

DRAFT

**Regional Framework for Harnessing
Traditional and Complementary Medicine
for Achieving Health and Well-being
in the Western Pacific**

Contents

Abbreviations	10
Executive summary	11
1. Background	12
1.1 Advancing health and well-being	12
1.2 Traditional and complementary medicine: role in achieving health and well-being	14
1.3 Harnessing T&CM for well-being and health as part of the vision of <i>For the Future: Towards the Healthiest and Safest Region</i>	17
2. Situation of traditional and complementary medicine in the Western Pacific Region	18
2.1 Current situation	18
2.2 Regional progress in traditional medicine 2011–2020	21
3. The Framework	26
3.1 Overarching goal	26
3.2 Issues: Why do we need this Framework?	27
3.3 Purpose of the Framework	29
4. Strategic actions	30
Strategic Action 1. Promoting and defining T&CM in national policies	30
Strategic Action 2. Strengthening context-specific mechanisms to ensure quality and safety	33
Strategic Action 3. Improve coverage and equitable access to T&CM services	37
Strategic Action 4. Promote documentation, research and innovation for T&CM services	41
5. <i>For the Future</i>: a pathway for harnessing the role of T&CM for the well-being and health of populations in the Western Pacific Region	45
Glossary of terms	47
References	48

Annex

Abbreviations

ACSS	Australia–Canada–Singapore–Switzerland Consortium
ASEAN	Association of Southeast Asian Nations
COVID-19	coronavirus disease 2019
CPGs	clinical practice guidelines
ICD-11	International Statistical Classification of Diseases and Related Health Problems, 11th Revision
NCDs	noncommunicable diseases
NRAS	National Registration and Accreditation Scheme (Australia)
PHC	primary health care
PICs	Pacific island countries and areas
T&CM	traditional and complementary medicine
TBA	traditional birth attendant
TCM	traditional Chinese medicine
TGA	Therapeutic Goods Administration (Australia)
TM	traditional medicine
UHC	universal health coverage
WHO	World Health Organization

Executive summary

The Western Pacific is a rapidly developing region with economic change, high urbanization, a rapidly ageing population and an increasing burden of noncommunicable diseases (NCDs). These rapid changes also impact how people live, work and play, as well as their ability to lead a healthy lifestyle. Health-care systems based on a model that provides episodic care to cure sickness or manage trauma are now adapting to promote lifelong improvements in health and well-being. Traditional and complementary medicine (T&CM) can play a key role in lifelong improvements in health and well-being.

T&CM is already widely practised and relied upon by a significant proportion of the population in many countries and areas in the Western Pacific Region. In some countries, T&CM represents a significant part of the health sector's economy. The draft Framework suggests ways in which T&CM can potentially play a larger role in all countries and areas in improving health and well-being, preventing disease and managing long-term chronic conditions at the primary health-care level.

This *Regional Framework for Harnessing Traditional and Complementary Medicine for Achieving Health and Well-being in the Western Pacific* articulates the contribution of T&CM for achieving the vision set out in *For the Future: Towards the Healthiest and Safest Region* – particularly in the areas of NCDs and ageing, and reaching the unreached – while contributing to building the resilience of populations to cope with the impact of health emergencies and climate change.

The Framework recognizes the diversity of T&CM practices across countries in the Region from the well-established concepts and practices of wellness that are indigenous and are fully rooted in culture, traditions and way of life in communities to institutionalized and formal systems of traditional medicines development and practice. Its aims are:

- to affirm the importance and contribution of T&CM to the achievement of broader health goals, such as universal health coverage and health and well-being;
- to guide countries to address the challenges of tomorrow by acting today, by outlining key strategic directions and a development pathway that countries may pursue in order to maximize possible contributions of T&CM to health and well-being;
- to guide countries in the Western Pacific Region to identify and focus efforts on priority areas for T&CM; and
- to outline areas of collaboration and WHO support to countries in T&CM over the next 10 years.

The Framework proposes four strategic actions:

- promoting the role of T&CM for health and well-being through national policies;
- strengthening context-specific mechanisms to ensure the safety, quality and effectiveness of T&CM services;
- increasing coverage and equitable access to safe and effective T&CM services; and
- supporting documentation, research and innovation for T&CM services.

Annex

1. Background

Over the past decade, countries in the World Health Organization (WHO) Western Pacific Region have made significant health gains and increased commitments to advance universal health coverage (UHC). Though intensively pursued in recent decades, UHC remains far from becoming a reality. In some countries in the Region, up to 60% of the population do not have access to essential health services. In many countries, the burdens of communicable diseases and noncommunicable diseases (NCDs) remain unacceptably high. Meanwhile, hard-to-reach populations continue to be left behind in terms of achieving better health outcomes. Acute public health emergencies, such as coronavirus diseases 2019 (COVID-19) and disasters, severely impact the delivery and access to essential health services, and affect the overall well-being of populations.

The current model of health care focused on disease-based management is complex and costly to health systems, individuals and society and often do not adequately cover important dimensions of social, mental and psychological well-being. To achieve UHC, health-care models will need to effectively and consistently strengthen health promotion and disease prevention and incorporate approaches that promote healing, health and well-being.

In this context, the push for health and well-being as part of UHC is of vital importance. UHC and the health and well-being of societies can only be achieved if the mental, social, emotional and environmental dimensions of illness are addressed and particular attention to holistic and person-centred approach to health and well-being is given. Of particular importance is the potential role of traditional and complementary medicine (T&CM) to contribute to health and well-being. However, this can be challenging for many of the countries and areas in the Western Pacific Region. While countries have made substantial efforts and demonstrated progress in utilizing T&CM to achieve their vision of health and well-being, many still find difficulties in establishing a unifying framework in public health policies, especially in maximizing the use of both traditional and conventional medicine. Some studies have shown that T&CM has made a demonstrable contribution to conditions where behavioural, emotional or spiritual factors have a dominant role in disease causation, for which biomedicine is less well suited.¹ T&CM including indigenous healing and long-held traditions of wellness that focus on physical, mental and spiritual components of health are important elements of the health and well-being of populations in some countries in the Region.² Finding a complementary and collaborative approach between Western and indigenous knowledge bases regarding human health is vital to create culturally and financially accessible health care for all citizens.

1.1 Advancing health and well-being

As population ageing increases across the Western Pacific Region, the need to promote health and well-being more broadly, rather than the disease-oriented approach to health, is becoming more apparent. Health promotion, which is important across the lifespan, supports healthy ageing. As people live longer, there is increased importance in promoting their health and well-being to enable a healthy and functional life. Health is less a dichotomous state and more a spectrum across which we seek to enable people to move to the healthier end of the scale. Disease processes, especially for older populations, are often accompanied or complicated by psychosomatic disturbances, and the overall outcome affected by the social, mental and environmental condition of the individual. In order to develop broader public health interventions to improve health, efforts have been made to better understand the

complex interplay among biology, environment, behaviour and socioeconomic factors that shape health and wellness. These efforts are relevant for achieving the health priorities in *For the Future: Towards the Healthiest and Safest Region*, the Western Pacific vision for improving health and well-being for the Region's 1.9 billion people in the coming years, particularly as they relate to ageing, chronic and infectious diseases, and the increasing vulnerability of populations, especially the unreached.

Ageing

The Western Pacific Region has undergone rapid demographic transformation over the past three decades. Demographic changes that took more than 140 years in Western Europe are occurring in countries such as China in less than 25 years.³ As of 2019, the Western Pacific Region was home to more than 240 million people 65 years and older. That figure is expected to double by 2050.⁴ Ageing is associated with a gradual decrease in physical and mental capacity and a growing risk of disease. As people age, they are more likely to experience comorbidities.⁵ In addition, the rapid social, economic and demographic changes affect the well-being of older people.³

Disease-specific management of health conditions in older people is not only costly but also fails to sustain and improve the quality of life of individuals if other support is not provided to help adults cope and thrive better, including mental, physical, psychosocial and environmental support. T&CM has a role to play, as evidence-based modalities can address functional decline and frailty among older people and reduce the burden of morbidity and mortality.⁶

The traditional biomedical model of disease management has been known to be poorly equipped to deal with maintaining mental, physical, emotional and social functionality during ageing, while the diverse therapeutic practices and a wide array of options to support wellness through T&CM can complement the conventional medicine model and could provide a prevention-oriented health-care model attuned to managing treatment and care for non-life-threatening, long-term chronic conditions.⁷

Evidence indicates that the use of T&CM is accepted by older populations and appears to play a role in achieving a good quality of life and in encouraging the participation of older people in health-care decisions.⁷ Specifically, T&CM offers an approach to disease management that enables older people to cope with chronic health conditions and other health problems often overlooked by primary care providers.⁷ In addition, T&CM may also help create a sense of empowerment, agency and independence among older people, which are important factors in achieving the goals of healthy and active ageing.⁷

Chronic and infectious diseases

The burden of NCDs and chronic conditions in the Region continues to increase. The four major NCDs – diabetes, cardiovascular diseases, cancer and chronic respiratory diseases – were responsible for 10 million deaths in 2016, or nearly three out of four deaths (73%) in the Western Pacific Region. The impact is more severe in poorer countries where death rates and the risk of premature death are three times higher than in high-income countries.^{8,9}

Despite these changes in disease epidemiology and the efforts to shift towards health promotion and disease prevention, the current health-care system in most countries is biased towards acute care. While

Annex

acute care models demonstrate success in treating acute conditions, as well as acute exacerbations of chronic diseases, there has been less success in preventing the onset and progression of chronic diseases.

Focusing on acute care without adequate prevention and health promotion contributes to the ongoing costs of chronic disease that account for nearly 75% of health-care expenditures each year.¹⁰ Modifiable and preventable factors, such as lifestyle and behaviour choices, account for the majority of premature mortality across the Region.¹⁰ A patient's course of care often requires multiple contacts with clinicians and caregivers and may require many transitions, for example, from hospital to home care. Care that emphasizes wellness and prevention is a major and growing need for people both with and without chronic diseases.

Increasing vulnerability of populations, especially the unreached

Unreached and vulnerable populations suffer most during disasters and public health emergencies. The COVID-19 pandemic has revealed the weaknesses of health service delivery, especially in areas where health systems are under-resourced.¹¹ COVID-19 has shown that for people to maintain health and well-being when basic health services are interrupted, health-care systems need to draw upon local resources and traditional practices that are close to the population, trusted and valued by communities.

