practitioners. T&CM providers practise in private clinics and public sector hospitals.

As at 2018, T&CM practitioners are not regulated in Lao People's Democratic Republic, and T&CM services are not reimbursed by health insurance. A 5-year traditional medicine special curriculum at the Faculty of Pharmacy was introduced in 2017.

132. Malaysia

National policy on T&CM

The development of T&CM in Malaysia began with the formation of a Standing Committee on T&CM in 1998. Many efforts have been taken to integrate T&CM into the national health care system. In the early 2000s, the Herbal Medicines Research Centre (HMRC) was formed under the Institute for Medical Research, and a national policy for T&CM was introduced (and was revised in 2007). In 2002, the Global Information Hub on Integrated Medicine (GlobinMed) and the National Committee in Research and Development (R&D) for Herbal Medicines were established; subsequently in 2004, the Traditional and Complementary Medicine Division (T&CM Division) was formed as the authority to regulate the practice and practitioners of T&CM in Malaysia.

The initiatives taken by the T&CM Division are aimed at ensuring the safety and quality of T&CM practices; this includes the enforcement of the T&CM Act (Act No. 775 of 2016), standardization and accreditation of T&CM training and education, provision of T&CM services in public health care facilities, promotion of the safe use of T&CM and enhanced collaboration in R&D. This is in line with the Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020) and the WHO Traditional Medicine Strategy 2014–2023, which emphasizes the important role of T&CM in overall health care management.

Regulatory status of herbal medicines

In January 1992, Malaysia initiated the registration of T&CM products, followed by the licensing of T&CM manufacturers and importers in January 1999. Of the 246 manufacturers licensed by the Drug Control Authority (DCA) as of June 2017, 136 are licensed traditional medicines manufacturers, according to 2017 data from the National Pharmaceutical Regulatory Agency.

The current legislation and regulations that govern herbal medicines and related T&CM products include but are not limited to the following:

- Sale of Drugs Act 1952;
- Control of Drugs and Cosmetics Regulations 1984;
- Dangerous Drugs Act 1952;
- Poisons Act 1952;
- Medicines (Advertisement & Sale) Act 1956;
- Patents Act 1983;
- Wildlife Conservation Act 2010 (Act No. 716 of 2010); and
- International Trade in Endangered Species Act 2008 (Act No. 686 of 2008).

According to the Control of Drugs and Cosmetics Regulations 1984, all T&CM products need to be registered, with the exception of herbal medicines that are traditional preparations containing plants, animal parts or mineral substance, or a mixture of these substances of natural origin that is produced only through drying, without any treatment or processing involved. Extemporaneous preparations that are prepared and given directly to the patient by any T&CM practitioner during the course of treatment are also exempt. T&CM products are also subject to criteria for regulation, surveillance, pharmacovigilance, licensing and ADR reporting that are similar to those for established for conventional pharmaceutical products.

International and local pharmacopoeias and monographs have been used to assist with the registration of T&CM products but these documents are not legally binding. Examples include:

- *British herbal pharmacopoeia*;
- *German homeopathic pharmacopoeia*;
- *Indian herbal pharmacopoeia*;
- *Pharmacopoeia of the People's Republic of China*;
- *Malaysian herbal monographs*;
- *Compendium of medicinal plants used in Malaysia*; and
- *WHO monographs in selected medicinal plants*.

Practices, providers, education and health insurance

Practices

Although conventional medicine is the primary health care system in Malaysia, T&CM continues to be practised and to be in high demand owing to the rich ethnic diversity and cultural beliefs of the Malaysian society.

The demand for T&CM is demonstrated in the findings of the 2015 National Health Morbidity Survey. It was found that 29.25% of the Malaysian population had used T&CM with consultation in their lifetime, and 21.51% had used T&CM with consultation within the past 12 months (Institute for Public Health, 2015). In an estimated population of 30 million Malaysians, 9 million would have used or are using T&CM for the prevention or treatment of medical ailments. The population of T&CM consumers and the inherent demand for T&CM is significant.

The T&CM Act defines the practice of T&CM as a “form of health-related practice designed to prevent, treat or manage ailment or illness or preserve the mental and physical well-being of an individual and includes such practices as traditional Malay medicine (TMM), traditional Chinese medicine, [traditional Indian medicine], Islamic medical practice, homeopathy, and complementary therapies, but excludes medical and dental practices used by medical and dental practitioners respectively.”

Following the Traditional and Complementary Medicine (Recognized Practice Areas) Order 2017, the seven practice areas currently recognized in Malaysia are traditional Malay medicine, traditional Chinese Medicine, traditional Indian medicine, homeopathy, chiropractic, osteopathy and Islamic medical practice.

Providers

According to the database of the T&CM Division, 16 050 local T&CM practitioners have registered with the eight T&CM practitioner bodies appointed by the MOH before enforcement of the T&CM Act from 2016. The breakdown according to the recognized practice areas is as follows: traditional Malay medicine, 1966 practitioners; traditional Chinese medicine, 7655; traditional Indian medicine, 42; homeopathy, 600; chiropractic, 112; osteopathy, zero; and Islamic medical practice, 5675. In addition, about 13 000 premises providing T&CM services have been mapped in the country. They are largely established by the private sector (e.g. private universities, nongovernmental organizations [NGOs], clinics, hospitals and private practitioners).

Education

T&CM education can be divided into the skills pathway and the higher education (academic) pathway.

With regard to the higher education pathway, there are nine standards for diploma (3) and degree (6) level programmes in T&CM that have been developed in collaboration with the Malaysian Qualifications Agency. Also, there are 10 private institutions of higher education offering T&CM courses at diploma or degree levels to date.

With regard to the skills pathway, 10 National Occupational Skills Standards (NOSS) have been developed in various T&CM fields, in collaboration with the Department of Skills Development, the T&CM Division and industry experts. NOSS is a specification of competencies expected of a skilled worker employed in Malaysia in a defined occupational area. The Malaysian Skills Certificate is awarded to those who qualify.

Health insurance

Health coverage by private insurance companies will follow when minimum safety standards for T&CM practice are ensured, registration of T&CM practitioners completed and appropriate regulations enforced in a highly professional T&CM industry.

133. Marshall Islands

National policy on T&CM

As at 2018, there is no policy, law or regulatory system for T&CM in the Marshall Islands. The medicines legislation or regulation includes T&CM, but there is no specific regulation on T&CM.

There are no regulations for herbal medicines or practices and practitioners of T&CM. The Marshall Islands government recognizes the need for regulations for T&CM before it can integrate T&CM into the national health care system.

In February 2018, the parliament introduced Nitijela Resolution 43 as a resolution requesting the cabinet to explore ways and means of integrating traditional treatment and use of indigenous TM, as an alternative preventive and curative method, into the national health care system.

Regulatory status of herbal medicines

There are no regulations for herbal medicines or practices and practitioners of T&CM.

The Marshall Islands Society for the Protection of Traditional Medicines is an NGO that was founded in 1998 and has published a book (in both Marshallese and English): *Traditional medicine of the Marshall Islands: the women, the plants, the treatments*.

Practices, providers, education and health insurance

There are no regulations for practices and providers of T&CM. However, the use of traditional medicine and practices is not prohibited or discouraged in the Marshall Islands.

The Marshallese have continued to use traditional birth attendants, traditional healers and traditional medicines from locally grown plants and materials. Many of these traditional practices have been passed down from generation to generation.

134. Micronesia (Federated States of)

National policy on T&CM

As at 2018, there is no existing national policy framework for T&CM. There is currently no national plan to integrate T&CM into national health service delivery. However, since the 4th [Federated States of Micronesia] Non-Communicable Diseases Conference in 2015, there have been ongoing efforts to develop policies or strategies to integrate TM into health service delivery to manage noncommunicable diseases.

- Pohnpei State has passed legislation calling on the Department of Health Services to investigate and integrate the safe use and practice of TM into the delivery of health care services.
- The State of Kosrae, in its Joint State Action Plan for disaster risk management and climate change, is calling for the strengthening and support of local TM practices.
- On 30 January 2013, the Federated States of Micronesia became the 15th party to the Convention on Biological Diversity (CBD) to ratify the CBD's Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their use.
- Establishment of the Federated States of Micronesia National Biodiversity Strategy and Action Plan in 2002, which includes the preservation of TM and Access to Benefit Sharing Policies, is pending in the Four State Legislatures.
- The first CM nonprofit organization has been registered in the State of Pohnpei.

Regulatory status of herbal medicines

There are no restrictions on selling herbal products.

As at 2018, herbal medicines are still not regulated or registered.

Practices, providers, education and health insurance

Indigenous TM is considered important in the Federated States of Micronesia, but the number of indigenous TM providers practising in the country is not known.

T&CM practices such as herbal medicines and osteopathy are used, but the percentages of use by the population and the number of providers are not known.

T&CM practitioners are not regulated.

The only Micronesian health insurance provider does not recognize and support T&CM practices.

135. Mongolia

National policy on T&CM

The national policy for T&CM in Mongolia is Parliament Resolution No. 46, Government Policy on Development of Traditional Mongolian Medicine, endorsed in 1999. The Government developed a national strategy for 2020, based on the national policy. This policy document has two chapters on general provisions and main directions for developing traditional Mongolian medicine, and 19 specific provisions for implementation during 1999–2015. Other policy documents on disease classification in traditional Mongolian medicine and curriculum were issued in 2011 and 2012.

The Medical Care Policy Implementation and Coordination Department of the MoH serves as the national office. As at end 2016, this role is shared by the Ministry of Health and Sport. In 2017, a Division of Traditional Medicine was set up under the Medical Service Department of the MoH.

Through legislation in the form of the health law and the medical services laws, the description of medicine must include traditional Mongolian medicine treatment. The law on medicine and medical devices also includes a definition of traditional Mongolian medicine. A person who has graduated from the School

of Traditional Medicine, National Medical University of Mongolia, has the right to practise and teach traditional Mongolian medicine.

The MoH's orders to implement the national policy, issued in 1996, have played a vital role in solving challenging issues of TM at that time, such as delivering traditional medical services to the population, establishing traditional medicine centres and pharmaceutical units at provincial level, and training of professionals.

The national health sector development policy (part of the Millennium Development Goals for Mongolia – Comprehensive Policy on National Development, of 2007) states the importance of integrating best practices of traditional Mongolian medicine into mainstream health services.

In 2006, the MoH developed an action plan for 2006–2010 to implement the Government Policy on Development of Mongolian Traditional Medicine after its mid-term evaluation.

In 2010, the national programme on traditional medicine for 2010–2018 was developed, with its action plan, by order of the health minister. The purpose of this national programme was to intensify implementation of the Government policy and reflect changes in the legal environment.

The Traditional Medical Science, Technology and Production Corporation serves as the national research institute for T&CM.

