Traditional and complementary systems of medicine

Ali Mehdi, Divya Chaudhry and Priyanka Tomar
Health in the G20

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ICRIER Health Policy Initiative
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Any fault that remains is entirely ours.

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# Abbreviations

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<th>Description</th>
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<tbody>
<tr>
<td>AM</td>
<td>Alternative Medicine</td>
</tr>
<tr>
<td>ASU</td>
<td>Ayurveda, Siddha and Unani</td>
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<td>ASUDCC</td>
<td>Ayurveda, Siddha and Unani Drugs Consultative Committee</td>
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<tr>
<td>AYUSH</td>
<td>Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homoeopathy</td>
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<tr>
<td>CAM</td>
<td>Complementary and Alternative Medicine</td>
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<tr>
<td>CAT</td>
<td>Complementary and Alternative Therapies</td>
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<tr>
<td>CCRAS</td>
<td>Central Council for Research in Ayurvedic Sciences</td>
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<tr>
<td>CDSCO</td>
<td>Central Drugs Standard Control Organization</td>
</tr>
<tr>
<td>CM</td>
<td>Complementary Medicine</td>
</tr>
<tr>
<td>CSIR</td>
<td>Council of Scientific &amp; Industrial Research (India)</td>
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<tr>
<td>CTR</td>
<td>Clinical Trial Registration</td>
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<tr>
<td>EBM</td>
<td>Evidence-based Medicine</td>
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<tr>
<td>ECHAMP</td>
<td>European Coalition on Homeopathic &amp; Anthroposophic Medicinal Products</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>EU-MS</td>
<td>European Union Member States</td>
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<td>FYP</td>
<td>Five Year Plans</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>HMPC</td>
<td>Committee on Herbal Medicine Products</td>
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<tr>
<td>HPCUS</td>
<td>Homoeopathic Pharmacopoeia Convention of the United States</td>
</tr>
<tr>
<td>I-CAM-Q</td>
<td>International Complementary and Alternative Medicine Questionnaire</td>
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<tr>
<td>ICD</td>
<td>International Classification of Diseases</td>
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<tr>
<td>ICTRP</td>
<td>International Clinical Trials Registry Platform</td>
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<td>IM</td>
<td>Integrative Medicine</td>
</tr>
<tr>
<td>IRDAI</td>
<td>Insurance Regulatory and Development Authority of India</td>
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<tr>
<td>ISM&amp;H</td>
<td>Indian Systems of Medicine and Homeopathy</td>
</tr>
<tr>
<td>JAOM</td>
<td>Japanese Association for Operative Medicine</td>
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<tr>
<td>JKMA</td>
<td>Japan Kampo Medicines Manufacturers Association</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>JLOM</td>
<td>Japan Liaison of Oriental Medicine</td>
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<tr>
<td>JP</td>
<td>Japanese Pharmacopoeia</td>
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<tr>
<td>MHLW</td>
<td>Ministry of Health, Labour and Welfare (Japan)</td>
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<tr>
<td>MoU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>NCCIH</td>
<td>National Center for Complementary &amp; Integrative Health (US)</td>
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<tr>
<td>NCI</td>
<td>National Cancer Institute (US)</td>
</tr>
<tr>
<td>NCM</td>
<td>Non-Conventional Medicine</td>
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<tr>
<td>NHSRC</td>
<td>National Health Systems Resource Centre (India)</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence (UK)</td>
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<tr>
<td>NIH</td>
<td>National Institutes of Health (US)</td>
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<tr>
<td>NPCDCS</td>
<td>National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke</td>
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<tr>
<td>OAM</td>
<td>Office of Alternative Medicine</td>
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<tr>
<td>PHC</td>
<td>Primary Health Care</td>
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<tr>
<td>RITOM</td>
<td>Research Institute of Traditional Oriental Medicine (Japan)</td>
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<tr>
<td>SDGs</td>
<td>Sustainable Development Goals</td>
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<tr>
<td>T&amp;CM</td>
<td>Traditional and Complementary Medicine</td>
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<tr>
<td>TCIM</td>
<td>Traditional, Complementary and Integrative Medicine</td>
</tr>
<tr>
<td>TCM</td>
<td>Traditional Chinese Medicine</td>
</tr>
<tr>
<td>TCSM</td>
<td>Traditional and Complementary Systems of Medicine</td>
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<tr>
<td>TKDL</td>
<td>Traditional Knowledge Digital Library</td>
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<td>TM</td>
<td>Traditional Medicine</td>
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<tr>
<td>TRDS</td>
<td>Trial Registration Data Set</td>
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<td>UHC</td>
<td>Universal Health Coverage</td>
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<tr>
<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<tr>
<td>USD</td>
<td>United States Dollar</td>
</tr>
<tr>
<td>USFDA</td>
<td>United States Food and Drug Administration</td>
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<tr>
<td>WHA</td>
<td>World Health Assembly</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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Introduction