The role of T&CM has been shown to be beneficial for improving the physical and mental health and well-being of the population, as these provide preventive and therapeutic options for strengthening physical and mental resilience.¹¹

The interruption of health services during the pandemic has increased the health vulnerability of individuals, including in relation to behavioural and psychosocial dimensions. However, the pandemic also presents opportunities to introduce safe, evidence-based T&CM, as well as promote indigenous and traditional healing occurring in the natural environment of communities to address the behavioural and psychosocial dimensions of poor health. These measures could be used to improve quality of life to overcome stress, fear, anxiety and depression among individuals and societies during the pandemic.¹²

Several complementary and integrative medicine interventions have been shown to be useful in helping people cope with stress, including yoga and meditation practices. There is wide research on the influence of psychological processes, as well as psychological and behavioural interventions, on the immune system, positive psychological well-being and physiological functions.¹²

This context necessitates a shift from a mainly disease-based intervention to holistic person-centred approaches that focus on achieving the outcome of an improved quality of life overall. This approach to promoting health and well-being in the Region brings together scientifically proven and evidence-based approaches to care with a focus on the full range of needs of the individual.¹³

1.2 Traditional and complementary medicine: role in achieving health and well-being

The practice of T&CM is defined by WHO to be the sum of 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 and in the prevention, diagnosis, improvement or treatment of physical and mental illness and the management of patients, as well as the provision of services to communities.

Annex

In addition, this Framework embraces the range of T&CM practices from the well-established indigenous concepts and practices of wellness in communities to formal and structured systems of traditional medicines development and practice. In many countries in the Region, there are indigenous and long-held traditions of wellness that are fully recognized in national health policies and are inherently and actively strengthened as part of the health and well-being programmes in communities, such as the Rongoa Maori system of New Zealand. The Rongoa Maori is a complex, holistic approach to healing that focuses on physical, mental and spiritual components of health.² Necessarily, the Framework recognizes and promotes the distinction between traditional medicine as understood and practised by indigenous people and complementary medicine, which may not be indigenous but adopted in many countries as a set of practices and interventions to promote health and well-being,

T&CM services that are evidence based, safe and of assured quality are valuable in contributing to a holistic patient-centred approach to healing, health and well-being. A growing body of evidence has shown that the relationships among health, the pace of healing and more intangible elements of the caring process, including empowerment of patients, play a central role in their care.¹⁴ There is also growing evidence that other factors, aside from pathophysiological processes and biologic agents, have important effects on health-care outcomes – such as the interaction between an individual’s social, economic, psychological and physical environments, on the one hand, and biological susceptibility to illness and responsiveness to treatment and the nature of the care process, as well as its content, on the other.¹³

Practices in T&CM empower individuals to actively participate in their health and thereby prevent disease through daily activities and practices that are amenable to self-care, cost-effective, minimally invasive and have limited side-effects.¹⁰ Central to these approaches are primary prevention and measures that can help maintain health over the life course, which can improve quality of life, rather than just a care-based approach focused on episodic care.¹⁰ A number of interventions have, for example, been shown to support palliative care and conditions in older people (Table 1).

Table 1. T&CM practices and the improvement of health and well-being

T&CM practice	Contribution to the improvement of health and well-being
Acupuncture	Studies conducted on acupuncture suggest that acupuncture can help pain management for certain chronic conditions such as back and neck pain, headache, and osteoarthritis/knee pain. ¹⁵
Spinal manipulative therapy	Spinal manipulative therapy is a practice performed by health-care professionals, such as chiropractors, osteopathic physicians, naturopathic physicians, physical therapists and some medical doctors, in which practitioners use their hands or a device to apply a controlled force to a joint of the spine. The goal of the treatment is to relieve pain and improve physical functioning. A systematic review by Furlan et al. suggests that spinal manipulation may be effective in relieving lower-back and neck pain. ¹⁶
Massage therapy	A systematic review on the impact of massage therapy suggests that massage therapy is beneficial for pain management, anxiety and health-related quality of life. ¹⁷

Annex

T&CM practice

Contribution to the improvement of health and well-being

Yoga

Studies suggest that yoga can lead to improvements in or buffer treatment-related changes in mental health, fatigue, sleep quality and other aspects of the quality of life.¹⁸

Tai chi

A review and meta-analysis by Du et al. report that tai chi exercise may improve self-rated sleep quality in older adults.¹⁹

Sensory therapy

A review by Livingston et al. demonstrated the cost-effectiveness of sensory, psychological and behavioural interventions for managing agitation in older adults with dementia.²⁰

Relaxation

A review by Klainin-Yobas et al. indicates that relaxation interventions can be beneficial for older people.²¹ As such, the relaxation interventions could be used as primary prevention and/or adjunctive therapy for depression and anxiety. As an example, yoga could be taught to older adults living in community facilities or residential facilities.²¹

Music therapy

In music therapy, recipients can be actively engaged in making music and singing, which is defined as an “interactive” method usually led by a music therapist, or they can listen to music that a therapist plays or sings, which is considered a “passive” method. Livingstone et al. note that agitation decreased in residents with structured music therapy, and when carrying out pleasant activities,²⁰ while Watson et al. report that music therapy has a significant effect in reducing physical aggressive agitation.²²

A review by Zhang et al. supports the use of music therapy in the treatment of disruptive behaviour and anxiety, cognitive function, depression and quality of life.²³ Older people living with dementia could be encouraged to accept music therapy, especially interactive.²³

A review by Zhao et al. suggests that music therapy when added to standard treatment has statistical significance in reducing depressive symptoms among older adults.²⁴ However, when compared with standard treatments, music therapy was not effective in reducing depressive symptoms in older adults. Music therapy can be used to decrease depressive symptoms for older people with depression, but there was no support for the use of music therapy as a treatment to reduce depressive symptoms for older people with dementia.²⁴

McConnell et al. found in their review that music therapy may be effective for reducing pain in the palliative care setting; however, this is based on studies with a high risk of bias.²⁵

In the Western Pacific Region, herbal medicines are widely used for the treatment and management of disease conditions. Herbal medicines or treatments – spanning from home remedies to large-scale production – also are widely available.

In the Region, herbal medicines are recognized and prescribed as medical products. In many countries, they are regulated by the regulatory authorities, prepared in facilities certified for good manufacturing practices and evaluated for cost-effectiveness as a prerequisite for health insurance coverage.²⁶ In the Republic of Korea, for example, medical doctors can prescribe 56 types of notified formulas for manufactured herbal medicines that are covered by national health insurance.²⁷ In Japan, the quality of *kampo* products is assured by a Government authority and pharmaceutical companies. They have been included in the Japanese national health insurance drug list since 1971.

1.3 Harnessing T&CM for well-being and health as part of the vision of *For the Future: Towards the Healthiest and Safest Region*

For the Future: Towards the Healthiest and Safest Region urges Member States in the Western Pacific to act today to address the challenges of tomorrow. *For the Future* provides guidance to Member States to harness T&CM to contribute to the vision of better health and defines the role of T&CM in national policies, thus ensuring the safety, quality and effectiveness of T&CM services, increasing coverage and equitable access, and fostering evidence generation, research and innovation.

The practice of traditional medicine (TM) varies widely, in keeping with the societal and cultural heritage of different countries.²⁸ This can be a unique advantage of T&CM – being close to the context and accepted by communities, it can hasten the improvement of local practices as a positive influence for health.

T&CM is widely used, trusted and relied upon by a significant proportion of the population in many countries in the Western Pacific Region. Its role in the health system and in UHC has been extensively recognized globally and in many countries in the Region.

All Member States in the Region use T&CM as a part of cultural and traditional healing, as well as for disease management. The practices are both indigenous and adopted from other countries. Within the *For the Future* vision, this *Regional Framework for Harnessing Traditional and Complementary Medicine for Achieving Health and Well-being in the Western Pacific*: will contribute in the promotion of healthy lifestyles and prevention of diseases, including the management of and palliative care for NCDs; will tackle the social, mental and physical dimensions necessary to support healthy ageing; and will promote local practices for health and well-being of unreached populations.

The promotion and development of T&CM will help bring about a shift from disease-oriented to person- and community-oriented approaches to health.

For the Future asserts that the health challenges of today – and tomorrow – are unprecedented in scale and complexity, and addressing them will require greater creativity, more innovation and stronger partnerships. This *Regional Framework for Harnessing Traditional and Complementary Medicine for Achieving Health and Well-being in the Western Pacific* will help fulfil this aspiration.

Annex

2. Situation of traditional and complementary medicine in the Western Pacific Region

2.1 Current situation

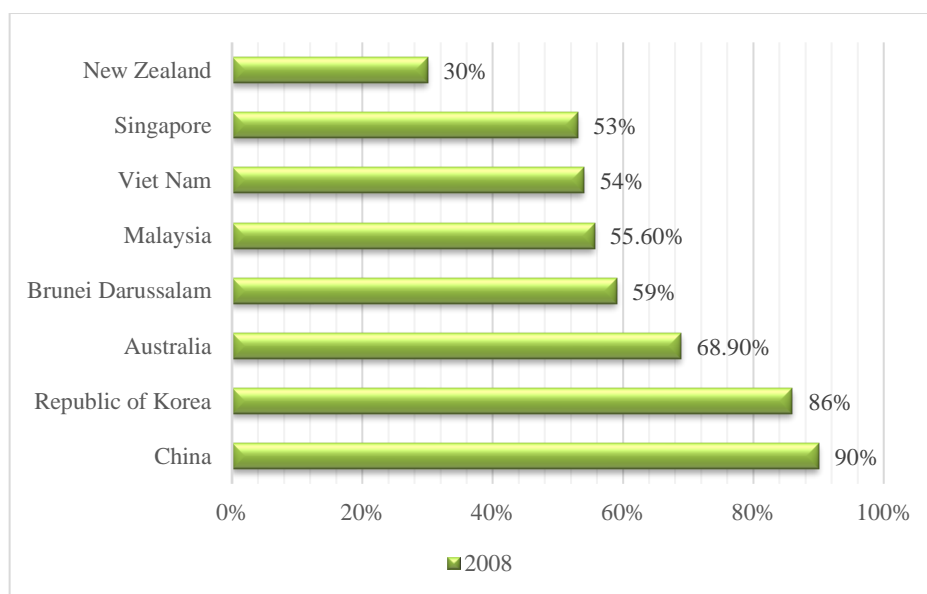
The Alma-Ata Declaration acknowledged the important role of TM in primary health care (PHC). Subsequent World Health Assembly resolutions on traditional medicine (WHA62.13) and on strengthening integrated, people-centred health services (WHA69.24) have asked WHO to support Member States in integrating TM in national health systems, while ensuring the quality, safety and effectiveness of T&CM services.