The State Policy on Health for 2017–2026 was approved by government resolution in January 2017. The long-term state policy has eight strategic directions. It includes two important strategic objectives related to strengthening traditional Mongolian medicine: (a) develop traditional medicine diagnostics and treatment along with modern medicine at primary and referral levels of health care (medical service); and (b) support manufacturing and export of traditional medicines of plant, animal and mineral origin (pharmaceutical service).

Regulatory status of herbal medicines

The regulation for herbal medicines is partly the same as that for conventional pharmaceuticals. National security policy places importance on developing national pharmaceutical factories to improve production of drugs and biological products; sets production aims of not less than 50% of essential drugs in national factories; and supports the production of drugs from national biological and mineral raw materials. Regulation on herbal medicines was updated in 2015 (registration requirements).

Herbal medicines are categorized as prescription medicines, non-prescription medicines and herbal medicines; they are sold with medical claims. The Chinese and Russian pharmacopoeias are used, and these are legally binding. There is a state standard for traditional herbal medicines that applies to the manufacturing of herbal medicines to ensure their quality. To ensure compliance, periodic inspections by authorities at the manufacturing plants or laboratories are carried out, and manufacturers are required to submit samples of their medicines to a government-approved laboratory for testing. Herbal medicines are checked for bacterial and fungal extracts and heavy metals.

About 30 herbal medicines are registered. The NEML has included herbal medicines since 1999; selection is based on the traditional use of the herbal medicines, clinical data, long-term historical use and laboratory testing. As of 2012, 22 herbal medicines were listed in the NEML.

Herbal medicines categorized as prescription medicines are sold in pharmacies and by licensed practitioners.

Data from tax and manufacturers' reports indicate that the total market sales of herbal medicines in Mongolia were US\$ 0.5 million, US\$ 1 million and US\$ 1.4 million in 2007, 2008 and 2009, respectively. (Total market sales of prescription medicines in 2009 were about US\$ 50 million.) Exact data are not available, but between 2002 and 2008, Mongolia imported 930 kinds of dietary supplements.

Practices, providers, education and health insurance

About 40–59% of the population uses indigenous TM, while T&CM practices such as acupuncture are used by 20–39% of the population. Traditional Mongolian medicine is used by 20–39% of the population. Traditional Mongolian medicine originated from ayurveda and Tibetan medicine in the 14th century; it was adopted and practised by Mongolian doctors until 1937, when it was prohibited by the communists. When Mongolia came to develop a market in 1990, traditional Mongolian medicine started to redevelop.

Acupuncture providers have been regulated since 1958. Regulations on T&CM practitioners were updated in 2011. T&CM providers practise in the private sector in clinics and hospitals, and in the public sector. National, state and city governments issue the licence required to practise T&CM.

Bachelor's, master's, PhD and clinical doctorate degrees in T&CM are available at university level. There are also certified training programmes in T&CM.

There are over 160 traditional Mongolian medicine providers in the country. T&CM practices are partially covered by social health insurance, provided that the practice has accreditation.

136. Nauru

National policy on T&CM

T&CM is integrated into the Republic of Nauru National Medicines Policy, published in 2009.

Regulatory status of herbal medicines

The National Medicines Policy recommended the regulation of herbal medicines, but there are no separate regulations for herbal medicines. Under medical laws they are categorized as herbal medicines and they are sold with medical claims.

Martindale, the extra pharmacopoeia (25th ed., 1967) is used. No regulations apply to the manufacturing of herbal medicines, and there is no mechanism to ensure compliance. There are currently no safety requirements, and no records kept of the sale of herbal medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Nauru. Indigenous TM and other T&CM practices are used by the population, but the percentages of use are not known. T&CM providers practise in their own households in their district.

A government-issued T&CM licence to practise will be required once regulations on practitioners have been implemented.

Providers of indigenous TM and T&CM practices such as acupuncture and herbal medicines are found in Nauru, but their numbers are unknown.

As at 2018, regulations on T&CM practitioners have not yet been established.

137. New Zealand

National policy on T&CM

In New Zealand there is a growing recognition of the body of knowledge and practice known as rongoa Maori – traditional Maori healing. Rongoa Maori is deeply rooted in a Maori cultural context, in which understanding of events contributing to health or ill health is reflected in a range of culturally bounded responses.

The MoH in consultation with rongoa providers promoted the development of a set of practice standards, Tikanga a-Rongoa, which were published in 2014. All MoH-funded rongoa providers are required to adhere to the Tikanga a-Rongoa standards. Other organizations can also use the standards.

In December 2011, a new national rongoa governance body – Te Kahui Rongoa Trust – was established to protect, nurture and promote rongoa Maori.

Regulatory status of herbal medicines

There is currently no specific regulatory framework in New Zealand for herbal medicines, complementary medicines or any other similar product category. These products are regulated through other frameworks.

Many natural health products in oral dose forms are regulated as dietary supplements under the Dietary Supplements Regulations 1985 (under the Food Act 1981). Other natural health products are regulated as

related products, medicines or herbal remedies under the Medicines Act of 1981. The regulatory framework for therapeutic products is generally accepted as being out of date and inappropriate. In addition, according to the MoH, a piecemeal approach to regulation has created a situation that is confusing for industry and difficult to enforce. The need for regulatory reform in this area has been discussed for some time.

Practices, providers, education and health insurance

Up to 20% of the New Zealand population consults T&CM practitioners or uses T&CM in some form. Generally, none is state-funded, but there is some support from the Accident Compensation Corporation (state-funded universal accident insurance) for osteopathy and chiropractic.

Chiropractic and osteopathy are regulated professions under the Health Practitioners Competence Assurance Act 2003. The Chiropractic Board and Osteopathic Council issue the licence required to practise. Apart from osteopathy and chiropractic, T&CM practitioners do not require a licence to practise, while traditional Chinese medicine providers have applied to be regulated under the Act.

Education in traditional and CM is provided at the tertiary education level. Nearly all education providers are independent private colleges, not linked to any university. Some courses lead to a diploma and some to a bachelor's degree. The Government does not officially recognize any training programmes for any health professions; this is the responsibility of the regulatory agencies.

138. Niue

Niue did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2018.

The National Medicine Policy, which has been in draft since 2007/2008, includes T&CM. There is not yet a national office for T&CM. The NEML was last updated in 2012–2014 but does not include herbal medicines.

139. Palau

National policy on T&CM

As at 2018, there is no national policy or office on T&CM in Palau.

Regulatory status of herbal medicines

No regulatory status is given to herbal medicines, and they are sold with medical and health claims that are unregulated. No regulations apply to the manufacturing of herbal medicines. No safety requirements currently exist for the safety assessment of herbal medicines. The exception is for OTC products with expiration dates: environmental health regulations (2007) issued by the Department of Environmental Health, Bureau of Public Health and the MoH prohibit the sale or supply of expired products.

There are private sector establishments manufacturing herbal or OTC products for human consumption, without testing being done by the health or other sectors, because of lack of capability and on-island expertise. These establishments operate on production plant permits under the national and state governments.

There are no restrictions on selling herbal products, and they are sold in outlets as non-prescription medicines, self-medication or OTC medicines.

As at 2018, there is still no regulation or registration of herbal medicines.

Practices, providers, education and health insurance

Indigenous TM is considered important in Palau, but the number of indigenous TM providers practising in the country is not known.

T&CM practices such as herbal medicines, homeopathy and osteopathy are used in Palau, but the percentages of use by the population and number of providers are not known. T&CM providers practise in the private sector.

As at 2018, there is no regulation or registration of T&CM practitioners.

140. Papua New Guinea

National policy on T&CM

The national policy on traditional medicine was developed in 2007 to provide direction in developing T&CM medicines and practices, and integrating them into the primary health care system. The National Medicine Policy 2014 outlines strategies on how to regulate natural health products in T&CM.

Regulatory status of herbal medicines

The legal framework for regulation of traditional medicines is generally covered under the Medicines and Cosmetic Act 1999 and Regulations 2002. The National Department of Health has developed a Product Registration Roadmap 2018–2023 and the Registration Guideline for Medicines (January 2018) to guide implementation of registration of medicinal products beginning 2018. Registration of complementary medicines and natural health products is also included in this implementation plan.

Practices, providers, education and health insurance

The use of indigenous TM is widespread in Papua New Guinea, with 80–99% of the population using indigenous TM practices. T&CM providers practise at district level and informally in village settings. As per the 2009 Traditional Medicine Database of the National Department of Health of Papua New Guinea, 600 indigenous TM providers practise in the country. There are no regulations on T&CM practitioners and services are not covered by health insurance.

141. Philippines

National policy on T&CM

The Traditional Medicine Unit of the Department of Health was created in 1992 to implement the Philippines' Traditional Medicine Program. The Traditional and Alternative Medicine Act (TAMA law), which commenced in December 1997, was created to improve the quality and delivery of health care services to the Filipino people through the development of traditional and alternative health care (TAHC) and its integration into the national health delivery system.

The Philippine Institute of Traditional and Alternative Health Care (PITAHC) was established in 2000 to implement the TAMA law. PITAHC and the Philippine Food and Drug Administration (PFDA) together serve as the national office on T&CM.

The Strategic Map 2017–2021 on T&CM has been developed by PITAHC in 2017.

Research on T&CM is undertaken by three national institutes: the National Institute for Health (established in 1996), the National Integrated Research Program on Medicinal Plants (established in 1977) and the Philippine Council for Health Research and Development (established in 1982).

Regulatory status of herbal medicines

The PFDA is the Government agency that has regulatory power over the production, distribution and use of products such as food, drugs, cosmetics, devices, biologics, vaccines, in vitro diagnostic reagents, and household hazardous substances, including combinations and derivatives of any product or substance. Also included are products that may have an effect on health.

Drug products are classified into 10 categories:

1. New drugs or new chemical entities
2. Biological products
3. Generic drugs
4. Traditionally used herbal products
5. Herbal medicines
6. Household remedies
7. OTC preparations
8. Veterinary drugs
9. Medical gases
10. Stem cell products.

The PFDA regulates registration of herbal medicines, including both the product name and the formulation or composition of the medicine. For herbal medicines and traditionally used herbal products, the generic name must be the botanical origin or as recognized by the PFDA, and the formulation or composition is according to the official Philippine pharmacopoeia, or as determined by the PFDA.

Herbal medicines and traditional herbal medicines are required to be registered unless they are medicines or drugs that are not herbal medicines as defined in the regulations, or they are herbal preparations made of fresh plant material that is unprocessed or untreated.

The official national pharmacopoeia is the *Philippine pharmacopoeia* (2004), which lists 52 monographs; it is legally binding. The *United States pharmacopoeia*, the *British pharmacopoeia* and the *European pharmacopoeia* are also used. The *Philippine national drug formulary* of 2006, which contains five national monographs on herbal medicines, is also used as reference.

The regulations for cGMP that apply to the manufacturing of herbal medicines are the same as those that apply to conventional pharmaceuticals. Compliance is ensured by periodic inspections by authorities at the manufacturing plants or laboratories. There are specific safety requirements for herbal medicines; reference is made to safety data in documented scientific research on similar products. New drugs (both herbal and conventional) that are not yet established in the Philippines are required to have preclinical and clinical studies, and post-marketing surveillance.

