The quest for traditional health knowledge began since the dawn of civilization. Currently at least 25% of all modern medicines are derived, either directly or indirectly, from medicinal plants. Traditional medicines and practices are in use in both industrialized and developing countries. More than three fourths of the populations of countries of the SEA Region use traditional medicines and practitioners for their health care. These traditional systems of medicine have the potential to improve health, wellness and people-centred health care.

This is the first ever regional publication on traditional medicine from the WHO South-East Asia Region. It enumerates the overall situation and development of traditional medicine from the perspective of health system building blocks, and analyses policies, regulations, training and education, as well as human resource development, service delivery, research and development. It highlights the key developments and progress made in recent years, and seeks to generate evidence and data that could serve as baseline for future assessments.

This publication provides a detailed account of work done in the last five years to strengthen traditional medicine in the Region by countries and WHO, and includes country profiles. It is a contribution to the efforts towards the evolution of traditional medicine and the quest for evidence-based, safe and quality health care.
Traditional medicine in the WHO South-East Asia Region

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The text was drafted by Mr Chris Zielinski, Visiting Fellow, University of Winchester, United Kingdom, and is largely based on data prepared by Dr Rachel Canaway, of the Victorian primary care practice-based Research and Education Network (VicREN) and Collaboration and Network Manager for Research at the Department of General Practice, University of Melbourne, Australia. The text was editorially reviewed by Mr Gautam Basu, editor with the WHO Regional Office.

Our sincere thanks to the contributors for their valuable contribution.
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<th>Description</th>
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<td>ACM</td>
<td>alternative complementary medicine (Bangladesh)</td>
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<td>ASU</td>
<td>Ayurveda, Siddha, Unani</td>
</tr>
<tr>
<td>AYUSH</td>
<td>Ayurveda, yoga and naturopathy, Unani, Siddha and homoeopathy</td>
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<tr>
<td>BCE</td>
<td>before Common Era</td>
</tr>
<tr>
<td>BTFTM</td>
<td>BIMSTEC Task Force on Traditional Medicine</td>
</tr>
<tr>
<td>BIMSTEC</td>
<td>Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation</td>
</tr>
<tr>
<td>CE</td>
<td>Common Era</td>
</tr>
<tr>
<td>DoHS</td>
<td>Department of Health Services (Nepal)</td>
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<tr>
<td>GMP</td>
<td>good manufacturing practice</td>
</tr>
<tr>
<td>ICD-11</td>
<td>International Classification of Diseases, 11th revision</td>
</tr>
<tr>
<td>ICSR</td>
<td>individual case safety reports</td>
</tr>
<tr>
<td>ICTs</td>
<td>information and communication technologies</td>
</tr>
<tr>
<td>MD</td>
<td>medical degree</td>
</tr>
<tr>
<td>MIM</td>
<td>Ministry of Indigenous Medicine (Sri Lanka)</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MoHFW</td>
<td>Ministry of Health and Family Welfare (Bangladesh)</td>
</tr>
<tr>
<td>MoPH</td>
<td>Ministry of Public Health (Thailand)</td>
</tr>
<tr>
<td>OPD</td>
<td>outpatient department</td>
</tr>
<tr>
<td>PPP</td>
<td>public–private partnership</td>
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<tr>
<td>SEA</td>
<td>(WHO) South-East Asia (Region)</td>
</tr>
<tr>
<td>SEARO</td>
<td>WHO Regional Office for South-East Asia</td>
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<tr>
<td>T&amp;CM</td>
<td>traditional and complementary medicine</td>
</tr>
<tr>
<td>TK</td>
<td>traditional knowledge</td>
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<tr>
<td>TM</td>
<td>traditional medicine</td>
</tr>
<tr>
<td>TT&amp;CM</td>
<td>Thai traditional and complementary medicine</td>
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<tr>
<td>TTM</td>
<td>Thai traditional medicine</td>
</tr>
<tr>
<td>UHC</td>
<td>universal health coverage</td>
</tr>
<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Foreword

Traditional and complementary medicine (T&CM) continues to be an important part of preventive and promotive health across the WHO South-East Asia Region, as across the world. Almost 90% of WHO Member States globally have developed policies, laws, regulations, programmes and offices for T&CM that are aligned with WHO’s Global Traditional and Complementary Medicine Strategy 2014–2023. Countries in the Region have been at the forefront of the global momentum on traditional and complementary medicine, reflecting their commitment to leverage the potential of T&CM to achieve the Region’s Flagship Priorities, WHO’s “Triple Billion” targets, and the health-related Sustainable Development Goal 3.

As this review of progress highlights, almost all the Region’s Member States have national policies on traditional medicine in place. Nine of the 11 Member countries have formal training and education systems for traditional medicine practitioners and 10 are regulating registered T&CM products. Six countries have co-located traditional medicine services within their health systems at some or all levels and seven have national T&CM institutes. Four countries have implemented a system to monitor T&CM safety.

Between 2016 and 2020 WHO collaborated with Member States to strengthen pharmacovigilance and research capacity and to set benchmarks for training and practices in several traditional medicine systems. In 2017 WHO published a set of standardized core and reference indicators that policy-makers have used to develop or revise national policies and to review programmes.

The Region must continue to strengthen standard monitoring and evaluation, the indicators for which are aligned with the six health-system building blocks and provide key insights into overall performance within each country and across countries. Pharmacovigilance must continue to be a core focus, for which the baseline surveys and best practices identified in 2019 will help countries plan and establish safety monitoring systems. Increased research capacity is needed to assess the efficacy of specific products, which WHO is supporting through a set of common regional research guidelines being developed. The Region’s progress has indeed been strong. More is needed.

I am certain that this review of progress will help all stakeholders appreciate how far we have come in leveraging the potential of T&CM and how far we still have got to go. Together we must continue to integrate safe and effective traditional medicine into health systems so that those systems are stronger and more culturally familiar, and also help meet all health needs of the people throughout the life-course.

Dr Poonam Khetrapal Singh
Regional Director
WHO South-East Asia Region
PART 1

Traditional medicine in the WHO South-East Asia Region

1.1 Introduction

Traditional medicine is 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”.¹

In addition to the ancient traditional medicine systems covered in this publication, we are including more recent forms of complementary or alternative medicine. These are defined as “a broad set of health-care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system”, and encompass products, practices and practitioners.

And finally, to distinguish these from modern conventional medicine, we will refer to the latter as “allopathic medicine”.

It should be noted that the common notion that traditional medicines are not prevalent in industrialized countries is clearly wrong. For instance, “Canada, France, Germany and Italy ... report that between 70% and 90% of their populations have used traditional medicines under the titles ‘complementary’, ‘alternative’, or ‘nonconventional’ (WHO 2011). Indeed, according to WHO’s recent Global Report on traditional and complementary medicine 2019², based on current information, 88% of Member States of WHO have acknowledged their use of traditional & complementary medicine (T&CM), which corresponds to about 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.”

In WHO’s Traditional Medicine Strategy 2014–2023, it was “anticipated that WHO will initiate a review of the implementation of this Strategy approximately halfway through its term. This mid-term review will be important in ensuring that the Strategy is still relevant

¹ http://www.who.int/medicines/areas/traditional/definitions/en/
and timely as WHO and its stakeholders move into the final five years of the forthcoming mandate.” This publication seeks to fulfil that expectation by providing a comprehensive review for the WHO South-East Asia Region.

This publication offers an account of the work being done in the last five years to strengthen traditional medicine in the Region by the countries and by WHO, with conclusions drawn in Part 3. Country profiles are provided in Part 4, including brief descriptions of the systems of traditional medicine used in each Member State, the organization of the traditional medicine system, the authority responsible and policy framework, finance and insurance, practitioners, education and research, manufacture and regulation, data and indicators, and references. Longer descriptions of the systems of traditional, complementary and alternative medicine are provided in Appendix 1.

1.2 The mandate

Traditional medicine has been on the WHO agenda for many years. The first of many resolutions on the subject (see Box 1) was adopted by the Twenty-second World Health Assembly in 1969. However, this resolution was titled “Establishment of Pharmaceutical Production in Developing Countries” and did not explicitly mention traditional medicines.

In 1976, resolution WHA29.72 of the Twenty-ninth World Health Assembly was on “Health Manpower Development”, but it contained the phrase “taking into account, where appropriate, the manpower reserve constituted by those practising traditional medicine”. Finally, resolution WHA30.49 in 1977 explicitly covered the subject of “Promotion and development of training and research in traditional medicine”.

Box 1: Sources of the mandate

- World Health Assembly resolutions WHA22.54, WHA29.72, WHA30.49, WHA31.33, WHA40.33, WHA41.19, WHA42.43, WHA 44.34, WHA54.11, WHA56.31, WHA61.21, WHA62.13 (2009) and finally WHA67.18 (2014).
- The WHO Regional Committee for South-East Asia resolution SEA/RC56/R6 (1998) on traditional systems of medicine which requested the Regional Director to assist Member States in developing/strengthening national policies, strategies and plans of action on traditional systems of medicine.
- The Delhi Declaration on Traditional Medicine for the countries of the South-East Asia Region adopted at the International Conference on Traditional Medicine on 13 February 2013 by all Member States.
- Resolution SEA/RC67/R3 titled “Traditional Medicine: Delhi Declaration” 3 adopted by the Sixty-seventh session of the Regional Committee for South-East Asia on 12 September 2014.
- The WHO Traditional Medicine Strategy 2014–2023 that was endorsed by World Health Assembly resolution WHA67.18.4

3 WHO, 2014. Regional Committee for South-East Asia Resolution SEA/RC67/R3 on “Traditional Medicine: Delhi Declaration”.
Since then, there has been a cycle of instruments on traditional medicine articulated and adopted at regional and international levels. The Delhi Declaration of 2013 was closely followed by the WHO Traditional Medicine Strategy 2014–2023, adopted by the World Health Assembly in May 2014. Both these instruments were endorsed by the WHO Regional Committee for South-East Asia in 2014.

These were followed by the SEA Region Action Plan on Traditional Medicines developed in October 2015 at a Regional Meeting on Appropriate Integration of Traditional Medicine into National Health Systems. In 2017, the Colombo Declaration helped the further development of the regional agenda on traditional medicine (see Chapter 2.2). These instruments are discussed in further detail below.

1.2.1 The Delhi Declaration

The Delhi Declaration on Traditional Medicine for the South-East Asian Countries⁵ was adopted on 13 February 2013 at the International Conference on Traditional Medicine for Member States of the South-East Asia Region, by all the Member countries of the Region. The countries declared their agreement to cooperate, collaborate and support each other mutually in all spheres of traditional medicine in accordance with national priorities, legislations and circumstances. Specific areas for collaboration included the following:

1. to promote National policies, strategies and interventions for equitable development and appropriate use of traditional medicine in the health care delivery system;
2. to develop an institutionalized mechanism for the exchange of information, expertise and knowledge with active cooperation with WHO on traditional medicine through workshops, symposia, visit of experts, exchange of literature etc.;
3. to pursue a harmonized approach for the education, practice, research, documentation and regulation of traditional medicine and involvement of traditional medicine practitioners in health services;
4. to explore the possibility of promoting mutual recognition of educational qualifications awarded by recognized universities, pharmacopoeias, monographs and relevant databases of traditional medicine;
5. to encourage development of common reference documents of traditional medicine for South-East Asian countries;
6. to develop regional cooperation for training and capacity building of traditional medicine experts;
7. to encourage sustainable development and resource augmentation of medicinal plants in the South East Asian regional countries;
8. to establish regional centres as required for capacity building and networking in the areas of traditional medicine and medicinal plants; and

9. to exchange views, experiences and experts for integration of traditional medicine into national health systems in accordance with national policies and regulations.

Much of the development in the field of traditional medicine in the Region has been a pursuit of these objectives.

1.2.2 The WHO Traditional Medicine Strategy 2014–2023

The WHO Traditional Medicine Strategy 2002–2005 was published in 2002. With the impetus received from World Health Assembly resolution WHA62.13 on traditional medicine, and the evolving changes in the practice of this school of medicine, the WHO Traditional Medicine Strategy 2014–2023 was adopted by all Member States at the World Health Assembly in May 2014. By that time, according to WHO’s then Director-General Dr Margaret Chan, “more countries had come to accept the contribution that T&CM could make to the health and well-being of individuals and to the comprehensiveness of their health-care systems. Governments and consumers (were) interested in more than herbal medicines, and are now beginning to consider aspects of T&CM practices and practitioners, and whether they should be integrated into health service delivery”.

The Strategy has two key goals: to support Member States in harnessing the potential contribution of T&CM to health, wellness and people-centred health care, and to promote the safe and effective use of T&CM through the regulation of products, practices and practitioners.

Three strategic objectives were identified as the route to implementing these goals:

1. To build the knowledge base for active management of T&CM through appropriate national policies.
2. To strengthen the quality assurance, safety, proper use and effectiveness of T&CM by regulating products, practices and practitioners.
3. To promote universal health coverage by integrating T&CM services into health-care service delivery and self health care.

On 12 September 2014, the WHO Regional Committee for South East-Asia adopted a resolution (SEA/RC67/R3) urging Member States to implement the Delhi Declaration. In addition, the resolution referred to the WHO Traditional Medicine Strategy 2014–2023, urging Member countries to adopt and implement it, taking into account national capacities, priorities and legislations; to integrate, as deemed appropriate, traditional medicine into the mainstream health-care systems in order to contribute to universal health coverage; and to strengthen systems, particularly pharmacovigilance systems, to ensure that all available traditional medicine products met safety, efficacy and quality standards.

The resolution addressed WHO as well, requesting the Regional Director of South-East Asia to support Member States in implementing the Delhi Declaration. Other areas for support included strengthening systems, particularly pharmacovigilance systems, to
ensure that all available traditional medicine products meet safety, efficacy and quality standards; allocating adequate funds towards the implementation of the Delhi Declaration and the WHO Traditional Medicine Strategy 2014–2023; and providing policy and technical guidance for the promotion of traditional medicine along harmonized lines for each type or school of TM in the Region.

1.2.3 The SEA Regional Traditional Medicine Action Plan

The WHO Traditional Medicine Strategy 2014–2023 stressed the need to fully harness traditional medicine and its contributions to maintaining health, wellness and people-centred and universal health care. It also underscored the need to ensure safety and efficacy of traditional medicines through regulation and research.

The regional workshop on Appropriate Integration of Traditional Medicine into National Health Systems in progress in Pyongyang, DPR Korea, in October 2015. All Member States of the Region and the WHO Regional Director attended the meeting.

During the Regional Workshop on Appropriate Integration of Traditional Medicine into National Health Systems held in Pyongyang, Democratic People’s Republic of Korea, in October 2015, a five-year action plan was adopted. This action plan was consistent with the objectives of the WHO Traditional Medicine Strategy 2014–2023.

It included strategies to improve monitoring of the performance of traditional medicine systems; steps to bolster research on new developments in traditional medicine; and measures to promote quality and safety by sharing best practices in national adverse events reporting systems for traditional as well as modern medicines.

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6 WHO, 2016. Regional workshop to share experience and evidence on appropriate integration of traditional medicine into national health-care systems, Report of the Regional Workshop, Pyongyang, Democratic People’s Republic of Korea, 20–22 October 2015. SEA-HSD-390
Five action areas were agreed upon; Figure 1 depicts these:

**Fig. 1:** Five action areas of the SEA Regional Traditional Medicine Action Plan

1. **T&CM systems monitoring:** Member States to improve performance monitoring of T&CM systems at all levels; WHO to convene a task group to develop a minimum set of indicators and associated definitions.

2. **T&CM research:** Member States to encourage research on new developments in T&CM and improve communication between policy-makers and researchers on the evidence base needed and available for T&CM policy development; WHO to support documentation of new developments in T&CM, facilitate identification and dissemination of emerging research issues, advocate for better communication between policy-makers and researchers, and develop policy briefs on emerging T&CM issues.

3. **T&CM practitioners/workforce:** Member States to foster greater understanding and mutual respect between traditional and modern practitioners, support the professional development of TM practitioners, and develop approaches to better identify the scale and practices of informal T&CM practitioners; WHO to encourage the documentation and exchange of country experiences through country case studies, inter-country exchanges and meetings.

4. **Adverse events reporting:** Member States to share their experiences and best practices in developing adverse event reporting systems; WHO to support case studies that document how Member States developed their adverse events reporting systems; and prepare a briefing note on the WHO global adverse event reporting system based in the Uppsala Monitoring Centre, Sweden, and share with Member States.

5. **Communication:** Member States to develop ways to better communicate the strengths and limitations of T&CM to general populations, and develop ways to improve communication between allopathic and traditional practitioners through joint activities; WHO to facilitate the development of a regional T&CM network to exchange information and experience.

### 1.3 An overview of traditional medicine in South-East Asia

Given the experience spanning centuries in the preparation and practice of traditional medicine in the WHO South-East Asia Region, the range of concepts used is extremely
broad-. The vision of health evinced in traditional medicinal settings are derived from a wide variety of spiritual and experiential sources. These range from religious and philosophical systems followed by billions to local folk beliefs and they are as distinct from each other as they can possibly be (see Figure 2).

This range of belief systems leads to a wide diversity of traditional medicine practitioners, some of whom gained their qualifications in oral, shamanistic or family-based traditions, and some pursued doctorate degrees. The sheer number of practitioners implies that they must be accounted for in any assessment of overall human resources in the health sector. In Indonesia, there are about 300 000 traditional therapists, while in Nepal there are reportedly 400 000 traditional healers.

In India, there are 799 879 registered traditional medicine practitioners (BIMSTEC 2019) and, according to the Medical Council of India (MCI), there were 988 922 allopathic doctors registered with the state medical councils or MCI in 2016. These figures give an idea of the balance between the prevalent health-care systems in India. In some other countries, traditional medicine practitioners outnumber allopathic practitioners.

**Fig. 2:** Origins of some systems of traditional medicine in the WHO South-East Asia Region

<table>
<thead>
<tr>
<th>Acupuncture</th>
<th>Believed to have originated around 100 BC in Ancient China. Some experts suggest it could have been practised even earlier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayurveda</td>
<td>Some scholars assert that Ayurveda originated in prehistoric times and some of the Ayurvedic concepts have existed since the time of the Indus Valley Civilization (from 3300 BCE to 1300 BCE) or even earlier</td>
</tr>
<tr>
<td>Traditional Chinese medicine</td>
<td>Based on more than 2500 years of Chinese medical practice.</td>
</tr>
<tr>
<td>Deshiya chikitsa</td>
<td>Existed in Sri Lanka before the advent of Ayurveda.</td>
</tr>
<tr>
<td>Dhivehi Beys or Dweep Unan (Maldives)</td>
<td>Legends talk about the existence of healers in the 16th century. The treatise, written by El-Sheikh El-Hakeem Ahmed Didi of Meedhoo (Seenu atoll), who died in 1937, forms the foundation of today’s traditional medicine in the country</td>
</tr>
<tr>
<td>gSo-ba Rig-pa (Bhutan)</td>
<td>This system came into being as Indian culture started gaining popularity in Tibet in the 11th and 12th centuries.</td>
</tr>
<tr>
<td>Jamu (Indonesia)</td>
<td>Claimed to have originated in the Mataram Kingdom era, about 1300 years ago.</td>
</tr>
<tr>
<td>Koryo medicine</td>
<td>Originated in ancient and prehistoric times and can be traced back to about 3000 BCE when stone and bone needles were found in North Hamgyong province in present-day Democratic People’s Republic (DPR) of Korea.</td>
</tr>
<tr>
<td>Myanmar traditional medicine</td>
<td>Evidence has been found of the first use of traditional medicine in Myanmar as far back as 600 BCE.</td>
</tr>
<tr>
<td>Siddha medicine</td>
<td>Originated in ancient Tamil Nadu, in South India, and Sri Lanka. Palm leaf manuscripts say that it was first linked to Lord Shiva and spread among communities by his devotees.</td>
</tr>
</tbody>
</table>
Traditional Thai medicine Stems from prehistoric indigenous regional practices with a strong animistic foundation. Animistic traditions were followed by Mon and Khmer people who occupied the region prior to the migration of the T’ai people in the 13th century.

Unani (“Greek”) The term for Perso-Arabic medicine as practised in Mughal India during the 13th century and in Muslim cultures in South Asia and modern-day Central Asia. Based on the teachings of Greek physicians Hippocrates and Galen.

Yoga May date back to pre-Vedic Indian traditions; it is mentioned in the Rigveda, but most likely developed around the sixth and fifth centuries BCE.

Chiropractic Founded in 1895 by Daniel David Palmer in Davenport, Iowa.

Homeopathy A system of alternative medicine created in 1796 by Samuel Hahnemann.

Naturopathy A form of alternative medicine with roots in the 19th-century ‘natural cure’ movement in Europe.

Source: Further details and sources provided in Appendix 1.

Table 1 shows the main conditions commonly treated with traditional medicine systems, as reported by Member States at the Regional Workshop on Appropriate Integration of T&CM into the Health System in 2015. As per this data, the leading health conditions/diseases treated with T&CM were: disorders of the bone and joints (such as spinal diseases); osteoarthritis; back pain (87.5%); stomach and indigestion (75%); cardiovascular diseases such as hypertension, paralysis after stroke (62.5%); respiratory conditions such as cold, asthma, and sinusitis (62.5%); neuro-muscular disorders (50%); metabolic disorders such as diabetes and gout (50%); skin diseases (37.5%); gynaecological disorders such as menstrual disorders and infertility (25%); mental and psychological disorders (12.5%); and liver diseases (12.5%).

Table 1: Five leading health conditions/diseases managed with T&CM by Member States in the WHO SEA Region

<table>
<thead>
<tr>
<th>Country</th>
<th>Top one</th>
<th>Top two</th>
<th>Top three</th>
<th>Top four</th>
<th>Top five</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>Skin diseases</td>
<td>Cold</td>
<td>Rheumatic arthritis</td>
<td>Stomach</td>
<td>Asthma</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Neurological</td>
<td>Stomach</td>
<td>Metabolic (gout)</td>
<td>Sinusitis</td>
<td>Cardiovascular/ HP</td>
</tr>
<tr>
<td>DPR Korea</td>
<td>Chronic gastritis</td>
<td>Bone</td>
<td>Respiratory</td>
<td>Cardiovascular/ HP</td>
<td>Diabetes</td>
</tr>
<tr>
<td>India</td>
<td>Bone and joint</td>
<td>Diabetes</td>
<td>Mental/ psychological</td>
<td>Psoriasis</td>
<td>Liver diseases</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Cardiovascular</td>
<td>Metabolic</td>
<td>Bone</td>
<td>Stomach</td>
<td>Stroke</td>
</tr>
<tr>
<td>Myanmar</td>
<td>Arthritis</td>
<td>Stroke</td>
<td>Skin diseases</td>
<td>Cerebral palsy</td>
<td>Menstrual disorders</td>
</tr>
<tr>
<td>Nepal</td>
<td>Chronic gastritis</td>
<td>Respiratory</td>
<td>Arthritis</td>
<td>Neurological</td>
<td>Gynaecological</td>
</tr>
<tr>
<td>Thailand</td>
<td>Neurological</td>
<td>Bone</td>
<td>Cough</td>
<td>Stomach</td>
<td>Cardiovascular</td>
</tr>
</tbody>
</table>
It is essential to fully capitalize on the large pool of human resources engaged in traditional medicine practices. According to the WHO Global Report on traditional and complementary medicine 2019, “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.” Therefore, integrating traditional medicine into the general public health system becomes an obvious and pressing need. In some counties, this integration was by and large achieved long ago; in others, it has barely been begun.

At the same time, the physical diversities of the Region provide extremes of their own. An unparalleled biodiversity of plant and herbal species, and availability of numerous animal byproducts and active minerals provide a rich palette of ingredients to choose from. The results are evident in the number of medicinal preparations that are registered – for example, in Myanmar, there are over 14 500 registered drugs in the National Traditional Medicine Formulary (BIMSTEC 2019). Indonesia too has more than 13 000 registered traditional drugs.

While many traditional medicines have been registered, this does not mean that they have all been studied scientifically. The evidence base is growing, but most of the work in assessing traditional medicines remains to be completed. Moreover, in most countries of the Region, unregistered folkloric medicine and home remedies continue to be used and these are rarely, if ever, assessed scientifically.

Work on applying good manufacturing practices (GMP), pharmacovigilance and other quality and safety measures is underway in most countries, but much remains to be done. The sheer range or diversity of practices and preparations makes the task harder.
PART 2
Progress in the WHO South-East Asia Region

This section seeks to present a dynamic picture of the developments occurring in this Region since 2015. These are in keeping with the commitment made in the WHO Traditional Medicine Strategy 2014–2023 to “initiate a review of the implementation of this Strategy approximately halfway through its term”.

While this regional report was being prepared, WHO published its Global Report on traditional and complementary medicine 2019, based on the third in a series of surveys on national policies regarding traditional medicine and regulation of herbal medicines. The first survey had been carried out in 2005. To identify global trends and the current situation in the realm of T&CM, WHO conducted a second global survey during 2010–2012, and another survey during 2016–2018. 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.