T&CM is extensively used for various health conditions across countries and areas in the Western Pacific Region. A 2018 survey showed that most Member States were using T&CM.

WHO estimates that 80% of the population from most Asian and African countries use TM for PHC. The TM market is projected to reach US\$ 115 billion by the end of 2023 (with a compound annual growth rate of 7.2% between 2017 and 2023).²⁹

A 2018 survey shows that all Member States in the Region use T&CM. By 2011, over 60% of the population in Australia, China and the Republic of Korea were using T&CM, while the figures were higher than 30% in Brunei Darussalam, Malaysia, New Zealand, Singapore and Viet Nam (Fig. 1).³⁰

Fig. 1. Percentage of population using T&CM in selected countries in the Western Pacific Region



Source: *The Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020)*. Manila: WHO Regional Office for the Western Pacific; 2012.

The experiences of countries in the Region with T&CM

Australia

The Australian Traditional Medicine Society reported in 2013 that natural therapy is an important and rapidly growing component of Australia's overall health system. More than 70% of Australians use a form of natural therapy as a regular part of their overall health care, with close to 2 million professional consultations conducted annually.³¹

China

China has a strong and extensive system for traditional Chinese medicine (TCM) with the formation of both urban and rural networks for TCM. The urban network comprises hospitals for TCM (including ethnic minority medicine and integrated Chinese and Western medicine), TCM clinics, and TCM clinical departments in general hospitals and community health centres. On the other hand, the rural TCM medical care network includes county-level TCM hospitals, TCM clinical departments within general hospitals, specialized hospitals and centres for maternal and child health, township-level health centres, and village health clinics that provide basic TCM health-care services.³²

At the end of 2015, there were 3966 TCM hospitals across the country, including 253 hospitals of ethnic minority medicine and 446 hospitals of integrated Chinese and Western medicine. At the same time, there were 452 000 practitioners and assistant practitioners of TCM (including practitioners of ethnic minority medicine and integrated Chinese and Western medicine) and 42 528 TCM clinics, including 550 for ethnic minority medicine and 7706 for integrated medicine. These facilities handled 910 million visits in 2015 for TCM medical and health services nationwide and 26.915 million in-patients treated.³²

Lao People's Democratic Republic³³

In the Lao People's Democratic Republic, 80% of the population lives in rural areas comprising 9113 villages, with each village usually having one or two traditional health practitioners. Some 18 226 traditional health practitioners provide a large portion of health-care services for 80% of the population's health.

Republic of Korea³³

The Republic of Korea reported that the top diseases for admission to medical hospitals in the country in 2011 were for bone, joint and muscle system disorders; dyspepsia; osteoarthritis of the knee; and facial nerve disorders. Huang et al. in their paper state that "The proportion of Koreans who used Korean Medicine in their lifetime accounted for 69.0%. The main purpose of using Korean Medicine was therapeutic treatments followed by health improvement and care. Diseases and disorders most commonly treated in the Korean Medicine institutions were musculoskeletal disorders (72.8%), followed by ligaments, lacerations and other types of damage, addiction and external factors (37.0%), digestive disorders (10.3%), and respiratory diseases (6.2%). The Health insurance coverage rate for Korean Medicine clinics is 52.7% and for Korean Medicine Hospitals is 34.9%." ³⁴

Annex

Malaysia³⁵

Traditional Malay, Chinese and Indian medicine, homeopathy and complementary medicines are widely used in Malaysia. The National Health and Morbidity Survey 2015, published by the Ministry of Health, reported that 29.25% of the population has used T&CM in consultations. The first T&CM unit was introduced at Hospital Kepala Batas, Penang, in 2007. Now there are 15 T&CM units in Ministry of Health hospitals. T&CM services offered include acupuncture, traditional massage, herbal therapy as an adjunct treatment for cancer patients, *Shirodhara*, external Basti therapy and Varma therapy. T&CM products have been regulated since 1992. Malaysia established the *Guidance Document for Natural Product with Therapeutic Claims* in 2020.

Pacific island countries and areas

Over the past 20 years, Pacific island countries and areas (PICs) have actively supported the appropriate use of TM in their national health systems. The potential role of TM in the Pacific was articulated in the *Apia Action Plan on Traditional Medicine in the Pacific Island Countries 2000*, which aligns with later WHO guidance, such as the *Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020)* and the global *WHO Traditional Medicine Strategy 2014–2023*.

The goals of the Apia Action Plan are to promote the appropriate use of TM and to encourage its appropriate integration with the mainstream health services. The focus is on strengthening primary health care through:

- development of national policies on TM;
- selection, assessment and promotion of commonly used local plants with medical value for use in national health systems;
- mobilization of TM practitioners as community health providers within the health system; and
- exploration of the potential contribution of scientifically proven TM in national health systems with a focus on PHC.

Some countries in the Pacific have officially included T&CM in their mental health policies. Papua New Guinea's *National Mental Health Policy* acknowledges the role of traditional health-care systems in the provision of current mental health services, specifically seeking to incorporate cultural norms and TM into the national mental health system in order to meet the specific needs of the people.

The *Samoa Mental Health Policy* advocates collaborative approaches to the prevention of mental health illnesses, including recognition for traditional and modern counselling support. It includes diverse perspectives such as religious, traditional and Western scientific/medical perspectives to be recognized as having a role in healing people who are mentally unwell or ill. Education and awareness programmes will give equal emphasis to the traditional, religious and Western scientific/clinical perspectives.

The Solomon Islands *National Mental Health Policy* encourages traditional healers to liaise with health workers and make early referrals to the health service, when necessary.

Meanwhile, the *Vanuatu Mental Health Policy and Strategic Plan 2016–2020* provides for the inclusion of TM healers in the prevention, detection and care of mental illness, in collaboration with the formal mental health system.

2.2 Regional progress in traditional medicine 2011–2020

The *Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020)* was developed to provide strategic guidance to Member States in maximizing the health potential of TM in national health systems in advancing the cause of PHC and UHC. The strategic objectives included: (1) to include TM in national health systems; (2) to promote the safe and effective use of TM; (3) to increase access to safe and effective TM; (4) to promote protection and the sustainable use of TM resources; and (5) to strengthen cooperation in generating and sharing TM knowledge and skills. Using this guidance for the past decade, Member States have planned and implemented strategies to appropriately integrate T&CM in their national health systems, depending on their situation and at their own pace. The following section describes the progress made in key indicators for the strategic objectives.

Regulations

Several Member States in the Western Pacific Region have made great efforts to improve the safe and effective use of T&CM through national regulations. A 2018 recent survey shows that 13 out of 27 Member States in the Region enacted national laws or established regulations for T&CM. The need to ensure patient safety and prevent patients from receiving care from unqualified or poorly qualified practitioners is crucial as the use of T&CM continues to expand.

Box 1. National policies on regulations for T&CM practitioners across countries in Western Pacific Region

Australia

- The national policy for T&CM is integrated into the National Medicines Policy of 2000.
- Recently, Australia implemented a National Registration and Accreditation Scheme (NRAS) for health professions that operate under the Health Practitioner Regulation National Law 2009.
- Chinese medicine practitioner registration commenced in July 2012 under the NRAS.³⁶
- T&CM providers practise in private sector clinics. The practice of some forms of complementary medicine is currently regulated. Osteopathy and chiropractic are currently regulated under the NRAS for health practitioners

Brunei Darussalam

- No overarching national policy on T&CM exists in Brunei Darussalam, but there are specific regulations for providers. Since 2009, there are regulations in progress for providers of acupuncture, ayurvedic medicine, chiropractic, homeopathy, naturopathy, TCM, Unani medicine and other practices such as spa, massage, beauty care and health practices.

Annex

- The Guidelines for Registration of Traditional and Complementary Medicine Practitioners in Brunei Darussalam were prepared based on qualification requirements set by WHO and regulatory authorities in other countries.

Cambodia

- There is a specific national policy for T&CM – Policy on Traditional Medicine of the Kingdom of Cambodia, which was issued in 2010.
- Regulations established in 1998 cover T&CM providers of herbal medicines at the national level, but enforcement suffers due to limited involvement by relevant bodies.
- State or provincial government issues the T&CM license required to practise.
- There are regulations on herbal medicine providers, dispensers and producers.

China

- The law on TCM was enacted in 2017.
- In 2016, the Central Committee of the Chinese Communist Party and the State Council issued the Outline of the Healthy China 2030 Plan, a guide to improving the health of the Chinese people in the coming 15 years. The plan sets out a series of tasks and measures to implement a programme for developing TCM. The State Council issued the Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016–2030), which made further development of TCM a national strategy.
- The Law on Licensed Doctors of the People’s Republic of China, which regulates all physicians including TCM doctors, commenced in 1998.

Fiji³⁷

- As of 2018, there was no separate national policy or strategy on T&CM, but it is included in the National Medicine Products Policy of 2013 and the pharmaceutical sector strategic plan for implementing the Fiji National Medicinal Products Policy 2013–2018.
- T&CM providers that have been regulated since 1976 include acupuncturists, chiropractors and chiropodists. These providers practise in the private sector.
- The national Government issues the T&CM license required to practise.

In 2011, Australia, Cook Islands and Malaysia developed their first regulations on T&CM practitioners at the national level. T&CM practitioners in Australia had been regulated by state and territory governments until 2011, when the country implemented a National Registration and Accreditation Scheme (NRAS) for health professions.

In 2013, Cook Islands started requiring indigenous traditional healers and complementary medicine professionals to be registered with the Cook Islands Allied Health Professionals if they wish to practise in the country. They are listed as allied health professionals in the law, which also applies to acupuncturists, chiropractors and naturopaths.

Malaysia enacted the Traditional and Complementary Medicine Act 2016, which governs T&CM practices and practitioners.

Meanwhile, some countries changed their national regulations on practitioners. For example, Brunei Darussalam revised the registration system of T&CM practitioners in 2015 to include more diverse types of T&CM professions in the registration system.

The role of professional associations

Professional associations play an important role in the quality assurance of T&CM practice and practitioners, especially when governments are facing a lack of resources or sufficient expertise to regulate T&CM practice and practitioners. However, insufficient progress has been made between 2011 and 2020 regarding the establishment of professional associations of T&CM practitioners.