Fifty herbal medicines and traditionally used herbal products were registered. Herbal medicines have been included in the NEML since 2000; selection for inclusions is based on clinical data and laboratory testing. As of 2012, five herbal medicines were listed in the NEML.

Herbal medicines categorized as prescription medicines are sold in pharmacies; those categorized as non-prescription medicines, self-medication or OTC medicines are sold in outlets other than pharmacies.

Practices, providers, education and health insurance

According to the Philippine Traditional Knowledge Digital Library on Health, as of 2017 there were 16 690 documented medicinal plants, 66 healing practices (rituals), 509 traditional healers and 43 research sites.

Acupuncture providers have been regulated at the national level since 2008; similar regulations are being established for providers of chiropractic and homeopathy. T&CM providers practise in public and private sector clinics and hospitals. PITAHC accredits and certifies T&CM practitioners, clinics and training centres.

A master's degree in T&CM and a master of science (MSc) in South Asian health practices are offered at universities in the Philippines. The MSc was first offered in 2008 and the first batch of graduates was in 2010. There are various other degree programmes on traditional medicine and indigenous health practices being offered in the Philippines. The Government also recognizes certified training programmes.

PITAHC has developed policies, standards and guidelines for the practice of various TM modalities – acupuncture, homeopathy, homotoxicology, chiropractic, naturopathy and hilot – as well as for clinics and training centres.

As at end 2017, the updated numbers of certified or accredited practitioners are as follows:

- Certified Medical Acupuncturist (MD) – 131
- Certified Associate Medical Acupuncturist – 70
- Certified Acupuncturist (Filipino) – 112
- Certified Acupuncturist (Foreign) – 164
- Certified Associate Acupuncturist – 416
- Certified Nonmedical Naturopath – 8
- Certified Medical Naturopath – 7
- Certified Nonmedical Homeopath – 1
- Certified Medical Homeopath – 2
- Certified Homotoxicologist – 25
- Certified Chiropractic practitioners – 42
- Accredited TAHC Organization – 9
- Accredited Acupuncture Clinic – 29
- Accredited Homeopathy/Homotoxicology Clinic – 5
- Accredited Naturopath Clinic – 1
- Accredited Homeopathy/Homotoxicology Training Center – 1
- Accredited Naturopath Training Center – 3
- Accredited Acupuncture Training Center – 10.

As at 2018, there are already laws and regulations on T&CM products and practices. There is no health insurance coverage for T&CM services.

142. Republic of Korea

National policy on T&CM

In the Republic of Korea, regulation of Korean medicine doctors was established in 1951 under medical services laws. To facilitate strategic planning and implementation of national policy on Korean medicine, the Bureau of Traditional Korean Medicine was established in 1993 under the then Ministry of Health and Social Affairs (now the Ministry of Health and Welfare [MoHW]). The Bureau was expanded in 2008 to have two divisions: Division of Traditional Korean Medicine Policy and Division of Traditional Korean Medicine Industry. These divisions cover industries for herbal medicines and medical devices related to traditional Korean medicine, as well as national policies, strategies and regulations on traditional Korean medicine. Further, the Ministry of Food and Drug Safety (MoFDS) regulates processed herbal materials and herbal medicinal products.

There are also public institutions that are important in the area of traditional Korean medicine. The Korea Institute of Oriental Medicine is a national research institute for Korean medicine established in 1994; it is in charge of overall planning and implementation of R&D of Korean medicine. The National Development Institute of Korean Medicine, established in 2016, is a national agency responsible for promoting the Korean medicine industry.

The Promotion of Korean Medicine and Pharmaceuticals Act, which provides overall strategic direction for development of Korean medicine, was enacted in 2003 and became effective in 2004. Under this Act, a national action plan on promotion and development of Korean medicine has been developed every 5 years since 2006: the first national plan (2006–2010), the second national plan (2011–2015) and the third national plan (2016–2020). The third national plan, which is currently being implemented, was developed based on national consultations and approved by the expert committee on development of Korean medicine chaired by the Vice-Minister of the MoHW under the vision “Promoting public health through Korean medicine and strengthening national capacity for international cooperation” in 2016.

Regulatory status of herbal medicines

The Regulation on Quality Control of Herbal Materials and Distribution (Supply) was developed in 1995, under which the regulatory system for quality control ("standardization") of herbal materials was established in 1996. From 2012, the system was strengthened by requiring that all herbal materials used for Korean medicine must be processed by GMP-certified manufacturers. The system also specifies that quality and safety standards set out in monographs on herbal materials contained in the *Korean pharmacopoeia* (165 monographs) and the *Korean herbal pharmacopoeia* (436 monographs) must be followed. Herbal medicinal products must obtain market authorization from the MoFDS based on the stability, safety and efficacy data of the products, and only GMP-certified manufacturers can produce approved herbal products.

Practices, providers, education and health insurance

The education system for traditional Korean medicine at the university level started at Dongyang University in 1947, and had evolved into 6-year medical education system by 1964. There are currently two education tracks to become a traditional Korean medicine doctor: via Korean medicine universities providing 6-year medical education or via a graduate school of Korean medicine providing 4-year medical education. Only graduates from accredited Korean medicine universities and graduate schools of Korean medicine can apply for the National Licensing Examination for traditional Korean medicine doctors, and those who pass the examination are licensed by the MoHW.

Licensed Korean medicine doctors are required to undertake continuing medical education every year. To strengthen research capacity in Korean medicine, every Korean medicine university offers master's and doctoral programmes in Korean medicine. Postgraduate medical education for Korean medicine specialists – 4-year clinical training (internship and residency) in hospitals – was introduced in 1999, and Korean medicine doctors who finish 4-year clinical training and pass the specialty certificate examination can be certified as specialists.

National health insurance has covered selected traditional Korean medicine services, including some acupuncture, moxibustion and herbal medicinal products, since 1987.

143. Samoa

Samoa did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2018.

National policy on T&CM

In Samoa, the National Medicines Policy of 2008 and the Samoa Health Sector Plan 2008–2018 both include T&CM. There is currently no national office, programme, expert or advisory committee for T&CM.

Regulatory status of herbal medicines

Herbal medicines are not registered or regulated.

Practices, providers, education and health insurance

There is no regulation on T&CM practitioners; however, the Government is currently trying to develop a registration system for traditional birth attendants and traditional medicine healers. T&CM services are not covered by health insurance.

144. Singapore

National policy on T&CM

In Singapore, the T&CM branch under the MoH is the national office for T&CM.

Currently, Singapore does not have a national research institute for traditional medicine. However, the MoH administers a dedicated traditional Chinese medicine research grant to encourage collaborative research between traditional Chinese medicine practitioners and researchers in their health care and academic institutions.

Regulatory status of herbal medicines

There are national regulations on herbal medicines in Singapore. Herbal medicines, including traditional Chinese, Indian and Malay medicines, are regulated by the Medicines Act, and are sold as OTC medicines. The regulation of herbal medicines focuses on certain aspects of safety and quality, including compliance with legally permissible limits of toxic heavy metals, and prohibition against adulteration and presence of western medicinal ingredients (e.g. corticosteroids and nonsteroidal anti-inflammatory drugs). In addition, herbal medicines in Singapore are not allowed to carry claims on the labels related to any of the 19 diseases or conditions specified in the Schedule of the Medicines (Advertisement and Sale) Act (e.g. cancer and diabetes).

Since 1999, Singapore has implemented controls for Chinese proprietary medicines (CPMs). CPMs are traditional Chinese herbal medicines in finished dosage forms (e.g. tablets or capsules) that contain one or more active substances, all of which are derived wholly from plants, animals and minerals described in reputable references including the Chinese pharmacopoeia, *A Dictionary of Chinese Pharmacy* and *The Chinese herbal medicine materia medica*.

Control mechanisms for CPMs include premarket product listing approval and licensing of manufacturers, importers and wholesale dealers. Before CPMs can be listed for sale in Singapore, dealers must provide information on their product specifications, manufacturer and manufacturing process, as well as documentary evidence that their products meet the relevant safety and quality requirements (e.g. test reports showing absence of prohibited substances and compliance with stipulated limits on toxic heavy metals and microbial contents). Local manufacturing facilities for CPMs are assessed and inspected for compliance with the PIC/S *Guide to GMP for medicinal products*. Importers and wholesale dealers are also assessed and audited in accordance with the Singapore Health Sciences Authority's guidance notes on good distribution practice.

As at end August 2018, about 11 000 CPM products have been listed in Singapore.

Singapore has in place a market surveillance system to monitor the safety of herbal medicines, and to initiate timely recall of harmful products when necessary. This has included ADR monitoring since 1993, and a risk-based surveillance programme that samples and tests health products in the market for potentially harmful ingredients.

Practices, providers, education and health insurance

In the National Health Surveillance Survey 2013, 26.5% of respondents had consulted a traditional Chinese medicine practitioner at least once in their lives, and 48% of those 26.5% had visited a traditional Chinese medicine practitioner within the previous year. Percentages of the population using other T&CM practices in Singapore are not known.

Currently, among T&CM practices, only traditional Chinese medicine practitioners are statutorily regulated. The Traditional Chinese Medicine Practitioners Act was established in year 2000, and the Traditional Chinese Medicine Practitioners (Registration of Acupuncturists) Regulations and the Traditional Chinese Medicine Practitioners (Registration of Traditional Chinese Medicine Physicians) Regulations came into force in 2001 and 2002, respectively. Practitioners of other T&CM, such as traditional Malay medicine, traditional Indian medicine and chiropractic, are encouraged to practise self-regulation through professional associations.

The Traditional Chinese Medicine Practitioners Board (TCMPB), a statutory board under the MoH, was set up in 2001 to regulate the practices and ethical code and conduct of practitioners, among other regulatory functions to ensure traditional Chinese medicine standards.

Practitioners of traditional Chinese medicine or acupuncture must be registered with the Traditional Chinese Medicine Practitioners Board. As of December 2017, there were 2952 registered traditional Chinese medicine practitioners and 254 registered acupuncturists. Most traditional Chinese medicine practitioners practise in charitable or private clinics, while acupuncture is allowed in public hospitals and nursing homes.

A 5-year (full time) or 7-year (part time) bachelor's degree in traditional Chinese medicine is available from three accredited training institutions. On average, these training providers enrol a total of about 150 students per year.

Acupuncture and traditional Chinese medicine treatment are partially covered by private insurance companies.

145. Solomon Islands

National policy on T&CM

Solomon Islands has a National Medicines Policy that has included a section on traditional medicines since it was first developed. The latest National Medicines Policy, issued in 2015, also includes a T&CM section. T&CM is also reflected in the National Strategic Health Plan, 2011–2015.