Overall, the picture was positive. As the report states, “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.”

2.1 Country progress and activities, 2014–2019

2.1.1 T&CM policies and institutional frameworks

According to the WHO Global Report on traditional and complementary medicine 2019, Member States in the Region in 2005–2018 demonstrated a persistent and strong...
commitment to regulating 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 highest 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 this is one area which has scope for further improvement.

Considering the infrastructure required for managing T&CM at the country level, the key components comprise having a responsive national policy, regulation of T&CM and herbal medicines, a national programme, a national office, an expert committee, a national research institute, and facilities for the regulation and registration of herbal medicines. Table 2 shows the current situation regarding these components in the WHO South-East Asia Region, as well as the use of T&CM among populations of Member States. The table also compares the percentage of Member States in the Region for each indicator with the equivalent global percentage.

The WHO survey showed that there was a consistent increase in the number of Member States having a national framework for T&CM. By 2018, each of the 10 out of 11 Member States reported having a national policy, national- or state-level laws and regulations, a national programme, a national office, and a national expert committee. Seven countries reported having national research institutes for T&CM and three (Democratic People’s Republic of Korea, India and Thailand) reported having government and public research funding for T&CM. Three Member States (DPR Korea, India and Thailand) stated that they had national plans for integrating T&CM into the national health service delivery8.

Table 2: Development of T&CM in the WHO South-East Asia Region, 2005–2018

<table>
<thead>
<tr>
<th>Category</th>
<th>WHO SEA Region affirmative responses in 2005 (of 11 countries)</th>
<th>WHO SEA Region affirmative responses in 2018 (of 11 countries)</th>
<th>WHO SEA Region affirmative responses in 2018 (%)</th>
<th>Global affirmative responses in 2018 (% N=194)</th>
</tr>
</thead>
<tbody>
<tr>
<td>National policy</td>
<td>8</td>
<td>10</td>
<td>91%</td>
<td>51%</td>
</tr>
<tr>
<td>Laws/ regulations</td>
<td>7</td>
<td>9</td>
<td>82%</td>
<td>56%</td>
</tr>
<tr>
<td>National T&amp;CM programme</td>
<td>9</td>
<td>10</td>
<td>91%</td>
<td>41%</td>
</tr>
<tr>
<td>National T&amp;CM office</td>
<td>10</td>
<td>10</td>
<td>91%</td>
<td>55%</td>
</tr>
</tbody>
</table>

8 As per the global survey there were only three countries: Democratic People’s Republic of Korea, India and Thailand that have national plans for integrating T&CM into national health service delivery. However, by the time the document is being prepared, three more countries, Bangladesh, Bhutan and Indonesia, have developed plans to integrate their TM services into the health care system, making it six countries in total.
Traditional medicine in the WHO South-East Asia Region

<table>
<thead>
<tr>
<th>Category</th>
<th>WHO SEA Region affirmative responses in 2005 (of 11 countries)</th>
<th>WHO SEA Region affirmative responses in 2018 (of 11 countries)</th>
<th>WHO SEA Region affirmative responses in 2018 (%)</th>
<th>Global affirmative responses in 2018 (% N=194)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expert committee</td>
<td>9 10 91% 48%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>National T&amp;CM research institute</td>
<td>7 7 64% 39%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulation of herbal medicines</td>
<td>7 10 91% 64%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration of herbal medicines</td>
<td>9 10 91% 64%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>11 11</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
<td></td>
</tr>
</tbody>
</table>

Note: The 2018 data set includes i) 2012 data, and ii) 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 that is not accounted for here.


Examples of the development of national T&CM frameworks in the Region during the last five years include the following:

- **Bangladesh:** In 2016, the Fourth Health, Population and Nutrition Sector Programme was approved, covering five-and-a-half years from January 2017. This aims to improve equity, quality and efficiency of the health and nutrition levels of the population in order to advance universal health coverage (UHC) to achieve the health-related Sustainable Development Goals (SDGs).

  The programme includes an operational plan managed by the Ministry of Health and Family Welfare (MoHFW) devoted to alternative medical care (AMC), with the aim “to scale up traditional medicine (Unani, Ayurvedic) services throughout the country along with allopathic treatment to ensure quality and equitable health services for all citizens of Bangladesh and develop the Unani and Ayurvedic education system”. The key components of AMC are, i) to provide preventive and curative services to service recipients at government health facilities; ii) to integrate AMC services with the national health-care delivery systems; and iii) to increase service facilities from the primary to the tertiary level (BIMSTEC 2019).
India:
The latest National Health Policy (2017) broadened the objectives for AYUSH towards mainstreaming (ensuring access to) the system. This included introduction of yoga in schools and workplaces, building research and public health skills for preventive and promotive health care, providing an AYUSH orientation to grassroots health workers and village health, sanitation and nutrition committees, offering bridge courses for mid-level health-care providers, and establishing a certification mechanism for traditional community health-care providers.

There are three flagship initiatives: (i) the National Health Mission, which is aimed at vertical and horizontal strengthening of health services and accountable health systems, including the mainstreaming of AYUSH; (ii) the National AYUSH Mission, aimed at augmenting the AYUSH sector in terms of health services, educational standards, drug quality control and sustainable development of medicinal plants; and (iii) Central sector schemes for direct funding of projects related to promotion and development of the AYUSH sector. The latter covers information, education and communication (IEC) activities, workshops, seminars, conferences, extramural research studies, international cooperation endeavours, public health interventions, and setting up centres of excellence and industry clusters.

In India, 88 research institutes have been established under five research councils: the Central Council for Research in Ayurvedic Sciences (with 30 institutes), the Central Council for Research in Unani Medicine (with 23 institutes), the Central Council for Research in Homoeopathy (with 29 institutes), the Central Council for Research in Siddha (with five institutes) and the Central Council for Research in Yoga & Naturopathy (with one institute). Numerous research articles on traditional medicine are published each year.

In 2017, the “Namaste portal” was launched (www.namstp.ayush.gov.in), with a vision “to develop a comprehensive web portal on AYUSH morbidity codes, interlinkages with WHO ICD (International Classification of Diseases) 10/11 and standardized Ayurveda, Siddha and Unani terminologies”.

Indonesia: Under the national programme for T&CM, the Centre of Traditional Medicine Development has been implementing traditional medicine practices in 34 provinces with integrated traditional medicine service at 7 hospitals and 4971 primary healthcare centres as of 2019.

Nepal: Among the national health policies published in 2018 is the one aiming “to develop the Ayurvedic medicine system through the systematic management and utilization of available herbs in the country as well as safeguarding and systematic development of other existing complementary medicine systems”. The national programme for T&CM is integrated into the Second Long-Term Health Plan, 1997–2017.
Yoga programme for schoolchildren in Nepal: A case study

Yoga is one of the traditional systems of medicine, which originated in ancient India and involves physical, mental and spiritual practices. The word “yoga” in Sanskrit means “to join or unite”, symbolizing the union of body and consciousness. Today, it is being practised in various forms around the world and continues to grow in popularity due to its potential for preventing lifestyle-related chronic noncommunicable diseases as well as other illnesses through its holistic approach to health and well-being. WHO has urged Member States to promote physical activities for healthier populations, particularly the use of traditional practices such as yoga, etc. This focus on yoga was enhanced after the UN General Assembly announced, at the initiative of the Government of India, the observance of the International Day of Yoga on 21 June every year starting from 2014.

The Government of Nepal has introduced a yoga programme for schoolchildren with WHO support, aiming at widespread dissemination of information about the health benefits of practising yoga for the population since 2019. The Department of Ayurveda and Alternative Medicine of the Ministry of Health and Population, which is responsible for traditional medicine services, has developed a school yoga programme that follows the recognition of the importance of school health programmes for improving physical, mental, emotional and educational status of schoolchildren.

During the period of 2007 to 2018, the programme spanned three to five days, functioning as a school awareness drive. Now it has been developed as an “Ayurveda and yoga education at school programme” targeting secondary school students. The module for “Ayurveda and yoga education at school programme” consists of (i) promotion of healthy lifestyle through Ayurveda and yoga; (ii) use of local herbs for primary health care; and (iii) yoga (practical) for physical and mental health. The programme includes orientation activities for teachers and nursing staff on Ayurveda and yoga. The programme has been found to improve learning capacity, instill a positive attitude and strengthen the health of the enrolled students through assessments with questionnaires. The demand for it is on the rise. The programme is planned to be implemented across the country in a phased manner.
○ **Sri Lanka:** Drafting of the Sri Lankan policy on indigenous medical systems was initiated in 2017. Discussions were ongoing as per reports updated till 2019.

○ **Thailand:**

Recent national laws and policies that support Thai traditional medicine (TTM) include the Constitution of the Kingdom of Thailand (2017), the 20-Year National Strategy (2017–2036), and the National Reform Plan in Public Health.

A major national reform planning effort was underway in Thailand in 2019, covering 10 issues, the fifth of which deals with traditional Thai medicine and products for the economy. This includes a TTM service reform plan, a TTM educational reform plan, and a TTM herbal products reform plan.

### 2.1.2 Regulation of production of T&CM products

The regulatory status of herbal medicines includes their regulation, regulatory categories and regulatory claims made about herbal medicines, pharmacopoeias and monographs, manufacture and safety assessment of herbal medicines and their registration systems, the existence of a national essential medicines list, a market surveillance system for the safety of herbal medicines, and marketing and sales of herbal medicines.

In respect of the regulatory status of herbal medicines, 10 of the 11 Member States regulated herbal medicines and had a registration system for these. Five Member States in the South-East Asia Region (Bangladesh, Bhutan, Democratic People’s Republic of Korea, India and Thailand) had herbal medicines included in their national essential medicines lists. In a number of countries in the Region, herbal medicines are produced by a government entity, either exclusively or alongside nongovernmental producers.

Specific developments in this area include:

○ **Bhutan:** Menjong Sorig Pharmaceuticals (MSP) was accorded government approval as a state-owned enterprise in July 2017. MSP manufactures and supplies T&CM medicines as its core business. It applies good manufacturing practices, carries out quality control for both raw materials and finished products, conducts research activities and undertakes marketing of products.

Currently, it manufactures 115 products that constitute the national essential traditional medicines list as well as 19 herbal products in various dosages. Other MSP activities include the collection and procurement of medicinal raw materials through community involvement; scientific research and standardization of traditional medicine; and establishing quality control parameters and monitoring the quality of products.

○ **India:** A number of national committees have been established for the regulation of ASU&H drugs. These include the Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB) for policy advice to the Union government on regulation of Ayurveda, Siddha and Unani, or ASU, drugs; the Ayurveda, Siddha, Unani Drugs
Consultative Committee (ASUDCC) for advice to the Central and state governments on enforcement issues of ASU drugs; the Sub-committee on Homoeopathy under the Drugs Technical Advisory Board (DTAB); the Pharmacopoeia Commission of Indian Medicine and Homeopathy; and pharmacopoeia committees for the development of standards of ASU&H drugs.

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 national essential medicines list were updated in 2013.

Myanmar: As of January 2019, there were 14 529 registered drugs in Myanmar’s National Traditional Medicine Formulary and 3206 licensed traditional medicine drug producers. Herbal medicines are regulated as “herbal medicines” and sold with medical and health claims. The Department of Traditional Medicine under the Ministry of Health and Sports developed GMP guidelines based on those of WHO and ASEAN countries. Two state-owned T&CM factories (in Yangon and Mandalay) manufacture about 15 000 kg of traditional medicines every year for the Department of Traditional Medicine.

GMP and traditional medicine products in Myanmar

GMP is one of the most important approaches for ensuring the quality of traditional medicine products. WHO developed the GMP guideline in 2007 and encouraged Member States to comply with the GMP requirements for manufacturing traditional medicine products.

Myanmar is one of the Member States complying with GMP principles monitoring the manufacture of TRM products in the Region. For instance, in 1996, the Government of Myanmar promulgated the law on traditional medicinal drugs in order to control the production, safety and quality of traditional drugs. This was then followed by a series of notifications concerning registration and licensing, labelling and advertising and related aspects.

The objectives of the drug law is “to enable the public to consume
genuine, quality, safe and efficacious traditional drugs”. According to the law, all the traditional medicines produced in the country have to be registered and all manufacturers have to be licensed. In 1999, the Department of Traditional Medicine, Ministry of Health, developed GMP guidelines with a standard checklist as per the WHO and ASEAN GMP guidelines. The first guideline covered the aspects of (i) personnel, (ii) premise, (iii) equipment, (iv) personal hygiene, (v) production, (vi) quality control, (vii) product recalls and complaints, and (viii) documentation. Later, it was updated with the following modules, i.e. (i) quality management, (ii) personnel, (iii) premises and equipment, (iv) sanitation and hygiene, (v) documentation, (vi) production, (vii) quality control, (viii) contract manufacturing and analysis, (ix) complaints and product recalls, (x) self-inspection, and (xi) verification.

There have been 15,018 items of drugs registered and 3,417 manufacturers licensed as of August 2020. Two out of 3,417 licensed manufacturers have met the GMP requirement. They are FAME Pharmaceuticals Industry Co. Ltd in 2003, and U Tha Yin Medicine Hall and Lwin Myint Aung Industrial Co. Ltd in 2011.

The Ministry of Health and Sports, Government of Myanmar, continues its efforts to strengthen GMP capacity by organizing trainings for traditional medicine manufacturers in the country.
Nepal: Singha Durbar Vaidhakahana Vikas Samiti (SDVKVS), the only government manufacturer of Ayurvedic medicines, produces 35 patent and more than 170 classical drugs using about 300 different medicinal plants, 32 metals and metal compounds, and 42 minerals and animal byproducts. SDVKVS mainly supplies its products to the Department of Ayurveda and private dispensaries within the country.

Other T&CM (not Ayurvedic) products are either prepared by practitioners or are imported. In addition, about 80 Ayurvedic pharmaceutical companies are producing patent and classical drugs. These meet only 30% of the country’s needs and, therefore, the rest of the medicines are imported from India and other countries. Wild medicinal herbs are means of employment and income generation for rural people.

Thailand: The first masterplan on the Development of Thai Medicinal Plants (2017–2021) was promulgated with the following key implementation tasks: manage the supply chain (strain selection and development), promote cultivation by good agricultural and collection practices (GACP) and good processing practices (GPP); use medicinal plants sustainably from natural sources; develop the herbal product industry; conduct R&D of herbal products and efficacy and safety studies (both pre-clinic and clinic); ensure quality; adhere to Thai herbal pharmacopoeia/TTPP; promote use of herbal extracts; ensure product development; build databases; develop herbal product markets through herbal expositions, roadshows, distribution, e-commerce and digital markets; and promote the use of herbal products for health care. Implementing this masterplan will require a collaborative effort among nine ministries.

Herbal medicines were introduced in the essential medicines list in 2006 (updated in 2016). The regulation on herbal medicines and list of registered herbal medicines were updated in 2017. It was observed that the existing Drug Act and Food Act was not suitable for the registration of traditional/herbal medicines and herbal dietary supplements. Therefore, a new Herbal Products Act was drafted in 2016, and promulgated in 2019, under the responsibility of the Thai FDA and the Department of Thai Traditional and Alternative Medicines (DTAM).

2.1.3 T&CM practitioners: Education, regulation and place of work

Summary information about practice, providers, education and health insurance is provided in the country profiles (Part 4). Presented below are some recent developments in the Member States regarding T&CM practices: the regulation, practice settings and licensing of T&CM providers; the education of T&CM providers; T&CM consumer education projects and programmes for self care for health using T&CM; traditional medicine facilities; and financing and health insurance.
**Practice and practitioners**

- **Bangladesh**: As of 2015, there were 179 medical officers (Unani and Ayurvedic) working in government medical college hospitals, district hospitals and upazila health complexes.

- **Bhutan**: It was reported that there were 35 *gSo-ba Rig-pa* physicians and 82 attendants employed in hospitals and health units providing T&CM, which is 2.65% of the total health workforce. The number of folk healers is reportedly almost equal to the number of conventional health-care providers.

- **Democratic People’s Republic of Korea**: As of 2013, there were 5249 registered Koryo traditional medicine doctors (2.3 per 10,000 population) and 1869 registered Koryo pharmacists. In addition, traditional Koryo technicians/assistants, such as manual therapists and natural therapists with diplomas, are part of the system.

- **India**: There were 773,668 registered T&CM practitioners as of 1 January 2017. The coverage, as of April 2017, was about 5.89 AYUSH practitioners per 10,000 population.

- **Indonesia**: The Ministry of Health reported over 88,920 traditional medicine practitioners registered for the period of 2010 to 2019. (MoH in 2019).

- **Maldives**: In 2010, there were reportedly 67 T&CM practitioners in the Maldives (*51 DhivehiBeys*, seven Ayurveda practitioners, four acupuncturists, three Chinese medicine practitioners, one Unani and one Qigong practitioner. As of December 2018, there were five Islamic physicians (*hakims*), 19 alternative medicine practitioners and 59 traditional medicine practitioners registered in the Maldives.

- **Myanmar**: In December 2018, there were 7262 registered indigenous traditional medicine providers and an estimated 2000 herbal medicine providers.

- **Nepal**: By 2018, there were about 70 postgraduates and more than 700 graduate doctors, and 3800 diploma technicians registered with the Nepal Ayurvedic Medical Council.

- **Sri Lanka**: The Sri Lanka Ayurvedic Medical Council is the licensing and regulatory body for T&CM practitioners. In 2017, there were 23,082 T&CM practitioners in the country, 8033 of them being holders of a degree or diploma. The T&CM practitioner density is 11 per 10,000 population. Of the general T&CM physicians registered, Ayurveda accounts for 84.6%, the Siddha system for 12.7% and the Unani system for 2.7%. Among the specialist physicians, those practising Ayurveda, Siddha and Unani account for 96.5%, 2.9% and 0.6% respectively.

- **Thailand**: The cumulative number of practitioners who passed the licensing examination and received licences between 1929 and 2017, in the category of TTM, were as follows: Traditional Thai medicine 21,495; pharmacy 29,165; midwifery 9851; *Nuad Thai* (traditional Thai massage) 4737; and applied traditional Thai medicine practitioners 2860.
Education

- **Bangladesh**: According to data from the Bangladesh Health Bulletin (SGHS Management Information System, 2017), there were 297 graduates and 491 diploma-holders in Ayurveda medicine, 616 graduates and 16,222 diploma-holders in homeopathic medicine and 364 graduates and 1,025 diploma-holders in Unani medicine.

- **Bhutan**: The Faculty of Traditional Medicine at the Khesar Gyalpo University of Medical Sciences of Bhutan is responsible for the development of human resources required for the delivery of traditional medicine services in the country. According to the Graduate Register, there are 78 traditional medicine providers holding Bachelor’s degrees and 114 holding diplomas, and 111 indigenous traditional medicine providers in Bhutan.

- **Democratic People’s Republic of Korea**: Primary-care physicians are trained to practise both Koryo and allopathic medicine. Medical students can major in allopathic medicine or traditional Koryo medicine; those majoring in allopathic medicine also compulsorily take courses in traditional medicine, and vice versa. The educational system provides diplomas, Bachelor’s, Masters and PhD degrees.

- **India**: There were 622 ASU&H teaching institutions in India, including 210 postgraduate institutions (annual intakes: 40,151 hold a first degree and 5,826 are postgraduates).

- **Indonesia**: Diplomas in Ayurveda or Jamu can be gained at the Hindu University, Denpasar, Airlangga University and the Surakarta Health Polytechnic. Vocational training is also available for “untrained” traditional healers so that their practice can become more standardised and their capacity to collaborate with conventional medical providers can be increased. Such training also aims to enhance their ability to provide a traditional medicine clinic under the supervision of a medical doctor.

- **Maldives**: An Advanced Certificate in Traditional Medicine is offered through the Faculty of Health Sciences, College of Higher Education. There is also a training programme for indigenous traditional medicine practitioners.

- **Myanmar**: In 2002, a University of Traditional Medicine was established in Mandalay, with regular and bridge Bachelor’s courses in Myanmar Traditional Medicine (1,500 graduates since 2001) and a Masters course started in 2011 (51 graduates).

- **Nepal**: Two universities conduct Bachelor-level education in Ayurveda and one of them provides a Masters degree as well. Between them, they enrol 80 students per year. The first formal Ayurvedic education institution was established in 1936, but the Bachelor of Ayurvedic Medicine and Medical Surgery is being offered since 1987.

- **Sri Lanka**: In 2017, the Postgraduate Institute of Indigenous Medicine was established to provide formal postgraduate training. Masters- and PhD-level training is available as well as MPhil and a postgraduate diploma in T&CM at the university level.
Allopathic medicine students receive 5–10 hours of education in Ayurveda and other T&CM systems whereas the curriculum of Ayurvedic students contains almost 50% allopathic medicine. About 145 new TM practitioners are produced by the universities each year.

- **Thailand:** A total of 1066 licensed TCM practitioners and 1863 allopathic medical doctors completed a three-month acupuncture and moxibustion training course in 2018.

- **Other: Democratic People's Republic of Korea, India and Thailand:** Each has a consumer education project or programme for self-health care using T&CM.

### Facilities

- **Bangladesh:** As of 2015, traditional medicine (Unani and Ayurveda) units with 179 medical officers were co-located at government medical college hospitals, district hospitals and *upazila* health complexes. About 28% of the patients are treated by traditional medicine doctors in the outpatient departments of government hospitals in Bangladesh (AMC, DGHS, 2015).

- **Bhutan:** A traditional medicine unit is co-located in 20 conventional district hospitals and 29 Basic Health Units, and the National Traditional Medicine Hospital provides standalone traditional medicine services. District T&CM units are directly under the administrative control of the district health sector. There is cross-referral of patients between the two systems and people can choose the alternative they prefer. About 10 to 30 per cent of patients in district hospitals use traditional medicine.

- **Democratic People’s Republic of Korea:** One central and 20 provincial Koryo traditional medicine hospitals provide specialist traditional medicine services. In addition, there are departments of Koryo traditional medicine co-located in every central and provincial biomedical facilities (133), and at all (7871) county-level hospitals and clinics. In practice, biomedicine and traditional treatments are often combined (Ministry of Public Health, 2014).

- **India:** T&CM providers practise in the public sector, in clinical and hospital settings. The delivery of formalized traditional medicine and conventional allopathic medicine are largely independent in terms of structures, organization and facilities, although there is co-location of traditional and conventional service provisions through the services of AYUSH practitioners in 15 525 government-sector facilities.

- **Indonesia:** T&CM providers practise in the public and private sectors, in clinical and hospital settings.

- **Maldives:** Employment is entirely through the private sector clinics, home-based practice and home visits.

- **Myanmar:** T&CM providers practise in the public and private sectors, in clinical and hospital settings. There are 37 traditional medicine hospitals of various sizes (in the
range of 16–100 beds), 50 district T&CM clinics and 210 township T&CM clinics. In 2017–2018, traditional medicine hospitals treated some 17 000 inpatients and 270 000 outpatients, while over half a million people attended township T&CM clinics and field visits reached out to about 300 000 patients. Altogether over 1.1 million people were treated in TM hospitals and clinics in 2017–2018 (BIMSTEC, 2019).

- **Nepal:** There is one government-run Ayurveda health centre in each district (for a total of 75 centres), two Ayurveda hospitals, 214 Ayurveda dispensaries, and one homoeopathic hospital (DoHS, 2015). In addition to these, there is an unknown number of facilities for other T&CM practices.

- **Sri Lanka:** There are about 270 institutions providing T&CM services in the country: 62 Ayurvedic hospitals and 208 central dispensaries. Over 3 million people seek treatment in these hospitals annually. In government ayurvedic hospitals, there are some 1424 physicians. The 62 Ayurvedic hospitals offer residential curative services to nearly 25 000 patients a year. In addition, there are 230 dispensaries administered by local government authorities, which offer free services to a large number people.

- **Thailand:** TTM providers practise in the public and private sector, in clinical and hospital settings. TTM is also prescribed by medical doctors in public health facilities that may not have a TTM practitioner on site. The percentage of OPD patients receiving TTM services in public health service facilities has been steadily rising in recent years, from 18% in 2016 to 20% in 2018.

### 2.1.4 Financing of T&CM

- **Bangladesh:** In 2013–2014, 0.57% of the total health financing was spent on the alternative medical care sector (MoHFW 2014).

- **Bhutan:** Full government insurance is available for gSo-ba Rig-pa (traditional Bhutanese medicine) as an integrated part of formal health care.

- **India:** AYUSH services are being provided freely to all the citizens at all level of public health facilities.

- **Indonesia:** Access to T&CM providers appears to be on a “user pays” system.

- **Maldives:** There is no government funding for T&CM yet.

- **Myanmar:** According to figures reported in the update survey, T&CM is reimbursed by both public and private insurance, as of the end of 2016.