There has been some progress in the area of education and training programmes for T&CM practitioners. The number of countries that provide T&CM education at the university level has increased from 12 to 13 from 2011 through 2020, as the Lao People's Democratic Republic introduced its first T&CM programme of five years at the university level in 2017, in addition to the courses below the university level provided by the Institute of Traditional Medicine and the Traditional Medicine Hospital. Although not at the university level, Cambodia has been providing a five-month training programme in traditional Khmer medicine and basic medical science through the National Centre for Traditional Medicine, a lead government agency for TM, since 2009.

Research

Between 2011 and 2020, the number of countries and areas with a national research institute for T&CM in the Region remained constant at 11.

As of 2020, the 11 countries or areas in the Region with national research institutes for T&CM are: Australia, Brunei Darussalam, China, Japan, the Republic of Korea, the Lao People's Democratic Republic, Macao SAR (China), Malaysia, Mongolia, the Philippines and Viet Nam.

Meanwhile, some countries promote research on traditional medicine through different paths, rather than establishing a national research centre. For example, the Government of Singapore, which does not have a national research institute for TM, has administered a dedicated TCM research grant since 2012 to encourage collaborative research between TCM practitioners and researchers in their health-care and academic institutions. The Scientific Research Organization of Samoa, established in 2006 to undertake scientific and technical research for the Government of Samoa, researches medicinal plants, although the institute is not dedicated solely to TM research.

Access to traditional medicine

As of 2020, the provision of T&CM services in public hospitals or clinics was identified in 12 Western Pacific Member States. Several countries showed progress in this area, such as the Philippines, where certified medical acupuncturists and certified acupuncturists were allowed provide their service in public or Government health facilities. Many countries and areas, especially in the Pacific, have tried to utilize the TM workforce to strengthen PHC.³⁸ For example, in Kiribati, the Ministry of Health and Medical Services issued the *Ministry Strategic Plan 2016–2019* that includes a strategic approach to strengthen collaboration with traditional birth attendants (TBAs) to improve maternal, newborn and child health by

Annex

exploring ways to increase the role of TBAs in providing care and support in hospitals. Similarly, in Samoa, the *Samoa Health Sector Plan 2008–2018* set “Strengthening closer working relationships, including negotiating referral pathways with TBAs” as one of the indicators for improved reproductive, maternal and child health. TBAs in Solomon Islands can work at nurse aide posts or rural health clinics that provide PHC and public health services.

Regarding the insurance for T&CM products and services, 13 countries had insurance for T&CM products and services as of 2020.

Cooperation between Member States to harmonize policies, regulations and standards

Harmonizing policies, regulations and standards across the Western Pacific Region and further across the world is central to promoting cooperation between the Member States, as such alignment will guide countries and areas to develop in similar directions and minimize technical and administrative barriers, especially when such barriers arise due to differences in standards referenced in regulations.

During the past decade, there has been notable progress among countries regionally and interregionally. The Forum for the Harmonization of Herbal Medicine is a government network for TM in the Western Pacific Region, aiming to harmonize various regulatory issues on herbal medicine and has worked on projects on pharmacopeia, reference materials for medicinal plant materials and adulterated herbal medicine. As of 2020, Australia, China, Hong Kong SAR (China), Japan, the Republic of Korea, Singapore and Viet Nam are Forum members, with Canada as a special member.

Inter-regionally, the Product Working Group for Traditional Medicines and Health Supplements was established in 2004 under the umbrella of the Association of Southeast Asian Nations (ASEAN) Economic Community, with seven of the members in the Western Pacific Region. As of 2020, the ASEAN Agreement on the Regulatory Framework for Traditional Medicine and Health Supplements is pending finalization, and once finalized, the member countries in the group will apply the agreed regulations into their health systems.

Another progress in the interregional effort for harmonization is the establishment of the Complementary Health Products Working Group in 2015 under the Australia–Canada–Singapore–Switzerland Consortium (ACSS). The ACSS Complementary Health Products Working Group aims to promote regulatory collaboration, share information and work towards the standardization of the technical guidelines and requirements for the assessment of complementary health products.

Furthermore, in 2019, WHO Member States adopted the 11th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-11), developed by WHO, which will come into effect on 1 January 2022. ICD-11 includes a supplementary chapter of standardized TM classification systems as a tool for classifying, diagnosing, counting, communicating and comparing conditions that can be managed or addressed by T&CM. The global use of harmonized and standardized terms and criteria is expected to facilitate research and assessment of the safety and efficacy of T&CM.

Summary

Over the past decade, Member States in the Western Pacific Region have implemented the strategic objectives of the *Regional Strategy for Traditional Medicine in the Western Pacific (2011–2020)*. Member States have shown their willingness to include T&CM in their national health systems and to ensure the safe and effective use of T&CM by establishing and implementing national policies and regulations. Access to safe and effective T&CM was enhanced through combined efforts to mainstream T&CM services and strengthen national regulations. Generating and sharing T&CM knowledge and skills has been encouraged in different forms – from establishing a national research centre for T&CM to creating a favourable research environment through research grants and encouraging collaborative research with other areas of science. The Strategy has also enhanced efforts for regional and interregional cooperation in policies, regulations, standards and research.

Annex

3. The Framework

For the Future: Towards the Healthiest and Safest Region, a vision for delivering better health in the Western Pacific Region, seeks to address the challenges of tomorrow by acting today. It brings into focus four areas, or thematic priorities, that can have the most impact on future health and well-being in the Region: health security and antimicrobial resistance; NCDs and ageing; climate change, the environment and health; and reaching the unreached.

This *Regional Framework for Harnessing Traditional and Complementary Medicine for Achieving Health and Well-being in the Western Pacific* articulates the contribution of T&CM for achieving the *For the Future* vision – particularly in the areas of NCDs and ageing, and reaching the unreached – while contributing to the building of resilience of populations to cope with the impact of health emergencies and climate change.

The new Framework seeks to harness the role of T&CM for well-being and health. The starting point for all countries is to define T&CM in health and social policies as an element for a long-term vision to ensure safety, quality and efficacy, to improve coverage and equitable access to services, and to foster evidence generation and dissemination, research and innovation in T&CM.

3.1 Overarching goal

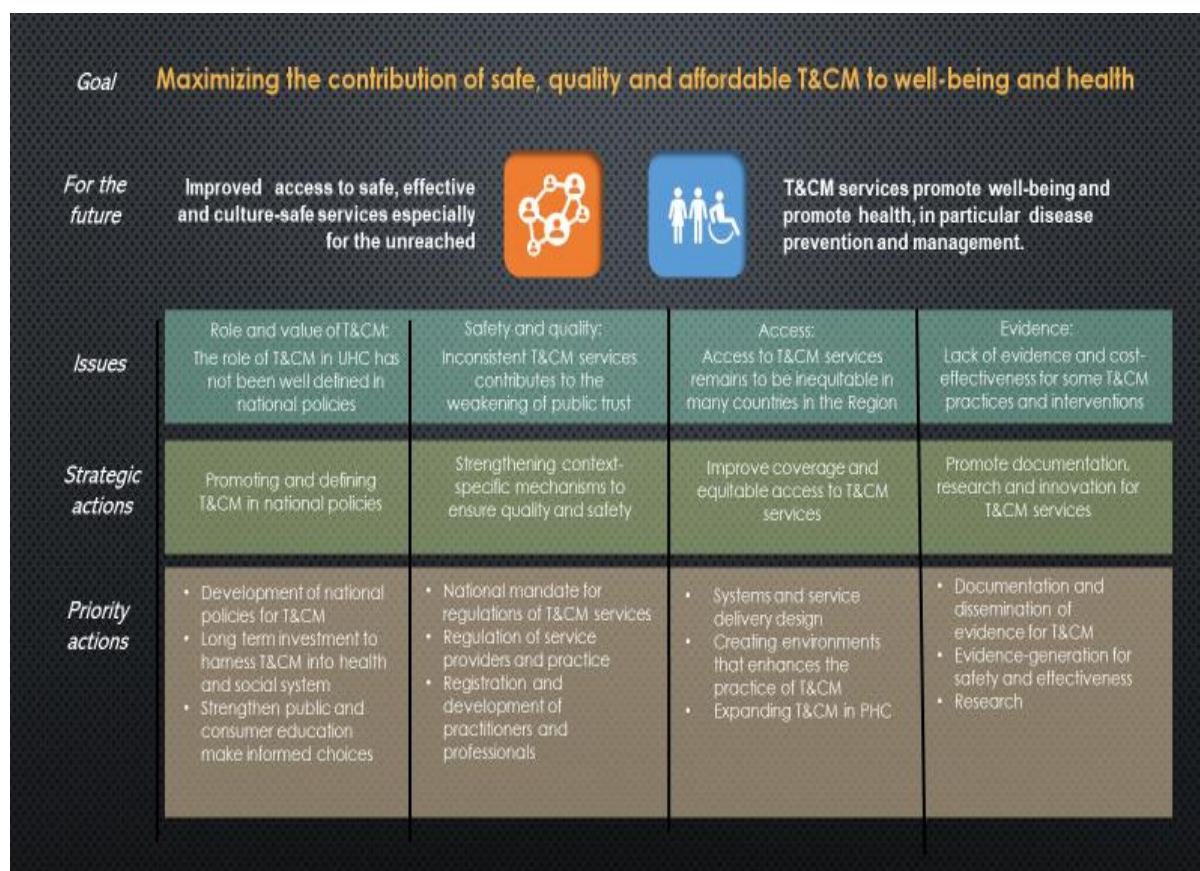
The overarching goal of the Framework is to maximize the contribution of safe, quality and affordable T&CM for the promotion of well-being and health.

For the Future envisions a region in which everyone can build a healthy and secure future for themselves, their families and communities. Its success is underpinned by the participation of people and communities in promoting their own health. T&CM can contribute hugely as it draws upon the resources and innate strengths of communities and societies, as well as their cultures and traditions. Such deep-rooted practices – especially when safe, of assured quality and evidence based – can serve as a foundation and stimulate innovation for new models of health care in the Western Pacific Region.

T&CM is a valuable resource, and its contribution to health and well-being has long been acknowledged. Over the next 10 years, Member States in the Region are encouraged to pay greater attention to T&CM and hasten its development as a crucial resource for achieving UHC and, more broadly, well-being and health.

In order to maximize the contributions of T&CM, countries will need to ensure that its development and full utilization will be guided by national policies that ensure quality and safety of services and increase coverage and equitable access to services. Such policies also can ensure the development of a well-designed system and models for service delivery that are built into broader health systems and are based on the context and needs of the population, with mechanisms to accelerate the generation and dissemination of evidence, research and innovation. These are the key elements of this Framework.