Regulatory status of herbal medicines

As at 2018, there is no regulatory scheme that specifically deals with traditional herbal medicines; however, the sale of traditional herbal medicines is covered by food, drug and consumer protection laws.

For example, the Pure Food Act 1996 prohibits any claims relating to food that cannot be substantiated or to the suitability of a food for use in the prevention, alleviation or cure of a disease, disorder, or particular physiological condition (unless in accordance with the *Codex Alimentarius*¹). This applies to any TMs that are intended to be used as food for human consumption, but does not include those medicines that are purely intended for use as a drug.

Under the Pharmacy and Poisons Act, it is an offence for any person to dispense drugs or medicine for payment (or other reward) unless they are a registered pharmacist. This would apply to any traditional medicines intended or dispensed for use as a drug.

The Consumer Protection Act applies generally to all goods traded in Solomon Islands. It prohibits traders from making false representations in relation to goods or engaging in conduct that is misleading or deceptive.

Practices, providers, education and health insurance

Traditional medicine is practised in communities throughout Solomon Island; however, no detailed data are available. T&CM providers practise in public and private sector clinics, and in home-based settings in villages.

146. Tonga

National policy on T&CM

As at 2018, there is no national policy, law or regulation for T&CM in Tonga.

Regulatory status of herbal medicines

Regulatory status is not given to herbal medicines, which are sold with medical, health and nutrient content claims that are unregulated. No regulations apply to the manufacturing of herbal medicines to ensure their quality, and there are currently no safety requirements and no restrictions on selling herbal products.

As at 2018, herbal medicines are not regulated or registered.

¹ See <http://www.fao.org/fao-who-codexalimentarius/en>

Practices, providers, education and health insurance

Indigenous TM and other T&CM practices are used in Tonga. T&CM providers practise in the private sector.

A T&CM licence or certificate is required to practise, issued for TM business by the national Government (Ministry of Labour, Commerce and Industries). Indigenous TM providers and providers of T&CM services – such as acupuncture, herbal medicines, traditional Chinese medicine and traditional Tongan medicine – are found in Tonga, but their numbers are unknown.

As at 2018, there are no regulations on T&CM practitioners or coverage by health insurance.

147. Tuvalu

National policy on T&CM

No information on national approaches to T&CM is available for Tuvalu.

Regulatory status of herbal medicines

As at 2018 the national Drug and Therapeutic Committee (DTC) regulates the importation and use of medicinal products, including herbal products. Under the new pharmacy and therapeutic products laws, the British pharmacopoeia, the United States pharmacopeia and international pharmacopoeia are recognized as legally enforced standards. Herbal medicines are categorized into two distinct products: herbal medicines that are imported and available in large quantities, and herbal medicines that are locally produced for individual use only. The imported products are regulated and those that are locally produced are not.

Traditional healers are generally encouraged to always sterilize equipment before use. There are currently no safety requirements. The DTC grants licences to import and sell to those that have satisfied all requirements specified in the pharmacy and therapeutic products laws. Herbal medicines are sold in outlets other than pharmacies as non-prescription medicines, self-medication or OTC medicines.

Practices, providers, education and health insurance

Indigenous TM and other T&CM practices are used by the population in Tuvalu. The general percentages of use are not known, but in 2015 it was reported that 3.6% of the studied population had seen a traditional healer for raised blood pressure and 6.0% of the population was taking herbal or traditional remedies. T&CM providers practise in the private sector. Indigenous TM providers and providers of T&CM services such as chiropractic, herbal medicines and osteopathy are found in Tuvalu, but their numbers are unknown.

148. Vanuatu

Vanuatu did not reply to the second survey but provided a voluntary update of the T&CM situation as at 2018.

There is no significant update to the T&CM landscape in Vanuatu. There is not yet a national policy on T&CM, and there is no regulation of herbal medicines or T&CM practitioners.

149. Viet Nam

National policy on T&CM

Viet Nam's national policy on T&CM was issued in 2003 and was applicable up to 2010. The Traditional Medicine Department (established in 1957) under the MoH acts as the national regulatory body. The National Institute of Medicinal Materials is a comprehensive research agency for medicinal materials in Viet Nam.

Regulatory status of herbal medicines

As at 2018, the MoH (Administration of Traditional Medicine) and National Institute of Drug Quality Control have strengthened consideration of issues relating to the quality of T&CM medicines.

Regulations on medical examination and treatment with TM were updated in the law on medical examination and treatment in 2009, and regulation on TM was updated in the pharmaceutical law in 2016. Regulations on herbal medicines and traditional medicines were updated in 2016, 2017 and 2018.

Herbal medicines are categorized as non-prescription medicines and functional foods. They are sold with medical, health and nutrient-related claims.

On 28 November 2017, the MoH officially published the fifth edition of the Vietnamese pharmacopoeia, comprising 1519 national drug standards, including 372 standards on medicinal materials and traditional medicines. This became legally binding on 1 July 2018.

On 12 May 2017, the Minister of Science and Technology announced 25 national standards of post-processing medicinal materials.

In addition, Vietnamese law allows reference to other countries' pharmacopoeias, including the national pharmacopoeias of China, Hong Kong, Japan and Korea.

On 21 December 2017, the MoH issued Circular 45/2011/TT-BYT on the application of GMP to regulations on herbal and traditional medicines, applying the principles of GMP to the manufacture of drugs, according to WHO recommendations and separate regulations on GMP, and providing principles to ensure compliance.

Safety requirements for herbal medicines are similar to those of conventional pharmaceuticals; for example, a herbal medicine product may be compared with safety data in scientific studies on similar products. There are 1500 herbal medicines registered. The list of traditional medicines and essential herbal materials in 2013 includes 186 herbal medicines and 334 traditional remedies (herbal remedies); selection for inclusion is based on the experience of long-term use of traditional medicines. Herbal medicines are sold at pharmacies as prescription medicines and non-prescription medicines.

Practices, providers, education and health insurance

There are no concrete statistics on the number of T&CM practitioners in Viet Nam.

The private practice of traditional medicine is governed under legislation on private medical and pharmaceutical practice (1993), and on medical examination and treatment by traditional medicine and acupuncture (2009). Decrees and circulars implementing the law on medical examination and treatment were updated in 2010, 2011, 2015, 2016, 2017 and 2018.

Regulations on practitioners of traditional medicines were most recently updated in 2016 and 2017.

Authorized state management agencies issue medical practice licences to individuals, and issue operation licences to state and private health facilities, professional associations and charity health care establishments.

Training in T&CM topics is available in bachelor's, master's and doctoral degrees, and for specialized doctors (grade 2) and technicians. According to data from the MoH (Administration of Traditional Medicine), the number of traditional medicine doctors increased from 600 in 2013 to 800 in 2017. The Government also recognizes certified training programmes in traditional medicines.

According to 2010 data from the MoH (Administration of Traditional Medicine), it is estimated that there were 1388 indigenous TM providers in Viet Nam and about 11 589 providers of other T&CM practices, of which 2094 were providers of herbal medicine.

Medical examination and treatment with traditional medicine is covered by health insurance as follows: medical examination and treatment with medicinal herbs and traditional remedies included in the list of medicines to be paid by the health insurance, and acupuncture and massage acupressure when combined with modern medicine.

5.7 Other territories

Territories that are not Member States, but that replied to the update survey are the following United Kingdom Overseas Territories:

- Bermuda: does not have a national policy, law, programme or office for T&CM. There is no regulation for practice or providers, and no allocation of government funding for research in this field. There is no regulation of herbal medicines, and such medicines are not registered. However, both public and private health insurance is available for some T&CM services.
- Cayman Islands: has no national policy, law, practice regulation or programme for TM. Regulations for T&CM providers are currently being developed. Under Schedule 6 of the Health Practice Law (2017 Revision), the following professions are registerable and regulated by the Council for Professions Allied with Medicine: acupuncturists, homeopaths, medical herbalists, massage therapists and naturopathic doctors. T&CM services are reimbursed by private health insurance.
- Turks and Caicos Islands: does not have a national policy, law, programme or office for T&CM. There is no regulation for T&CM practice or providers, and no allocation of government funding for research in this field. There is no regulation of herbal medicines, and such medicines are not registered. T&CM services are not reimbursed by private health insurance.

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ANNEX 1.

TEXT OF THE SECOND WHO GLOBAL SURVEY ON T&CM, (2010-2012)

The Second WHO Global Survey on National Policy and Regulation for Traditional and Complementary/ Alternative Medicine	
Date	
Country	
Name of Respondent(s)	
Title of Respondent(s)	
Address for primary contact	
Telephone for primary contact	
Fax for primary contact	
Telephone for primary contact	

INSTRUCTIONS

Some participants reported that they were unsure of how to reply to the questions of the first survey. Therefore, we are providing instructions on how to complete this new survey.

Always begin each section by thoroughly reading the definitions and explanations provided. These definitions are provided to facilitate consistent understanding of the questions. These definitions and explanations may include revised definitions for key words, or clarification for key concepts related to that particular section. Please refer to these definitions and explanations as needed.

In each section and subsection there will be a “main question” numbered 1 to 34 and in bold font. After each “main question”, there may be up to six “secondary questions”. The “secondary questions” may begin with either “If yes,…” or “If no, …”. In these situations, the “secondary question” will be related to your response to the “main question”.

Recognizing that there may not be one single person able to respond to all questions in the survey, we encourage each Member State to seek the person(s) best suited to answer each section and / or subsection. It is possible and acceptable to have a different individual respond to each subsection, or to have it split between a few individuals with the knowledge and authority to correctly and appropriately complete the survey. In the event that several people are responsible for the information in a section, please provide the name and contact information for the person accountable for obtaining the responses.

Development of national policy, law and regulation takes time. Therefore, the questions on these topics are intended to identify at which stage of development the policy, law or regulation is. The process is generally divided into seven stages; please select the relevant number from 1 to 7 that best describes which stage the process is at.

At the beginning of each section, the name and contact e-mail address is requested both for the person who responds to the survey and for the person who verifies that the responses are correct. This process is to ensure that the information gathered is an accurate representation of your national circumstance and to provide us with a contact in the event that further clarification is needed on a response.

If you have any questions, comments, suggestions, or need further clarification on a particular question, please send inquiries to: trmsurvey@who.int with the subject heading “2010 WHO Global Survey on TM/CAM”.

1. NATIONAL POLICY ON TM/CAM

Name of individual completing this section: _____

E-mail address of individual completing this section: _____

Name of individual verifying information provided: _____

E-mail address of individual verifying information provided: _____

Definitions & Explanations:

Traditional Medicine (TM) and Complementary and Alternative Medicine (CAM): “Traditional medicine” is a comprehensive term used to refer to both various forms of indigenous medicine and to TM systems such as traditional Chinese medicine, Indian ayurveda, and Arabic unani medicine. TM/CAM practices include medication based practices—involving the use of herbal medicines, animal parts, and/or minerals—and procedure based practices—carried out primarily without the use of medication, as in the case of acupuncture, manual practices and spiritual therapies. In countries where the dominant health care system is based on allopathic medicine, or where TM has not been incorporated into the national health care system, TM is often termed “complementary”, “alternative” or “non-conventional” medicine.