- **Nepal:** Government services are often free and ayurvedic products have been available in dispensaries since the 1960s.

- **Sri Lanka:** In 2017, the public expenditure for TM was US$ 13.8 million (per capita public expenditure was US$ 0.6) while the government allocation in the annual budget for TM research was US$ 2.4 million.
Thailand: The budget allocated by the National Health Security Office for TT&CM services has grown more than 20-fold, from 0.5 baht (US$ 0.02) per capita in 2007 to 11.61 baht (US$ 0.36) in 2018. A total of US$ 30.85 million from government/public research funding has been allocated. As of the end of 2016, all traditional Thai medicine services are covered by health security systems.

2.1.5 T&CM research

Democratic People’s Republic of Korea: The Academy of Koryo Medicine, a national research institute for T&CM, was established in 1961. In addition, there are reportedly 28 research institutions for Koryo medicine in the DPR Korea.

India: Five central councils have been established under AYUSH for research in (i) Ayurvedic sciences (CCRAS, with 30 institutes), (ii) Unani medicine (CCRUM, with 23 institutes), (iii) homeopathy (CCRH, with 29 institutes), (iv) Siddha (CRS, with 5 institutes), and (v) yoga and Naturopathy (CCRYN). The objectives of these councils include the development of safe and effective formulations/therapies for management of diseases of national and global importance, revalidation of classical formulations for generating evidence on safety and efficacy, dissemination of research outcomes, capacity-building in core research areas, and patenting and commercialization of formulations/therapies and technologies developed by the councils. The core research activities include: clinical research (validation of classical Ayurvedic formulations, clinical safety and efficacy of new formulations), drug research (medicinal plants, quality assurance and drug standardization, and pharmacological research), literary research (revival, retrieval and preservation of Indian medicinal heritage, medico-historical studies, and publishing efforts, including collation, transcription, translation and publication), fundamental research and other research activities (documentation of ethno-medicine and validation of local health traditions, as well as research-oriented public health activities).

Indonesia: In 1977, the National Institute of Health Research and Development (NIHRD), Ministry of Health (Indonesia), set up an R&D Institute of Medicinal Plants and Herbal Medicines. The development of standard quality of herbal medicine (Indonesian Herbal Pharmacopoeia) took place in 2008 and national research and development in herbal medicine started in 1980.

Myanmar: Myanmar has a TM research roadmap under which the University of Traditional Medicine has submitted 22 non-clinical studies on Myanmar herbal medicines, 15 clinical studies on Myanmar herbal medicines, three literature research projects. In addition, a TM Kit Project is being prepared in collaboration with Nippon Foundation, Japan, as well as numerous implementation research projects and clinical research projects are on the anvil.

According to National Health Accounts studies of the share of T&CM in overall health expenditure during 2015 and 2016, the shares in Bhutan were 4.60% and 4.84% respectively and those in India were 0.80% and 11.90% respectively. In Nepal, the percentages were 0.57% and 0.56% respectively and in Sri Lanka, 1.43% and 1.46% respectively.

Source: National Health Accounts
The MoH Department of Traditional Medicine includes a Research and Development Division, which was established in 1998. Research and scientific analyses involve botanical, chemical, pharmaceutical, pharmacological and clinical investigations into traditional drug samples. Scientific analyses usually aim to distribute safe and effective traditional medicines among the people by investigating quality assurance and to improve T&CM clinical practice. The Department of Traditional Medicine also conducts research in collaboration with universities (through the Ministry of Education), the Department of Pharmaceutical and Household Products (at the Ministry of Industry), the Department of Medical Research (at the Ministry of Health and Sports), Forest Research Institute (through the Ministry of Natural Resources and Environmental Conservation) and the Department of Research and Innovation (at the Ministry of Education).

- Nepal: In 2011, the National Ayurveda Research and Training Centre was established on the premises of Tribhuvan University. Its scope is to develop traditional medicine to provide evidence-based therapy, transfer advanced skills and technology to practitioners, and develop high-quality research laboratories in toxicology, immunology, drug formulation, quality control and assurance, pharmacology, cellular biology, microbiology and pathology.

- Sri Lanka: The Bandaranaike Memorial Ayurvedic Research Institute and four local universities engage in TM research. The Central and provincial governments organize annual research symposia. Journals are published by the Department of Ayurveda and the universities.

- Thailand: The Traditional Thai Medicine Research Institute (under the Institute of Traditional Thai Medicine) was established in Bangkok in 2010.

2.2 International cooperation and support 2014–2019

There have been considerable international and regional activities in the field of traditional and complementary medicine in the years under review. Specific activities at the country level are described in this section, and these include national frameworks for traditional and complementary medicine, regulatory status of herbal medicines, and the practice, providers, education and health insurance related to T&CM. A focus on WHO activities relating to traditional medicine in the Region follows this narration.

While the country profiles provided in Part 4 set out the situation in the countries as it has developed over the years, we will cover below the main new developments since 2015 in respect of the national framework for traditional and complementary medicine, the regulatory status of herbal medicines, and practice, providers, education and health insurance.
2.2.1 The Colombo Declaration

An International Symposium on Traditional, Complementary and Indigenous Medicine was held in Colombo, Sri Lanka, on 23–25 November 2017. This symposium was co-organized by the Government of Sri Lanka and WHO. Its overall aim was to share the expertise and evidence-based practices of traditional medical systems in disease prevention, diagnosis and management, and use of modern science and technology, diagnostic tools and biomedical information system in traditional medicine in relation to the safe and effective product development with quality and standard.

The symposium issued the Colombo Declaration on Traditional Medicine specifying the commitments of the WHO Member countries to implementing important outcomes of the conference. The key commitments by Member States in the Colombo Declaration included the following:

- Integrate T&CM into national health systems.
- Establish national education and training programmes, accreditation and licensing procedures for educational institutions and T&CM practitioners.
- Initiate appropriate legislation, codes of ethics and oversight mechanisms to strengthen and ensure quality and safety.
- Collaborate in training, research and development of courses that integrate T&CM with modern sciences.
- Strengthen the knowledge base, regulations and collaborations among all stakeholders to generate safe, efficacious and quality T&CM products and procedures.
- Promote research, development and innovation for safe, efficacious and quality T&CM products and procedures.
- Protect T&CM knowledge and natural resources, and prevent their misappropriation by adopting appropriate national intellectual property legislation.
- Cooperate to promote the sustainable use and conservation of traditional medicinal plants.
- Collaborate in developing technical guidelines and methodology for evaluating and ensuring safety, efficacy, quality and effectiveness of T&CM products and procedures.
- Share knowledge and resources to ensure safety, efficacy, quality and sustainable use of T&CM products and procedures.

2.2.2 Bilateral memorandum of understanding (MoU)

Among the specific activities related to international cooperation among Member States are memorandums of understanding (MoUs) signed by India with 16 countries (including
Bangladesh, Myanmar and Nepal from the WHO South-East Asia Region, and 17 MoUs with selected international institutions for research/academic collaboration in areas of mutual interest. Box 2 provides further information on these MoUs.

India’s Ministry of AYUSH has also been providing international scholarships/fellowships to the WHO SEA Region countries and Malaysia during 2014–2018 to enable students to undertake AYUSH courses in premier institutions in India. Study tours were arranged for delegations from the Democratic People’s Republic of Korea in 2017 and from Bhutan in 2018 covering various areas of traditional medicine in India. The Ministry of AYUSH also organized several significant international conferences on T&CM topics in India in recent years.

**Box 2: MoUs signed between India’s Ministry of AYUSH and WHO SEA Region Member countries**


- **BANGLADESH: Establishment of an Academic Chair in Unani in Bangladesh**, between the Central Council for Research in Unani Medicine and Hamdard University, Bangladesh. Signed on 10 February 2018.

- **MYANMAR: Cooperation in the field of traditional systems of medicine**, between the Ministry of AYUSH and the Department of Traditional Medicine, Ministry of Health and Sports, Myanmar. Signed on 29 August 2016. A bilateral meeting between the Ministry of Health, Government of Myanmar, and the Ministry of AYUSH held on 18 May 2017 to discuss the roadmap for cooperation in traditional medicine. Plans to establish an Academic Chair in Ayurveda at the University of Myanmar.

- **INDONESIA: Establishment of an Academic Chair in Ayurveda in Indonesia**, between the Central Council for Research in Ayurvedic Science, the Ministry of AYUSH and Udayana University, Bali. Signed on 4 November 2015.


- **NEPAL: Cooperation in the field of traditional systems of medicine**, between the Ministry of AYUSH and the Ministry of Health and Population, Government of Nepal. Signed on 25 November 2014. To support the recognition of Ayurveda as a system of medicine, recognition of BAMS degree of Tribhuvan University under IMCC Act 1970, organizing the India-Nepal Inter Governmental Sub-Committee meeting to discuss WHO GMP and bilateral discussions on the non-tariff barriers imposed on the export of Indian Ayurveda products held in Kathmandu, Nepal.

- **BANGLADESH: Cooperation in the field of traditional systems of medicine**, between the Ministry of AYUSH and the Ministry of Health and Family Welfare, Bangladesh. Signed on 9 September 2014. Topics included the recognition of Bangladeshi ASU&H degrees, bridge courses for Bangladeshi diploma holders and technical assistance in setting standards in AYUSH systems, including medicinal plants.
2.2.3 The Bay of Bengal Initiative for Multisectoral Technical and Economic Cooperation

A key initiative for traditional medicine for seven countries in the Region has been the Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation (BIMSTEC). BIMSTEC was established as a regional organization on 6 June 1997 through the Bangkok Declaration. Its member countries are Bangladesh, Bhutan, India, Myanmar, Nepal, Sri Lanka and Thailand. All these countries lie in the littoral and adjacent areas of the Bay of Bengal, constituting a contiguous regional unity. Its Secretariat is based in Dhaka, Bangladesh.

BIMSTEC is a sector-driven organization. “Public health” is one of its important priority areas, led by Thailand. During the third meeting of the BIMSTEC Network of National Centres of Coordination in Traditional Medicine (Thailand, 20–22 July 2015), a workplan for a BIMSTEC Task Force on Traditional Medicine was adopted. This task force was mandated to share information on T&CM, exchange human resources for capacity-building, sharing information on traditional medicines and herbal pharmacopoeia and collaborative research on common diseases in the Region, and to formulate a regional strategy for the protection of genetic resources and other traditional knowledge.

An early product of this initiative was the publication of “Traditional Systems of Medicine of BIMSTEC Member Countries”9 in October 2015. This was a compilation of the presentations on traditional systems of medicine and the policies of the respective governments of the BIMSTEC member states, and this set the baseline for further BIMSTEC activities on T&CM.

Key results of the first and second meetings of the BIMSTEC Task Force on Traditional Medicine include:

- A concept note on the protection of genetic resources (GR) and associated traditional knowledge (TK) (presented by Thailand).
- The adoption of a base paper on the protection of genetic resource associated with traditional medicine knowledge and intellectual property rights, submitted by India.
- Each country agreed to nominate a nodal agency and a country-specific nodal group.
- India proposed to host a workshop in 2019 on the harmonization of curricula for mutual recognition of traditional medicine degrees.
- With the aim of developing a BIMSTEC Pharmacopoeia on Traditional Medicine, a BIMSTEC pharmacopoeia format/template was developed, and it was agreed that there would be collaboration to develop a template/BIMSTEC traditional medicine portal in 2019.

India’s proposal to establish a BIMSTEC Ayurveda and Traditional Medicine University to act as a model institution in the region. Member states could then develop their own Ayurveda and traditional medicine colleges affiliated to the university in order to enable sustainable capacity development in traditional medicine.

2.3 WHO activities 2015–2019

As described in Section 1.2.3, the five priority areas for action identified in the WHO SEA Region Traditional Medicine Action Plan10 were:

1. T&CM systems monitoring
2. T&CM research
3. Developing the T&CM practitioners/workforce
4. Adverse events reporting
5. Communication.

In support of this agenda, among the key areas of activity during the period under review have been developing indicators appropriate for T&CM, global guidance (benchmarks, guidelines and the International Classification of Diseases), pharmacovigilance, intellectual property aspects and supporting integration of T&CM and allopathic systems of medicine. These are summarised below.

2.3.1 Indicators improving monitoring of T&CM performance

The Regional Workshop on Appropriate Integration of Traditional Medicine into National Health Systems, held in Pyongyang, Democratic People’s Republic of Korea in October 201511 proposed that an indicator set should be developed. These core and reference indicators were agreed upon and refined through a series of technical working group meetings that included traditional medicine policy-makers and managers, and indicator experts during 2016 and 201712.

The core indicator set consists of 16 indicators that were considered essential and were collectively able to provide information on T&CM inputs, processes and outputs. A longer list of reference indicators is also available for countries that wish to monitor more indicators or want to consider alternative metrics that would better suit each country’s traditional and complementary medicine situation, priorities and monitoring capacities.

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10 WHO, 2016. Regional workshop to share experience and evidence on appropriate integration of traditional medicine into national health-care systems, Report of the Regional Workshop, Pyongyang, Democratic People’s Republic of Korea, 20–22 October 2015. SEA-HSD-390
Each core and reference indicator is accompanied by a set of metadata. This provides information on the indicator rationale, definitions, data elements (numerator, denominator and data disaggregation), frequency of measurement and data sources. It is a guide for more standardized data measurement as well as data interpretation.

The standard core and reference indicators were tested in four countries: Bhutan, Myanmar, Sri Lanka and Thailand. Data reporting in the countries is summarized in Table 3. This table illustrates, for the test set of indicators, what data are available in these four countries and what are missing.

**Table 3: Data availability for specific indicators**

<table>
<thead>
<tr>
<th>No</th>
<th>Indicators/Member States</th>
<th>Bhutan</th>
<th>Myanmar</th>
<th>Sri Lanka</th>
<th>Thailand</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Number of T&amp;CM research results in the national research registry</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>2</td>
<td>Number of T&amp;CM products with a pharmacopoeia or monograph</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>3</td>
<td>Number of T&amp;CM graduates with PhD degree</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>4</td>
<td>Number of peer-reviewed T&amp;CM scientific publications in international journals</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>Total health expenditure for T&amp;CM (in US$)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>Total health expenditure for T&amp;CM (in local currency)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>7</td>
<td>Proportion of T&amp;CM manufacturers that are licensed</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>8</td>
<td>Proportion of licensed T&amp;CM manufacturers that meet GMP standards</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>9</td>
<td>T&amp;CM regulated practitioner density and distribution (per 10 000 population)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>10</td>
<td>T&amp;CM reflected in the national health sector plan</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>11</td>
<td>Public health expenditure allocated to T&amp;CM at the national and regional levels in local currency</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>12</td>
<td>Existence of a national adverse event reporting system for T&amp;CM practice</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>13</td>
<td>Existence of a continuing professional development programme for T&amp;CM practitioners</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>4</td>
</tr>
<tr>
<td>14</td>
<td>Number of T&amp;CM graduates with diploma or degree</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
</tr>
<tr>
<td>15</td>
<td>Existence of a reference laboratory for testing of T&amp;CM products</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
</tr>
<tr>
<td>16</td>
<td>Existence of a national body to oversee T&amp;CM-related research</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
</tr>
<tr>
<td>17</td>
<td>T&amp;CM outpatient department visits as a percentage of all outpatient department visits</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
</tr>
<tr>
<td>18</td>
<td>Per capita public health expenditure allocated to T&amp;CM at the national and regional levels in US$</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
</tr>
<tr>
<td>19</td>
<td>Per capita public health expenditure allocated to T&amp;CM at the national and regional levels in local currency</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
</tr>
</tbody>
</table>
## Traditional medicine in the WHO South-East Asia Region

<table>
<thead>
<tr>
<th>No</th>
<th>Indicators/Member States</th>
<th>Bhutan</th>
<th>Myanmar</th>
<th>Sri Lanka</th>
<th>Thailand</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>Number of T&amp;CM graduates with clinical doctorates</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>3</td>
</tr>
<tr>
<td>21</td>
<td>Number of reported T&amp;CM-related adverse events for T&amp;CM products</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>22</td>
<td>Number of monographs for herbal raw materials</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>23</td>
<td>Number of hospitals and clinics providing both T&amp;CM and modern medicine services</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>24</td>
<td>Number of T&amp;CM products included in the national essential medicines list</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>25</td>
<td>Existence of regulatory mechanism to oversee advertising of T&amp;CM products</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>26</td>
<td>Number of research institutions or centres that conduct research on T&amp;CM including network universities</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>3</td>
</tr>
<tr>
<td>27</td>
<td>Number of T&amp;CM graduates with postgraduate diploma</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>28</td>
<td>Number of outpatient department visits for T&amp;CM services</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>29</td>
<td>Existence of conservation and cultivation programme to protect biodiversity and endangered species of medicinal plants and non-plants</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>30</td>
<td>Existence and continuing development of a mechanism and database to protect traditional knowledge and associated genetic resources</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>31</td>
<td>Existence of a national adverse event reporting system for T&amp;CM products</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>32</td>
<td>Existence of national mechanism to ensure quality of T&amp;CM education and training</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>33</td>
<td>Number of T&amp;CM graduates with Masters degrees</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>34</td>
<td>Number of T&amp;CM graduates with Bachelor’s degrees</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>35</td>
<td>Number of peer-reviewed T&amp;CM scientific publications in local journals</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>36</td>
<td>Number of hospitals and clinics offering T&amp;CM</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>37</td>
<td>Number of agricultural and collection practice guidelines (GACP) for medicinal plants</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>38</td>
<td>Existence of a communication mechanism to provide public information related to T&amp;CM products and services</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>1</td>
</tr>
<tr>
<td>39</td>
<td>Number of reported T&amp;CM-related adverse events for T&amp;CM practice</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>40</td>
<td>Integration of T&amp;CM with a national research council or a national health council</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>41</td>
<td>Existence of T&amp;CM practice guidelines</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>42</td>
<td>Existence of a protocol or guidelines for referral between T&amp;CM and modern medical services</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>0</td>
</tr>
</tbody>
</table>

**Total (Number and percentage)**

<table>
<thead>
<tr>
<th></th>
<th>Bhutan</th>
<th>Myanmar</th>
<th>Sri Lanka</th>
<th>Thailand</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>29 (69%)</td>
<td>25 (59.5%)</td>
<td>31 (75%)</td>
<td>24 (57%)</td>
<td>109 (57%)</td>
</tr>
</tbody>
</table>
Altogether, of the 42 core and reference indicators, 13 were reported as being available from all four countries (30.9%); 13 more indicators were available from three of the countries (30.9%); six from two countries (14.3%); and six from only one country (14.3%), while data on four of the indicators were not available from any of the countries studied (9.5%). Considering the results by country, Bhutan could report on 29 indicators (69%); Myanmar on 25 indicators (59.5%); Sri Lanka on 31 indicators (75%); and Thailand on 24 indicators (57%). These findings will guide future work in establishing and improving the T&CM monitoring systems at the country and regional levels.

This set of indicators is intended as a guide and reference for country T&CM policy-makers and managers. It is not a mandatory set of indicators based on which countries are expected to report to WHO. However, the WHO Regional Office for South-East Asia does recommend that countries develop and/or maintain a conscious approach to monitoring this important field of health care for which data are so scarce.

Traditional medicine services and their monitoring system in Bhutan

In Bhutan, traditional medicine (gSo-ba Rig-pa) has been integrated into the national health-care delivery system since 1968. The traditional medicine unit is co-located in 20 conventional district hospitals out of 22, and 29 basic health units out of 41 in total, together with the National Traditional Medicine Hospital, which provides standalone traditional medicine services. There is cross-referral of patients between the two systems and people in Bhutan can choose a service as per their preference.

Traditional medical services are monitored and evaluated through the hospital management information system, in terms of number of OPD visits and health conditions, in comparison with allopathic medical services. For instance, according to the data from 2018, about 10%–15% OPD services at the district and BHU levels were associated with traditional medical services.

The main health conditions managed with traditional medicines were gastrointestinal conditions such as indigestion, stomach pain, constipation, diarrhoea, bone and joint disorders, respiratory disorders (such as sinusitis, cold, cough, sputum and asthma), cardiovascular diseases (such as hypertension, hyperlipidaemia and stroke), chronic liver and kidney disorders, skin diseases and mental disorders. These were managed with about 128 items of traditional medical products that are included in the national essential drugs list.

2.3.2 Pharmacovigilance

Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems”. A resolution (WHA16.36) passed at the Sixteenth World Health Assembly in 1963 led to the establishment of the WHO Programme for International Drug Monitoring (PIDM) in 1968. This global mechanism for monitoring drug safety is operated to ensure...
that evidence about harm to patients is collected from adverse events reports. In 1978, the Uppsala Monitoring Centre (UMC) in Sweden was appointed as a WHO Collaborating Centre to manage the PIDM network and be responsible for its technical and operational aspects.

One of the common challenges that Member States face is how to establish and further strengthen the safety monitoring system for traditional medicine products, particularly with regard to pharmacovigilance. This was one of the action points of the regional workshop on the appropriate integration of traditional medicine into national healthcare delivery systems, held in the Democratic People’s Republic of Korea in October 2015. Accordingly, two country case studies on the subject were carried out in 2016, and the WHO Regional Office for South-East Asia commissioned a regional survey on pharmacovigilance for traditional and complementary medicine products in 2018.

The survey was carried out between June and November 2018. The principal findings and conclusions of the survey were as follow:

- Pharmacovigilance has been established in eight of the WHO SEA Region countries, but it is not fully functioning in all of them (see Table 4). In addition, T&CM products tend to be accorded low priority. Only three countries have integrated T&CM products into the existing systems and one country has organized a separate pharmacovigilance programme for T&CM products.

- Although most of the countries did not have a dedicated annual budget to cover their operations, pharmacovigilance funding was available to enable capacity-building and training of personnel in pharmacovigilance from WHO and other donors.

Table 4: Structure and resources of the PV systems in WHO SEA Region countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Start of WHO PIDM membership (Year*)</th>
<th>PV centre as part of NRA†</th>
<th>No. of PV staff (tech/admin)</th>
<th>National database</th>
<th>Fixed government budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>2014</td>
<td>Yes</td>
<td>7 (4–3)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Bhutan</td>
<td>2014</td>
<td>Yes</td>
<td>4 (4–0)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>India</td>
<td></td>
<td>No*</td>
<td>NA</td>
<td>No</td>
<td>Yes*</td>
</tr>
<tr>
<td>Indonesia</td>
<td>1990</td>
<td>Yes</td>
<td>18 (16–2)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Maldives</td>
<td>2016</td>
<td>Yes</td>
<td>2 (1–1)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Nepal</td>
<td>2006</td>
<td>Yes</td>
<td>1 (1–0)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td></td>
<td>No*</td>
<td>NA</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Thailand</td>
<td>1984</td>
<td>Yes</td>
<td>13 (9–4)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Abbreviation: Admin = Administrative staff, NA= Not Applicable, NRA = National Regulatory Authority, PV = Pharmacovigilance, Tech= Technical staff, WHO PIDM = WHO Programme for International Drug Monitoring.

* As listed in https://www.who-umc.org/global-pharmacovigilance/members/who-programme-members/
† Within or appointed by national regulatory authorities, *Source: literature review
A wide range of products and events are covered under the pharmacovigilance system in the Region: vaccines, cosmetics, medical devices, food/food supplements and veterinary medicines. Patient safety issues associated with the quality, interaction and medication errors are also considered (see Table 5).

Table 5: Type of products and events covered under the PV systems

<table>
<thead>
<tr>
<th>Countries</th>
<th>Product</th>
<th>Patent safety events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Allopathic medicine</td>
<td>T&amp;CM product</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>India</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Indonesia</td>
<td>Yes'</td>
<td>Yes</td>
</tr>
<tr>
<td>Maldives</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Thailand</td>
<td>Yes'</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Abbreviation:** C = Cosmetics, F = food, FS = Food supplement, MD = medical device, VM = Veterinary medicine, AE = adverse event, DI = drug interaction, PQ = product quality, ME = medication error

* Source: literature review, † Including biological product

Regarding the main achievement, 503 individual case safety reports (ICSRs) associated with T&CM products were forwarded to the WHO VigiBase from India, Indonesia, Nepal and Thailand as shown in Table 6. In addition to signal detection, safety signals of an adverse event associated with T&CM products have been generated and some of them have led to regulatory action. In Thailand, for example, *Cassia siamea* (leaf) with hepatotoxicity was detected in 2000 and resulted in the registration being cancelled. A warning of the risk of serious hypersensitivity reaction was required for products containing *Andrographis paniculata* in 2018, which was a result of the signal generation of this issue in 2012.