Fig. 2. The role of T&CM in achieving the vision of *For the Future*



3.2 Issues: Why do we need this Framework?

The role of T&CM in UHC has not been well defined in national policies

The use of T&CM in many countries in the Western Pacific Region is rapidly expanding, but national policies to maximize its use, guide its long-term development and prevent the risk of misuse have not been fully and uniformly defined in many countries. Despite a commitment by WHO and Member States, the advancement of T&CM has often been sidelined in national policies and strategies.³⁹ Barriers to the inclusion of TM include ongoing concerns about safety and quality, the complexity of regulations, and the lack of national consensus on safety and quality. These uncertainties have not been directly addressed by national policies, resulting in missed opportunities to maximize the contribution of T&CM in UHC.

Safety, quality, and effectiveness of T&CM services across countries are inconsistent and contribute to the weakening of public trust in traditional medicine systems

The expanding use of T&CM across the Region in the context of undefined mechanisms for regulation, governance and oversight raises the risk of misuse and unsafe practices. Regulation and standardization are difficult because of the wide range of methods used and the wide variation across countries. Countries in the Region use both indigenous T&CM practices and practices adopted from other countries. While indigenous practices deeply rooted in culture and tradition are often regulated based on

Annex

local contexts, many countries that adopt T&CM practices from elsewhere face challenges in adopting standards for safety and quality. In addition, there is currently no mechanism for setting standards and sharing regulatory information for T&CM across countries. In some countries, such as the Philippines, T&CM is part of a vast informal enterprise that is not fully regulated.⁴⁰

Regulations for T&CM vary widely across countries in the Region. In some countries – such as Australia, China, Japan and the Republic of Korea – comprehensive regulatory and quality assurance programmes for T&CM exists. In New Zealand, guiding standards for the practice of indigenous healing and products have been promulgated under the *Standards for Maori Healing of 1999*. Most countries regulate specific practice areas, such as homeopathy, while T&CM products are regulated separately as a part of the overall regulation of medical products. While T&CM services are widely provided, there are no clinical practice guidelines in place, unlike in conventional medicine.

The lack of evidence of the cost-effectiveness of T&CM services contributes to inefficient use of resources for health. Several traditional medicines therapies and complementary medicines used as an adjunct to biomedicine are not supported by rigorous clinical trials and cost-effectiveness studies. The introduction of these modalities to new areas such as palliative care and ageing necessitates evidence on appropriate use, benefits and risks.

Access to safe and effective T&CM services remains inequitable in many countries in the Region

In many parts of the Region, wide gaps in the provision of T&CM health services remain. In 2018, an overwhelming 93% of the Member States in the Region reported the use of T&CM in their populations. But only about half reported the existence of national policies and programmes, as well as systems for regulations, research practitioner development and health insurance coverage. These systems are important to improve the availability and delivery of products and services of proven safety, quality and efficacy. Countries that have made T&CM available in hospitals, clinics and PHC – and have registered products and services performed by well-trained professionals and covered by health insurance such as Australia, China, Japan, the Republic of Korea and Singapore – have utilization rates of around 60% or higher, while countries where these systems are still being established or developed have reported utilization T&CM rates under 30% in their populations.

It is increasingly recognized that safe and effective T&CM could contribute to the health of the population. However, although T&CM services are widely available, access to safe and effective has been inequitable due to several factors including the lack of information on their availability and use, as well as the fact that they have not been mainstreamed into the overall design of health service delivery. One direction pursued to increase coverage is to move towards the integration of T&CM into the health system,⁴¹ particularly at the level of primary care, by including T&CM practitioners in the service delivery and referral system, and utilizing T&CM practitioners as community health workers in areas where the health workforce is limited, especially hard-to-reach areas.

Lack of evidence and cost-effectiveness for some T&CM practices and interventions

Evidence supporting the potential benefits of T&CM has been central to the debate and underpins the extent of its integration or mainstreaming into the health-care system. Research and the generation and dissemination of evidence are not well established in the Region, being limited to countries with more

developed health systems. Ethnobotanical and ethnopharmacological research is being used to inform clinical practice and identify potential herb–drug interactions. This includes, for example, documenting and protecting proprietary traditional knowledge on behalf of traditional practitioners.³⁹ However, overall there is a paucity of clinical research evaluating the safety and effectiveness of T&CM in PICs. It is also unclear how published literature is utilized to guide clinical practice, service delivery and policy.³⁹

3.3 Purpose of the Framework

The Regional Framework aims:

- to affirm the importance and contribution of T&CM to the achievement of broader health goals, such as UHC and health and well-being;
- to guide countries to address the challenges of tomorrow by acting today, by outlining key strategic directions and a development pathway that countries may pursue in order to maximize possible contributions of T&CM to health and well-being;
- to guide countries in the Western Pacific Region to identify and focus efforts on priority areas for T&CM; and
- to outline areas of collaboration and WHO support to countries in T&CM over the next 10 years.

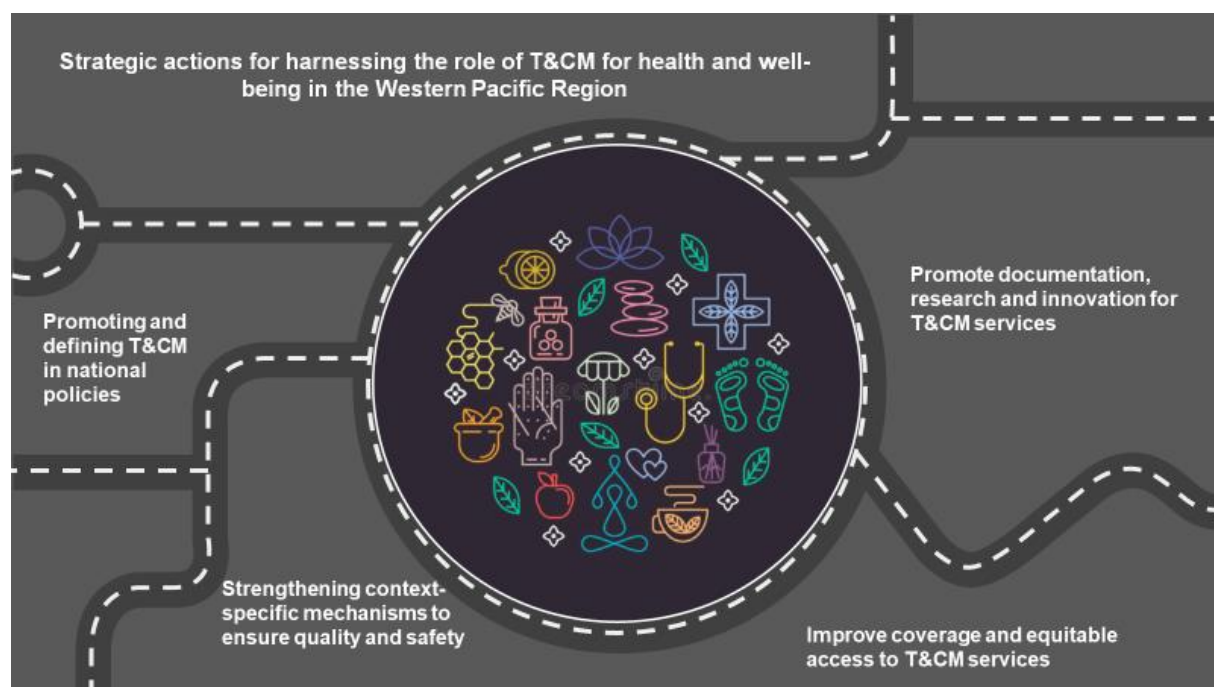
Annex

4. Strategic actions

For countries and the entire Western Pacific Region to harness the role of T&CM in achieving health and well-being, four strategic actions are proposed:

- promoting the role of T&CM for health and well-being through national policies;
- strengthening context-specific mechanisms to ensure the safety, quality and effectiveness of T&CM services;
- increasing coverage and equitable access to safe and effective T&CM services; and
- supporting documentation, research and innovation for T&CM services.

Fig. 3. Strategic actions for harnessing the role of T&CM for health and well-being in the Western Pacific Region



Source of central figure: dreamstime.com

Strategic Action 1. Promoting and defining T&CM in national policies

Rationale and purpose

The use of T&CM in many countries in the Western Pacific Region is rapidly expanding, but national policies to maximize its use, guide its long-term development and prevent the risk of misuse have not been fully and uniformly defined in many countries. A policy is needed to define long-term vision and political commitment, guide the pathway for development, identify priority areas of action, promote stakeholder engagement, and provide the basis for financing and engagement. T&CM policies should be a part of the broader vision for health and development and fulfil the vision and goals of the country.

The current policy landscape for T&CM in the Region is varied across countries (see Section 2) and mostly addresses narrow dimensions, such as the regulation of products and registration of practitioners. While there is wide recognition of the role of T&CM in UHC, there is insufficient policy basis to guide its actualization and realization. Through this Regional Framework, WHO will encourage countries to set firm policies that strengthen the role of T&CM as a significant player in UHC and in the attainment and promotion of health and well-being.

Key actions areas

Development of national policies for T&CM	Long-term investment to harness T&CM into health and social systems	Strengthen public and consumer education to make informed choices
<ul style="list-style-type: none"> Position T&CM in broader policies for health and development Long-term policies to guide the development and investment in T&CM Define mechanisms for stakeholder engagement 	<ul style="list-style-type: none"> Investments for enabling environment to improve practice of T&CM Investments for training and development Investments for designing service delivery systems to streamline T&CM services into social and health care 	<ul style="list-style-type: none"> Provide information on T&CM services that have proven safety, quality, and effectiveness and where these can be accessed Address medical pluralism

4.1. National policies that define the value of T&CM in broader health and social programmes

Member States are encouraged to develop or expand national policies that are:

- broad, to enable mainstreaming of T&CM into the overall vision for health and development of the country and to accommodate creativity and innovation on how T&CM could be maximized to promote health and well-being;
- forward-looking to set out a long-term vision and guide the development of each country's vision for the well-being and health of its population; and
- definitive on assigning institutional mandates, while setting up platforms for collaboration and engagement of a wide range of stakeholders.

4.2 Long-term investment to harness T&CM into health and social system

Broad changes would be required for countries to mainstream T&CM services into broader health and social programmes. A national investment plan that can be covered as a part of a general appropriations act or equivalent can ensure the availability of resources to implement long-term development and T&CM policies.

The range of investments may include modification of the built environment for physical activities and institutional programmes that accommodate mental health and wellness programmes. Viet Nam is a good example of promoting a conducive environment for physical and mental wellness – transforming

Annex

parks and public spaces and equipping them for physical activities. Investments should also be provided to design wellness and healing services in health-care facilities.