In the process of being established: To say that something is in the process of being established, it must be true that documents or organizational plans have been drafted, whether completely or only partially, by the relevant government authority, but that final approval has not yet been achieved.

Herbal medicines: Herbal medicines include herbs, herbal materials, herbal preparations, and finished herbal products, that contain as active ingredients parts of plants, plant materials, or combinations thereof.

Source:

WHO Traditional Medicine Strategy 2002-2005.

POLICY

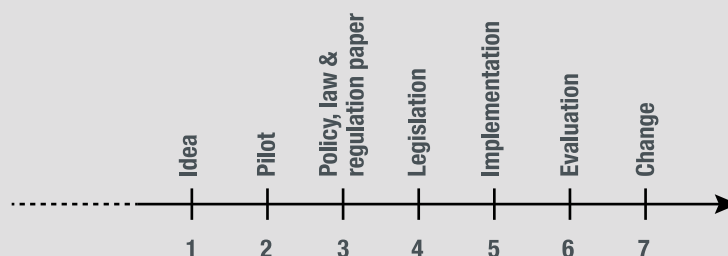
Definitions & Explanations:

Policy: A course of action adopted and pursued by a governing body of a country, such as a government, ruler, political party, etc.

National policy on TM/CAM: Guiding principles regarding policy, planning or future direction of TM/CAM created by the relevant government authority of the country. The national policy on TM/CAM may be a policy designed exclusively for TM/CAM, or it may be integrated into other national policies, such as the national medicines policy, trade policy or other policies.

Contents of a national policy on TM/CAM: In general, the national policy should include a definition of the role of the government in the development of TM/CAM in the health care delivery system. Safety and efficacy may be stated as guiding principles. The policy may also include vision and mission statements as well as goals and objectives of the TM/CAM policy.¹

Development of national policy, law and regulation takes time. Therefore, the questions on these topics are intended to identify at which stage of development the policy, law or regulation is. The process is generally divided into seven stages; please select the relevant number from 1 to 7 that best describes which stage the process is at.



Idea: refers to new and newly raised approaches voiced or discussed in different forums. Idea could also mean “early stage”

Pilot: characterizes any innovation or model experiment implemented at a local or institutional level.

Policy, law and regulatory paper: means any formal written statement or policy paper short of a draft bill.

Legislation: covers all steps of the legislative process.

1. Is there a national policy on TM/CAM? YES ☐ NO ☐

1.1. If yes, how was this policy written?

- ☐ Exclusive national policy on TM/CAM.
- ☐ Integrated into other national policy, please describe: _____
- ☐ Other, please describe: _____

1.2. If yes, title of policy document: _____

1.3. If yes, year of issue: _____ and at which stage? _____

Please submit a copy of the policy or the relevant section of the policy document, in English if available, otherwise in original language.

1.4. If no, is such a policy in the process of being established? YES ☐ NO ☐

LAW AND REGULATION

Definitions & Explanations:

Law: 1. A rule of conduct or procedure established by custom, agreement or authority. 2. A set of rules or principles for a specific area of a legal system. 3. A piece of enacted legislation.¹

Law on TM/CAM: A set of rules concerning areas of TM/CAM. These rules are established by an authority, usually the government and advisory committees, and are enforced by the judicial and legal systems of that country. The laws can cover a wide range of topics such as education of professionals, licensing of providers or manufacturers, sale of herbal medicines, and so forth.

Regulation: A principle, rule or law designed to control or govern conduct.²

Regulation on TM/CAM: A set of rules that specifically governs the conduct of the above-mentioned wide range of topics related TM/CAM.

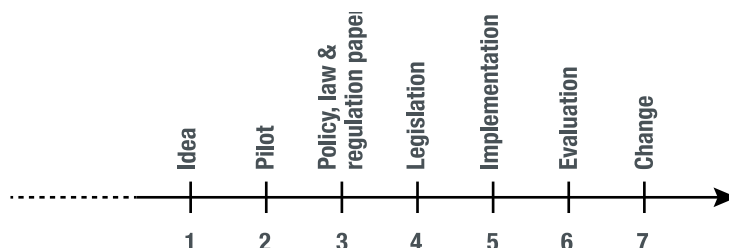
Therefore, the questions on these topics are intended to identify at which stage of development the policy, law or regulation is. The process is generally divided into seven stages; please select the relevant number from 1 to 7 that best describes which stage the process is at.

Sources:

1. "law" The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. 09 July 2007. <Dictionary.com <http://dictionary.reference.com/browse/law>>.
2. "regulation" The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. 09 July 2007. <Dictionary.com <http://dictionary.reference.com/browse/regulation>>.

2. Is there a national law on TM/CAM? YES ☐ NO ☐

2.1. If yes, year of issue: _____ and at which stage? _____



Please submit a copy of the law, in English if available, otherwise in original language.

2.2. If no, is such a law in the process of being established? YES ☐ NO ☐

3. Is there a national regulation on TM/CAM? YES ☐ NO ☐

3.1. If yes, year of most recent regulation or update: _____

Please submit a copy of the regulation, in English if available, otherwise in original language.

3.2. If no, is such a regulation in the process of being established? YES ☐ NO ☐

NATIONAL PROGRAMME

Definitions & Explanations:

National Programme on TM/CAM: Any programme performed on the local or national level by the ministry of health, by other ministries or by local government bodies, whose mandate is to take concrete action in order to achieve the objectives outlined in the national TM/CAM policy.

4. Is there a national programme on TM/CAM? YES ☐ NO ☐

4.1. If yes, year of establishment: _____

Please submit a copy of a description of the programme, in English if available, otherwise in original language.

4.2. If no, is such a programme in the process of being established? YES ☐ NO ☐

NATIONAL TM/CAM OFFICE

Definitions & Explanations:

National TM/CAM Office: Any government sponsored office that is officially mandated and in charge of issues related to TM/CAM. This office may be located in the ministry of health or other relevant national agency.

5. Is there a TM/CAM national office? YES ☐ NO ☐

5.1. If yes, year of establishment: _____

Please provide the contact address for the national office.

5.2. If yes, under which ministry or government authority is it administered?

☐ Ministry of health.

☐ Other ministry, please identify: _____

☐ Other government authority, please describe _____

5.3. If no, did such an office exist previously? YES ☐ NO ☐

5.4. If no, is such an office in the process of being established? YES ☐ NO ☐

NATIONAL EXPERT COMMITTEE

6. Is there a national expert committee for TM/CAM? YES ☐ NO ☐

6.1. If yes, year of establishment: _____

6.2. If no, is such an committee in the process of being established? YES ☐ NO ☐

NATIONAL RESEARCH INSTITUTE

Definitions & Explanations:

National Research Institute on TM/CAM: A national research institute on TM/CAM that is either fully or partially funded by the government.

7. Is there a national research institute for TM/CAM? YES ☐ NO ☐

7.1. If yes, year of establishment: _____

Please provide the contact address for the national research institute(s).

7.2. If no, is such an institute in the process of being established? YES ☐ NO ☐

2. REGULATORY SITUATION OF HERBAL MEDICINES

Name of individual completing this section: _____

E-mail address of individual completing this section: _____

Name of individual verifying information provided: _____

E-mail address of individual verifying information provided: _____

Definitions & Explanations:

Herbal medicines are an important and widely used therapy intervention and are incorporated into many TM/CAM practices. Because of this, Section 2 seeks to gather additional information more specific to herbal medicines in addition to the general TM/CAM information collected in Section 1.

Herbal Medicines: Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, other plant materials or combinations thereof. In some countries herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials).¹

Regulation of herbal medicines: A principle, rule or law designed to control or govern manufactures and producers of herbal medicine.² For example, a regulation would state that herbal medicines must have been proven to be safe, effective and of good quality before reaching the public.

Conventional Pharmaceuticals: Conventional pharmaceuticals are here defined as medicinal drugs used in conventional systems of medicine with the intention to treat or prevent disease, or to restore, correct or modify physiological function.³

Source:

1. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems, WHO Geneva 2004, page 6.
2. "regulation" The American Heritage® Dictionary of the English Language, Fourth Edition. Houghton Mifflin Company, 2004. 09 July 2007. <Dictionary.com <http://dictionary.reference.com/browse/regulation>>.
3. Dorlands Illustrated Medical Dictionary, 29th edition, 2000.

REGULATION

8. Is there national regulation on herbal medicines? YES ☐ NO ☐

8.1. If yes, year of issue: _____ and at which stage? _____

8.2. If yes, please select the type of regulation on herbal medicines.
Check all that apply.

- ☐ Same regulation as for conventional pharmaceuticals
- ☐ Exclusive regulation for herbal medicines
- ☐ The regulation for herbal medicines is partly the same as for conventional pharmaceuticals, please describe: _____
- ☐ Other, please describe: _____

8.3. If yes, title of regulation document: _____ and at which stage? _____

Please submit a copy of the regulation, in English if available, otherwise in original language.

REGULATORY STATUS

Definitions & Explanations:

Medicines, including herbal medicines, may be categorized under any of the definitions below, or others. These categories are for data collection purposes only, and are not intended to be comprehensive.

Regulatory Status: A legislative procedure designed to provide the procedure under which to administer a law or procedure. Regulations may include things such as descriptions or obligations for products or producers, or the title a product must use.

Prescription Medicines: Medicines/drugs which can only be purchased with a prescription or a physician's order.¹

Non-prescription Medicines: Medicines/drugs which can be purchased without a prescription or a physician's order, often at a pharmacy. The definition of "non-prescription medicines" may also often include the terms "self-medication" and/or "over-the-counter (OTC)" medicines.²

Dietary Supplements: A dietary supplement could be intended to supplement the diet and will contain, for instance, a vitamin, a mineral, a herb, a botanical or an amino acid. A dietary supplement might also be intended to supplement the diet by increasing the total daily intake of a concentrate, a metabolite, a constituent, an extract or a combination of these ingredients.

Health Foods (including functional foods): Any natural food popularly believed to promote or sustain good health by containing vital nutrients.³ Functional foods also include any foodstuff enhanced by additives and marketed as beneficial to health or longevity. Examples include cereals, breads or beverages which are fortified with vitamins and herbs.⁴ Health foods and/or functional foods may be advertised or marketed with specific health claims and may therefore be regulated differently than other foods.

Note: Definitions for the above terms may differ among nations. For example, in one country garlic extract may be regulated as a dietary supplement while in another country it may be regulated as a health food. Therefore, please use these definitions as reference only.