Objective

This report aims to provide recommendations\(^{1}\) for the Government of India for its G20 health engagement – especially for its G20 Presidency in 2022 – vis-à-vis traditional and complementary systems of medicine (TCSM) in general, AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha & Homoeopathy) in particular.

Definitions and nomenclature

One of the most significant and persistent challenges vis-à-vis TCSM has been the search for the right terminology and definition, both from a conceptual and policy / operational perspective. We, therefore, start out with a brief discussion of the key terms and definitions put forth over the years. We then briefly characterize the various contexts – the G20, SDGs, philosophical, epistemological and the political economic – that need to be borne in mind for the promotion of TCSM. The chapter ends with some estimates of the market size of traditional medicines.

Several efforts have been made over the years to define traditional medicine (TM) on its own or vis-à-vis ‘conventional’, ‘mainstream’ Western medicine (WM) – as ‘unconventional’ / ‘alternative’ / ‘complementary’ / ‘complementary and alternative medicine’ (CAM), for instance – or with WM – as ‘integrative’ / ‘holistic’, for instance. We present and discuss some of the prominent definitions here, and subsequently make a few comments and recommendations vis-à-vis the nomenclature.

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\(^{1}\) Recommendations are marked with the bullet ® in the chapters.
Table 1: Definitions of traditional medicine and related terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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| Traditional medicine  | The sum total of all the knowledge and practices, whether explicable or not, used in diagnosis, prevention and elimination of physical, mental or social imbalance and relying exclusively on practical experience and observation handed down from generation to generation, whether verbally or in writing.  
Traditional medicine might also be considered as a solid amalgamation of dynamic medical know-how and ancestral experience. | WHO 1976: 3-4      |
|                       | Includes a diversity of health practices, approaches, knowledge, and beliefs incorporating plant, animal, and/or mineral-based medicines; spiritual therapies; manual techniques; and exercises, applied singly or in combination to maintain well-being, as well as to treat, diagnose, or prevent illness.  
The comprehensiveness of the term “traditional medicine” and the wide range of practices it encompasses make it difficult to define or describe, especially in a global context. … However, in most cases, a medical system is called “traditional” when it is practised within the country of origin. | WHO 2001: 1-2      |
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Traditional medicine has a long history. It is the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.</td>
<td>WHO, WHO 2019: 8</td>
<td></td>
</tr>
<tr>
<td>Traditional medicine refers to the knowledge, skills and practises based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health and in the prevention, diagnosis, improvement or treatment of physical and mental illness.</td>
<td>WHO Regional Office for Africa</td>
<td></td>
</tr>
<tr>
<td>Conventional medicine</td>
<td>A system in which medical doctors and other healthcare professionals (such as nurses, pharmacists, and therapists) treat symptoms and diseases using drugs, radiation, or surgery. Also called allopathic medicine, biomedicine, mainstream medicine, orthodox medicine, and Western medicine.</td>
<td>National Cancer Institute (NCI), an institute of the National Institute of Health (NIH), USA</td>
</tr>
<tr>
<td>Unconventional therapies</td>
<td>Medical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals.</td>
<td>Eisenberg et al 1993: 246</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Source</th>
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<tr>
<td>Alternative medicine</td>
<td>If a non-mainstream practice is used in place of conventional medicine, it’s considered “alternative”. Treatments that are used instead of standard treatments. Standard treatments are based on the results of scientific research and are currently accepted and widely used. Less research has been done for most types of alternative medicine. Alternative medicine may include special diets, megadose vitamins, herbal preparations, special teas, and magnet therapy. For example, a special diet may be used instead of anti-cancer drugs as a treatment for cancer.</td>
<td>National Center for Complementary and Integrative Health (NCCIH), NIH³</td>
</tr>
<tr>
<td>Complementary medicine</td>