4.3 Strengthened public and consumer education to support informed choices

Providing accurate and timely information to patients and consumers is a part of the duty of care of health professionals, service providers and healers. This should be supported or framed within overarching policies to make information available on what services are proven safe and of assured quality and effectiveness, as well as where and how services can be accessed. The public requires adequate accurate information on T&CM practices and products to make informed decisions. An assessment of public awareness and knowledge of T&CM may be required to advise decision-makers on the way forward in formulating and implementing suitable programmes and activities to help inform people's decisions.⁴²

One issue that needs to be addressed to protect the consumer is medical pluralism. Medical pluralism means the employment of more than one medical system or the use of both conventional and T&CM for health and illness.⁴³ In the recent past, the public and consumers of health care worldwide have continued to include T&CM in their health choices. Many consumers turn to T&CM products and practices operating under a flawed assumption that "natural means safe".

However, there is a need to create the conditions for the correct and appropriate use of T&CM, especially when these are applied in combination with other treatment modalities that may result in high burden of cost for patients and risk harmful adverse events.

In many Member States, consumers of T&CM services contact T&CM providers and conventional health-care providers separately. Coordination of treatments by consumers with insufficient knowledge of either T&CM or conventional medicine poses a risk of adverse therapy interactions. In addition, T&CM products are increasingly being used for health self-care as consumers become more proactive about health. Empowering consumers with appropriate information is important to prevent harmful and inappropriate use.

Member States may consider supporting consumers to make informed decisions about their options by:

- providing information and advice to consumers on T&CM, including the potential risk of practices and products, including those obtained outside national regulatory controls (online purchases, etc.);
- encouraging patients to declare their use of T&CM to their conventional medicine practitioners to ensure providers have a full understanding of their patients' health and practices;
- improving accessibility to T&CM professionals through public health centres so that consumers can seek advice; and
- developing mechanisms or guidelines for consumer education and protection, complaint channels, and the proper use of T&CM products, practitioners and services, including promotion, advertising and advocacy for responsible and accurate advertising and promotion.

Strategic Action 2. Strengthening context-specific mechanisms to ensure quality and safety

Rationale and purpose

The operational definition of quality is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.¹³ Patient safety (or safety in the context of this Regional Framework) has been extensively defined as “the prevention of harm to patients”. There is an emphasis on the system of care delivery that prevents errors, learns from errors that do occur and is built on a culture of safety that involves health-care professionals, organizations and patients. This definition has also been expanded to encompass the prevention of harm, such as freedom from accidental or preventable injuries resulting from medical care.⁴⁴

Ensuring quality and safety of services and interventions is a statutory responsibility of the state, service providers and T&CM practitioners. Such statutory responsibility is operationalized through governance structures and mechanisms that will ensure the delivery of quality and safe services, as well as ethical accountability within the whole system of T&CM practice.

The need for ensuring quality, safety and effectiveness is universal and has been a primary objective in many countries. The urgency is increasing as T&CM use is expanding and is increasingly being commoditized. WHO estimates that 80% of the population from most Asian and African countries use traditional medicine for PHC.

While use is extensive, a review on the level of regulations for T&CM practices points out that quality control across complementary methods for the management of disease conditions is poor, whether it is in evidence about safety and efficacy, labelling, or the regulation and training of practitioners. The review also asserts the urgent need for professionalization in T&CM.⁴⁵

The breadth of variation of T&CM practice makes standardization extremely challenging. Often, there are no standards or parameters to establish and determine quality. The tools that are being utilized are not prescriptive,⁴⁶ and users commonly find information from historical accounts. There is also a wide range of practitioners.

Practitioners are classified by WHO into two main groups.³² The first group is indigenous traditional medicine providers. These are generally understood to include those who practice indigenous traditional medicine, such as traditional healers, bonesetters, herbalists and traditional birth attendants. Usually, most of these practitioners have been practising at the PHC level or in communities where traditional healing is embedded in the culture and traditions. The second group is T&CM providers. They include both T&CM practitioners, allopathic medicine professionals and health-care workers, such as doctors, dentists, nurses, midwives, pharmacists and physical therapists who provide T&CM services to their patients, for example, medical doctors who use acupuncture to treat their patients or TCM doctors who provide services in clinics and hospitals.

T&CM practice is undertaken in various settings. The 2018 WHO global report on T&CM indicated that of the countries surveyed, 97 reported that T&CM providers are practising in the private sector, 55 in

Annex

the public sector and 20 in other settings, such as home-based settings and traditional healing centres.³² A substantial proportion of these practitioners are in the informal sector, which is largely unregulated and lacking oversight.

While T&CM is trusted and accepted, countries in the Western Pacific Region will need to reduce the risk of misuse and malpractice of T&CM that can cause adverse consequences, including harm, inefficient use of resources and loss of trust in the system.⁴⁷ Poorly regulated practices can lead to a poor standard of care, indirect harm that may result in the delay of appropriate diagnosis and treatment, adverse events, harmful drug interactions and even financial harm.⁴⁸

Considering the variability of T&CM practices and the level of development of regulatory systems in the Region, it is important for countries to determine the level of regulatory stringency and the mode of regulations that can be undertaken based on their context and resources, with consideration of the following key principles:

- the scope of T&CM services and interventions allowed in the country must be chronicled in a statutory or government document, which can be reviewed and adjusted based on evidence and the needs of the country;
- a mechanism to formalize the practice and provision of services by practitioners, professionals and providers; and
- a designated institution or institutional arrangement to implement and enforce statutory mandates for regulations, governance and oversight.

Key action areas

National mandate for regulations of T&CM services	Regulation of service providers and practice	Registration and development of practitioners and professionals
<ul style="list-style-type: none"> ● A national list of T&CM services and interventions that are appropriate to the needs of the population ● Design risk-based approaches to regulations of T&CM ● Incorporate regulations of T&CM in the mandate of national regulatory bodies ● Designate and build the capacity of institutions to implement context-specific and risk-based regulations 	<ul style="list-style-type: none"> ● Formalizing, licensing and accreditation of service providers ● Setting the scope and standards of practice ● Registration of T&CM services, modalities and types of practice 	<ul style="list-style-type: none"> ● Registration of T&CM practitioners and professionals, including licensing ● Mechanisms for professional discipline and ethical practices

4.4 National mandate for regulations of T&CM services

The mandate of the state to protect public health welfare is enshrined in the constitutions of Member States. These high-level mandates are the foundation of rules and regulations or broader regulatory frameworks to ensure the safety, quality and effectiveness of health and social services. WHO supports the development of such regulatory frameworks. In 2017, the *Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce* was endorsed by the WHO Regional Committee for the Western Pacific to guide countries in the development of regulatory systems in countries, encompassing regulatory mechanisms for T&CM products and practitioners.

Government oversight is critical. Quality assurance, safety and efficacy are recognized as legitimate concerns. Without government oversight, the objectives and credibility of T&CM may be undermined.

The government must take an active role in the design and discharge of regulatory mechanisms. The government must actively take part in the settlement of competing and conflicting claims about the costs and benefits of T&CM.⁴⁰ It is also important that governments engage in continued dialogue and cooperation among stakeholders and users to achieve consensus on the span and stringency of regulations.⁴⁰

It may not be possible for countries to regulate all the practices, interventions and products that are used for T&CM, in terms of financial and technical resources. In such cases, a risk-based approach to regulations can be adopted. One example is the regulatory approach by Therapeutic Goods Administration (TGA) of Australia around complementary medicines, wherein the amount and nature of regulatory control exerted varies depending on the level of risk that a product poses to the Australian public. In determining risk, the TGA takes into account a range of factors, including:⁴⁹ (1) the inherent properties of the therapeutic product; (2) the way in which the product is designed to be used; (3) potential for misuse; (4) the potential severity and consequences of adverse events; and (5) the quality of the product.

4.5 Regulation of service providers (establishments)

T&CM facilities, such as clinics, hospitals, pharmacies and other centres offering T&CM practices, should be regulated through a mechanism of registration and continuing accreditation. The registration and licensing of establishments will ensure the standard of safety and help eliminate the risk of fly-by-night establishments as well as malfeasance in practice. T&CM facilities should also be made accountable to a certain set of performance indicators to ensure positive health outcomes through a process of accreditation. Member States may employ a wide range of mechanisms depending on their context including:

- registration and licensing of TM establishments that offer services and products for T&CM;
- accreditation of these establishments against a set of indicators for quality, safety and ethical practice; and
- setting up of communities of practices or networks to promote self-governance and progressive adoption of standards of practice.

Annex

4.6 Regulations and development of practitioners and professionals

Development of T&CM professionals

The quality and accountability of the T&CM practitioners can be built into the development pathway of a T&CM professional, starting from formal education to entry-to-practice requirements such as licensing and accreditation, and in practice process such as continuing education. The system to ensure the quality and accountability of T&CM practitioners is essential to ensure that individuals entering professional practice have obtained and maintained the core competencies required for safe practice.

Education and training

T&CM education may be formalized into academic training. In countries with well-developed T&CM systems like China, medical professionals are educated at medical schools or pharmacy schools with the same standards, admissions and years of training as Western medical professionals.⁵⁰ Education and training in T&CM will equip future T&CM professionals or practitioners with evidence-based knowledge, skills, and standards of scientific and ethical practice. Education and training promote the credibility of the T&CM practice and T&CM providers, and they enhance consumer trust in T&CM services.

Entry to practice

Entry to practice encompasses the range of formalities that can be adopted to enlist or bring practitioners under the oversight of the system. This will include mechanisms for enlisting indigenous traditional medicine practitioners and healers to more formal licensing systems. An entry-to-practice system will enable Member States to assure that only those that meet qualifications and with the appropriate level of knowledge, skills and competencies can provide T&CM services. In several countries, T&CM is under the same registration and licensing procedures as is Western medicine.⁵⁰ In addition to licensing, a certification process may also be undertaken to cover the entry of practitioners along lines of specialization such as acupuncturists, naturopaths, homeopaths, homotoxicologists and chiropractors.

Continuing education and professional development

Continuing professional education is the ongoing process of developing, maintaining and documenting professional skills, stipulating that continuing professional development must be undertaken to maintain registration. Continuing professional development for TM practitioners is often voluntary in many Member States.

Mutual recognition

The *Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce* laid the foundation for strengthening regulatory systems for medical products and human resources. Recognizing that countries are in varying degrees of regulatory capacity and development, the Action Agenda outlined a continuous process for strengthening regulatory systems with the aim in view that all systems will have a convergence of outcomes that could be achieved through regulation.