Table 6: Individual case safety reports (ICSRs) and T&CM products

<table>
<thead>
<tr>
<th>Country</th>
<th>ICSRs of T&amp;CM in the national database</th>
<th>Contribution of ICSRs to WHO VigiBase by National Centre (2016–2017)*</th>
<th>No. of safety signals detected (T&amp;CM)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total ICSRs of T&amp;CM (year of first report received)</td>
<td>ICSRs of T&amp;CM (2016–2017)</td>
<td>All ICSRs</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>0</td>
<td>0</td>
<td>154</td>
</tr>
<tr>
<td>Bhutan</td>
<td>0</td>
<td>0</td>
<td>192</td>
</tr>
</tbody>
</table>
The major challenges in accomplishing the safety surveillance of T&CM products in the Region are not only the limited resources, but also the lack of knowledge and expertise regarding the analysis of the causal relationship between products and adverse drug reactions (ADR). Insufficient information and difficulties in accessing reliable information support are other critical challenges.

The findings are consistent with several studies that identified manpower constraints as the main challenge for pharmacovigilance systems to function. In addition, investigating the quality of suspected products is troublesome due to their multiple ingredients. This leads to poor assessments of the causal relationship between products and ADRs.

The research shows that it is feasible to implement/strengthen pharmacovigilance for T&CM products in all participating countries. To overcome the challenges, enabling methodologies, such as workshops/toolkits and information-sharing platforms, should be developed. The mapping of the training needs of each country so that capacity-building in the Region can be planned is a priority. People involved in the system need to be trained.

The detection and assessment of adverse reactions are crucial for all stakeholders in pharmacovigilance.

Risk communication and information cutting across participating countries should be strengthened.

It is feasible to implement pharmacovigilance for T&CM products in participating countries. Pharmacovigilance for T&CM could either be integrated with or separated from the existing national pharmacovigilance system, depending on the context of
each country. In either case, these schemes should be closely linked with the national pharmacovigilance system.

- All ICSRs should be sent to the national databases and the Global Vigilance Database for aggregated assessment and signal detection. To enhance the system functions, it should operate alongside an effective national drug regulatory system, so that the signal could be aligned with proper regulatory measures.

### Pharmacovigilance for traditional medicine products in Thailand

The country has been participating in the global drug monitoring programme since 1984. As of 7 August 2020, the total number of adverse events (AE) reported to the global programme was 375,030 and out of them, 916 were related to traditional medical products.

PV has played a crucial role in ensuring the safety of herbal products. In particular it has contributed greatly towards ensuring the safety of the newly added traditional medicine and herbal products of the National Essential Drugs List (NEDL) in Thailand. There are rules and a regulatory system in the country for monitoring any adverse events relating to herbal products, particularly when new items are added to the national essential herbal products list. To promote traditional medicine and herbal products in primary health care, the government has a policy to add the products as a part of NEDL. In the latest version (2019) of NEDL, there are 50 traditional medicines and 24 herbal products.

To promote the reporting of adverse events pertaining to traditional medicines, several active surveillance initiatives were undertaken through a spontaneous reporting system, especially after traditional medicine was included in NEDL in 1999. The targeted spontaneous reporting had been introduced later for monitoring these products since 2012 and was then integrated into routine practices. For example, the Centre of Applied Thai Traditional Medicine (CATTM), Faculty of Medicine at Siriraj Hospital, Mahidol University, which was designated as the World Health Organization Collaborating Centre in 2018, initiated the intensive monitoring programme to ensure safety of the products that had the potential for being included in NEDL. The regulatory authority concerned is developing the compulsory requirement for marketing authorization holder of herbal product in accordance with the Herbal Products Act 2019.

During 1999–2019, several potential and significant signals for traditional herbal medicines were detected. These included *Tinospora crispa* or *Cassia siamea* (leaf) associated with hepatotoxicity, *Andrographis paniculata* with serious hypersensitivity, *Derris scandens Benth.* with angioedema, green traditional medicine with Stevens-Johnson syndrome, and *Sahatsatara*, a Thai traditional medicine used to treat musculoskeletal and joint diseases, with GI disturbances.

Two of the detected signals led to regulator actions to minimize risk. The registration of products with *Cassia siamea* (leaf) as a single component was cancelled. Several studies were conducted to investigate the toxicity of barakol, either as a chemical or in a prepared form. A warning of the risk of serious hypersensitivity reaction is required for products containing *Andrographis paniculata*, according to the ministerial notification on product legal warnings in 2018. The others are being monitored and kept under review.
2.3.3 Intellectual property

In 2012, global sales of Chinese herbal medicine reached US$ 83 billion, up by more than 20 per cent from 2011. The global market for all herbal supplements and remedies could reach US$ 115 billion by 2020, with Europe being the largest and the Asia-Pacific the fastest growing markets. This is, therefore, a large industry and where there is such a major commercial interest, intellectual property issues inevitably arise.

The WHO Traditional Medicine Strategy 2014–2023 highlights that it is necessary to prevent the misappropriation of T&CM by implementing the relevant international instruments in line with the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (Resolution WHA61.21), adopting or amending national intellectual property legislation and enacting other defensive protection strategies.

It is important to balance the need to protect the intellectual property rights (IPR) of indigenous people and local communities, and their health-care heritage while ensuring access to T&CM and fostering research, development and innovation. Protecting traditional knowledge would improve the lives of communities who depend on such ancient systems for their livelihoods, health and well-being. Increasing the use of technology to utilize traditional knowledge could enable greater commercial use of its biological wealth and boost exports of traditional knowledge-related products.

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A Sri Lanka study on intellectual property rights and traditional medicine

A recent study commissioned by the WHO Regional Office examined the interface between intellectual property rights and trade in traditional medicine relating to Sri Lanka. It also sought to identify the best possible methods that the country could adopt in order to protect TM and traditional knowledge, while providing the opportunity to get the best possible benefits for the country from these. A series of country case studies considered the legal position regarding traditional medicine and traditional knowledge in China, India and Thailand. As this study has potential applicability to the rest of the SEA Region, its principal conclusions are cited below:

- There is a need for a properly established system to protect traditional knowledge. Very few developing countries have implemented the Convention on Biological Diversity and even fewer have set up mechanisms to implement legislation. Thus, they are highly vulnerable to exploitation from outside. It is important to identify ways and devise means to strengthen customary laws for the protection of the TM knowledge of the community from biopiracy. Each country should have a well-established national policy on TM, traditional medicinal knowledge and traditional plant varieties as part of their national health policy.
Conventional IPR regimes discourage disclosure of traditional knowledge and hamper its documentation. Thus, there is a need to develop an alternative sui generis system that will meet the needs of the holders of traditional knowledge. Such a system will not only ensure the sharing of benefits, but will also create an environment that would encourage disclosure of traditional knowledge, which would otherwise be lost to the world. The development of such a sui generis system is, however, no easy task and requires concerted efforts of the local community. For example, Thailand’s Act on Protection and Promotion of Traditional Thai Medicinal Intelligence protects “formulas” of traditional Thai drugs and “texts on traditional Thai medicine”. Only those who have registered their IP rights can research, develop and produce drugs using traditional medical knowledge.

It is important to develop guidelines or laws and enforce them to ensure benefit-sharing with the community for commercial use of traditional knowledge. Creating a system for the registration of innovations by inventors would be equivalent to giving inventors the right to challenge any use of their innovations without prior permission. Obtaining patents in the herbal/TM pharmaceutical sector should be encouraged by developing research, technology and other leading issues through effective private–public partnerships.

Traditional knowledge that is in the public domain needs to be documented in the form of traditional knowledge digital libraries. Documenting traditional knowledge includes recording it, writing it down, taking pictures of it or filming it – anything that preserves it in an accessible form. It is different from the traditional ways of preserving and passing on knowledge within a community and can promote or damage a community’s interests, depending on how the documentation is carried out.

Some immediately applicable and generalizable practical suggestions include:

- Enforce and monitor national and international laws/policies relating to the import and export of biodiversity-related items.
- Promote development programmes through revenue collection, facilitation and enforcement in import and export of raw materials and herbal products in a manner that will not harm the rich biological heritage of the country.
- Exchange information and develop intelligence with the national and international institutions concerned, and build a special network for IPR and trade in the South-East Asia Region.
- Attend and conduct meetings, seminars and workshops at governmental and nongovernmental institutions and take expert opinion on policy and other matters related to IPRs.
- Conduct education, training and awareness programmes on IPR and trade-related matters for the benefit of the public and schools, and at the university level.
- Develop and maintain a database on IPR-related detections of TM and related knowledge.
- Maintain a proper relationship with line ministries, government departments, etc. and exchange information with national and international organizations.
- Prepare and develop related publications and distribute these.
- Establish a TM and traditional knowledge digital library and document traditional knowledge.
- Establish a TM and traditional knowledge-specific registration and innovation patent system.
India’s traditional knowledge digital library

In 2001, India’s Council for Scientific and Industrial Research launched a traditional knowledge digital library (TKDL) of remedies and medicinal plants. Its genesis dates to the Indian effort on revocation of patent on wound-healing properties of turmeric at the United States Patent and Trademark Office (USPTO). In 2005, the TKDL expert group estimated that about 2000 wrong patents concerning Indian systems of medicine were being granted at the international level every year. This was mainly a result of India’s traditional medicinal knowledge being written in local languages not spoken by patent examiners at the international patent offices.

The digital library has overcome the language and format barrier by scientifically converting and structuring the available contents (till date 0.29 million medicinal formulations) of the ancient texts on Indian Systems of Medicines, i.e. Ayurveda, Siddha, Unani and yoga, into five international languages, namely English, Japanese, French, German and Spanish, with the help of information technology tools and an innovative classification system known as Traditional Knowledge Resource Classification (TKRC). From 2009, the European Patent Office (EPO) has been able to consult the 34 million-page, multilingual database before granting patents and has cancelled or withdrawn 36 applications to patent traditionally known medicinal formulations in just under two years.17

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2.3.4 Integration

One of the four main objectives of the WHO traditional medicine strategy 2002–2005 was to support countries to integrate traditional medicine with their own health systems. In 2003, a World Health Assembly resolution (WHA56.31) on traditional medicine urged Member States, where appropriate, to formulate and implement national policies and regulations on traditional and complementary and alternative medicine to support their proper use. Further, Member States were urged to integrate T&CM into their national health-care systems, depending on their relevant national situations.

In her Foreword to the Strategy (WHO traditional medicine strategy: 2014–2023. World Health Organization. Geneva ISBN 978 92 4 150609 0), the then Director General, Margaret Chan, wrote: “Across the world, traditional medicine is either the mainstay of health-care delivery or serves as a complement to it.” Noting that T&CM is found in almost every country in the world and that the demand for its services is increasing, she said, “A global strategy to foster its appropriate integration, regulation and supervision will be useful to countries wishing to develop a proactive policy towards this important – and often vibrant and expanding – part of health care. Governments and consumers are interested in more than herbal medicines, and are now beginning to consider aspects of T&CM practices and practitioners, and whether they should be integrated into health service delivery.”
The question of how to integrate traditional medicine into health services required a separate analysis and solution in each country. Research was required.

To help Member States to better understand appropriate integration of T&CM into health systems and to strengthen national capacity, WHO SEARO organized a workshop on the subject in October 2015. It also conducted a literature review on integration of T&CM into health-care delivery system in terms of policy, service delivery, T&CM workforce, including education, products and its regulatory system, and financing in 2015. The summary of the key findings is given in Table 7.

Moreover, WHO has organized regular interregional workshops on the integration of T&CM into health systems (see Table 8). These were attended by all Member States of the WHO South-East Asia Region on different occasions during 2014–2018. This has contributed to the strengthening of the national capacity for appropriate integration of T&CM into national Health systems in the Region. WHO SEARO also provided a study tour programme for some Member States (Bhutan, DPR Korea and Sri Lanka) on the integration of T&CM into national health systems during the last 3–4 years.
Table 7: Level of integration of T&CM into health-care systems, WHO SEA Region Member States

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Bangladesh</th>
<th>Bhutan</th>
<th>DPR Korea</th>
<th>India</th>
<th>Indonesia</th>
<th>Maldives</th>
<th>Myanmar</th>
<th>Nepal</th>
<th>Sri Lanka</th>
<th>Thailand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy</td>
<td>National Health Policy for T&amp;CM</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>National Program for T&amp;CM or integration of T&amp;CM</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td></td>
<td>National Officer for T&amp;CM</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>National T&amp;CM report (May be part of national health report)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Service delivery</td>
<td>Co-located T&amp;CM and allopathic medical care in Public sector: Yes (number) or No</td>
<td>Yes (45)</td>
<td>Yes (78)</td>
<td>Yes (8004)</td>
<td>Yes (22)</td>
<td>Yes (15 525)</td>
<td>Yes (10 692)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Stand-alone public T&amp;CM service; Yes (number) or No</td>
<td>Yes (1)</td>
<td>Yes (21)</td>
<td>Yes (29 733)</td>
<td></td>
<td>Yes (259)</td>
<td>Yes (292)</td>
<td>Yes (500)</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T&amp;CM worker &amp; education</td>
<td>Formal training /Education system for T&amp;CM</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Number of T&amp;CM practitioners registered in total during 2015-2018</td>
<td>31 000</td>
<td>7118</td>
<td>736538</td>
<td>67</td>
<td>6963</td>
<td>2000</td>
<td>19 529</td>
<td>58 935</td>
<td>951</td>
<td></td>
</tr>
<tr>
<td>Products &amp; Regulation</td>
<td>Number of manufacturers with license* * 2018 Regional survey on PV</td>
<td>509</td>
<td>1</td>
<td>230</td>
<td>8667</td>
<td>530</td>
<td>3</td>
<td>3132</td>
<td>80</td>
<td>Nil</td>
<td>951</td>
</tr>
<tr>
<td></td>
<td>GMP for T&amp;CM products</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>In-process</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
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<tr>
<td>Category</td>
<td>Description</td>
<td>Bangladesh</td>
<td>Bhutan</td>
<td>DPR Korea</td>
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<td>----------</td>
</tr>
<tr>
<td>Pharmacopiea or Monograph for T&amp;CM as quality and formular standard</td>
<td>In-process</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>In-process</td>
<td>In-process</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Number of T&amp;CM products registered as of 2018**</td>
<td>**2018 regional survey on PV</td>
<td>10729</td>
<td>128</td>
<td>4200</td>
<td>Nil</td>
<td>9057</td>
<td>413</td>
<td>14200</td>
<td>3000</td>
<td>960</td>
<td>14805</td>
</tr>
<tr>
<td>Inclusion of T&amp;CM products in National Essential Medicine Lists (numbers)</td>
<td>Yes (128)</td>
<td>Yes (28)</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td>Yes (59)</td>
<td></td>
<td></td>
<td></td>
<td>Yes (71)</td>
</tr>
<tr>
<td>T&amp;CM product adverse event reporting system (PV for T&amp;CM products)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Financing</td>
<td>National budget/Public funding for T&amp;CM</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Health Insurance cover T&amp;CM services (Yes: partial and full or No)</td>
<td>Nil</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Nil</td>
<td></td>
<td>Yes</td>
<td>Nil</td>
<td>Nil</td>
<td>Nil</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Note: Timor-Leste has a National Health Policy for T&CM products
Source: 2015 Literature Review on T&CM and others
Harmonization of training and practices in traditional medicine and integration of TM services into the national health-care delivery system in DPR Korea

Since 1977, there has been a national plan for integrating Koryo medicine, i.e. Korean traditional medicine, into the national health-care delivery system in DPR Korea. Now, traditional medicine services are provided at all levels of the public health facilities together with modern allopathic medical services at the central, provincial, county, as well as the peripheral administrative level or Ri, levels. For instance, there are one central and 20 provincial Koryo traditional medicine hospitals where specialized traditional medicine services are being provided. Moreover, departments of Koryo traditional medicine are co-located at all central and provincial biomedical facilities (133), at all country/district-level hospitals (7871) and at Ri-level health-care facilities.

In practice, biomedicine and traditional treatments are often combined and primary care physicians are trained to practise both Koryo medicine and allopathic medicine. The robust training and education system in traditional medicine support the government policy towards implementation of a combination of traditional and allopathic medicines for public health service. For instance, all medical students can major in allopathic medicine or traditional Koryo medicine; those majoring in allopathic medicine also compulsorily pursue courses in traditional medicine and vice versa. The educational system provides diplomas and Bachelor’s, Masters and PhD degrees in traditional Koryo medicine. Doctors train for six years, pharmacists for five years, assistant medicine dispensers and masseurs for three years and traditional medicine specialist nurses for two years in DPR Korea.
In order to support Member States in developing T&CM, WHO has initiated a number of projects aiming to provide global guidance. For instance, in 2010, WHO developed a series of benchmarks for training in traditional/complementary and alternative medicine care as part of the implementation of the World Health Assembly resolutions WHA56.31 and WHA62.13 on traditional medicine of 2003 and 2009 respectively. Specifically, the benchmarks are for training in Ayurveda,\(^{18}\) naturopathy,\(^{19}\) Nuad Thai,\(^{20}\) osteopathy,\(^{21}\) traditional Chinese medicine,\(^ {22}\) Tuina,\(^{23}\) and Unani medicine,\(^{24}\) as well as for Guidelines on Basic Training and Safety in Chiropractic Medicine\(^{25}\) and Guidelines on Basic Training and Safety in Acupuncture.\(^{26}\) These documents are intended to:

- support countries in establishing systems for the qualification, accreditation or licensing of practitioners of traditional medicine;
- assist practitioners in upgrading their knowledge and skills in collaboration with providers of conventional care;
- facilitate better communication between providers of conventional and traditional care as well as other health professionals, medical students and relevant researchers, through appropriate training programmes; and
- support the integration of traditional medicine into the national health system.

Under the terms of a project collaboration agreement signed between the Ministry of AYUSH, India, and WHO in 2016, the Government of India pledged US$ 687 040 towards collaboration aimed at a specific set of project activities to be carried out between July 2016 and December 2020. These include working closely with the Government of India on developing WHO benchmarking documents for training in yoga and practising in Ayurveda, Unani and Panchakarma (or “five actions” – a cleansing and rejuvenating programme for the body, mind and consciousness) and other therapies in AYUSH systems.

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\(^{25}\) WHO Guidelines on Basic Training and Safety in Chiropractic Medicine

\(^{26}\) WHO Guidelines on Basic Training and Safety in Acupuncture
Other activities covered in this project include the development of a publication on essential terms for T&CM, establishing a WHO database for global T&CM practitioners and establishing a network of international regulatory cooperation for T&CM practices.

Table 8: WHO HQ meetings and workshops for T&CAM, 2014–2018

<table>
<thead>
<tr>
<th>Date</th>
<th>Theme</th>
<th>Participating Member States</th>
</tr>
</thead>
<tbody>
<tr>
<td>18–20/6/2014</td>
<td>WHO interregional training workshop on registration and qualified practice of TM/CAM, Macao SAR, China</td>
<td>India</td>
</tr>
<tr>
<td>5–7/11/2014</td>
<td>WHO interregional training workshop on consumer information and education in TM/CAM, Macao SAR, China</td>
<td>Maldives, Myanmar, Thailand</td>
</tr>
<tr>
<td>25–27/3/2015</td>
<td>WHO interregional training workshop on developing national policy and regulation of TM/CAM, Macao SAR, China</td>
<td>India, Thailand</td>
</tr>
<tr>
<td>25–27/11/2016</td>
<td>WHO interregional training workshop on quality of traditional and complementary medicine services, Macao SAR, China</td>
<td>DPR Korea, Nepal</td>
</tr>
<tr>
<td>22–24/3/2017</td>
<td>WHO Working Group Meeting on Benchmark for Practice in Tuina, Changchun, People’s Republic of China</td>
<td>India, Thailand</td>
</tr>
<tr>
<td>7–9/7/2017</td>
<td>WHO interregional training workshop on quality of traditional and complementary medicine (T&amp;CM) services, Macao SAR, China</td>
<td>Bhutan, Myanmar, Sri Lanka, Thailand</td>
</tr>
<tr>
<td>7–9/6/2018</td>
<td>WHO interregional training workshop on appropriate integration of traditional and complementary medicine into health systems and health-care services, Macao SAR, China</td>
<td>Bhutan, DPR Korea, Indonesia, Thailand, Sri Lanka</td>
</tr>
<tr>
<td>3–5/7/2018</td>
<td>WHO Working Group Meeting on Benchmark for Practice in Cupping Therapy, Jinan, People’s Republic of China</td>
<td>Bhutan, India, Thailand</td>
</tr>
<tr>
<td>17–19/9/2018</td>
<td>WHO Working Group Meeting on WHO Benchmark for Practice in Ayurveda, WHO Benchmark for Practice in Unani and WHO Benchmark for Practice in Panchakarma</td>
<td>Bangladesh, Bhutan, India, Nepal, Sri Lanka</td>
</tr>
<tr>
<td>7–9/11/2018</td>
<td>WHO Working Group Meeting on Standard Terminology in Traditional Chinese Medicine, Macao SAR, China</td>
<td>Thailand</td>
</tr>
<tr>
<td>12/11/2018</td>
<td>Brainstorming session of international yoga experts, Goa, India. Organized by the WHO Collaborating Centre for Traditional Medicine at the Morarji Desai National Institute for Yoga, New Delhi</td>
<td>India</td>
</tr>
<tr>
<td>20/12/2018</td>
<td>Interaction meeting of AYUSH minister with mission heads of WHO Member States to create awareness and consensus for the inclusion of AYUSH systems in ICD classification of WHO</td>
<td>Bhutan, Bangladesh, India, Nepal, Sri Lanka</td>
</tr>
</tbody>
</table>
Also included in the agreement with the Government of India were efforts to incorporate a section on traditional medicine in the new edition of the International Classification of Diseases (ICD-11). The International Statistical Classification of Diseases and Related Health Problems, to give it its full name, is the global standard classification for mortality and morbidity statistics. Such data, broken down by age, sex and cause of death, constitute the foundation of public health. Progress towards the Sustainable Development Goals and universal health coverage is measured with several cause-specific mortality and morbidity indicators.

In accordance with resolutions, WHA62.13 (2009) and WHA67.18 (2014), which request the Director General to promote international cooperation and collaboration in traditional and complementary medicine in order to share evidence-based information, ICD-11 includes a supplementary chapter for optional use, entitled “Traditional medicine conditions – Module 1”. This chapter classifies traditional medicine conditions that originated in ancient China and are now commonly seen in China, Japan, Republic of Korea and other countries. The Director General’s report notes that: “these categories are intended for optional dual coding of traditional medicine diagnoses and patterns. They do not refer to – or endorse – any form of treatment. Additional modules classifying diagnostic concepts of other standardized forms of traditional medicine may be developed in the future. The inclusion of a supplementary chapter on traditional medicine in ICD will, for the first time, enable the counting of traditional medicine services and encounters; the measurement of their form, frequency, effectiveness, safety, quality, outcomes and cost; comparison with mainstream medicine; and research, due to standardized terms and definitions nationally and internationally”.

WHO formally launched the process of revising ICD-10 in 2007 and ICD-11 finally appeared in 2019, after more than a decade of study and wide consultation at the highest levels. This represents another milestone in the history of traditional and complementary medicine.

PART 3
Conclusions

As noted in the WHO Global Report on Traditional and Complementary Medicine 2019, the Thirteenth General Programme of Work (GPW13) of WHO 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 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.

In order to contribute to the “Triple Billion” targets of the Thirteenth General Programme of Work 2019–2023, UHC and SDGs, the WHO SEA Region will continue its efforts to strengthen national capacity for appropriate integration of T&CM into national health systems through technical support and training workshops. A key task is to improve safety of T&CM products, by strengthening pharmacovigilance for T&CM products among Member States through regional training and intercountry cooperation/collaboration.

National research capacity needs to be strengthened through training workshops and intercountry cooperation/collaboration. Knowledge is the key and the Region will continue to facilitate the exchange of information on T&CM systems in Member countries, by making regional data more easily accessible through a regional portal.

Much remains to be done. According to the recent global survey of traditional and complementary medicine in Member States, the difficulties (ranked as per the challenges posed) reported by the South-East Asia Region (N=10) were:

1. lack of research data (stated by 90% of the respondent SEA Region Member States);
2. lack of financial support for research on T&CM (70%);
3. lack of expertise within national health authorities and control agencies (50%);
4. lack of appropriate mechanisms to control and regulate herbal products (50%).

Regarding the type of support for T&CM issues that Member States are interested in receiving from WHO, the following were highlighted:
General technical guidance for research and evaluation of T&CM related to safety, quality and efficacy.

Information sharing on regulatory issues.

Provision of research databases.

Seminars/workshops on:
- national capacity-building on safety monitoring of herbal medicines.
- integration of T&CM in the context of primary health care.
- national capacity to establish regulations for herbal medicines.
- developing national policies and programmes for T&CM.
- national capacity to establish regulations on T&CM practices.

Provision of guidelines or minimum requirements for basic training of T&CM providers.

Arrangement of global meetings.

Provision of technical support to promote safe and effective use of indigenous traditional medicine in primary health care.

Provision of cooperation channels between national health authorities.

Provision of guidance on self-care and information for the public on primary health care or at the community level.