<td>Diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual frameworks of medicine. If a non-mainstream practice is used together with conventional medicine, it’s considered “complementary”.</td>
<td>Ernst et al 1995: 506</td>
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<tr>
<th>Term</th>
<th>Definition</th>
<th>Source</th>
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<td>Complementary and alternative medicine</td>
<td>A broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp and fixed.</td>
<td>OAM 1995 conference (reported in O’Connor 1997: 50)</td>
</tr>
<tr>
<td></td>
<td>A broad domain of resources that encompasses health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the dominant health system of a particular society or culture in a given historical period. CAM includes such resources perceived by their users as associated with positive health outcomes. Boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp or fixed.</td>
<td>IOM 2005: 19</td>
</tr>
<tr>
<td></td>
<td>These practices generally are not considered standard medical approaches. Standard treatments go through a long and careful research process to prove they are safe and effective, but less is known about most types of complementary and alternative medicine. Complementary and alternative medicine may</td>
<td>NCI7</td>
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6 ‘Politically dominant’ was clarified as ‘the social fact that the dominant system has a reputation for efficacy and broad cultural authority as well as dominant (or perhaps even exclusive) access to legislative and social institutional supports’ (O’Connor 1997: 50).

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<th>Term</th>
<th>Definition</th>
<th>Source</th>
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<tr>
<td>Dietary supplements, megadose vitamins, herbal preparations, special teas, acupuncture, massage therapy, magnet therapy, spiritual healing, and meditation.</td>
<td>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. T&amp;CM merges the terms TM and CM, encompassing products, practices and practitioners.</td>
<td>WHO 2019: 8</td>
</tr>
<tr>
<td>Integrative medicine</td>
<td>The practice of medicine that reaffirms the importance of the relationship between practitioner and patient, focuses on the whole person, is informed by evidence, and makes use of all appropriate therapeutic approaches, healthcare professionals, and disciplines to achieve optimal health and healing.</td>
<td>American Board of Integrative Medicine and Consortium of Academic Health Centers for Integrative Medicine</td>
</tr>
<tr>
<td>Healing-oriented medicine that takes account of the whole person, including all aspects of lifestyle. It emphasizes the therapeutic relationship between practitioner and patient, is informed by evidence, and makes use of all appropriate therapies.</td>
<td>Andrew Weil Center for Integrative Medicine, University of Arizona</td>
<td></td>
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<th>Term</th>
<th>Definition</th>
<th>Source</th>
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<td>Integrative health care</td>
<td>Often brings conventional and complementary approaches together in a coordinated way. It emphasizes a holistic, patient-focused approach to health care and wellness—often including mental, emotional, functional, spiritual, social, and community aspects—and treating the whole person rather than, for example, one organ system. It aims for well-coordinated care between different providers and institutions.</td>
<td>NCCIH</td>
</tr>
<tr>
<td>Integrative preventive medicine</td>
<td>The coordinated delivery of evidence-based, conventional and CAM medical practices for the primary, secondary, and tertiary prevention of disease and illness.</td>
<td>Jonas and Calabrese 2018: 1</td>
</tr>
<tr>
<td>Holistic medicine</td>
<td>The art and science of healing that addresses the whole person—body, mind, and spirit. The practice of holistic medicine integrates conventional and alternative therapies to prevent and treat disease, and most importantly, to promote optimal health. This condition of holistic health is defined as the unlimited and unimpeded free flow of life force energy through body, mind, and spirit. Holistic medicine encompasses all safe and appropriate modalities of diagnosis and treatment. It includes analysis of physical, nutritional, environmental, emotional, spiritual and lifestyle elements.</td>
<td>American Holistic Health Association⁹</td>
</tr>
<tr>
<td></td>
<td>It emphasizes prevention; concern for the environment and the food we eat; patient responsibility; using illness as a creative force to teach people to change; the ‘physician, heal thyself’ philosophy; and appropriate alternatives to orthodox medicine.</td>
<td>Borins 1984: 101</td>
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WHO definitions of traditional medicine