Sources:

1. Dorlands Illustrated Medical Dictionary, 29th ed, 2000.
2. World Self-Medication Industry, 2009. <http://www.wsmi.org/aboutsm.htm>
3. "health food." *Dictionary.com Unabridged* (v 1.1). Random House, Inc. 09 Jul. 2007. <Dictionary.com [http://dictionary.reference.com/browse/health food](http://dictionary.reference.com/browse/health%20food)>.
4. "functional food." Webster's New Millennium TM Dictionary of English. Preview Edition (v 0.9.7). Lexico Publishing Group, LLC. 09 Jul.2007. <Dictionary.com [http://dictionary.reference.com/browse/functional food](http://dictionary.reference.com/browse/functional%20food)>.

9. Is regulatory status given to herbal medicines? YES ☐ NO ☐

9.1. If yes, what regulatory status is given to herbal medicines?

Please check all that apply.

- ☐ Regulated as prescription medicines.
- ☐ Regulated as non-prescription medicines.
- ☐ Regulated as herbal medicines.
- ☐ Regulated as dietary supplements.
- ☐ Regulated as health foods.
- ☐ Regulated as functional foods.
- ☐ Regulated as general food products.
- ☐ Other, please describe: _____

9.2. If available, please submit your national definition of these terms, even if they are different than the definitions used in this survey, if these terms are used in your country:

Prescription medicines: _____

Non-prescription medicines: _____

Self-medications: _____

Over the Counter (OTC) medicines: _____

Dietary supplements: _____

Health foods: _____

Functional foods: _____

Other, please describe: _____

CLAIMS

Definitions & Explanations:

Medical Claims: Medical claims are here defined as those claims specified to treat, cure or prevent a disease or restore, correct or modify physiological functions. Frequently, products with medical claims have to be registered by the medical products agency before being allowed onto the market.¹

Example: This herbal medicine will treat cough or will treat influenza.

Health Claims: Health claims could, for instance, include “any statement, suggestion, or implication in labelling or advertising that a product carries a specific health benefit, but not nutritional claims nor medical claims. The term ‘health claims’ further includes claims which refer to nutrient function and recommended dietary practice.”²

Example: This herbal medicine will give you more energy.

Nutrient Content Claims: Nutrient content claims, for instance, indicate that a certain product is particularly rich or low in a nutritional component such as fibre or fat².

Example: This herbal medicine contains a high amount of fibre.

Sources

1. Joint Health Claims Initiative Body- www.jhci.co.uk 2001-12-12.
2. Swedish Food Administration- www.slv.se/download/document/approveddocs/funrapp0601.pdf, 2001-12-12.

10. Are herbal medicines sold with any type of claims in your country? YES ☐ NO ☐

10.1. If yes, with which type of claims are herbal medicines sold in your country?

Please check all that apply.

- ☐ Medical claims.
- ☐ Health claims.
- ☐ Nutrient content claims.
- ☐ Claims are made, but are unregulated by law.
- ☐ Other claims, please describe:

PHARMACOPOEIA

Definitions & Explanations:

National Pharmacopoeia: A formulary, usually having legal force in all pharmacies of a given country, containing a description of drugs in current medical practice and noting their formulae, analytical composition if known, physical constants, main chemical properties useful in identification and mode of preparation of compound / combination products. Details may also include specifications of assay methods to regulate purity, content of active constituents, preservation of quality, and, where appropriate, biological potency.

Source:

Churchill Medical Dictionary, 1989.

11. Is there a national pharmacopoeia including herbal medicines? YES ☐ NO ☐

11.1. If yes, please provide the following information:

Title: _____

Edition number: _____

Year of issue: _____

Title: _____

Edition number: _____

Year of issue: _____

Title: _____

Edition number: _____

Year of issue: _____

*Please submit a copy of the pharmacopoeia, in English if available, otherwise in original language.
If several pharmacopoeias exist including herbal products, please submit information about all.*

11.2. If yes, is the information in the pharmacopoeia legally binding? YES ☐ NO ☐

11.3. If no, is a national pharmacopoeia including herbal medicines in the process of being established? YES ☐ NO ☐

12. Is there any other pharmacopoeia used in your country? YES ☐ NO ☐

12.1. If yes, please provide the following information:

Title: _____

Edition number: _____

Year of issue: _____

Title: _____

Edition number: _____

Year of issue: _____

Title: _____

Edition number: _____

Year of issue: _____

12.2. If yes, is the information in the pharmacopoeia legally binding? YES ☐ NO ☐

MONOGRAPHS

Definitions & Explanations:

Monographs on herbal products: Descriptions of different herbal medicinal formulae which can either be included in a pharmacopoeia or exist separately.

13. Are there national monographs on herbal medicines? YES ☐ NO ☐

13.1. If yes, please provide the following information:

Title: _____

Edition number: _____

Year of issue: _____

Number of monographs issued: _____

Title: _____

Edition number: _____

Year of issue: _____

Number of monographs issued: _____

Title: _____

Edition number: _____

Year of issue: _____

Number of monographs issued: _____

Please submit a copy of the monograph(s), in English if available, otherwise in original language.

13.2. If yes, is the information in the monographs legally binding? YES ☐ NO ☐

13.3. If no, are national herbal monographs in the process of being established? YES ☐ NO ☐

14. Are any other monographs used in your country? YES ☐ NO ☐

14.1. If yes, please provide the following information:

Title: _____

Edition number: _____

Year of issue: _____

Number of monographs issued: _____

Title: _____

Edition number: _____

Year of issue: _____

Number of monographs issued: _____

Title: _____

Edition number: _____

Year of issue: _____

Number of monographs issued: _____

14.2. If yes, is the information in the monographs legally binding? YES ☐ NO ☐

MANUFACTURING

Definitions & Explanations:

Good Manufacturing Practices (GMP): Codes of practice designed to reduce to a minimum the chance of procedural or instrument/manufacturing plant problems that could adversely affect a manufactured product.¹

GMP specifies many requirements for quality control of starting materials, including correct identification of species of medicinal plants, special storage and special sanitation and cleaning methods for various materials.²

Sources:

1. Food and Agricultural Organization of the United Nations, Glossary, <http://www.fao.org/glossary>.
2. National Policy on Traditional Medicine and Regulation of Herbal Medicines, Report of a WHO Global Survey, WHO, page iii.

15. Do GMP exist for herbal medicines? YES ☐ NO ☐

15.1. If yes, please provide the following information:

Title: _____

Year of issue: _____

*Please submit a copy of the GMP documentation,
in English if available, otherwise in original language.*

15.2. If no, are GMP for herbal medicines in the process of being established? YES ☐ NO ☐

16. What regulations apply to the manufacturing of herbal medicines to ensure their quality? Please check all that apply.

- ☐ Adherence to manufacturing information in pharmacopoeia/monographs.
- ☐ Same regulations for GMP as for conventional pharmaceuticals.
- ☐ Exclusive regulations for GMP, separate from conventional pharmaceuticals. Please describe these regulations. How are they different? Are they geared specifically toward herbal medicines?

☐ No regulations.

☐ Other, please describe: _____

Please submit a copy of the regulations for manufacturing herbal medicines, in English if available, otherwise in original language.

17. Are there mechanisms in place to ensure compliance with these or other manufacturing requirements? YES ☐ NO ☐

17.1. If yes, how is compliance ensured? For example, if your country has GMP rules, how do you ensure that a manufacturer is following the rules of GMP? Please check all that apply.

- ☐ Periodic inspections by authorities at the manufacturing plants or laboratories.
- ☐ Manufacturers are required to submit samples of their medicines to a government approved laboratory for testing.
- ☐ Manufacturers are required to assign a person(s) to the role of ensuring compliance with manufacturing requirements. This person(s) reports back to government authorities.
- ☐ Others, please describe:

SAFETY

18. What are the regulatory requirements for the safety assessment of herbal medicines? Please check all that apply.

- ☐ Same safety requirements as for conventional pharmaceuticals.
- ☐ Exclusive safety requirements for herbal medicines. Please describe how the safety requirements differ from the requirements for conventional pharmaceuticals:

- ☐ Traditional use without demonstrated harmful effects is sufficient.
- ☐ Reference to safety data in documented scientific research on similar products is sufficient.
- ☐ Other safety requirements, please describe: _____
- ☐ No safety requirements currently exist.

REGISTRATION

19. Is there a registration system for herbal medicines? YES ☐ NO ☐

19.1. If yes, how many herbal medicines are registered? _____

Please submit a list of registered herbal medicines.

19.2. If no, is such a registration system in the process of being established? YES ☐ NO ☐

ESSENTIAL MEDICINES LIST

Definitions & Explanations:

Essential medicines: Those medicines that satisfy the priority health care needs of the population.

Sources:

WHO definition, http://www.who.int/medicines/services/essmedicines_def/en/.

20. Does your country have a national essential medicines list? YES ☐ NO ☐

20.1. If yes, year of issue of the national essential medicines list:

Please submit a copy of the national essential medicines list.

21. Does your country have a national essential medicines list including herbal medicines? YES ☐ NO ☐

21.1. If yes, in what year were herbal medicines first included in the national essential medicines list?

21.2. If yes, how many herbal medicines are included in the national essential medicines list?

21.3. If yes, do you have a criteria for selection of herbal medicines for the national essential medicines list? YES ☐ NO ☐

21.4. If your country has a national essential medicines list including herbal medicines, please indicate your criteria for selection. Please check all that apply:

☐ Based on traditional use of the herbal medicine.

☐ Based on clinical data.

☐ Based on long term, historical use.

☐ Based on laboratory testing.

☐ Other, please describe: _____

POST-MARKETING SURVEILLANCE

Definitions & Explanations:

Post-Market Surveillance System: To monitor the ongoing safety of products (drugs, devices) in the market.¹ Post-market surveillance requires manufacturers, importers, and distributors to keep distribution records and to have written procedures to handle complaints and investigate them, and to recall defective products from the market.²

Sources:

1. <http://www.fda.gov/cder/handbook/postmark.htm>.

2. WHO, International Digest of Health Legislation, Canada Gazette, Part II, Vol. 132, No.11, 27 May 1998, pp. 1625-1698.

22. Is there a post-market surveillance system for safety of medicines in your country?

YES ☐ NO ☐

22.1. If yes, year of establishment: _____

22.2. If no, is such a system in the process of being established? YES ☐ NO ☐

23. Is there a post-market surveillance system for safety of medicines which includes herbal medicines? YES ☐ NO ☐

23.1. If yes, in what year did the post-market surveillance of the safety of herbal medicines first begin?

23.2. If no, is the inclusion of herbal medicines in the national post-market surveillance system in the process of being established? YES ☐ NO ☐

MARKET

24. How are herbal medicines sold? Please check all that apply.

- ☐ In pharmacies as prescription medicines.
- ☐ In pharmacies as non-prescription medicines, self-medication, or over-the-counter medicines.
- ☐ In other outlets as non-prescription medicines, self-medication, or over-the-counter medicines.
- ☐ In special outlets (for example, in herbal medicines stores, TM/CAM supply stores, etc).
- ☐ By licensed practitioners.
- ☐ No restrictions for selling herbal products.
- ☐ Other, please describe: _____

25. What are the annual market sales for herbal medicines?

Please fill in data or market estimates from the last three years. Also, please describe the source of the data/estimates, for example, “data published by Ministry of Health”, “estimate made by herbal manufacturers” or “scientific study”. Estimates should be in the format of currency equivalent, not inventory of product sold, for instance “\$10,000 USD” not “100 bottles of tablets”.