Strengthening the regulatory systems for TM will take the same approach, emphasizing that national systems will converge towards an outcome of improved quality and accountability of T&CM practice and practitioners.

To facilitate this convergence, countries may engage in mutual recognition among jurisdictions based on the risk assessment of similarities and differences between countries.⁵¹ International collaboration is also encouraged through various platforms including WHO collaborating centres and through global regulatory, research and professional alliances.

Setting standards on T&CM practices

Clinical practice guidelines (CPGs) are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. CPGs have the potential to influence the care delivered by health-care providers and the outcomes of patients. Evidence-based CPGs ensure standardization and evaluation of practice. CPGs should be developed using an unbiased and transparent process of systematically reviewing, appraising and using the best clinical research findings of the highest value to aid in the delivery of optimum clinical care to patients.

Clinical and practice governance through professional bodies

Clinical governance entails placing duties and expectations on local health-care organizations, as well as individuals, to ensure quality and clinical excellence.⁵² It fosters accountability and continuous improvement to ensure quality services and safeguard high standards of care, by creating an environment in which clinical excellence⁵² and ethical practices can be demonstrated. In combination with other regulatory policies, clinical governance can be enforced through professional bodies that can provide oversight of the knowledge, skills, conduct and practice of its members.

Professional associations are important regulatory agents.⁵³ Professional societies can guide ethical and evidence-based practice and can hold their members accountable to such a level of standards. Their influence flows from their continuing and highly visible functions, including publishing professional journals, developing professional excellence and raising public awareness. Through their work, they help to define and set standards for their professional fields and promote high standards of quality through awards and other forms of recognition.⁵⁴ Countries should create mechanisms for the establishment of professional bodies or societies with their current regulatory frameworks.

Professional societies can also facilitate change and continuous improvement within their areas of practice and will ensure each practitioner is part of the continuous improvement process.

Strategic Action 3. Improve coverage and equitable access to T&CM services

Rationale and purpose

T&CM is considered by many as more accessible, more affordable and more acceptable to local populations. However, to optimize this advantage, T&CM services need to be strengthened and carefully designed within the broader health-care system so that they can contribute to improving health and well-being.⁵⁵

Annex

In the Western Pacific Region, TM has already played an important role in the provision of PHC, being widely used as the first response to a variety of health problems, from minor ailments to life-threatening diseases. However, the availability and access to these services vary across countries. In many Member States, T&CM practice remains outside the mainstream of health service delivery.

Recent evidence has pointed out the increasing acceptance of T&CM as an important contributor to the prevention and management of disease. Increasing coverage would mean expanding the type of service provided and making it available and accessible at all levels of health care, but most especially at the primary level and in hard-to-reach areas, and ensuring financial coverage for safe, quality and cost-effective practices and interventions.

Key action areas: Increasing coverage and equitable access to T&CM services

Systems and service delivery design	Creating environments that enhance the practice of T&CM	Expanding T&CM in PHC
<ul style="list-style-type: none"> ● Design systems for the delivery of T&CM ● Design models of care for PHC, healthy ageing, NCDs ● Inclusion of T&CM services in health facility settings 	<ul style="list-style-type: none"> ● Built environments ● Multidisciplinary health teams ● Collaboration within and across areas of practice ● Engagement with patients and communities 	<ul style="list-style-type: none"> ● Expand human resources for T&CM ● Financing and incentives to promote T&CM services ● Inclusion of T&CM services in health insurance

4.7 Designing T&CM service delivery as a part of the overall health system

Systems design in the context of this Regional Framework encompasses the structural and functional design to deliver T&CM services, as well as designing models of care to maximize the contribution of T&CM into the process of healing and the achievement of better health and well-being.

As a general principle, Member States may work towards transforming health facilities as centres for wellness where T&CM services that are safe, effective and of assured quality are available, as are measures to reduce patient, family and staff stress and increase positive influences on health status.¹³

Design of service delivery and health care models

A model of care broadly defines the way health services are organized and delivered, and the basic elements upon which an intervention or service is delivered by whom, when, where, how, to whom and for what purpose.⁵⁶

To maximize the role of T&CM, the concept of integrative medicine is also advanced as a potential model for health service delivery and could be the central point of reference in designing services around patient-centred care.

Integrative medicine advances the seamless engagement of the full range of established health factors – physical, psychological, social, preventive and therapeutic – into the management frame, as well as the integration of these services across the life course. It asserts that the orientation of health care is integrated around – and within – each person, thus care not only accounts for differences in individual conditions, needs and circumstances, but it also engages patients as partners in addressing the various biological, psychological spiritual, and social and economic reference points that shape patients' wellness, illness and healing.¹³

4.8 Creating environments that enhance T&CM practice

The creation of environments that enhance T&CM practice fails to consider that a lot of T&CM practices happen within the natural environment.

Enhancing the built environment of health facilities to allow areas where patients can access healing and wellness programmes may be considered to expand access to T&CM and make these services available when and where individuals need them. Promoting a team-based approach is also an important element for transforming environments for T&CM.¹³ A multidisciplinary team of registered and competent practitioners that provide care can overcome difficult patient journeys where services are often compartmentalized, fragmented and often delivered in multiple centres and settings. An integrated health-care team would employ professionals with a wide spectrum of expertise and skills, as well as diverse, interdisciplinary education and training in a set of core competencies.¹³

4.9 Expanding T&CM services in primary health care

The PHC system forms the widest base for catering to the diverse needs of the population, not only for the promotive, preventive, curative and rehabilitative services, but also for promoting the overall health and well-being of populations. Improving access to T&CM services can be best achieved by designing these services into the PHC system. Several strategies would include:

- a. Designing service delivery and care models that encompass services for health promotion and prevention and for behaviour change, and that include the role of T&CM. The contribution that individual behaviour choices can make in preserving health or causing disease has been well described.⁵⁷ Yet, the health system is not currently geared towards supporting individuals through the long and difficult behaviour change process. The design of health service delivery could be a part of broader health reform and should touch many aspects of people's lives, especially outside the health sector.⁵⁸ These include, for example, better nutrition in schools and exercise opportunities in the built environment, such as sidewalks and bicycle paths; wellness programmes in workplaces and community centres; opportunities for wellness services, exercise, stress reduction and socialization in senior centres; widely available information, screening and counselling programmes that help people take charge of their own health.⁵⁹
- b. Enlisting T&CM practitioners as a part of the PHC system, as T&CM practitioners are widely available. The Department of Health in the Philippines, for example, reports that the ratio of traditional, complementary and alternative medicine health practitioners is 1 to every 300 Filipinos, in contrast to the doctor–population ratio, which is as low as 1 to more than 26 000.⁴⁰

Annex

- c. Expanding therapeutic options for chronic disease with proven evidence and cost-effectiveness. Lifestyle interventions for diabetes are examples. The Diabetes Prevention Programme, for example, that is implemented in the United States of America using lifestyle interventions has been shown to be more effective than first-line pharmacotherapy for diabetes.¹³ Table 2 provides some examples of therapeutic options for treating chronic diseases as part of complementary and alternative medicine in integrative patient-centred medicine.

- d. Design service delivery models for older people. Older people in residential care often encounter complex issues commonly associated with cognitive impairment and dementia, which may lead to increased anxiety, depression and agitation.⁶⁰ Care models for older people should include services that address these conditions and prevent deterioration of functions. For instance, McFeeters et al. have found evidence that massage is effective in promoting comfort through the reduction of pain. This appears particularly relevant for the cognitively impaired client whose ability to self-report may be limited. Reduction of pain has the capacity to promote relaxation and induce quality sleep. They have also found evidence that massage can reduce anxiety-related behaviours and agitated dementia behaviours including wandering, verbal agitation, physical agitation and resistance to care.⁴⁰ Meanwhile, the National Health Service (NHS) in the United Kingdom of Great Britain and Northern Ireland is promoting tai chi as it contributes to a 60% reduction of risks of falls in older people.⁶¹

- e. Consider shifting financing from disease packages to models of care that incorporate interventions to improve healing and well-being. A new approach to financing may also consider wellness and preventive services that are delivered in other environments outside the traditional health providers, such as for example, in schools, workplaces and homes.

- f. Mechanisms for stakeholder engagement in T&CM should be put in place. Stakeholder engagement improves acceptance and ownership of reforms in the design and implementation of service delivery design. Moreover, the engagement of patients and the community will ensure that the needs of the population and communities are the basis of overall planning and design.

Table 2. Examples of combined conventional and complementary medicine practices in the management of chronic disease

	Conventional approaches	Complementary and alternative medicine in integrative preventive medicine
Cardiovascular disease	Statins for hyperlipidaemia, antihypertensive medications for hypertension	Omega 3 fish oil for hypertriglyceridemia, anti-inflammatory diet, integrative lifestyle intervention
Diabetes	Oral hypoglycaemic medication, insulin therapy	Lifestyle intervention such as a diabetes prevention programme tailored to specific dietary interventions such as the Glycaemic Index Guide, functional foods
Chronic pain	Nonsteroidal anti-inflammatory drugs, nerve blocks and interventional pain, steroids	Mind–body therapies including tai chi, yoga, acupuncture, anti-inflammatory diet, Omega 3 fish oil, evidence-based supplements

Source: <https://oxfordmedicine.com/view/10.1093/med/9780190241254.001.0001/med-9780190241254-chapter-9>

Strategic Action 4. Promote documentation, research and innovation for T&CM services

Rationale and purpose

The value of traditional medicine, as well as many modern medical treatments, has not been fully tested by using modern scientific means,⁶² and there is a wide gap of knowledge on the cost-effectiveness of many T&CM interventions and practices.

While several countries in the Western Pacific Region have been undertaking efforts to evaluate the efficacy and safety of T&CM medicinal products and practices, often in the form of randomized controlled trials, there remains a general consensus that for most conditions, there is not enough rigorous scientific evidence to know whether T&CM methods work for the conditions for which they are used. TM practices that are indigenous to specific regions and cultures around the world are also considered to be largely under-investigated or under-reported.⁶³

There is scope to improve the evidence on the safety, quality and effectiveness of T&CM practices. While T&CM services have been practised across thousands of years, and is part of the folklore in many areas, they require continuing documentation and research into their efficacy and safety. The availability of evidence generated through continuing research and investigation of the origins and basis of folklore and traditional practices, for example, will aid in the incorporation of T&CM into models of care and in the promotion treatment and prevention of diseases.