Priorities need to be established and resources found. The roadmap is there. The achievements of the last five years provide a basis for appropriate integration of T&CM into national health-care delivery systems for achieving UHC, SDGs and the new target of the latest WHO general programme of work.
PART 4
Country profiles

These profiles provide a more extensive and referenced summary of the situation regarding traditional and complementary medicine in South-East Asia as of mid-2019. They take as their principal sources the report of the “Regional workshop to share experience and evidence on appropriate integration of traditional medicine into national health-care systems”28 and the WHO Regional Office report on “Integration of traditional and complementary medicine in South-East Asia: Public health, safety and management”.29

These primary sources were updated using country summaries from the Second Global Survey of Traditional Medicine (dated 13 April 2018)30 and the country presentations from the report of the Second Meeting of the BIMSTEC Task Force on Traditional Medicine,31 as well as from numerous other sources indicated in the text.

The profiles note the traditional medical systems practised in each country, the organization of traditional medicine, the authority responsible and the policy framework in place, indications about the financing of traditional medicine and insurance aspects, information about practitioners, a summary of education and research aspects of traditional medicine, indications about manufacture and regulation, and what is known about data collection at the country level. References additional to those mentioned above are listed at the end of each country chapter.

Generic definitions and descriptions of the principal systems of traditional medicine are given in Appendix 1 while shorter notes about the systems and their variants, practised in individual countries, are given in the profiles.

Although there are clear signs that the field of traditional medicine is attracting increasing attention, there continues to be a shortage of documentary evidence in some countries. It is vital that knowledge about traditional medicine and its associated practices be collected and amplified as a part of the process of strengthening the associated scientific evidence base. Here are the points covered in each country profile below:

30 WHO, Second Global Survey of Traditional Medicine (dated 13 April 2018)
31 The Second Meeting of the Bay of Bengal Initiative for Multisectoral Technical and Economic Cooperation (BIMSTEC) was held on 24–25 January 2019 in Nay Pyi Taw, Myanmar
- Traditional medical systems practised.
- Organization of traditional medicine.
- Authority responsible and policy framework.
- Finance and insurance.
- Practitioners.
- Education and research.
- Manufacture and regulation.
- Data and indicators.
4.1 Bangladesh

**Traditional medicine systems practised:** Ayurveda, Unani and homeopathy. In Bangladesh, TM is based on traditional uses of plants, animals or their products, other natural substances (including some inorganic chemicals), religious verses, cultural practices and physical manipulations.

**Organization of traditional medicine:** Health services in Bangladesh are provided by the public, private and nongovernmental sectors. There are both trained T&CM providers and “untrained” folk healers (Canaway 2015 citing Ahmed et al. 2011; Mollax 2015; Vaughan et al. 2000).

The accessibility of practitioners, particularly for people in rural areas, and plants for medicine-making are assets. Antibiotic resistance is combated by using herbal medicines. Overall, the government promotes and supports T&CM as an essential mechanism towards the goal of providing universal health coverage. As a result of the recent government policy, as of 2015, there were 179 medical officers (Unani and Ayurvedic) working in government medical college hospitals, district hospitals and upazila health complexes. About 28% of patients are treated by traditional medicine doctors in the outpatient departments of government hospitals in Bangladesh (AMC, DGHS /2015).

**Government authorities responsible and policy:** The Office of the Director, Homeopathy and Traditional Medicine, was established in 1991 as part of the Directorate General of Health Services within the Ministry of Health and Family Welfare (MoHFW). The Ministry of Forests and Environment and the Ministry of Hill Tracts are facilitating preservation and documentation of traditional medicine plants (Haque 2013).

Since 1982, there has been a national law on “alternative medical care (AMC)”. The law was amended in 2006. In 2016, the Fourth Health, Population and Nutrition Sector Programme was approved, covering five-and-a-half years from January 2017. This aims to improve equity, quality and efficiency for gradually moving towards universal health coverage and achieving health-related SDGs.

Five of the associated 29 operational plans are attributed to MoHFW. One of these five is devoted to AMC with the aim “to scale up traditional medicine (Unani, Ayurvedic) service throughout the country along with allopathic treatment to ensure quality and equitable health services for all citizens of Bangladesh, and develop the Unani and Ayurvedic education systems”.

The key components of AMC are to:

1. Provide preventive and curative services to service recipients at government health facilities.
2. Integrate AMC services into the national health-care delivery systems.
3. Increase service facilities from primary to tertiary level (BIMSTEC 2019).
Finance and insurance: In 2013–2014, 0.57% of the total health financing was spent on the alternative medical care sector (MoHFW 2014).

As per the 2010 internal records of the Unani Ayurvedic Herbal Homeopathic Manufacturers Association, the total market sales of herbal medicines amounted to US$ 43 million, US$ 64 million and US$ 86 million in 2007, 2008 and 2009 respectively.

T&CM is not covered by health insurance.

Practitioners: National-level regulations covering providers of Ayurvedic, herbal, homeopathic and Unani medicines have been in existence since 1983. National-level regulations for indigenous traditional medicine providers have been in force since 2005. Practitioners and education are governed by regulation, registration and certification. Currently, there is no separate registration council for traditional medicines; the Director General of Health Services acts as an interim registration council, providing registration only for graduate Ayurvedic, Unani and homoeopathic doctors. The Bangladesh Board of Unani and Ayurvedic Systems of Medicine provides registration for diploma certificate holders.

Up to 75% of the population utilize traditional medicine, particularly through the informal sector of folk healers. T&CM providers also practise in clinic settings in the private sector and in hospitals in the public sector. About 20% of outpatient treatments in district hospitals are provided by doctors of alternative medical care (Islam 2012; MoHFW 2012; Molla 2015).

As of 2015, there were 179 medical officers (Unani and Ayurvedic) working in government medical college hospitals, district hospitals and upazila health complexes. About 28% of patients are treated by traditional medicine doctors in the outpatient departments (OPD) of government hospitals in Bangladesh (AMC, DGHS /2015).

Education and research: According to data from the Bangladesh Health Bulletin (SGHS Management Information System, 2017), there were 297 graduates and 491 diploma holders in Ayurveda medicine, 616 graduates and 16 222 diploma holders in homeopathic medicine, and 364 graduates and 1025 diploma holders in Unani medicine.

Diplomas awarded include the DUMS (Diploma in Unani Medicine and Surgery), DAMS (Diploma in Ayurvedic Medicine and Surgery) and DHMS (Diploma in Homeopathic Medicine and Surgery) while the Bachelor’s degrees awarded include the BUMS (Bachelor of Unani Medicine and Surgery), BAMS (Bachelor of Ayurvedic Medicine and Surgery) and BHMS (Bachelor of Homeopathic Medicine and Surgery).

Table 4.1 shows the academic courses and places available in T&CM disciplines in Bangladesh.
Table 4.1: Academic courses, places and certifying authorities in Bangladesh, 2018

<table>
<thead>
<tr>
<th>Degrees offered</th>
<th>No. of courses</th>
<th>No. of places</th>
<th>Course duration</th>
<th>Internship duration</th>
<th>Certifying authority</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diploma</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. DUMS (Diploma in Unani Medicine and Surgery)</td>
<td>73 (A-9, U-13, H-51)</td>
<td>3650</td>
<td>4 years</td>
<td>6 months</td>
<td>1. Board of Homeopathic Medicine and 2. Board of Unani and Ayurvedic Systems of Medicine</td>
</tr>
<tr>
<td>2. DAMS (Diploma in Ayurvedic Medicine and Surgery)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. DHMS (Diploma in Homeopathic Medicine and Surgery)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bachelor's</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. BUMS (Bachelor of Unani Medicine and Surgery)</td>
<td>3 (A-25, U-125)</td>
<td>150</td>
<td>5 years</td>
<td>12 months</td>
<td>1. University of Dhaka 2. University of Chittagong</td>
</tr>
<tr>
<td>2. BAMS (Bachelor of Ayurvedic Medicine and Surgery)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BHMS (Bachelor of Homeopathic Medicine and Surgery)</strong></td>
<td>1</td>
<td>H-50</td>
<td>5 years</td>
<td>12 months</td>
<td>University of Dhaka</td>
</tr>
<tr>
<td><strong>Postgraduate</strong></td>
<td>Still no facility available for postgraduate study in Bangladesh. The faculty at BSMMU is not functioning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: BIMSTEC 2019

**Manufacture and regulation**: While four big pharmaceutical companies produce more than 80% of traditional medicine products (Islam 2012), there are reportedly around 500 manufacturers of T&CM medicine products: 261 Unani, 161 Ayurvedic and 76 homeopathic, and around 100 or more street vendors or smaller-scale producers. There are 470 herbal gardens in selected district hospitals and *upazila* health complexes operating as a part of the Alternative Medical Care Operational Programme.

Around 55 brands of herbal medicines are registered. There are no restrictions on selling herbal products. Herbal medicines are sold in pharmacies as prescription medicines, non-prescription medicines, self-medication items or over-the-counter medicines, and are also sold at other outlets and special outlets, as well as by licensed practitioners. The regulations covering herbal medicines and the list of registered herbal medicines and regulations on practitioners were updated in 2016.
The regulation for herbal medicines is the same as that for conventional pharmaceuticals (the Registration Guidelines of Herbal Medicine were issued in 2006). Licences for the manufacture of Unani, Ayurvedic and herbal medicines are issued by the Director General of Drug Administration (DGDA).

Herbal medicines are sold with medical claims. There is no national pharmacopoeia, but other kinds of pharmacopoeia are used. These include the British Herbal Pharmacopoeia, American Herbal Pharmacopoeia and Therapeutic Compendium, these are not legally binding though. The WHO Monographs on selected medicinal plants are used, again these are not legally binding. The national Unani and Ayurvedic formulary has recently been revised, and World Health Organization GMP guidelines are reportedly used. The Drug Act (1940), the Drug (Control) Amendment Act (2006), the Drug Regulation (1946) and the Bangladesh Export Policy serve to guide regulations for manufacturing.

Bangladesh follows the WHO GMP guidelines for herbal medicines. The regulations for GMP are the same as those for conventional pharmaceuticals. Mechanisms for GMP compliance reportedly include period inspections, submitting samples for government testing and assignment by manufacturers of a person to ensure compliance with manufacturing requirements and report to government (Various, 2010). Despite these measures, inadequate monitoring and poor implementation of regulations reportedly lead to improper preparation of traditional medicine products, poor quality and manufacturing without legal permission (Huque 2014). Lack of oversight in product manufacture could lead to product adulteration and ingredient substitution with potentially dangerous outcomes for the public (Das et al. 2014).

About half of the raw materials used for medicine manufacture are imported (Haque 2013). It is likely that this will rise as increasing urbanization, deforestation and over-harvesting lead to decreased availability of medicinal plants.

For product registration, effective ingredients must be identified, and the product must be tested for effectiveness. To ensure compliance, there are periodic inspections by authorities at manufacturing plants or laboratories. Manufacturers are required to submit samples of their medicines to a government-approved laboratory for testing and also assign a person(s) to the role of ensuring compliance.

Data and Indicators: Some data on T&CM are regularly collected by MoHFW and published in the annual health bulletin. But notable gaps in easily accessible data reporting included those pertaining to the number of people treated in public facilities, therapies received, and conditions treated.

References


4.2 Bhutan

Traditional medical systems practised: Bhutanese traditional medicine gSo-ba Rig-pa is based on the teachings of Buddha. Traditional medicine is particularly popular for treating chronic conditions that do not respond to allopathic treatment.

Organization of traditional medicine: Traditional medicine was formally incorporated into the mainstream of the national health-care system in 1968 by a royal decree. gSo-ba Rig-pa is administered alongside conventional health care by the Ministry of Health. It is fully integrated into the national health-care delivery system. Traditional and allopathic medicine services follow the same health plans and policies set by the Ministry of Health. Traditional physicians are on a par with allopathic doctors in terms of civil service grades and entitlements.

In the Kingdom of Bhutan, health-care services are delivered entirely by the public or informal sectors. There is no formalised private sector, although there has been debate on privatized health-care delivery (Pelden 2013).

Indigenous traditional medicine is widely used, but the percentage of usage by the population is not known. Around 20% to 39% of the population opt for T&CM practices and herbal medicines. According to hospital morbidity reports, 10% to 20% of outpatient department patients use gSo-ba Rig-pa.

Authority responsible and policy framework: The Institute of Traditional Medicine Services in Thimphu, under the Ministry of Health, has served as the national office for T&CM since 1993. In June 2011, a Division for the Traditional Medicine System was established. This was upgraded to the Department of Traditional Medicine Services in May 2013 with three functional divisions: the Traditional Healing Centre Division, the Menzerigpa and Zhibjuk Division (Medicine and Research), and the Local Healing and Spiritual Health Division. The department is also responsible for the National Traditional Medicine Hospital, Indigenous Clinic and Indigenous Hospital (http://www.health.gov.bt/about/organogram/accessed 16/5/19).

In Bhutan, the national policy on T&CM is integrated into the national health policy. The national health policy outlines a vision of equitable and appropriate provision of “integrated” modern and traditional medicine to efficiently meet the needs of all Bhutanese citizens (MoH 2011). This policy is backed by the Constitution of Bhutan, which instructs the state to provide free access to basic public health services in both modern and traditional medicines. The equitable treatment of T&CM and allopathic medicine is part of a conscious decision to conserve part of Bhutan’s “rich and varied cultural heritage” (Dendup & Jamphel n.d.; Wangchuk 2010).

Finance and insurance: According to the Revolving Fund Annual Report (2009), the total market sales of herbal medicines amounted to Bhutanese Ngultrum (BTN32) 10.53 million,

32 US$ 1 = BTN 70.1 on 16 May 2019

Indigenous traditional medicine is covered by government health insurance. There is full government insurance coverage available for the practice of gSo-ba Rig-pa.

**Practitioners:** The Bhutan Medical and Health Council Act (2002) regulates standards for traditional medicine and practice licences are granted by the government. T&CM providers practise in hospitals in the public sector.

There is one national referral hospital, with two regional referral hospitals, 22 district hospitals and 41 basic health units. (BIMSTEC, 2019)

A traditional medicine unit is co-located in 20 conventional district hospitals and 29 basic health units, and the National Traditional Medicine Hospital provides standalone traditional medicine services. District T&CM units are directly under the administrative control of the district health sector. There is cross-referral of patients between the two systems and people can choose the alternative they prefer. (BIMSTEC 2019). Around 10% to 30% of patients in district hospitals opt for traditional medicine.

It was reported that there were 35 gSo-ba Rig-pa physicians and 82 attendants employed in the hospitals and health units providing T&CM (2.65% of the total health workforce). The number of folk healers is reportedly almost equal to the number of conventional health-care providers (MoH 2014; Wangchuk et al. 2013).

**Education and research:** The Faculty of Traditional Medicine at the Khesar Gyalpo University of Medical Sciences of Bhutan is responsible for the development of human resources required for the delivery of traditional medicine services in the country. The faculty offers university-validated programmes awarding a Bachelor’s degree in traditional medicine (5.5 years), a diploma in traditional medicine (3 years), a diploma for gSo-ba Rig-pa pharmacy technicians (3 years) and a two-year Masters degree in traditional medicine (BIMSTEC 2019).

According to the Graduate Register, there are 78 traditional medicine providers having Bachelor’s degrees and 114 providers with diplomas in Bhutan.

**Manufacture and regulation:** All traditional medicines are regulated and registered with the Drug Regulatory Authority (DRA) in the same way as conventional pharmaceuticals.

The Traditional Medicine Formulary 1st edition (1983) and 2nd edition (2007) are used as the National Pharmacopeia and are legally binding. Monographs on medicinal plants (1st edition, 2006, 20 monographs and 2nd edition, 2009 with 20 monographs) are used. Regulations for GMP are the same as those for conventional pharmaceuticals. To ensure compliance, there are periodic inspections by authorities at manufacturing plants or laboratories. Traditional use without demonstrated harmful effects is considered a sufficient safety requirement.
There are 128 registered herbal medicines. In 2017, these 128 were included in the national essential medicine list based on traditional use of the herbal medicines. Herbal medicines are sold in pharmacies as prescription medicines and by licensed practitioners. The bulk ingredients of traditional medicines include medicinal plants, but prescriptions can also include gem stones, metals, minerals, soil and animal parts.

There is just one manufacturer licensed to provide traditional medicines to the government. Menjong Sorig Pharmaceuticals (MSP) was accorded government approval as a state-owned enterprise in July 2017. MSP is responsible for manufacturing and supplying T&CM medicines as its core business. It applies Good Manufacturing Practices and carries out quality control for both raw materials and finished products, research activities and marketing of products. It currently manufactures 128 products that constitute the national essential traditional medicines list. Other MSP activities include the collection and procurement of medicinal raw materials through community involvement; scientific research and standardization of traditional medicine; and establishing quality control parameters and monitoring the quality of products (BIMSTEC 2019).

There are also dispensaries in hospitals which dispense herbal medicines. The Quality Assurance and Standardization Division of MoH and the Drug Regulatory Authority (enacted by the Bhutan Medicine Act, 2005) regulate production and product registration. The Essential Drug Programme for allopathic medicine has been replicated for traditional medicines. GMP includes examination of raw and finished products by the Pharmaceutical and Research Unit of the Institute of Traditional Medicine Services.

There is a concern that the burgeoning plant-based industry in Bhutan might lead to unsustainable harvesting. Currently, 70–85% of raw plant materials are collected in Bhutan, of which 85% are wild-harvested. Quality parameters are given to collectors who are often farmers or yak herders (Unknown 2007a; Wangchuk & Olsen 2010; Wangchuk et al. 2013; Wangchuk et al. 2007). Other issues include patenting, intellectual property rights, bioprospecting, sourcing of animal parts for medicine production (including milk, blood, bile, bone, horn, insects, marine organisms and reptiles) and raising sufficient investment to further develop research and infrastructure (Dendup & Jamphel 2015; Dukpa 2013).

Data and indicators: Data on traditional medicine is regularly collected by the Ministry of Health and published in the *Annual Health Bulletin* alongside data on allopathic medical services. Published T&CM data include numbers of practitioners, clinics, patients and types of therapies and conditions treated by clinics within each of the 20 administrative districts.

References


4.3 Democratic People’s Republic of Korea

**Traditional medical systems practised:** Koryo medicine is based on ancient tradition but is now practised with modern diagnosis facilities, laboratory examinations and objective testing alongside traditional methods.

**Organization of traditional medicine:** In the Democratic People’s Republic of Korea (DPR Korea), the health-care sector is entirely state-run with service delivery at the central, provincial and county/primary health-care levels. A dual system of conventional allopathic and traditional Koryo medicine is provided by the government with free in and outpatient treatment and traditional medicines are sold at low cost from dispensaries.

**Authority responsible and policy framework:** The Department of Koryo Traditional Medicine under the Ministry of Public Health in Pyongyang serves as the national office for T&CM. The national policy on T&CM (*Developing Koryo Traditional Medicine*) was issued in 1979.

Since 1977, there has been a national plan for integrating T&CM into the national health service delivery.

**Finance and insurance:** Traditional medicine is covered by the government health insurance and there is full government insurance coverage available for T&CM practices of acupuncture, chiropractic, herbal medicines and naturopathy.

**Practitioners:** Between 40% and 59% of the population use indigenous traditional medicine – its level of utilization by the public is around 30–40% at the central level, 40-60% at the county level and 70% at the primary health care level (WHO-SEARO 2005). Acupuncture, chiropractic and naturopathy are used by 20% to 39% of the population while 40% to 59% of the population use herbal medicines.

There are national-level regulations on indigenous traditional medicine and acupuncture providers, chiropractic and herbal medicine providers, and providers of naturopathic medicine.

T&CM providers practise in the public sector in clinic and hospital settings. The national government issues the licences required for practice. As of 2013, there were 5249 Koryo traditional medicine doctors (2.3 per 10 000 population) and 1869 registered Koryo pharmacists. In addition, traditional Koryo technicians/assistants such as manual therapists and natural therapists with diplomas exist in the system.

One central and 20 provincial Koryo traditional medicine hospitals provide specialist traditional medicine services. In addition, there are departments of Koryo traditional medicine co-located in every central and provincial biomedical facilities (133) and at all (7871) country-level hospitals and clinics. In practice, biomedicine and traditional treatments are often combined (Ministry of Public Health 2014). Articles of the public
health law cover many aspects of traditional medicine production, education, practice and service delivery levels.

Traditional medicine doctors have equal rights and the same legal protection as allopathic doctors.

**Education and research:** Primary-care physicians are trained to practise both Koryo and allopathic medicines. Medical students can major in allopathic medicine or traditional Koryo medicine; those majoring in allopathic medicine also take compulsory courses in traditional medicine and vice versa. The educational system offers diplomas, Bachelor’s, Masters and PhD degrees. Doctors train for six years, pharmacists for five years, assistant medicine dispensers and masseurs for three years, and traditional medicine specialist nurses for two years.

Since 1980, there has been a consumer education programme for self-health care using T&CM.

The Academy of Koryo Traditional Medicine, a national research institute for T&CM, was established in 1961. In addition, there are reportedly 28 research institutions for Koryo medicine in DPR Korea.

**Manufacture and regulation:** Traditional medicine physicians can legally prescribe conventional pharmaceuticals and allopathic physicians can provide acupuncture and traditional medicines. The Traditional Medicine Council regulates practitioner licensing, qualification and continuing professional education systems, and issues treatment guidelines.

The regulation for herbal medicines is the same as that for conventional pharmaceuticals. Herbal medicines are regulated 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 Pharmacopoeia of DPR Korea (6th edition, 2003) is legally binding. National monographs on herbal plants and their use in Koryo traditional medicine as well as monographs on clinical acupuncture, moxibustion and manual therapy are legally binding.

Regulations for GMP are the same for T&CM as those for conventional pharmaceuticals and include adherence to manufacturing information in pharmacopoeia/monographs. To ensure compliance, there are periodic inspections by authorities at manufacturing plants or laboratories while manufacturers are required to submit samples of their medicines to a government-approved laboratory for testing and also assign a person(s) to the role of ensuring compliance. Safety requirements are the same as those for conventional pharmaceuticals and traditional use without demonstrated harmful effects is sufficient.

As of 2010, 671 herbal medicines were registered. Overall, 19 kinds of herbal medicines were first included in the national essential medicines list in 1972 and 28 kinds were incorporated in 2006. They were selected based on traditional use of the herbal
medicines, clinical data, long-term historical use and laboratory testing. The Production and Management Bureau of the Ministry of Public Health oversees manufacture of Koryo medicine at 210 factories. The Drug Management Law and Herb Law of the Democratic People’s Republic of Korea are put into practice by the Drug Regulatory Authority. The laws control quality and production, including good agricultural practices – cultivation, protection of resources and storage.

Raw materials are mostly locally produced, including deer horn and musk. There are 160 management centres for raw materials. Traditional medicine manufacturers and pharmacists do not produce or handle biomedical pharmaceuticals and biomedical manufacturers and pharmacists do not produce or handle traditional medicine products. The regulatory requirements for traditional medicines are the same as those for conventional medicines. GMP requirements include periodic inspections, requirement to submit samples for testing and the appointment of a factory employee to ensure compliance.

Data and indicators: There is no publicly available annual compilation of statistics, although data on traditional medicine use is no doubt collected by the Ministry of Public Health. There is a lack of information about consumers’ interactions with the health-care system, including data pertaining to the number of people who access traditional medicine services, for which conditions, what therapies are received and what the outcomes are.

References


4.4 India

**Traditional medical systems practised:** A wide range of T&CM systems is practised in India, collectively grouped under the acronym AYUSH, which stands for Ayurveda (A), yoga and naturopathy (Y), Unani (U) Siddha and *gSo-ba Rig-pa* (S) and homoeopathy (H) (BIMSTEC 2019).

**Organization of traditional medicine:** The health-care delivery system in India engages regulated public and private sectors to deliver pluralistic health care across Central and state jurisdictions. There is also an unregulated informal sector delivering traditional and folk healing.

While there is a long history of combining allopathic and traditional medicine systems in India, including through medical education, AYUSH and conventional allopathic systems remain separate and parallel at the levels of governance, organisation, education and service delivery. A national plan for integrating T&CM into national health delivery was announced in 2014.

The delivery of formalised traditional medicine and that of conventional allopathic medicine are largely independent in terms of structures, organization and facilities, although there is co-location of traditional and conventional services through the provision of AYUSH practitioners in 15,525 government-sector facilities. In rural areas, traditional practitioners can outnumber conventional biomedical doctors (Torri 2013).

**Authority responsible and policy framework:** There have been legislations regulating the traditional medicines sector, at least since the 1940s, including the Drugs and Cosmetics Act (1940, amended in 2009), Indian Medicines Central Council Act (1970) and Homoeopathy Central Council Act (1973). It was not until 1995 that the Department of Indian Systems of Medicine and Homeopathy was established in the Ministry of Health and Family Welfare (MoHFW). This was renamed as the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) in 2003, and elevated to the status of an independent ministry in November 2014. The Tibetan system of traditional medicine, *gSo-ba Rig-pa*, was formally recognized in 2010.