Year	Total market sales of herbal medicines	Source of data/estimate
2007		
2008		
2009		

Source of data _____

Year of issue _____

If available, please provide sales data on prescription medicines, non-prescription medicines, and dietary supplements. Estimates should be in the format of currency equivalent, not inventory of product sold.

Year	Total market sales of Prescription Medicines	Source of data/estimate
2007		
2008		
2009		

Year	Total market sales of non-prescription medicines, not including herbal medicines reported above	Source of data/estimate
2007		
2008		
2009		

Year	Total Market Sales of Dietary Supplements	Source of data/estimate
2007		
2008		
2009		

Source of data _____

Year of issue _____

3. PRACTICE, PROVIDERS, EDUCATION AND HEALTH INSURANCE

Name of individual completing this section: _____

E-mail address of individual completing this section: _____

Name of individual verifying information provided: _____

E-mail address of individual verifying information provided: _____

TM/CAM PRACTICES

Definitions & Explanations:

The term “traditional medicine” may vary from country to country and region to region. The following explanation of the terms “traditional medicine” and “complementary/ alternative medicine” are only to facilitate consistent understanding of the questions by the respondents.

Indigenous traditional medicine: The total summary of knowledge and practices, whether explicable or not, used in diagnosing, preventing or eliminating physical, mental or social diseases. This knowledge or practice may rely exclusively on past experience and observation handed down from generation to generation, verbally or in writing. These practices are native to the country in which they are practiced. The majority of *indigenous traditional medicine* has been practiced at the primary health care level.

Traditional or complementary/alternative medicine (TM/CAM) systems: Traditional medicine and complementary/alternative medicine systems have been defined as those which have their own unique, independent and comprehensive theory, diagnosis, treatment and practice, such as traditional Chinese medicine, ayurveda, unani and others. Some of these have been more recently adopted into other cultures and are now practiced outside of their countries of origin, though they may be considered “CAM”. Other systems, such as chiropractic, homeopathy, and naturopathy, evolved following the development of modern medicine and are also now practiced internationally. These therapies may also be considered “CAM”

Note: If there is a commonly used technique (medication therapy or procedure-based practice) that is not listed, please describe the practice in the “Other” option. Furthermore, a technique may also fit into more than one category, such as in both indigenous traditional medicine and TM/CAM. This attempts to capture information regarding the more dominant TM/CAM practices. This classification is for data collection purposes and is not intended to be definitive or comprehensive.

26. Is the use of indigenous traditional medicine important in your country? YES ☐ NO ☐

26.1. If yes, what percentage of the population uses indigenous traditional medicine:

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

27. Is traditional or complementary/alternative medicine used in your country? YES ☐ NO ☐

27.1. If yes, what percentage of the population uses the following types of traditional or complementary/alternative medicine?

Acupuncture

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Ayurvedic medicine

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Chiropractic

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Herbal medicines

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Homeopathy

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Naturopathy

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Osteopathy

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Traditional Chinese medicine

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Unani medicine

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

Other, please describe:

- ☐ Unknown / Data not available
- ☐ 100%
- ☐ between 80% and 99%
- ☐ between 60% and 79%
- ☐ between 40% and 59%
- ☐ between 20% and 39%
- ☐ between 1% and 19%
- ☐ 0%

Source of data _____

Year of issue _____

TM/CAM PRACTICES

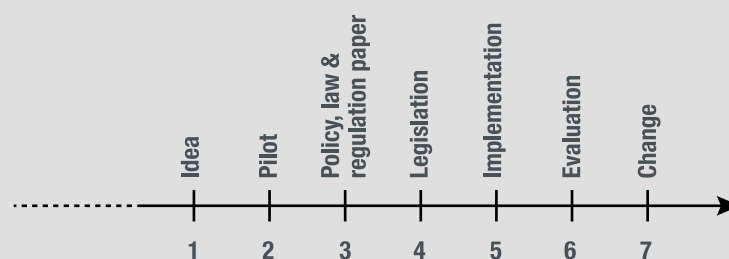
Definitions & Explanations:

Indigenous traditional medicine providers: Generally understood to include those who practice indigenous traditional medicine, such as traditional healers, bone setters, herbalists, traditional birth attendants, etc. Usually, the majority of these practitioners have been practicing at the primary health care level.

TM/CAM providers: Includes both TM/CAM practitioners, allopathic medicine professionals and healthcare workers such as doctors, dentists, nurses, midwives, pharmacists and physical therapists who provide TM/CAM services to their patients (e.g., medical doctors who use acupuncture to treat their patients, or traditional Chinese medicine doctors who provide services in clinics and hospitals).

TM/CAM License or Certificate: The documentation of the authority of a TM/CAM provider to practice TM/CAM within a defined locality.

Therefore, the questions on these topics are intended to identify at which stage of development the policy, law or regulation is. The process is generally divided into seven stages; please select the relevant number from 1 to 7 that best describes which stage the process is at.



Idea: refers to new and newly raised approaches voiced or discussed in different forums. Idea could also mean “early stage”

Pilot: characterizes any innovation or model experiment implemented at a local or institutional level.

Policy, law and regulatory paper: means any formal written statement or policy paper short of a draft bill.

Legislation: covers all steps of the legislative process.

Implementation: this stage is about all measures taken toward legal and professional implementation and adoption of a policy.

Evaluation: refers to all health policy issues scrutinized for their impact during the period observed.

Change: may be a result of evaluation or abandonment of development.¹

Source:

1. Health Policy Developments 13, pg 126, in 2009, www.HealthPolicyMonitor.org.

28. Are there any regulations on indigenous traditional medicine providers? YES ☐ NO ☐

28.1. If yes, year of issue _____ and at which stage? _____

Please submit a copy of the regulation(s), in English if available, otherwise in original language.

28.2. If yes, at which level are the regulations enforced?

- | | |
|--|-----------------------|
| ☐ National level | at which stage? _____ |
| ☐ State or province level | at which stage? _____ |
| ☐ City or county level | at which stage? _____ |
| ☐ Community or village level | at which stage? _____ |
| ☐ Other, please describe: _____ | |

29. Are there any regulations on TM/CAM providers? YES ☐ NO ☐

29.1. If yes, please select the specific TM/CAM providers to which the regulations apply. Please check all that apply. Please include year of issue.

- | | |
|---|---|
| ☐ Regulation on acupuncture providers | year of issue _____ and at which stage? _____ |
| ☐ Regulation on Ayurvedic medicine providers | year of issue _____ and at which stage? _____ |
| ☐ Regulation on chiropractic providers | year of issue _____ and at which stage? _____ |
| ☐ Regulation on herbal medicines providers | year of issue _____ and at which stage? _____ |
| ☐ Regulation on homeopathic medicine providers | year of issue _____ and at which stage? _____ |
| ☐ Regulation on naturopathic medicine providers | year of issue _____ and at which stage? _____ |
| ☐ Regulation on osteopathic providers | year of issue _____ and at which stage? _____ |
| ☐ Regulation on traditional Chinese medicine providers | year of issue _____ and at which stage? _____ |
| ☐ Regulation on Unani medicine providers | year of issue _____ and at which stage? _____ |
| ☐ Others, please describe, including | year of issue _____ and at which stage? _____ |

Please submit a copy of the regulation(s), in English if available, otherwise in original language.

29.2. If yes, at which level are the regulations enforced?

- ☐ National level at which stage? _____
☐ State or province level at which stage? _____
☐ City or county level at which stage? _____
☐ Community or village level at which stage? _____
☐ Other, please describe: _____

29.3. Are any regulations in the process of being established? Please check all that apply.

- ☐ Regulation on acupuncture providers at which stage? _____
☐ Regulation on Ayurvedic medicine providers at which stage? _____
☐ Regulation on chiropractic providers at which stage? _____
☐ Regulation on herbal medicines providers at which stage? _____
☐ Regulation on homeopathic medicine providers at which stage? _____
☐ Regulation on naturopathic medicine providers at which stage? _____
☐ Regulation on osteopathic providers at which stage? _____
☐ Regulation on traditional Chinese medicine providers at which stage? _____
☐ Regulation on Unani medicine providers at which stage? _____
☐ Others, please describe: _____

29.4. If more specific regulations are in the process of being established, please describe:

30. TM/CAM providers practice in which of the following settings? Please check all that apply.

- ☐ Private sector: ☐ clinic ☐ hospital
☐ Public sector: ☐ clinic ☐ hospital
☐ Other: please describe: _____

31. Is a TM/CAM license or certificate required for practice? YES ☐ NO ☐**31.1. If yes, by whom is the license or certificate issued?**

- ☐ National government
☐ State or province government
☐ City or county government
☐ Community or village government
☐ Relevant academic institution
☐ Self-regulation by delegated special technical association
☐ Other, please describe: _____

EDUCATION OF TM/CAM PROVIDERS

32. Is TM/CAM education provided at the university level? YES ☐ NO ☐

32.1. If yes, please provide the type of degree a student of TM/CAM would obtain at the university level. Check all that apply.

- ☐ Bachelor
- ☐ Master
- ☐ PhD _____
- ☐ Clinical doctorate (e.g. DAOM, DC, DO, MD, ND)
- ☐ Other higher education or university degree, please describe:

Please provide the number of students that have received a TM/CAM degree at the university level in the past three years in your country.

Year	Number of Bachelors	Number of Masters	Number of PhDs	Number of Clinical Doctorates	Other
2007					
2008					
2009					

Source of data _____

Year of issue _____

32.2. If no, are there any other TM/CAM training programmes which the government officially recognizes? YES ☐ NO ☐

32.3. If yes, please provide examples of such training programmes. Please check all that apply:

- ☐ Apprenticeship with a TM/CAM provider, without certificate or licensure
- ☐ Certified training programme. (Eg. A specialized training programme for acupuncture where, after completion, the student receives a certificate or license)
- ☐ Training programme for indigenous traditional medicine practitioners
- ☐ Training programme for TM/CAM technicians or equivalent (not at university level)
- ☐ Other, please describe: _____

STATISTICS ON TM/CAM PROVIDERS

Definitions & Explanations:

For explanations of indigenous traditional medicine providers and traditional medicine/complementary or alternative medicine providers, please see textbox on page #213.

33. Do indigenous traditional medicine providers practice within your country?

33.1. If yes, what is the approximate number of indigenous traditional medicine providers?

YES ☐ NO ☐

Source of data _____

Year of issue _____

34. Please indicate if the following types of TM/CAM providers practice within your country and the approximate numbers of each.