International efforts to define TM go as far back as February 1976, when the WHO Regional Office for Africa (WHOROA) convened a meeting of regional experts in Brazzaville (the Republic of the Congo), which agreed on the definition ‘WHO 1976’ in table 1. Forty-three years later, however, we still have a relative and negative definition (WHO 2019, table 1), despite changes in the specific terminology. For instance, the phrase ‘whether explicable or not’ has persisted in WHO’s standard definition of TM, reflecting – and possibly reinforcing – the widespread negative perception that it is potentially inexplicable / irrational / unscientific – and everything that such a perception implies (unsafe, etc.). Interestingly, WHOROA has removed this phrase from the TM definition that it has put up on its website (table 1). On the other hand, what should have been retained, even if in a modified form, has been removed from both the standard WHO as well as WHOROA definitions – the additional sentence in the 1976 definition, that ‘traditional medicine might also be considered as a solid amalgamation of dynamic medical know-how and ancestral experience’. Inclusion of the word ‘dynamic’ could have taken off some of the negativity associated with TM, and made it sound progressive rather than something frozen in time. This is also factual. TCSM have modernized over time (Mukharji 2016). In fact, in China, even as TM underwent state-sponsored modernization and moved towards modern science during the 20th century, practitioners of WM were trying to align themselves with traditional styles to enhance their acceptance in the local population. Furthermore, although the term ‘ancestral experience’ might not sound very progressive and positive, one could as well argue that ‘today, in the West, Chinese medicine is successful in large part because people perceive it as embodying the accumulated wisdom of a five-thousand-year-old culture, able to communicate eternal truths about the body, unlike the seemingly fickle here-today-outdated-tomorrow approach of scientific medicine’ (Andrews 2014: 4). The same could be said about the widespread popularity of other TCSM as well in the West, particularly Yoga.

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10 A volume to introduce CAM to general practitioners (GPs) in the UK admits that ‘patients are becoming increasingly vociferous about the limits of conventional medicine, and more aware of the possible benefits of complementary medical techniques: yet the benefits claimed for some techniques simply do not stand up to close scrutiny’ (Lewith, Kenyon and Lewis 1996: v). This is a classic case of widespread public acceptance and institutional/technical hesitance towards TM.

11 According to the National Health Interview Survey (NHIS), Yoga ‘was the most commonly used complementary health approach among U.S. adults in 2012 (9.5%) and 2017 (14.3%)’ (Clarke et al 2018: 1). Among children aged 4–17 years too, Yoga was the most highly used complementary health approach in 2017 (8.4%), up from being the second highest in 2012 (3.1%), according to
If the ‘ancestral experience’ / ‘accumulated wisdom’ perception of TM has contributed ‘in large part’ to their success in the West vis-à-vis the ‘seemingly fickle here-today-outdated-tomorrow approach of scientific medicine’, one could argue that – on the basis of a purely practical perspective – following the methodology of the latter (as called for in the G20 and other forums – ‘scientifically proven’) could end up diminishing the popular appeal of TM. This should be weighed vis-à-vis the potential benefits of making TM ‘scientifically proven’ – for instance, higher acceptance of TM by policymakers, modern medicine practitioners, health insurance companies and others, leading to higher institutionalization, expenditure coverage and commerce. Institutionalization / mainstreaming of TM is presently quite low, despite their public acceptance being quite high, which means most TM users don’t inform their mainstream doctors about TM use, and largely pay out-of-pocket (OOP) for their use, given their limited insurance coverage. A cost-benefit analysis of following / not following the scientific approach for TCSM needs to be done from a purely practical perspective. However, from the principled perspective of patient safety, regulatory requirements of safety, efficacy and quality are non-negotiable.