The Ministry of AYUSH is mandated to mainstream and propagate Indian systems of medicine locally and globally (Government of India 2014; Shrivastava et al. 2015). Various policy initiatives have contributed to the development of AYUSH in India (BIMSTEC 2019):

- National Health Policies (1983 and 2002) focused on the integration of AYUSH into the health-care delivery system and national health programmes, and on evidence-based application and research. The “national policy on Indian systems of medicine and homeopathy” was issued in 2002.

The latest National Health Policy (2017) broadened the objectives for AYUSH with the aim of mainstreaming (ensuring access) it. It also featured the introduction of yoga in schools and workplaces, bolstering of research and public health skills for preventive and promotive health care, providing AYUSH orientation to grassroots health workers and village health sanitation and nutrition committees, providing bridge courses for mid-level health-care providers and establishing a certification mechanism for traditional community health-care providers.

There are three flagship initiatives:

1. The **National Health Mission**, whose objectives include vertical and horizontal strengthening of health services and ensuring accountable health systems, including the mainstreaming of AYUSH.

2. The **National AYUSH Mission**, which aims to augment the AYUSH sector in terms of health services, educational standards, drug quality control and sustainable development of medicinal plants.

3. **Central Sector Schemes** for direct funding of projects related to promotion and development of the AYUSH sector.

The latter covers IEC activities, CME programmes, workshops/seminars/conferences, extramural research studies, international cooperation endeavours, public health interventions and setting up centres of excellence and industry clusters (BiTSEC 2019).

**Finance and insurance:** AYUSH services are being provided to the citizens freely at all level of public health facilities.

T&CM is reimbursed by both public and private insurance as of the end of 2016.

**Practitioners:** Registration of practitioners at both state and Central levels is mandatory for clinical practice. Registration requires the possession of a recognized medical qualification awarded by a university. Registered practitioners are permitted to prepare medicines for their individual patients and are exempted from Drugs Act provisions.

T&CM providers practise in the public sector in clinic and hospital settings. There are national and state-level regulations on providers of Ayurvedic, homeopathic and Unani medicines. The national government issues the licences required for practice. Licences and certificates are issued after graduation and subsequent training through a compulsory rotating internship. The regulations for homeopathy practitioners were updated in 2014 and the list of registered T&CM practitioners was updated in 2016.

There were 771 468 registered T&CM practitioners as of 1 January 2016, distributed as follows: Ayurveda 419 217 (54.3%), Unani 48 196 (6.2%), Siddha 8528 (1.1%), naturopathy 2220 (0.3%) and homeopathy 293 307 (38.0%).
Table 4.2 shows the registered practitioners and AYUSH hospitals and dispensaries in 2017. Coverage as on 1 April 2017 was about 5.89 AYUSH practitioners per 10 000 population.

**Table 4.2: India: Registered practitioners and AYUSH hospitals and dispensaries, 2017**

<table>
<thead>
<tr>
<th>Item</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered practitioners</td>
<td>773 668</td>
</tr>
<tr>
<td>Hospitals in government sector</td>
<td>3 639</td>
</tr>
<tr>
<td>Hospitals teaching AYUSH (out of the above)</td>
<td>550</td>
</tr>
<tr>
<td>Primary health centres (PHCs)</td>
<td>31 849</td>
</tr>
<tr>
<td>PHCs with AYUSH dispensaries</td>
<td>26 405</td>
</tr>
</tbody>
</table>

Source: BIMSTEC 2019

**Education and research**

**Education:** Ayurveda, Siddha and Unani education and practice fall under the Indian Medicine Central Council (IMCC) Act 1970 and is regulated by the Central Council of Indian Medicine (CCIM). Homoeopathy education and practice fall under the Homoeopathy Central Council (HCC) Act 1973 and are regulated by the Central Council of Homoeopathy (CCH).

A student can obtain Bachelor’s, Masters, PhD and clinical doctorate degrees in T&CM at the university level. Table 3 shows the distribution of teaching and degree-granting institutions in the different systems of T&CM.

**Table 4.3: Distribution of teaching and degree-granting institutions, by T&CM system, 2018**

<table>
<thead>
<tr>
<th>Item</th>
<th>Numbers by T&amp;CM system*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ASU&amp;H teaching institutions: 622, of which:</td>
<td>A  U       S    H</td>
</tr>
<tr>
<td>Postgraduate institutions: 210, of which:</td>
<td>138   14    3    52</td>
</tr>
<tr>
<td>Annual intake in degree courses: 40 151, of which:</td>
<td>21 387 2 705 520 13 909</td>
</tr>
<tr>
<td>Annual intake in PG courses: 5826, of which:</td>
<td>4 269 202 140 1 170</td>
</tr>
</tbody>
</table>

*NOTE: A = Ayurveda, U = Unani, S = Siddha & gSo-ba Rig-pa, H = Homoeopathy

Source: BIMSTEC 2019

Around 513 colleges provide undergraduate education (101 government and 412 nongovernment) and 151 provide postgraduate training (46 government and 105
nongovernment). There is standardization in education and qualifications, with all AYUSH diplomas spanning two years in duration, Bachelor’s degrees of 5.5 years (including one year of internship) and postgraduate degrees extending to three years. Central councils are responsible for curricula and syllabi and for maintaining the central register of practitioners. Central government approval needs to be obtained prior to establishing an AYUSH college. Since 1997, there has been a consumer education programme for self-health care using T&CM in place.

Over 30 AYUSH information cells have been established in 28 countries (including two in Indonesia). Active AYUSH representation has been promoted in WHO and a number of other key multilateral forums.

**Research:**

The traditional medicine research sector is highly evolved with 88 research centres established under five research councils:

- Central Council for Research in Ayurvedic Sciences (CCRAS): 30 institutes.
- Central Council for Research in Siddha (CCRS): 5 institutes.
- Central Council for Research in Yoga & Naturopathy (CCRYN).

A vast number of traditional medicine research articles are published each year and the Ministry of AYUSH and other council websites publish a wide variety of information on the AYUSH sector.

**International cooperation:** Initiatives of international cooperation include Memorandums of Understanding (MoUs) with 16 countries (including Bangladesh, Myanmar and Nepal from the WHO South-East Asia Region) and 17 MoUs with selected international institutions for research/academic collaboration in areas of mutual interest.

India’s Ministry of AYUSH has also been providing international scholarships/fellowships to other institutions during 2014–2018 to enable students to undertake AYUSH courses in premier institutes in India. The number of scholarships/fellowships is as follows: 2014–2015: 10 scholarships/fellowships; 2015–2016: 50; 2016–2017: 63; and 2017–2018: 40.

The Ministry of AYUSH has organized a number of significant international conferences on T&CM topics in India in recent years.

Collaboration with WHO in this area has been extensive. A “Project Collaboration Agreement 2016–2020” was signed with WHO on 13 May 2016 for cooperation on promoting the quality, safety and effectiveness of service provision in traditional and complementary medicine and for developing WHO Benchmarks for Training in Yoga,
Practice in Ayurveda, Unani and Panchkarma. WHO has named two collaborating centres for traditional medicine in the South-East Asia Region:

1. The Institute of Post Graduate Teaching & Research in Ayurveda (IPGTRA) in Jamnagar, Gujarat.
2. The Morarji Desai National Institute of Yoga (MDNIY) in New Delhi.

The inclusion of Ayurveda, Unani and Siddha in the International Classification of Diseases (ICD-11) is now in progress.

**Manufacture and regulation:** According to ministerial sources (BIMSTEC 2019), there are 8667 licensed drug manufacturing units (by T&CM system: 7439 for Ayurvedic, 585 for Unani, 235 for Siddha and 408 for homeopathy). Almost all are private enterprises.

There are Ayurveda, Siddha and Unani sections to the Drugs and Cosmetics Act (1940), separate licensing authorities for these traditional medicine systems in addition to homoeopathy, a technical board and a drugs consultative committee. Systems are in place for manufacturer licensing and renewal (every three years to ensure GMP compliance), product registration, GMP and pharmacovigilance. Since 2013, there are essential medicines lists for Ayurveda, Unani, Siddha and homoeopathy. Commercial manufacture of traditional medicines is not allowed without licence and GMP certification.

In general, legal provisions are established and amended by the Central government, while enforcement is carried out by the state governments. A number of national committees have been established for the regulation of ASU&H drugs. These include the Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB: for policy advice to Central government on regulation of ASU drugs); the Ayurveda, Siddha, Unani Drugs Consultative Committee (ASUDCC), for advice to Central and state governments on enforcement issues of ASU drugs; the Sub-committee on Homoeopathy under Drugs Technical Advisory Board (DTAB); the Pharmacopoeia Commission of Indian Medicine and Homoeopathy; and pharmacopeia committees for development of standards of ASU&H drugs.

They are regulated as prescription and non-prescription medicines and sold with medical, health and nutrient content claims. Regulations for herbal medicines were updated in 2006 and 2017, and the list of registered herbal medicines in 2016. The herbal medicines included in the national essential medicine list were updated in 2013.

India has a rich biological diversity, which includes over 40 000 species of plants and 75 000 species of animals. About 8000 of these plant species have medicinal properties. India has about 12% of the global plant wealth, among which there are nearly 3000 tree species. Nearly a third of the total plant species of India are endemic (BIMSTEC 2017).

The Ayurveda Pharmacopoeia of India Parts 1 and 2, Unani Pharmacopoeia of India and Siddha Pharmacopoeia of India are widely used, and are legally binding. These also have monographs on single herbs and formulations. Apart from these, the Indian herbal pharmacopoeia is also used, but it’s not legally binding. National ASU formularies exist –
the Ayurvedic Formulary of India covers 985 formulations, including 280 mineral-based formulations, the National Formulary of Unani Medicine lists 1229 formulations while the Siddha Formulary of India lists 399 formulations.

The national quality certification systems for drugs include GMP certification as well as WHO-GMP/COPP certification for ASU herbal drugs. These are separate from conventional pharmaceuticals, applied to the manufacture of herbal medicines to ensure their quality, and adherence to manufacturing information in pharmacopoeia/monographs is ensured. A licence is required for manufacturing drugs in compliance with GMP, pharmacopoeial and quality control parameters. Voluntary certification of quality through the Quality Council of India (QCI) provides the AYUSH Standard Mark (based on compliance more with the standards than with the domestic regulatory requirements) and the AYUSH Premium Mark (broadly based on compliance with WHO-GMP/USFDA criteria or GMP prescribed by importing country or fulfilment of quality requirements according to international norms).

Overall, 83% of the manufacturing units are GMP-compliant: 88.5% of Ayurveda units, 72.1% of homoeopathy units, 45.4% of Unani units and 27.7% of Siddha units (Chandra 2011; Ministry of AYUSH 2015).

To ensure compliance, periodic inspections are carried out 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 assign a person(s) to the role of ensuring compliance. Licences for manufacturing units are renewed every three years to ensure compliance with GMP.

Traditional use without demonstrated harmful effects is considered a sufficient safety requirement. T&CM medicines are also included under Schedule E of Drugs and Cosmetics Rules in India. There is no separate category for herbal medicines, but they are regulated under the Ayurveda, Siddha, and Unani traditional medicines. There is a separate essential drug list for Ayurveda/Unani medicines, based on traditional use of the herbal medicine and long-term historical use as well as disease-related classification.

Data and indicators: The Ministry of AYUSH collects and annually publishes extensive data on government facilities by type of AYUSH practice and by state (Ministry of AYUSH 2015). This includes data on infrastructure (number of hospitals, beds, dispensaries); registered practitioners; education and educational institutions; sector growth rates; licensed pharmacies (government and nongovernment, GMP and non-GMP-compliant); co-location of AYUSH facilities with rural health infrastructure; outlay and expenditure; patients’ presenting conditions (inpatient, outpatient, dispensaries); AYUSH-related foreign trade; organization; and the number of patients visiting government facilities and the reasons(conditions) for visits.

In 2017, the Namaste Portal was launched (www.namstp.ayush.gov.in), with a vision “to develop a comprehensive web portal on AYUSH Morbidity Codes, Inter-Linkages with WHO-ICD 10/11 and Standardized Ayurveda, Siddha and Unani Terminologies”.
References


2. Bhalerao MS, Bolshete PM, et al. Use of and satisfaction with complementary and alternative medicine in four chronic diseases: A cross-sectional study from India. *National Medical Journal of India* 26:2; 2013; 75-77.


4.5 Indonesia

**Traditional medical systems practised:** The traditional medicine system in Indonesia is called Jamu, which is based on medicines made from roots, bark, flowers, seeds, leaves and fruits. Some animal products, such as honey, royal jelly, milk and ayam kampung eggs, are also often used.

**Organization of traditional medicine:** The Republic of Indonesia has a pluralistic public and private health-care delivery system with conventional allopathic medicine considered primary and T&CM secondary. There is formal government recognition and regulation for practitioners, education, practice and products for Jamu and non-traditional/non-conventional medicine (CAM).

Although modern health services have developed in Indonesia, the number of people who use traditional medicine systems that include massage, treatment of fractures, traditional birth attendants, dental artisans and others remains high. As per 2010 data from the National Basic Health Survey, between 40% and 59% of the population use indigenous traditional medicines. TM practices of acupuncture, Ayurvedic medicine and chiropractic therapy are followed, but their rate of use is not known. Between 40% and 59% of the population use herbal medicines.

In a speech in 2011, a former Minister of Health noted that, based on data from basic health research in 2010, almost half (49.53%) of the Indonesian population, aged 15 years and over, consumed herbs. About five per cent (4.36%) consume herbal medicines every day while the rest (45.17%) consume herbal medicines occasionally. The proportion of the types of herbal medicine that is mostly chosen for consumption include liquid herbal medicine (55.16%); powder (43.99%); brewed herbs (20.43%); and the smallest proportion is that of modern packaged herbal medicine in the form of capsules/pills/tablets (11.58%).

**Authority responsible and policy framework:** In 2011, a Directorate of Traditional, Alternative and Complementary Services was established under the Ministry of Health; previous T&CM activities were conducted under a number of different directorates within MoH (Various 2010).

Indonesia’s “National Traditional Medicine Policy” was issued in 2007. Traditional health practice has been regulated under Health Act No. 36 of 2009. This Act divides T&CM practice into three levels:

1. T&CM practised by medical doctors in conventional health settings.
2. T&CM practised by T&CM practitioners with formal education.
3. T&CM practised by traditional healers within the informal health system.

T&CM regulations include Ministry Decree of Health No. 1076/2003 Kepmenkes No. 1076 (Role of Traditional Medicine Practitioner), Ministry Decree of Health of Complementary and Alternative Medicine No. 1109/2007 Kepmenkes No.1109 (Role of CAM Practitioner), and the Draft of National Policy of the Practice of T&CM.
The Deputy of Traditional Medicines, Cosmetics and Complementary Product Control at the National Agency of Drug and Food Control serves as the point of contact for T&CM.

**Finance and insurance:** Access to T&CM providers appears to be based on a “user pays” system.

**Practitioners:** The Ministry of Health reported over 88,920 traditional medicine practitioners registered for the period of 2010 to 2019. (MoH in 2019).

T&CM providers practise in the public and private sectors in clinic and hospital settings. State and city authorities issue the licences required for practice. There is also self-regulation by a delegated special technical association.

In 2003, a Ministerial Decree (1076/2003) was promulgated on T&CM practices by traditional healers, another in 2007 on T&CM practices by medical doctors (1109/2007) and in 2008, on standardisation of herbal medicine services for medical doctors (121/2008). Medical doctors with additional training can provide T&CM. Then there are traditional medicine practitioners with formal training certified by the Ministry of Education and traditional healers without formal training. The latter acquire skills through apprenticeship, “divine inspiration” and meditation or ancestrally (NADFC 2007; WHO 2001).

There are also separate regulations for acupuncture providers (1996 and 2003), chiropractic providers (MoH policy, Ministerial Decree, 1076/2003) and herbal medicine providers (2008) enforced at national, state and city levels. Regulations for hypnotherapy are being established.

The Health Act 36 (2009) states that every health facility, whether hospital or primary health centre, has to provide a comprehensive set of 17 health services including traditional health services (MoH 2015a). In practice, the conventional allopathic and T&CM sectors coexist mostly in parallel, but this is changing. The number of T&CM facilities was reported to be nine hospitals and 12 training centres, along with a model community health centre for CAM service in Surabaya, East Java, where allopathic medical doctors first diagnose conditions and then patients decide whether to choose conventional or T&CM treatment (Anonymous 2010b; Various 2014).

T&CM practitioners self-regulate through professional associations, but all traditional therapists must register with the provincial or municipal health service to obtain a “Registered Traditional Therapist Certificate”. Religious healers must have recommendation from the Department of Religious Affairs while supernatural healers must have recommendation from the District Attorney’s Office (NADFC 2007; Various 2010).

**Education and research:** A student of T&CM can obtain Bachelor’s and Masters degrees at the university level. The government also recognises a certified training programme, a training programme for indigenous traditional medicine practitioner and a training
programme for T&CM technicians or equivalent (not at the university level). Allopathic medical doctors access T&CM courses within their educational institutions.

Diplomas in Ayurveda or Jamu can be gained at the Hindu University, Denpasar, Airlangga University, and the Surakarta Health Polytechnic. Vocational training is also available for “untrained” traditional healers so that their practice can become more standardised. The training also aims to increase their capacity for collaborating with conventional medical providers, and to enhance their ability to provide a traditional medicine clinic under the supervision of a medical doctor (Anonymous 2010b; Ramakrishnan et al. 2014; Various 2014).

A national working group on Indonesian medicinal plants was established in 1991. An expert team for traditional medicine product evaluation and a working group of T&CM practices were formed in 2001 and 2007 respectively.

Access to T&CM providers appears to be on a “user pays” system. In 1977, the National Institute of Health Research and Development (NIHRD), Ministry of Health (Indonesia), set up an R&D Institute of Medicinal Plants and Herbal Medicines. The standard quality of herbal medicines (Indonesian Herbal Pharmacopoeia) was developed in 2008 and national research and development in herbal medicine started in 1980.

Under the National Programme for T&CM, the Centre for Traditional Medicine Development has been implementing T&CM practices in 13 provinces since 1995. Pilot projects for the integration of traditional medicine into primary health care were carried out in 12 secondary hospitals in 2010.

**Manufacture and regulation:** Around 1000 small-, medium- and large-scale manufacturers produce traditional medicine products. Raw materials are mostly plant-based, but some animal and mineral products are also used. Herbal medicines are regulated as non-prescription medicines. They are sold with medical and health claims in pharmacies and in other outlets as non-prescription medicines for self-medication or as over-the-counter medicines in special outlets and by licensed practitioners.

There are three levels of product registration: Jamu (for traditional products based on empirical evidence); standardized herbal products (which have evidence based on pre-clinical studies); and phytopharmaca (standardized products based on clinical trials). There are around 13 000 registered products, but only 36 in the standardized category and 6 in the phytopharmaca category. Non-branded traditional medicine products do not need to be registered (Anonymous 2010b; Elfahmi et al. 2014; Various 2010, 2014). Post-marketing surveillance of products is undertaken (Siswanto 2013).

The National Agency of Drug and Food Control (NADFC) oversees regulation of the traditional medicine products. Traditional medicine products have been regulated and registered since the 1970s, under an exclusive regulation for herbal medicines, titled “Criteria and Procedure for Registration of Traditional Medicines, Standardized Herbal Medicines and Phytopharmaca”, issued in 1976, and revised in 2005. More recently, the focus has been on standardization and scientific development of T&CM.
The Indonesian Herbal Pharmacopoeia (4th edition 1995 and 1st supplement for 4th edition 2009) is used and legally binding. Monographs used are from Materia Medika Indonesia (Editions 1–4, 1977–1995, issued as 237 monographs) and Vademekum Bahan Obat Alam (Edition 1, 1989, issued as 100 monographs), and these are legally binding. Apart from these, WHO monographs on selected medicinal plants (Editions 1–4, 1999–2009) are also used and are legally binding.

**Good manufacturing practices (GMP) on traditional medicine products**, issued in 1991 and revised in 2005, is followed. GMP standards are separate for conventional pharmaceuticals, but the same safety requirements as those for conventional pharmaceuticals must be followed. Traditional use without demonstrated harmful effects is sufficient and there is post-marketing surveillance for herbal medicines.

To ensure compliance, there are periodic inspections by authorities at manufacturing plants or laboratories and sampling of products in the market ensures that a manufacturer is following the rules of GMP.

**Data and indicators:** All public information is provided on the Ministry of Health website at http://www.depkes.go.id. Although there is a bilingual interface, documentation is still mainly in Bahasa Indonesia.

**References**


4.6 Maldives

**Traditional medical systems practiced:** Dhivehi Beys (or Dweep Unani) is the Maldives’ traditional system of herbal medicine.

**Organization of traditional medicine:** There is government interest in expanding and integrating T&CM into the national health system and steps are being taken to increase governance, quality and safety of T&CM product manufacture and practice.

**Authority responsible and policy framework:** The Ministry of Health is responsible for T&CM in the Maldives. There is an exclusive policy framework for T&CM. The national policy and law for T&CM were updated in 2016.

**Finance:** There is no government funding yet for T&CM.

**Practitioners:** The Maldives Health Care Professional Act (13/2015) specifies conditions of practice in the Maldives “as an allied health professional” (which includes the category of “professionals of traditional, alternative and complementary medicine”). Practitioners are required to register at the Maldives Allied Health Council and practise under a licence issued by the Council.

In 2010, there were reportedly 67 T&CM practitioners in the Maldives (51 Dhivehi-beys, seven Ayurveda, four acupuncturists, three Chinese medicine, one Unani and one Qigong). As of December 2018, there were five Islamic physicians (hakims), 19 alternative medicine practitioners and 59 traditional medicine practitioners registered in the Maldives.35

Employment is entirely through private-sector clinics, home-based practice and home visits. The national government issues the licence required for practice.

**Education and research:** An Advanced Certificate in Traditional Medicine is offered through the Faculty of Health Sciences, College of Higher Education. There is also a training programme for indigenous traditional medicine practitioners. No higher degrees are offered in the country.

There are no research institutions and no systematic research on the safety, efficacy or quality of T&CM care.

**Manufacture and regulation:** About 241 herbal medicines are registered. There are no restrictions on selling herbal products. Herbal medicines are sold in pharmacies as non-prescription medicines for self-medication or over-the-counter medicines in special outlets and by licensed practitioners. Health and medical claims are not regulated by law.

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34 Data from the Quality Assurance and Improvement Division

35 H.E. Prime Minister Mr Ibrahim Mohamed Solih (speech at the National Symposium on Traditional and Alternative Medicine on 31 December 2018, [https://maldivestimes.com/president-dhivehi-beys-a-legacy-which-must-be-passed-down-to-future-generations/](https://maldivestimes.com/president-dhivehi-beys-a-legacy-which-must-be-passed-down-to-future-generations/))
The Maldives Food and Drug Authority of the Ministry of Health and Family is mandated to regulate all medicines and medical products, and import and dispense traditional and alternative medicines. The Quality Assurance and Improvement Division of the Ministry of Health and Family is mandated to regulate traditional and alternative medicine services, practitioners and facilities.

There is relevant legislation on traditional medicine practice (1978) and on import and dispensing of medicines and medical products (1978, revised in 1995), a regulation on traditional and alternative medicine service provision (2006), a guideline on providing practising licences to traditional medicine practitioners and a regulation on traditional and alternative medicines.

All herbal and alternative medicines are dispensed as over-the-counter products. Herbal medicines are sold with medical, health and nutrient content claims, but these are unregulated by law.

Currently, no regulations apply to the manufacture of herbal medicines in order to ensure their quality. There are no existing safety requirements.

References
4.7 Myanmar

Traditional medical systems practised: Myanmar’s traditional medicine is based on four main systems:

1. **Desana** (based on Buddhist philosophy, focusing on diet modifications and use of herbs and mineral compounds).
2. **Bethitzza** (based on Ayurvedic concepts).
3. **Netkhatta** (based on astrology).
4. **Veizzadhara** (based on meditation and alchemy).

There are also witchcraft healers and practitioners of *maekalaung* (scratching) and other indigenous healing traditions.

Organization of traditional medicine: Public-sector departments of traditional medicine are in each tier of the health system: Central, state and regional, and district and township. Traditional medicine services are independent of conventional allopathic medicine services and providers (Naing Oo 2013; Sein et al. 2014).

According to a “knowledge, attitudes and practices (KAP)” survey conducted in 2009, indigenous traditional medicine is used by 80–99% of the population, with (80–99%) using acupuncture and (80–99%) using herbal medicines.

Myanmar has developed a “traditional medicine kit project” to promote use of T&CM in rural and remote geographical areas of the country. According to country data, over 26 000 traditional medicine kits have been distributed in villages, particularly in remote areas.