- | | |
|---|--------------|
| ☐ Acupuncture providers | number _____ |
| ☐ Ayurveda medicine providers | number _____ |
| ☐ Chiropractic providers | number _____ |
| ☐ Herbal medicines providers | number _____ |
| ☐ Homeopathic medicine providers | number _____ |
| ☐ Naturopathic medicine providers | number _____ |
| ☐ Osteopathic providers | number _____ |
| ☐ Traditional Chinese medicine providers | number _____ |
| ☐ Unani medicine providers | number _____ |
| ☐ Others | number _____ |

please describe: _____

Source of data _____

Year of issue _____

HEALTH INSURANCE AND TM/CAM

Definitions & Explanations:

Health Insurance: Broadly defined to include both public and private payors who cover medical expenditures incurred by a defined population in a variety of settings.

35. Is indigenous traditional medicine covered by health insurance in your country?

YES ☐ NO ☐

35.1. If yes, who provides the health insurance under which indigenous traditional medicine is covered?

Please check all that apply.

☐ Government agency

☐ Private organization

☐ Other, please describe: _____

36. Is TM/CAM covered by health insurance in your country? YES ☐ NO ☐

36.1 If yes, please indicate

☐ Fully

☐ Partially

36.2. If yes, who provides the health insurance under which TM/CAM is covered?

Please check all that apply.

☐ Government agency

☐ Private organization

☐ Other, please describe: _____

36.3. If yes, for which TM/CAM practices is coverage available?

TM/CAM Practices	GOVERNMENT		PRIVATE	
	Full	Partial	Full	Partial
☐ Acupuncture	☐	☐	☐	☐
☐ Ayurvedic medicine	☐	☐	☐	☐
☐ Chiropractic	☐	☐	☐	☐
☐ Herbal medicines	☐	☐	☐	☐
☐ Homeopathic medicines	☐	☐	☐	☐
☐ Naturopathy	☐	☐	☐	☐
☐ Osteopathy	☐	☐	☐	☐
☐ Traditional Chinese medicine	☐	☐	☐	☐
☐ Unani	☐	☐	☐	☐
☐ Other,	☐	☐	☐	☐

please describe: _____

4. MEMBER STATES AND WHO

Name of individual completing this section: _____

E-mail address of individual completing this section: _____

Name of individual verifying information provided: _____

E-mail address of individual verifying information provided: _____

Definitions & Explanations:

WHO wants to learn more about the needs of each Member State and feedback from each country is therefore essential for successful future support from WHO to the Member States.

37. What are the main difficulties faced by your country with regard to regulatory issues related to the practice of TM/CAM? Please check all that apply.

- ☐ Lack of research data
- ☐ Lack of expertise within national health authorities and control agencies
- ☐ Lack of appropriate mechanisms to control and regulate herbal products
- ☐ Lack of appropriate mechanisms to monitor and regulate TM/CAM providers
- ☐ Lack of mechanisms to control and regulate TM/CAM advertising and claims
- ☐ Lack of education and training for TM/CAM providers
- ☐ Lack of mechanisms to monitor safety of TM/CAM practice
- ☐ Lack of mechanisms to monitor safety of TM/CAM products, including herbal medicines
- ☐ Lack of cooperation channels between national health authorities to share information about TM/CAM
- ☐ Lack of financial support for research on TM/CAM
- ☐ Other, please describe: _____

38. What type of support for TM/CAM issues is your country interested in receiving from WHO?
Please prioritize the options below.

	Great Need	Some Need	No Need
Information sharing on regulatory issues	☐	☐	☐
Seminar/workshop on developing national policy and programmes for TM/CAM	☐	☐	☐
Seminar/workshop about national capacity to establish regulations for herbal medicines	☐	☐	☐
Seminar/workshop about national capacity to establish regulations on TM/CAM practice	☐	☐	☐
Seminar/workshop about national capacity building on safety monitoring of herbal medicines	☐	☐	☐
Seminar/workshop about integration of TM/CAM in the primary health care context	☐	☐	☐
General technical guidance for research and evaluation of TM/CAM related to safety, quality and efficacy	☐	☐	☐
Provision of research databases	☐	☐	☐
Provision of cooperation channels between national health authorities	☐	☐	☐
Provision of guidance on self-care, information for the public in primary health care or at the community level	☐	☐	☐
Provision of technical support to promote safe and effective use of indigenous traditional medicine in Primary Health Care	☐	☐	☐
Provision of guidelines or minimum requirements for basic training of TM/CAM providers	☐	☐	☐
Arrangement of global meetings	☐	☐	☐
Other, please describe: _____			

39. In what way would you like WHO to present the results from this survey.
Please check all that apply.

As a descriptive report	☐
As a condensed report with results presented in figures/tables	☐
Results/analysis presented in a database	☐

Other suggestions or comments: _____

ANNEX 2.

REGIONAL BREAKDOWN OF THE MEMBER STATES THAT RESPONDED TO THE SECOND WHO GLOBAL SURVEY ON T&CM, 2012

African Region	Region of the Americas	Eastern Mediterranean region	European Region	South-East Asia Region	Western Pacific Region
Benin	Argentina	Afghanistan	Albania	Bangladesh	Australia
Burkina Faso	Barbados	Bahrain	Andorra	Bhutan	Brunei Darussalam
Burundi	Bolivia	Iran (Islamic Republic of)	Armenia	Democratic People's Republic of Korea	Cambodia
Cameroon	Brazil	Iraq	Austria	India	China, People's Republic of
Central African Republic	Canada	Jordan	Azerbaijan	Indonesia	Fiji
Chad	Chile	Kuwait	Belarus	Maldives	Japan
Comoros	Colombia	Morocco	Belgium	Myanmar	Kiribati
Congo	Costa Rica	Oman	Bosnia and Herzegovina	Nepal	Lao People's Democratic Republic
Côte d'Ivoire	Cuba	Pakistan	Croatia	Sri Lanka	Malaysia
Democratic Republic of the Congo	El Salvador	Qatar	Cyprus	Thailand	Marshall Islands
Equatorial Guinea	Grenada	Saudi Arabia	Czech Republic		Micronesia (Federated States of)
Eritrea	Honduras	Somalia	Denmark		Mongolia
Ethiopia	Mexico	Sudan	Estonia		Nauru
Gabon	Panama	Syrian Arab Republic	Finland		New Zealand
Gambia	Paraguay	Tunisia	Germany		Palau (Republic of)
Ghana	Peru	United Arab Emirates	Hungary		Papua New Guinea
Guinea-Bissau	Saint Lucia	Yemen	Iceland		Philippines
Liberia	Saint Vincent and the Grenadines		Ireland		Republic of Korea
	Trinidad and Tobago				
Madagascar			Israel		Singapore
Mali			Lithuania		Solomon Islands

Mozambique			Malta		Tonga
Namibia			Montenegro		Tuvalu
Niger			Netherlands		Viet Nam
Sao Tome and Principe			Norway		
Senegal			Poland		
South Africa			Portugal		
Uganda			Republic of Moldova		
United Republic of Tanzania			Romania		
			Serbia		
			Slovakia		
			Slovenia		
			Spain		
			Sweden		
			Switzerland		
			Turkey		
			Ukraine		
			United Kingdom of Great Britain and Northern Ireland		

ANNEX 3.

TEXT OF THE UPDATE SURVEY ON T&CM, 2016

T&CM: Traditional and Complementary Medicine

Please answer these questions based on the T&CM situation in your country.

Q1. As of the end of 2016, do you have:

a. National policy and law on T&CM:

(Yes/No) _____

Year of most recent update _____

b. Regulation on T&CM practice:

(Yes/No) _____

Year of most recent update _____

c. National office and programme on T&CM:

(Yes/No) _____

Year of establishment _____

d. National expert committee and research institute on T&CM:

(Yes/No) _____

Year of establishment _____

e. Governmental/public research funding for T&CM:

(Yes/No) _____

<i>Governmental/public research funding for T&CM (in US\$)</i>						
2010	2011	2012	2013	2014	2015	2016

f. National plan for integrating T&CM into national health service delivery:

(Yes/No) _____

Year of establishment _____

Q2. As of the end of 2016, do you have:**a. National regulation on herbal medicines:**

(Yes/No) _____

Year of most recent update _____

b. Registered herbal medicines:

(Yes/No) _____

Year of most recent update _____

c. Herbal medicines included in national essential medicine list:

(Yes/No) _____

Year of most recent update _____

Q3. As of the end of 2016, do you have:**a. Regulations for T&CM practitioners:**

(Yes/No) _____

Year of most recent update _____

b. Consumer education project/programme for self-health care using T&CM:

(Yes/No) _____

Year of establishment _____

Q4. As of the end of 2016, are T&CM services reimbursed by health insurance?

(Yes/No) _____

If yes, please indicate (Public, Private, Both or Others) _____

Please feel free to share any additional information/ update you would like.

ANNEX 4.

REGIONAL BREAKDOWN OF THE MEMBER STATES THAT RESPONDED TO THE UPDATE SURVEY ON T&CM, 2016 OR FOR WHICH DATA WERE PROVIDED THROUGH ADDITIONAL SOURCES (2016-2018)

African Region	Region of the Americas	Eastern Mediterranean region	European region	South-East Asia Region	Western Pacific Region
Angola	Argentina	Afghanistan	Cyprus	Bangladesh	Brunei
Benin	Bahamas	Bahrain	Hungary	Bhutan	Cambodia
Botswana	Belize	Iran	Italy	Democratic People's Republic of Korea	China
Burkina Faso	Bolivia	Jordan	Portugal	India	Cook Islands
Burundi	Brazil	Lebanon	Turkey	Maldives	Fiji
Cameroon	Canada	Morocco		Thailand	Japan
Cape Verde	Chile	Oman		Timor-Leste	Kiribati
CAR	Colombia	Pakistan			Lao People's Democratic Republic
Chad	Costa Rica	Qatar			Malaysia
Comoros	Cuba	Saudi Arabi			Marshall Islands
Congo	Ecuador	Somalia			Micronesia (Federated States of)
Côte d'Ivoire	Guatemala	Syrian Arab Republic			Mongolia
DRC Congo	Guyana	Tunisia			Nauru
Equatorial Guinea	Haiti				New Zealand
Eritrea	Mexico				Niue
Ethiopia	Nicaragua				Palau (Republic of)
Gabon	Panama				Papua New Guinea
Gambia	Paraguay				Philippines
Ghana	Peru				Republic of Korea
Guinea	Saint Lucia				Samoa
Guinea-Bissau	Trinidad and Tobago				Singapore

Kenya	United States of America				Solomon Islands
Lesotho	Uruguay				Tonga
Liberia					Vanuatu
Malawi					Vietnam
Mali					
Mauritania					
Mauritius					
Mozambique					
Namibia					
Niger					
Nigeria					
Rwanda					
Sao Tome					
Senegal					
Sierra Leone					
South Africa					
Togo					
Uganda					
Zambia					
Zimbabwe					



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