Annex

Generation of evidence is necessary for the following reasons:

- The public and users of T&CM demand safe, quality-assured and effective services and remedies.
- Medical scientists request more scientifically sound evidence before comfortably accepting many TM practices. Many health professionals have doubts about the usefulness of TM. In many cases, they require more scientifically based evidence to trust its safety and effectiveness.
- Governments need to establish and update mechanisms for the regulation of traditional medicine and its practitioners and, in doing so, require more scientifically based evidence to support decision-making. As traditional systems of medicine become better documented and more scientifically credible, usage is only likely to increase further.⁶⁴

Key action areas

Documentation and dissemination of evidence for T&CM	Evidence generation for safety and effectiveness	Research
<ul style="list-style-type: none"> ● Codification of practice, types and modalities ● Dissemination of existing evidence to guide use and decision-making for T&CM 	<ul style="list-style-type: none"> ● Clinical trials ● Health technology assessments ● Evidence-based health care practice 	<ul style="list-style-type: none"> ● Expanding the research agenda ● Collaboration in research ● Innovation and research that will support the value of T&CM in promoting health and wellness beyond treating diseases²⁸

4.10 Documentation of traditional medicines practices

Documentation of TM practices is the basis for traditional medicine to be recognized and gain its status in the national health system.⁶⁵ TM knowledge in many countries tends to be transmitted orally from generation to generation. This makes it difficult for most researchers to access such knowledge upon which they would develop their research. It is essential to have TM knowledge in a permanent and transferable form to increase access to a wider audience. To build a comprehensive information base for TM, the scope of documentation should include not only its benefits but also potential harms and adverse effects it may cause. Documenting TM practice, including the inclusion of these services into medical records, would also contribute to preserving the knowledge of TM in indigenous communities and also assist clinical practice and teaching.⁶⁶

It is also important to disseminate existing evidence. In the United States of America, the White House Commission on Complementary and Alternative Medicine Policy has asserted that much more evidence for complementary and alternative medicine exists than is commonly recognized. The Cochrane Collaboration alone lists well over 4000 randomized studies on complementary and alternative medicine therapies.¹⁰

4.11 Evidence generation for safety and effectiveness

Over the years, clinical evidence on T&CM has emerged and has been used by clinicians and patients to make informed choices.⁶ The Institute of Medicine in the United States of America, for instance, has developed a guiding principle on how evidence can support decision-making based on categorization (Box 2).

Box 2. Guiding principles for evidence-based decision-making for T&CM interventions and modalities

Category 1. If evidence supports both safety and effectiveness, clinicians may recommend the therapy but continue to monitor the patient conventionally.

Category 2. If evidence supports safety but is inconclusive about effectiveness, the treatment may be cautiously offered with monitoring of patient outcomes.

Category 3. If evidence supports effectiveness but is inconclusive about safety, close monitoring on both patient outcome and safety should be implemented while offering the interventions.

Category 4. Therapies for which evidence indicates either serious risk or inefficacy obviously should be avoided and patients actively discouraged from pursuing such a course of treatment.

4.12 Research

The continuous improvement, innovation and modernization of T&CM need a robust and sustainable system for research. This would include the scientific identification, cataloguing and assessment (safety and efficacy) of T&CM components and products.⁶⁷ In other countries such as the PICs, T&CM research may also include cultural and social research, for example, a systematic documentation of traditional herbs and practices, as well as country-specific history and research on T&CM.

Basic academic research is vital to this process as peer-reviewed research published in reputable academic journals enhances the credibility of new practices, drugs and health products, which in turn builds the evidence base for the regulatory approvals and practice.⁶⁷

While the evidence base on T&CM is gradually emerging, a wide range of significant issues requires further research attention. The need for more rigorous research examining T&CM use in the prevention, management and treatment of chronic illness and other conditions needs to be sustained. Future research should also address issues of ethnic and geographical diversity related to T&CM use, including the differences in experiences and practices across cultures or in various spatial settings. It is also important to encourage countries where T&CM is well established to carry out cooperation with other countries in the protection and research of TM.

Annex

4.13 Innovation

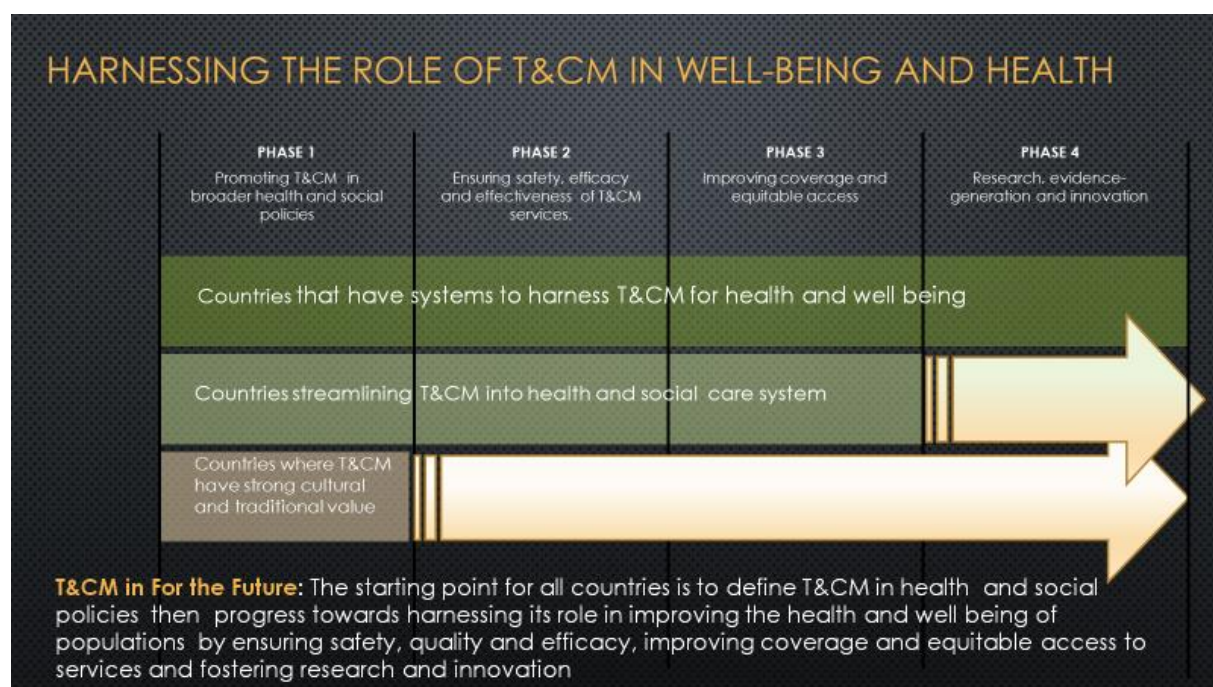
In recent years, consumer health technologies including wearables, health software applications that support wellness and healthy lifestyles, emerged rapidly. However, only a few of these new technologies have been certified or adopted for use as medical products or for use in health care.⁶⁸

Innovations in monitoring and modelling biomedical, health-care and wellness data from individuals and for converging data on a population scale have tremendous potential to improve understanding of chronic NCDs, and they will inform the need to incorporate interventions for wellness in new health-care models. This will also improve primary care and will help quantify transitions from healthy to a diseased state, thus strengthening the importance of prevention strategies at an early stage and enabling the analysis of data in different contexts, thus guiding options for early diagnosis and treatment.⁶⁸

5. *For the Future*: a pathway for harnessing the role of T&CM for the well-being and health of populations in the Western Pacific Region

T&CM can help promote the well-being and health of populations throughout the Western Pacific Region, as envisioned in *For the Future*. This can be achieved by working backwards from the vision of well-being and good health and determining the actions and policies required to achieve it. The starting point for all countries is to define and enshrine in national health policies the role of T&CM in the achievement of well-being and health, and then incrementally establish or strengthen other key components such as ensuring quality, safety and efficacy of health-care services, increasing coverage and equitable access to services, and enhancing research, evidence generation and innovation over time.

Fig. 4. Proposed development pathway for T&CM in the Western Pacific Region



The pathway for this development, illustrated in Fig. 4, acknowledges that countries in the Western Pacific Region are at different levels of development with regards to T&CM. Collaboration across traditional and conventional health systems can be continuously enhanced, even as populations adopt many different approaches to health and well-being that may exist as distinct systems:

- a. The first tier is countries where T&CM is well established in the social and health system. These are countries with a long history of T&CM development and where policies are in place; systems to regulate T&CM practice, practitioners and products are undertaken by designated and functional institutions; and services and interventions are part of health promotion and disease prevention and management based on evidence from research and documentation over time. This is the level that countries may aim to achieve in the long term in order to harness and fully maximize the contribution of T&CM to the health and well-being of their populations.

Annex

- b. The second tier is countries where policies are well defined and are moving towards mainstreaming T&CM services in their health-care delivery systems while expanding the range of T&CM services and interventions – both indigenous and adopted from other countries – to be more equitable and accessible. The regulatory systems in these countries are not well defined, and access to safe, quality and effective services is not equitable. Countries in this tier will need to continue to strengthen regulatory systems for T&CM, as well as design their health-care delivery system to improve coverage. Mechanisms to setup documentation of T&CM services, as well as to collaborate with more advanced countries in research and generation of evidence while improving the national capacity of institutions for continuing research, are recommended.
- c. The last tier includes those with strongly held values of T&CM as part of healing and well-being and where most of the practices are indigenous and strongly tied to culture and tradition. These services and practices are not yet formally recognized as part of the broader health system. These countries are recommended to move into the next phase by establishing mechanisms for the recognition, registration and regulation of T&CM services to maximize the safe, quality and effective use of these services to improve health and well-being.

Member States may consider the strategic actions in this Regional Framework as they plan a long-term development of T&CM depending on their current context and stage of development.

Glossary of terms

Complementary medicine	The terms “complementary medicine” and “alternative medicine” refer to a broad set of health-care practices that are not part of that country’s own traditional or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries.
Herbal medicine	Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain, as active ingredients, parts of plants, other plant materials or combinations thereof. In some countries, herbal medicines may contain, by tradition, natural organic or inorganic active ingredients that are not of plant origin (for example, animal and mineral materials).
Indigenous traditional medicine	Indigenous traditional medicine is defined as the sum 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 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. Most of the indigenous traditional medicine has been practised at the primary health-care level.
Traditional medicine	Traditional medicine has a long history. It is the sum 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.
Traditional and complementary medicine	Traditional and complementary medicine merges the terms “traditional medicine” and “complementary medicine”, encompassing products, practices and practitioners.

Annex

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