Authority responsible and policy framework: In 1989, the Department of Traditional Medicine was formed within the Ministry of Health and Sports (MoHS). This department was expanded in 1998 to provide comprehensive traditional medicine services through the existing health-care system in line with the National Health Plan. The latter includes bringing traditional medicine service and research up to an international level and involving the community health sector by integrating traditional medicine into it.

The national policy on T&CM is integrated into the National Health Policy of 1993. The national office for T&CM is located in Naypyidaw, established in 1989 under the Ministry of Health and Sports.

Practitioners: As of December 2018, there were 7262 registered indigenous traditional medicine providers and an estimated 2000 herbal medicines providers. T&CM providers practise in the public and private sectors in clinic and hospital settings.

There are 37 traditional medicine hospitals of various sizes (16–100 beds), 50 district T&CM clinics and 210 township T&CM clinics. In 2017–2018, traditional medicine hospitals treated about 17 000 inpatients and 270 000 outpatients while over half a million people
attended township T&CM clinics and field visits reached close to 300 000 patients. Altogether over 1.1 million people were treated in TM hospitals and clinics in 2017–2018 (BIMSTEC, 2019).

The leading conditions treated were disorders of the musculoskeletal system and connective tissues (31.02% of cases), followed by trauma/injuries (6.95%), disturbance of skin sensation (5.43%), hypertension (4.93%), cough (4.57%), spondylosis (4.56%), indigestion (4.46%), stroke (3.97%) and scabies (3.34%).

Since 2000, there have been regulations at national, state and city levels relating to indigenous traditional medicine and herbal medicine providers. The national government issues the licence required for practice.

The Indigenous Myanmar Medical Practitioners Board advises government on revival, development and modernization of traditional medicine, research and promotion of public health. It also decides on subjects for examination, registers and de-registers practitioners and is seeking a means to consolidate the four systems of Myanmar’s traditional medicine. Around two thirds of the T&CM practitioners are members of the Myanmar Traditional Medicine Practitioners’ Association (formed in 2002). Registration of practitioners is governed by the Traditional Medicine Council Law 2000 (Chaudhury & Rafei 2001; Various 2010, 2013; WHO 2001).

There are at least 14 traditional medicine hospitals and 243 traditional medicine clinics run by the state (MoH 2015b); private practices are in addition to these.

**Education and research:** In 2003, basic principles of Myanmar Traditional Medicine (MTM) were introduced in the curriculum of allopathic medical students (Naing Oo 2013).

In 2002, a University of Traditional Medicine was established in Mandalay, with regular and bridge Bachelor’s courses in Myanmar Traditional Medicine (1500 graduates since 2001) and a Masters course started in 2011 (51 graduates). Registered practitioners receive either diplomas or Bachelor’s or Masters degrees or undertake a one-year bridge course to qualify for registration. Bachelor’s degrees require five years’ study, including a one-year internship, while diplomas take three years, including a one-year internship.

The MoH Department of Traditional Medicine includes a Research and Development Division, which was established in 1998. Research and scientific analyses involve 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 T&CM clinical practice. The Department of Traditional Medicine also conducts research in collaboration with universities (through the Ministry of Education), the Department of Pharmaceutical and Household Products (at the Ministry of Industry), the Department of Medical Research (at the Ministry of Health and Sports), Forest Research Institute (through the Ministry of Natural Resources and Environmental Conservation) and the Department of Research and Innovation (at the Ministry of Education).
To promote the development of Myanmar Traditional Medicine, the Myanmar Traditional Medicine Practitioners’ Conference has been held annually since 2000.

**Manufacture and regulation:** The National Food and Drug Authority (FDA) is responsible for regulating traditional medicine manufacture and products, including labelling, licensing, advertising and registration, as stipulated by the Myanmar Traditional Medicine Drug Law (1996). This law was followed by a series of notifications concerning registration and licensing, labelling and advertising. The objective of the TM Drug Law is to enable the public to consume genuine, quality, safe and efficacious traditional drugs. According to this law, all the traditional medicine drugs produced in the country must be registered and manufacturers must have licences to produce their products.

As of January 2019, there are 14,529 registered drugs in the National Traditional Medicine Formulary and 3206 licensed traditional medicine drug producers. Herbal medicines are regulated as herbal medicines and sold with medical and health claims. The Department of Traditional Medicine under the Ministry of Health and Sports developed GMP guidelines based on WHO and ASEAN countries’ guidelines. GMP standards apply to public and private manufacturers. Traditional use of traditional medicine drugs without demonstrated scientific research on similar products is considered a sufficient safety requirement (BIMSTEC 2019).

With the aim of perpetuating medicinal plant species, the Department of Traditional Medicine established nine herbal gardens around the country, aiming for the sustainable development of herbal medicines and provision of raw materials for public and private pharmaceutical factories.

Two state-owned T&CM factories (in Yangon and Mandalay) manufacture about 15,000 kg of traditional medicines annually for the Department of Traditional Medicine – 25 products in a powder form for use in public TM hospitals and clinics, 10 products in a tablet form and one ointment for commercial sale.

**Data and indicators:** The annual Health in Myanmar report evidences the integral place that traditional medicine has in the health system (MoH 2015). Information relating to traditional medicine in national policy, reforms, health laws, health development and national health plans is included. Brief health statistics include counts of traditional medicine workforce (public and private) and facilities.

**References**


4.8 Nepal

Traditional medical systems practised: Ayurveda is considered indigenous to the country, but other systems of traditional or complementary and alternative medicine (T&CM) are also recognised, including Unani, homoeopathy, naturopathy, Amchi (gSo-ba Rig-pa) and acupuncture.

Organization of traditional medicine: Nepal has a pluralistic health-care system that offers traditional medicine and conventional allopathic medicine. Formalised health services are mostly in urban areas; rugged terrains can make accessing these facilities difficult.

About 75%–80% of the people in Nepal reportedly depend on traditional medicine (WHO SEARO 2009). Traditional medicine is often the first choice for many people in rural and remote areas where there is often a shortage of conventional health providers and the cost of accessing traditional medicine providers is lower (Byrne et al. 2013; Jimba et al. 2003; Tamang & Broom 2010).

Authority responsible and policy framework: Ayurveda services have been provided under the Ministry of Health and Population (MoHP) since 1956. The Department of Ayurveda was established in 1981. The department primarily manages the delivery of Ayurveda services and promotes healthy lifestyle through its network facilities across the country. The department is responsible for programming, management of information and supervision, monitoring and evaluation of the Ayurveda service programmes. It works to provide preventive, promotive and curative health services in the country; establish and develop skilled human resources and to bolster and expand Ayurveda health services; strengthen monitoring and supervision activities; develop an information, education and communication centre in the department; strengthen and expand research and training in Ayurveda; and collaborate and coordinate among ministries, nongovernmental organizations and international nongovernmental organizations.

The Department of Ayurveda and Alternative Medicine has one zonal office, 14 regional offices, 61 district centres, 305 rural dispensaries and one central pharmacy.


Ayurvedic clinics are considered part of the basic health service. The government acknowledges that traditional medicine can maximise the potential of the health workforce to more effectively serve the population. It also acknowledges the ability of T&CM to treat some conditions better than the conventional medical system.
Furthermore, T&CM can also be a source of income and help to reduce poverty (Mahto 2013).

The national programme for T&CM is integrated into the Second Long-Term Health Plan, 1997–2017. The national T&CM policy is integrated into the National Drug Policy issued in 1995. There is no separate national law or regulations, especially on T&CM.

**Finance:** Government services are often free and Ayurvedic products have been available in dispensaries since the 1960s (Cameron 2009b; Jha et al. 2007; Unknown 2007b).

**Practitioners:** There is one government-run Ayurveda health centre in each district (for a total of 75 centres), two Ayurveda hospitals, 214 Ayurveda dispensaries and one homoeopathic hospital (DoHS 2015). In addition to these, there is an unknown number of facilities for other T&CM practices.

The informal traditional medicine sector is vast, with reportedly around 400 000 traditional healers (Koirala *et al.* 2013), including spiritual healers, astrologers, priests, birth attendants and others.

In the formal traditional medicine sector, there are about 450 registered Ayurvedic physicians and around 1300–1900 diploma-level auxiliary workers or paramedics (Various 2013; WHO-SEARO 2009).

T&CM providers practise in the public and private sectors in clinic and hospital settings. Just under 1 million people were served in government Ayurvedic facilities in 2013–2014 and 67 082 people in the government homoeopathic hospital (DoHS 2015).

Since 2001, the Nepal Ayurvedic Medical Council has regulated Ayurvedic practitioners, defined their scope of practice and issued registrations concerning traditional health-care services, education, licensing traditional organizations/institutions or practitioners.

By 2018, there were about 70 postgraduates, more than 700 graduate doctors and 3800 diploma technicians registered with the Council (BIMSTEC 2019).

The Nepal Health Professional Council works in the same way for overseas-trained graduates such as homoeopaths and naturopaths. Direct or indirect practice of Ayurveda is now legal and can be carried out only by suitably qualified and registered practitioners.

**Education and research:** Two universities conduct Bachelor’s-level education in Ayurveda and one of them provides a Master’s degree as well. Between them, they enrol 80 students per year. The first formal Ayurvedic education institution was established in 1936, but the Bachelor of Ayurvedic Medicine and Medical Surgery has been offered since 1987. It takes five-and-a-half years to complete the Bachelor’s degree.

Apart from these degrees, the government also recognises training programmes for T&CM technicians or equivalent (not at the university level) courses. Diploma courses and vocational training in Ayurveda, herbs and herbal products are conducted by many
institutions in the country. Auxiliary Ayurveda workers complete their training through the Department of Ayurveda.

A National Ayurveda Research and Training Centre was established on the premises of Tribhuvan University in 2011. Its scope is to develop traditional medicine to provide evidence-based therapy, transfer advanced skills and technology to practitioners, and develop high-quality research laboratories in toxicology, immunology, drug formulation, quality control and assurance, pharmacology, cellular biology, microbiology and pathology (BIMSTEC 2019).

Manufacture and regulation: Nepal has rich biodiversity with 1400–1600 plant species used medicinally across the country. Good growing conditions enable the export of raw herbs to neighbouring countries. The need to document, protect and conserve herbal medicines has been acknowledged with the programmes to support conservation and promotion being envisioned (Mahto 2013; WHO-SEARO 2009).

There are about 260 registered traditional medicine products and 60 products on the Essential Ayurvedic Drugs List (developed by the Department of Ayurveda).

In addition, about 80 Ayurvedic pharmaceutical companies are producing patent and classical drugs. These meet only 30% of the country’s needs, and so the rest of the medicines are imported from India and other countries. Wild medicinal herbs are means of employment and income generation for rural people. Herbal medicines are sold in pharmacies as prescription medicines, non-prescription medicines, self-medication or over-the-counter medicines.


The Ayurvedic Pharmacopoeia of India (First Edition Vol I, 1999, Vol II, 2001, III, 2004, and IV) are used (but not legally binding) along with classical texts such as Bhaisajya Ratnawali, Siddayog Sangrah, Rasashastra, etc.

GMP standards are not specific for traditional medicine, but are the same as that for conventional pharmaceuticals. However, there is limited capacity for quality assessment and testing, and there are currently no mechanisms to ensure compliance. Safety requirements for herbal medicines are the same as those for conventional pharmaceuticals (WHO-SEARO 2009).

The government manufacturer of Ayurvedic medicines, Singha Durbar Vaidhakahana Vikas Samiti (SDVKVS), produces 35 patent and more than 170 classical drugs using about 300 different medicinal plants, 32 metals and metal compounds, and 42 minerals and
animal by-products. SDVKVS mainly supplies to the Department of Ayurveda and private dispensaries within the country (BIMSTEC 2019).


**References**


4.9 Sri Lanka

Traditional medical systems practised: Ayurveda, Siddha and Unani medical systems are practised, along with Sri Lankan indigenous traditional medicine (Deshiya chikitsa). Traditional medicine therapies also commonly include panchakarma, herbal, mineral and metal-based products, magico-ritual performance, massage, diet and lifestyle change.

Organization of traditional medicine: The public health sector within Sri Lanka provides allopathic medicine and indigenous (Ayurvedic) medicine. These two systems of medicine operate independently as separate sectors governed by the Ministry of Health, Nutrition and Indigenous Medicine.

According to the Medicine Statistics Section, Department of Ayurveda (2007), 40–59% of the population is estimated to be using indigenous traditional medicine. Acupuncture, homeopathy and Unani medicine are used by 1%–19% of the population and Ayurvedic medicine by 40–59% of the population. Overall, out of a total population of 19.7 million in the country (2006), about 11% seek treatment at government-operated Ayurvedic hospitals.

Authority responsible and policy framework: The Department of Ayurveda leads the development of T&CM. Each province has its own provincial department of Ayurveda to administer its T&CM institutions.

All systems are controlled by the policy document, titled "Ayurveda Act No. 31 of 1961". The Sri Lankan policy on indigenous medical systems was in draft stage in 2017.

The department is responsible for the formulation of policies required to enhance public health through the extension of Ayurveda system across the country; to maintain the best possible services for the prevention of diseases, health-care rehabilitation and development; and to identify and implement strategies necessary for the propagation of the Ayurvedic system globally.

Finance: In 2017, the public expenditure for TM was US$ 13.8 million (per capita public expenditure was US$ 0.6) while the government allocation in the annual budget for TM research was US$ 2.4 million.

There is a full government insurance coverage available for Ayurvedic medicine and Unani medicine. Partial private insurance coverage is also available for Ayurvedic medicine. A national programme has been initiated to maximize the contribution of TM in the health tourism sector.

Practitioners: National-level regulation of indigenous traditional medicine providers and Ayurvedic medicine providers has been applied since 1962. National-level regulation of homeopathic providers has been in effect since 1972. All indigenous medicine practices are controlled by the Ayurveda Act No. 31 1961, which makes it illegal for a medical doctor to practise Ayurveda unless he/she is also registered as an Ayurvedic practitioner.
The reverse is not true though – an Ayurvedic practitioner will commonly prescribe pharmaceuticals (Forsberg 2013). The Ayurveda (Disciplinary) Regulations 1973 and the Registered Ayurvedic Medical Practitioners (Professional Conduct) Rules of 2014 regulate practitioners’ professional conduct.

The Sri Lanka Ayurvedic Medical Council (AMC) is the licensing and regulatory body for T&CM practitioners. In 2017, there were 23,082 T&CM practitioners in the country, 8,033 of them being degree or diploma holders. The T&CM practitioner density is 1.1 per 1000 population (BIMSTEC 2019).

Of the general, registered T&CM physicians, Ayurveda accounts for 84.6% practitioners, the Siddha system for 12.7% and the Unani system for 2.7%. Among the specialist physicians, Ayurveda accounts for 96.5% practitioners, Siddha for 2.9% and Unani for 0.6%.

In 2007, there were 500 acupuncture providers, 350 homeopathic medicine providers, 300 Unani medicine providers and 500 Siddha providers in Sri Lanka. About 1,424 Ayurveda medical practitioners are employed in government hospitals and others are deployed across the country to implement disease prevention programmes (MIM 2015).

Apart from these physicians registered at the Ayurveda Medical Council, there are more than 8,000 traditional medical practitioners engaged in public health care, who are descendants of reputed families believed to have secret formulas for curing diseases.

The sector has grown considerably over the years. “In 1977, there existed only 10 Ayurvedic hospitals and central dispensaries in the island. Today, this has jumped to 270 institutions scattered across the country – 62 Ayurvedic hospitals and 208 central dispensaries. Over 3 million people seek treatment at these hospitals annually. In government Ayurvedic hospitals, there are about 1,424 physicians. The 62 Ayurvedic hospitals offer residential curative services to nearly 25,000 patients in a year. In addition, there are 230 dispensaries administered by local government authorities, which offer free services to a large number of people. Though they are administered by the local government bodies, the responsibility of providing them with required drugs is vested with the Ministry of Indigenous Medicine and the Sri Lanka Ayurveda Drug Corporation. The provincial departments of Ayurveda are also involved in this process by way of coordination (Ministry of Indigenous Medicine, http://www.indigenousmedimini.gov.lk/About_us.html accessed on 20 May 2019).”

**Education and research:** About 70% of registered practitioners are traditionally trained via apprenticeship rather than being institutionally trained. Graduates of government-recognized courses automatically meet practitioner registration requirements while non-institutionally trained practitioners must meet minimum standards and pass a written examination and/or interview conducted by the AMC.

Apart from these, the government also recognises certified training programmes and a training programme for indigenous traditional medicine practitioners.
A medical consultant should pursue a specialist training in a particular form of traditional medicine, such as an MD (3 years) course, or post-MD (2 years) training and Board certification as a specialist.

Four universities provide Bachelor’s degrees in five- to six-year courses and 16 Ayurveda colleges offer diploma-level courses. In 2017, the Postgraduate Institute of Indigenous Medicine was established to provide formal postgraduate training (BIMSTEC 2019). Masters and PhD-level training are available, along with MPhil and the postgraduate diploma courses in T&CM at the university level. Allopathic medicine students receive 5–10 hours of education in Ayurveda and other T&CM systems whereas almost 50% of the curriculum for Ayurvedic students includes subjects related to allopathic medicine. About 145 new TM practitioners are produced by the universities each year (BIMSTEC 2019).

The Bandaranayake Memorial Ayurvedic Research Institute has served as the national research institute for T&CM since 1961. T&CM research is also carried out in four local universities. The National Institute of Traditional Medicine provides continuous medical education programmes.

**Manufacture and regulation**: Although recent figures relating to the value of production of private firms are not available, it is generally accepted that Sri Lanka Ayurvedic Drugs Corporation is the biggest single manufacturer of Ayurvedic drugs in the country. According to older data from the Department of Ayurveda, the total market sales of herbal medicines amounted to US$ 500 million, US$ 500 million and US$ 550 million in 2007, 2008 and 2009 respectively. The Department of Ayurveda maintains six large medicinal plant gardens, covering 394.5 acres, with more than 700 plant species.

All traditional medicine products are categorised as indigenous medicines and are controlled by the Ayurveda Act No. 31 (1961), overseen by the ministry and the Sri Lanka Ayurveda Drug Corporation (MIM 2015; Various 2010).

Approximately 960 medicines are registered. There are no restrictions on selling herbal medicinal products. Herbal medicines are sold in pharmacies and other outlets as prescription medicines, and as non-prescription, self-medication or over-the-counter medicines in special outlets (for example, in herbal medicines stores, T&CM supply stores, etc.). These are sold by licensed practitioners only.

The regulation "Ayurvedic code" was established in 1929 and renewed in 2012.

The licensing and regulatory mechanism for T&CM products is implemented by the Department of Ayurveda; an independent review body (the Drug Formulary Committee) comprehensively reviews every T&CM product prior to the approval for marketing.

Three pharmacopoeias are available (one each for Ayurveda, Siddha and Unani), listing 1193 T&CM products. The Ayurvedic Pharmacopeia (1st edition 1975) is used and is legally binding. Under certain circumstances, references are made to the Indian Pharmacopeia. The "Thalpathe pilium" contains the national monographs on herbal medicines, but
it is not legally binding. The pharmacopoeias are being reviewed to ensure that they incorporate modern quality standards.

GMP is followed and adherence to manufacturing information in pharmacopoeia/monographs is ensured for the manufacture of herbal medicines in order to maintain their quality. 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. Requirements for safety are the same as those for conventional pharmaceuticals and traditional use without demonstrated harmful effects is considered sufficient.

The Ayurvedic Drugs Corporation is the only state-sponsored organization in Sri Lanka for the manufacture and sale of Ayurvedic drugs. The Corporation was established in 1969 by order, under the Industrial Corporations Act No. 49 of 1957, of the Minister of Industries and Fisheries. The main objectives of the Corporation are to manufacture, sell and distribute Ayurvedic drugs and pharmaceuticals and Ayurvedic medicinal preparations; to import Ayurveda, Siddha and Unani preparations (both raw and manufactured drugs) and sell and distribute these drugs; to carry out pharmacological and pharmaceutical research on Ayurvedic drugs; and to maintain Ayurvedic herbaria and produce indigenous varieties of Ayurvedic herbs required for the manufacture of drugs. It manufactures a variety of items for Ayurveda, Siddha and Unani systems of medicine. Of importance is the production of Rasa medicines (metallic preparations). These medicines are comparatively expensive, and the preparation of these drugs involves an elaborate process (http://www.indigenousmedimini.gov.lk/SLADC.html).

The Corporation supplies a large proportion of the manufactured drugs required by the Department of Ayurveda and free dispensaries in the provincial councils. Recently, the Corporation ventured into a new field of commercial activity, namely the export of locally available crude drugs and locally manufactured drugs to foreign countries.

**Data and indicators:** An annual statistics report is published.

**References**


4.10 Thailand

Traditional medical systems practised: Traditional medicine systems and alternative medicines recognized by the Ministry of Public Health include Traditional Thai Medicine (TTM), traditional Chinese medicine (TCM) and chiropractic therapy.

Organization of traditional medicine: The Kingdom of Thailand has a pluralistic health-care delivery system with traditional Thai medicine (TTM) being widely available through both public and private sectors.

Government promotion of traditional medicine supports a shift in the health-care paradigm to one where people have increased knowledge and participation in their own health care. It is also considered to ease the financial burden of funding allopathic drugs and technologies in the public health system; address the increasing prevalence of chronic diseases; meet the public demand for natural health products and holistic services; meet the requirements not fulfilled by conventional medical services; and align with policies for economic stimulus and sustainable development (Suwankhong et al. 2011a; Thavatchai 2015; Thongruang 2014).

The Thai government is seeking to develop alternative forms of health care by blending Thai and international wisdom to develop “tai wisdom” or the knowledge, technology, practices and biodiversity existing in Thailand that cover the context of traditional Thai medicine, Thai indigenous medicine and alternative medicine (Anonymous 2010a), and “tai ways of health” or pathways that lead to health and allow people to be free from sickness, unhappiness and all kinds of stress (Anonymous 2010a).

Authority responsible and policy framework: All public-health activities are coordinated by the Ministry of Public Health (MoPH). The Department for the Development of Thai Traditional and Alternative Medicine within MoPH was established in 2002 and is the national authority in Thai traditional and alternative medicine (TT&AM).

A strong policy and governance sector ensure that TTM has a significant amount of policy, strategy and programme attention with multi-layered activities facilitating integration and collaboration between TTM and a variety of other departments and sectors (Thongruang 2014). There is a three-tiered system with provincial, district and sub-district service delivery levels. Conventional biomedicine is dominant in both public and private sectors, and health promotion, protection and holistic care underpin the current health delivery strategies.

National laws and policies that support TTM include the Constitution of the Kingdom of Thailand (Buddhist Era i.e. B.E. 2560) (2017) (in particular, Articles 55 & 57 – Section 16 Country Reform), the 20-Year National Strategy (2017–2036) and the National Reform Plan in Public Health.
The policy on TTM is integrated into the National Health Act B.E. 2550 (2007). There is also an exclusive national policy on TTM included in the 10th National Health Development Plan (2007–2011). Laws and regulations related to TTM include the Practice of the Art of Healing Act (B.E. 2542), the Drug Act (B.E. 2510) and the Protection and Promotion of Thai Traditional Medicine Wisdom Act (B.E. 2542). The regulation was updated in 2013 while the national policy and law on TTM were updated in 2016.

Various expert committees and sub-committees focus on different areas of traditional Thai medicine. These include the Committee on the Protection and Promotion of Traditional Thai Medicine, the Profession Commission for Traditional Thai Medicine, the Profession Commission for Applied Traditional Thai Medicine, the Network of Graduate Schools (comprising deans from each school) and the National Expert Working Group on the Selection of Herbal Medicinal Products.

The First Master Plan on the Development of Thai Medicinal Plants (2017–2021) was promulgated, with the following key implementation tasks: manage the supply chain (strain selection and development; promote cultivation by GAP/GACP/organic); manage processing of herbal materials; promote sustainable use of medicinal plants from natural sources; ensure development of the herbal product industry; boost R&D of herbal products; ensure efficacy and safety (pre-clinic/clinic); ensure quality; maintain Thai Herbal Pharmacopoeia/TTPP; manage herbal extracts; ensure product development; maintain databases; ensure development of herbal product markets (herb expos, road shows, distribution, e-commerce, digital market); and promote the use of herbal products for health care. Implementing this masterplan will require a collaborative effort among nine ministries.

A major national reform planning effort had been underway in Thailand in 2019, covering 10 issues, the fifth of which was the use of traditional Thai medicine and products to improve the economy. This included a TTM service reform plan, a TTM educational reform plan and a TTM herbal products reform plan (BIMSTEC 2019).

**Finance and insurance:** The budget allocated by the National Health Security Office (NHSO) for TT&CM services has grown more than 20-fold, from 0.5 Baht (US$ 0.02) per capita in 2007 to 11.61 Baht (US$ 0.36) in 2018 (NHSO 2017). Considering that there are 48,797 million beneficiaries, this represents a total of 566.53 million Baht (US$ 17.7 million) to help support hospitals providing TT&CM services (BIMSTEC 2019). A sum of US$ 30.85 million from government/public research funding has been allocated (BIMSTEC 2019).

As of the end of 2016, traditional Thai medicine services are covered by health security systems, with three key schemes:

1. The universal coverage scheme of the National Health Security Office, covering 48.8 million people (about 75% of the population).
2. The social security scheme of the Social Security Office for employees of private businesses, covering 13 million people (about 20% of the population).

3. The Civil Servant Medical Benefit Scheme (for civil servants, including their parents and children less than 20 years of age), covering 5 million people (about 5% of the population) (BIMSTEC 2019).

Treatments with T&CM available in public health service facilities covered by the national health security systems include treatment, diagnosis and rehabilitation with traditional medicine approaches. These include acupuncture, traditional herbal medicines or traditional recipes based on medicinal plant materials, therapeutic massages for treatment and rehabilitation, herbal steam baths for therapeutic purposes, hot herbal compresses for therapeutic purposes and hot salt pot compresses for postpartum care.

**Practitioners:**

The number of licensed practitioners in traditional Thai medicine are as follows:

2. Traditional pharmacy: 28 161.
3. Thai traditional midwifery: 8986.

(Note that one TTM practitioner may hold more than one licence). The number of licensed practitioners in applied traditional Thai medicine is 2568 (TT&AM Health Profile, 2014–2016).

**Table 4.4:** Distribution of TTM practitioners in public health service facilities

<table>
<thead>
<tr>
<th>Type of health service facility</th>
<th>Total</th>
<th>Service facilities with TTM practitioners</th>
<th>%</th>
<th>TTM practitioners</th>
<th>Ratio of facility to TTM practitioners</th>
<th>Ratio of TTM practitioners to population</th>
</tr>
</thead>
<tbody>
<tr>
<td>RHs/GHs</td>
<td>116</td>
<td>116</td>
<td>100</td>
<td>378</td>
<td>1:3.23</td>
<td>1:25 000</td>
</tr>
<tr>
<td>CHs</td>
<td>762</td>
<td>762</td>
<td>100</td>
<td>1327</td>
<td>1:1.74</td>
<td></td>
</tr>
<tr>
<td>Health centres</td>
<td>9 777</td>
<td>939</td>
<td>9.15</td>
<td>987</td>
<td>1:0.1</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>10 655</strong></td>
<td>1817</td>
<td><strong>17.05</strong></td>
<td><strong>2692</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Data & Knowledge Bank Office (2016) Institute of Traditional Thai medicine (2017)

NOTE: RHs/GHs = Regional/general hospitals, CHs = community hospitals

TTM providers practise in the public and private sectors in clinical and hospital settings. TTM is also prescribed by medical doctors in public health facilities that may not have a TTM practitioner on site. The percentage of OPD patients receiving TTM services in public health service facilities has been steadily rising in recent years, from 18% in 2016 to 20% in 2018 (source: HDC-TTM 30 Sep 2018).
The Department for the Development of Thai Traditional and Alternative Medicine has established standards for TTM public facilities that cover facilities, equipment and environment; personnel; job description; quality assurance; and provision of services. In 2008, 65% of health centres met the standards, as did 95% of community hospitals and 100% of general hospitals (Anonymous 2010a). The role of TTM practitioners in the public health system is not only to provide appropriate service, but also to be proactive about family care teams, mobile clinics and community care (Thavatchai 2015).

National-level regulations on indigenous traditional medicine providers were issued in 1999 in the form of Practice of the Art of Healing Act (1999), Ministerial Notification: Code of Ethics for traditional Thai medicine providers (2002) and Ministerial Notification: Code of Ethics for Applied Traditional Thai Medicine Providers (2002). There are also national-level regulations on TTM providers such as chiropractic providers (2006) and traditional Chinese medicine providers (2000, revised in 2009). These regulations were updated in 2013 and the list of registered practitioners was also updated.

The various Acts and regulations governing the practice of TTM are overseen by the relevant profession commissions. Licensing requirements include either completed apprenticeship and licensing examination or study at certified academic institutions and licensing examination (Chuthaputti 2013).

Table 4.5 shows the cumulative number of practitioners who passed the licensing examination, registered and received the licences between 1929 and 2017, by branch of TTM.

<table>
<thead>
<tr>
<th>Branch of TTM practitioners</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional Thai medicine</td>
<td>21,495</td>
</tr>
<tr>
<td>Traditional Thai pharmacy</td>
<td>29,165</td>
</tr>
<tr>
<td>Traditional Thai midwifery</td>
<td>9,851</td>
</tr>
<tr>
<td><em>Nuad Thai</em> (traditional Thai massage)</td>
<td>4,737</td>
</tr>
<tr>
<td>Applied traditional Thai medicine practitioners</td>
<td>2,860</td>
</tr>
</tbody>
</table>

NOTE: This excludes information about those who passed away.
Source: Medical Regulation Division, Department of Health Service Support

Thai pharmacists are also referred to as herbal medicine providers. There are also providers of chiropractic and traditional Chinese medicine practising in the country. Since 1996, there has been a consumer education programme for self-health care using TTM.

**Education and research:** A student of TTM can obtain Bachelor’s, Masters and PhD degrees in TTM at the university level. PhD courses in public health sciences (Thai traditional and alternative medicines) are available at Chulalongkorn University. The
government also recognises apprenticeship with TTM providers, certified training programmes, training programmes for indigenous traditional medicine practitioners and T&CM technicians.

There are 27 certified TTM-teaching institutes offering Bachelor’s degrees (of which 18 teach traditional Thai medicine and nine teach applied TTM), and 81 TTM-teaching institutes or health facilities (using an apprenticeship system) certified by the TTM Council (TT&AM Health Profile 2014–2016).

The traditional Chinese medicine (TCM) Profession Commission recognized 31 universities in China and 9 universities in Thailand that offer Bachelor’s degrees in TCM. There were 1066 licensed TCM practitioners and 1863 allopathic medical doctors who had completed a three-month acupuncture and moxibustion training course in 2018.

The Traditional Thai Medicine Research Institute (under the Institute of Traditional Thai Medicine) was established in 2010 in Bangkok.

**Manufacture and regulation:** The list of herbal medicinal products produced since 2014 include 50 traditional medicinal preparations and 24 single herbal medicines. The traditional medicinal preparations include remedies for the gastrointestinal system (15 items), cardiovascular system (5 items), antipyretics (6 items), obstetrics and gynaecology (6 items), respiratory system (8 items), nourishing blood (1 item), musculoskeletal system (8 items) and nourishing and balancing body elements (4 items). The herbal medicines include remedies for the gastrointestinal system (6 items), respiratory system (1 item), skin system (7 items), smoking cessation (1 item), musculoskeletal system (5 items), urinary system (2 items), antipyretic and relieving internal heat (4 items), and detoxifying (1 item).

The Thai Food and Drug Administration classifies registered herbal medicines products into four categories: traditional drugs; modified traditional drugs; modern herbal medicines or phytopharmaceuticals (standardised and derived from scientific research); and new drugs (purified, isolated active substances with chemical structures identified as new chemical entities). The latter group is classified as modern rather than traditional drugs (Anonymous 2010a).

Preparation of herbal medicines regularly occurs in hospitals and health clinics and the government has its own pharmaceutical organisation for TTM manufacture. There were 12 625 registered herbal medicines in 2010, around 90% of which were locally made. Herbal medicines were introduced to the Essential Medicines List in 2006 (updated in 2016).

GMP standards were introduced in 2005 and training to achieve GMP compliance is available through government offices and universities. The Department for the Development of Thai Traditional and Alternative Medicine is supporting the development of GMP-certified herbal medicine production units in 39 hospitals. No indication is given in the literature consulted on the overall number of manufacturers that are GMP-compliant, the number of public or private traditional medicine manufacturers, licensing arrangement for manufacturers or quality assurance measures for raw materials.
An exclusive regulation for herbal medicines was issued in 1967 (B.E.2510) under the Drug Act (B.E.2510) and its amendments. Herbal medicines are regulated as non-prescription medicines and herbal medicines and sold with medical and health claims.

The Thai Pharmacopeia (Volume 1 Parts 1&2, Volume 2 Parts 1–3 including supplements) are used. The traditional pharmacopeia includes Wetchasuksa of Phraya Phitsanuprasatwet, Books 1, 2 and 3 (the medical study of Phraya Phitsanuprasatwet), A Treatise on Traditional Medicine by Khun Sophitbunnalak, Books 1, 2 and 3, The Phaetthayasatsongkhro, Books 1, 2 and 3, and Thai Herbal Pharmacopeia Volume 1–3, which are legally binding. Apart from these, Pharmacopoeia of the People’s Republic of China, Japanese Pharmacopoeia and British Herbal Pharmacopoeia are used, but are not legally binding.

The monographs used include Thai Herbal Pharmacopoeia Volume I (11 monographs), Volume II (10 monographs), and Volume III (11 monographs); these are not legally binding. The Commission E Monograph and Monographs of Selected Thai Materia Medica Volume I (54 monographs) are also used.

The GMP of herbal medicinal products, issued in 2005 (Thai B.E. 2548), are followed. Regulations for GMP of herbal medicines are different from conventional pharmaceuticals on certain aspects owing to the differences in the sources of raw materials. As the former are derived from natural sources while the latter are chemically synthesized, the quality assurance processes of herbal medicines are different. To ensure compliance, periodic inspections are carried out by authorities at manufacturing plants or laboratories and manufacturers are required 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 safety requirements. Tests for the microbial contamination limit and the heavy metals limit are carried out.

In the List of Herbal Medicinal Products 2006, 21 single herbs and 50 formulas of combined herbs are included, based on traditional use of the herbal medicine, clinical data, long-term and historical use, and laboratory testing. Herbal medicines are sold in pharmacies and other outlets as prescription medicines, as non-prescription, self-medication or over-the-counter medicines in special outlets and by licensed practitioners. The regulation on herbal medicine and the list of registered herbal medicines were updated in 2017.

Earlier, the registration of traditional medicines or herbal medicines was regulated under the Drug Act B.E. 2510 (1967). It was then believed that the Drug Act and Food Act were not suitable for the registration of traditional/herbal medicines and herbal dietary supplements. A new Act, called Herbal Products Act, has therefore been drafted since 2016 and promulgated in 2019. Thai FD has set up a new division to oversee those products since 2020.
According to 2010 data from the Drug Control Division, Thai FDA, the total manufacture of herbal medicines (for both human and animals) in Thai Baht amounted to 2188.12 million, 2547.30 million and 2804.15 million in 2007, 2008 and 2009 respectively.

**Data and indicators:** Thailand has a well-functioning, real-time monitoring system on traditional medicine system performance. Based on the information from the system, monthly reports are prepared by the Department for the Development of Thai Traditional and Alternative Medicine based on data from 76 provinces and divided into 13 health service areas. Collected data include: number of OPD visits; TTM services given; percentage of TTM/CAM services given per OPD visit; number of hospitals providing parallel TTM OPD services according to department criteria; top 10 diseases people seek TTM treatment for; number of herbal medicine prescriptions; prescribed herbal medicines classified by age group of patients; prescribed herbal/traditional medicines (top 10) and quantity prescribed; value of medicines prescribed; number of massages, herbal steam and herbal compress services provided inside and outside hospitals; number of traditional postpartum care services; number of acupuncture services; and number of health promotion services with TTM and CAM (number of times, number of patients) (Canvey 2015).

**References**


3. Thongruang C (2014). The barriers to the adoption of Thai traditional medicine services in Thai community hospitals: a case study of community hospitals in Phitsanulok Province. PhD, University of Wollongong.


4.11 Timor-Leste

**Traditional medical systems practised:** Folk traditional medicine in Timor-Leste is mostly linked with religious beliefs. Folk therapies include herbal medicines that are often accompanied by a spell, mantra or prayer. The indigenous traditional medicine in Timor-Leste is not highly systematised.

**Organization of traditional medicine:** The health system in Timor-Leste is dominated by the public sector and includes only allopathic curative and public-health prevention and promotion services.

Since independence, there has been a renewed focus on local healing practices and related activities, in part to restore a sense of well-being and community health (McWilliam 2008). People will often combine biomedical and traditional approaches to health care. The two systems are perceived as “mutually reinforcing” with traditional approaches supplementing biomedical treatment – for example, bringing traditional remedies into hospitals to supplement biomedical treatment (de Araujo 2013; McWilliam 2008). A strong focus on spiritual or religious healing can be a ready health-care adjunct without interference in biomedical treatments.

**Authority responsible and policy framework:** There is not a national policy, law or regulation on T&CM or regulation on herbal medicines or T&CM practitioners yet. Traditional medicines were included in the National Drug and Medicine Policy 2013 (MoH, no date).

**Finance and insurance:** Public health services are free.

**Practitioners:** The main diseases managed with T&CM in Timor-Leste during the period of resistance against colonial rule included bone and joint diseases (musculoskeletal disorders, wounds and injuries), digestion and stomach diseases (diarrhoea and mouth sores), infections (malaria, hepatitis, "pink eye" and urinary tract infections), epilepsy, birth, cancer and diabetes (Collins et al 2007).

According to the Timor-Leste health care-seeking behaviour study in 2009 (the sample included 4500 households, comprising 25 000 individuals), the following health providers were visited by 531 households for any illness in the 12 preceding months:

**Table 4.6:** Use of health providers by households in the last 12 months (HCSBS sample)

<table>
<thead>
<tr>
<th>Health Provider</th>
<th>Households visiting provider n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traditional Providers</strong></td>
<td></td>
</tr>
<tr>
<td>Traditional Birth Attendant</td>
<td>104 (19.6)</td>
</tr>
<tr>
<td>Traditional Bone Setter</td>
<td>101 (19.0)</td>
</tr>
<tr>
<td>Traditional Healer-Shaman</td>
<td>78 (14.7)</td>
</tr>
</tbody>
</table>
### Health Provider

<table>
<thead>
<tr>
<th>Health Provider</th>
<th>Households visiting provider n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Government Providers</strong></td>
<td></td>
</tr>
<tr>
<td>Nurse/Paramedic</td>
<td>219 (41.2)</td>
</tr>
<tr>
<td>Midwife</td>
<td>202 (38.0)</td>
</tr>
<tr>
<td>Doctor</td>
<td>190 (35.8)</td>
</tr>
<tr>
<td>Family Health Promoter (PSF)</td>
<td>70 (13.2)</td>
</tr>
<tr>
<td><strong>Private Providers</strong></td>
<td></td>
</tr>
<tr>
<td>Midwife</td>
<td>96 (18.1)</td>
</tr>
<tr>
<td>Nurse/Paramedic</td>
<td>92 (17.3)</td>
</tr>
<tr>
<td>Doctor</td>
<td>79 (14.9)</td>
</tr>
<tr>
<td><strong>Other Providers</strong></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>72 (13.6)</td>
</tr>
<tr>
<td>Dentist</td>
<td>28 (5.3)</td>
</tr>
</tbody>
</table>

**Education and research:** No formal education in T&CM is currently available in Timor-Leste. Traditional knowledge is shared by old methods through personal interactions.

**Manufacture and regulation:** About 37 indigenous medicinal plants are recognized by the government. Medicinal plants are commonly cultivated in home gardens or harvested wild from forests (Collins et al. 2007; de Araujo 2013; McWilliam 2008). The development of regulations for herbal the manufacture of medicine products and their quality and safety has been discussed, including local GMP and standards.

Traditional medicines with claiming therapeutic, diagnostic or preventive effects cannot be sold unless these are accorded full registration approval as a medicine or pharmaceutical product (MoH n.d.). Legislation to support this vision is yet to be established (de Araujo 2013). The government also aims to restore knowledge of traditional medicine flora and fauna, establish a traditional medicine research centre, mainstream traditional medicine and establish cross-country linkages in the sector (de Araujo 2013).

**References**


Appendix 1

In this publication, we use the term "traditional, complementary and alternative medicine" (T&CM) for the forms of medicine briefly described below. Conventional modern medicine is termed allopathic medicine in this text.

Terms used in the report

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allopathic medicine</td>
<td>Conventional &quot;modern&quot; medicine</td>
</tr>
<tr>
<td>Complementary and alternative medicine</td>
<td>The terms, “complementary medicine” and “alternative medicine”, refer to a broad set of health-care practices that are not part of a country's own traditional or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicines in some countries.</td>
</tr>
<tr>
<td>Herbal medicines</td>
<td>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 traditionally contain natural, organic or inorganic active ingredients that are not of plant origin (e.g. animal and mineral materials).</td>
</tr>
<tr>
<td>Indigenous traditional medicine</td>
<td>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 medicines have been practised at the primary health care level.</td>
</tr>
<tr>
<td>Traditional medicine</td>
<td>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 illnesses.</td>
</tr>
<tr>
<td>Traditional and complementary medicine (T&amp;CM)</td>
<td>T&amp;CM merges the terms TM and CM, encompassing products, practices and practitioners.</td>
</tr>
</tbody>
</table>

36 The definitions in this sub-section are from WHO. 2019. Global report on traditional and complementary medicine 2019
Definitions of T&CM systems

Ayurvedic medicine

Ayurveda is one of the world’s largest holistic (“whole body”) healing systems. It was developed more than 3000 years ago in India. It is based on the belief that health and wellness depend on a delicate balance between the mind, body and spirit. Its main goal is to promote good health, not fight diseases. But treatments may be geared towards specific health problems.

Chiropractic

Chiropractic is a form of alternative medicine mostly concerned with the diagnosis and treatment of mechanical disorders of the musculoskeletal system, especially the spine. Some proponents, especially those in the field’s early history, have claimed that such disorders affect general health via the nervous system. The main chiropractic treatment technique involves manual therapy, especially spinal manipulation therapy, manipulations of other joints and soft tissues. Source: https://en.wikipedia.org/wiki/Chiropractic

Dhivehi Beys (or Dweep Unani)

Dhivehi Beys (or Dweep Unani) is the traditional system of herbal medicine in the Maldives. Treatments include herbal and mineral medicines, cupping, cauterisation and massage. Spiritual healing was previously incorporated into the Dhivehi-beys practice and the branch of Ruggalu-beys, which deals with bone injury, is still popular.

gSo-ba Rig-pa

Bhutanese traditional medicine is based on the teachings of Buddha. It applies a well-documented and complex approach to diagnosis, such as pulse reading, urine analysis, behaviour and
dietary modification, pharmacotherapy and application of different external therapeutic procedures such as golden needle therapy, hot compression, massage, venesection, moxibustion, herbal bath, nasal cleansing and various cauterizations. Since the mid-2000s acupuncture and panchakarma have been incorporated to some extent (Wangchuk et al. 2013).

**Homeopathy**

Homeopathy is a system of alternative medicine created in 1796 by Samuel Hahnemann based on his doctrine of “like cures like” (in Latin: *similia similibus curentur*), a claim that a substance that causes the symptoms of a disease in healthy people would cure similar symptoms in sick people.

**Jamu**

The traditional medicine system in Indonesia is called Jamu, which is based on medicines made from roots, barks, flowers, seeds, leaves and fruits. Some animal materials, such as honey, royal jelly, milk and ayam kampung eggs, are also often used. Herbal medicines are widely used. Indonesia has an extremely wide variety of medicinal plants, estimated at about 30,000 species. Jamu is not one modality but a diverse and pluralistic system with practitioners operating under a spectrum of disease theories.

**Koryo medicine**

Koryo medicine is practised in the Democratic People’s Republic of Korea. It is based on ancient tradition but is now practised with modern diagnosis facilities, laboratory examinations and objective testing alongside traditional methods. Traditional treatments include acupuncture, moxibustion, cupping, massage, hydrotherapy and herbal, mineral and animal-based medicines. It applies a systematic approach, which has been built on its specific concept, theory and principle, to diagnose and manage various health conditions.
Myanmar’s traditional medicine

Myanmar’s traditional medicine is based on four main systems: i) Desana (based on Buddhist philosophy, this system follows the natural course of life and treats ailments through diet modifications and use of herbs and mineral compounds on the basis of their therapeutic qualities); ii) Bethitzza (based on Ayurvedic concepts, this system helps to restore any imbalance in the body); (iii) Netkhatta (based on astrology, this system seeks to cure illnesses by applying a diet on the basis of the patient’s astrological chart); and (iv) Veizzadhara (based on meditation and alchemy). Therapies include herbal, mineral and metal-based products, dietary and lifestyle changes, panchakarma, massage, acupuncture and moxibustion (Chaudhury & Rafei 2001; Naing Oo 2013; Various 2013).

Qigong

Qigong is a holistic system of coordinated body posture and movement, breathing, and meditation used for the purposes of health, spirituality, and martial arts training. With its roots in Chinese medicine, philosophy, and martial arts, Qigong is traditionally viewed as a practice that aims to cultivate and balance qi (chi), translated as “life energy” (source: https://en.wikipedia.org/wiki/Qigong, Segen’s Medical Dictionary. 2012, Farlex, Inc.)

Siddha medicine

Siddha medicine is a form of traditional medicine that originated in South India. It is one of the oldest schools of medicine in India, dating back to the 3rd millennium BCE. Siddha practitioners study the five basic elements – earth, water, fire, air and sky – and the “humours” of the human body, and incorporate these elements along with herbal, animal and inorganic chemical compounds in their therapies. (source: https://en.wikipedia.org/wiki/Siddha_medicine)
Sri Lankan indigenous traditional medicine (Deshiya chikitsa)

*Deshiya chikitsa* is the indigenous medicine of Sri Lanka (apart from Ayurveda). This system has been practised for many centuries in the island nation. The Sri Lankan Ayurvedic tradition is a mixture of the Sinhala traditional medicine, Ayurveda and Siddha systems of India, and Unani medicine of Greece (source: https://en.wikipedia.org/wiki/Sri_Lankan_traditional_medicine)

Traditional Chinese medicine

Traditional Chinese medicine (TCM) is a style of traditional medicine based on more than 2500 years of Chinese medical practice that includes various forms of herbal medicines, acupuncture, massage (*tui na*), exercise (qigong) and dietary therapy. One of the basic tenets of TCM is that “the body’s vital energy (ch’ī or qi) circulates through channels, called meridians that have branches connected to bodily organs and functions”. Concepts of the body and of disease used in TCM reflect its ancient origins and its emphasis on dynamic processes over material structure (source: https://en.wikipedia.org/wiki/Traditional_Chinese_medicine)

Traditional medicine of Timor-Leste

Plants and honey have been and are used to prevent, treat and cure diseases by the people of Timor-Leste. Timor was known for a medicinal plant, sandalwood, which was used during the Middle Ages in Europe almost exclusively in medicine. The knowledge of the traditional healers (*matan-dooc*) is kept secret – medicinal plants are in many cases considered sacred or “lulic”.
Traditional Thai medicine

Nuad Thai, a branch of Thai traditional medicine, has gained wider acceptance for its dual role as a culturally empowering self-care practice for the family and the community and as an effective treatment option along with the allopathic health care.

Unani system of medicine

Unani medicine, as its name suggests, owes its origin to Greece. However, it has undergone several transformations and is known at present by different names in different parts of the world, such as Greco-Arab medicine, Ionian medicine, Arab medicine, Islamic medicine, traditional Medicine, etc.

It was the Greek philosopher physician, Hippocrates, regarded as the Father of Medicine, who liberated medicine from the realm of superstition and magic, and bestowed on it the status of a science. An Islamic healing philosophy incorporates major elements of ancient Greek medicine (Unani means “Greek” in Arabic), which assumes four elements – earth, fire, water and air – and four corresponding humours, namely phlegm (balgham), blood (dam), yellow bile (safra) and black bile (sauda); it also incorporates minor elements of Ayurvedic medicine.

Yoga

Yoga is a group of physical, mental, and spiritual practices or disciplines which originated in ancient India. Yoga is one of the six orthodox schools of Hindu philosophical traditions. There is a broad variety of yoga schools, practices and goals in Hinduism, Buddhism and Jainism. The term, “yoga”, in the Western world often denotes a modern form of hatha yoga, consisting largely of the postures called asanas (source: https://en.wikipedia.org/wiki/Yoga).
The quest for traditional health knowledge began since the dawn of civilization. Currently at least 25% of all modern medicines are derived, either directly or indirectly, from medicinal plants. Traditional medicines and practices are in use in both industrialized and developing countries. More than three fourths of the populations of countries of the SEA Region use traditional medicines and practitioners for their health care. These traditional systems of medicine have the potential to improve health, wellness and people-centred health care.

This is the first ever regional publication on traditional medicine from the WHO South-East Asia Region. It enumerates the overall situation and development of traditional medicine from the perspective of health system building blocks, and analyses policies, regulations, training and education, as well as human resource development, service delivery, research and development. It highlights the key developments and progress made in recent years, and seeks to generate evidence and data that could serve as baseline for future assessments.

This publication provides a detailed account of work done in the last five years to strengthen traditional medicine in the Region by countries and WHO, and includes country profiles. It is a contribution to the efforts towards the evolution of traditional medicine and the quest for evidence-based, safe and quality health care.