All WHO definitions of TM include the term ‘practices’ / ‘practises’ (WHOROA). Some of the TCSM are completely drugless – for instance, naturopathy, Yoga, meditation and prayers – while others – for instance, Ayurveda and Unani – include prescriptions beyond drugs. Even allopathic doctors do. While non-drug and non-food health interventions obviously do not fall under the ambit of health regulation (drug and food), calls for scientific evidence to assess their efficacy particularly, through clinical trials / studies13 (CTs), have

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12 Yoga is defined as ‘a discipline to improve or develop one’s inherent power in a balanced manner’ (Ministry of AYUSH, Government of India). https://bit.ly/2Nz07mD (27/8/2019, 10:18 hours).


13 According to the NIH, a clinical trial / study is ‘a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes’, defined as ‘the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life’. https://grants.nih.gov/policy/clinical-trials/definition.htm (21/8/2019, 12:19 hours).
been made. The website www.clinicaltrials.gov lists 819 CTs for meditation, 612 for Yoga, 17 for naturopathy and 14 for prayer as ‘intervention/treatment’.

In the interest of evidence-based policy and prescription, we do need evidence for all sorts of health interventions. However, it is a matter of debate if evidence for non-drug and non-food practices – or, for that matter, more broadly for health and non-health sector policies and programs, including action on what is widely referred to as the ‘social determinants of health’ – should necessarily be scientific / clinical in nature. Health, as defined in the WHO constitution (1948), and to which WHO ‘remains firmly committed’, ‘is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’. The WHO 1976 TM definition refers to its function in ‘diagnosis, prevention and elimination of physical, mental or social imbalance’, which is in sync with the WHO definition of health. We recommend that this phrase from WHO’s 1976 definition be reinstated in the definition of TM, while insistence on scientific / clinical evidence for non-drug and non-food aspects of TM be reconsidered. The G20 and other international forums should call for developing an alternative evidence framework for at least such, if not all, aspects of TM.

At the same time, the G20 and other forums should consider if TM’s ‘knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures’ (2019 definition) can be leveraged not only for complementary / integrative health practice, but also for ‘diversifying the conceptual frameworks of medicine’ (Ernst et al 1995: 506) and making science itself more inclusive and ‘less homogeneous’. The insistence of the dominant medical and scientific frameworks on its ‘indigenous’ Western methodology and approach – expecting all else to come up to its standards – is parochial and exclusionary.

14 ‘A database of privately and publicly funded clinical studies conducted around the world … ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine’, as the website says.

15 416 in North America (374 in the US, 42 in Canada, 1 in Mexico), 73 in Europe, 22 in East Asia, 18 in South Asia (all in India), 13 in South America, 7 in the Middle East, 3 in Southeast Asia and 1 in the Pacific. These studies were done / are being done for mental disorders and psychotic disorders (121 each), pain (86), depression (81), quality of life (80), etc. On the other hand, while 13 studies were listed for Ayurveda – 6 in North America (all in the US), 4 in Europe and 3 in South Asia / India – there were 2,359 for Chinese herbs and medicines. ClinicalTrials.gov (21/8/2019, 12:54 hours).

16 https://www.who.int/about/who-we-are/constitution (27/8/2019, 11:47 hours).

While Yoga was the most highly used complementary health approach among US adults and children (footnote 12), Ayurveda use has been extremely low among both groups, as per NHIS surveys 2002, 2007 and 2012 (Black et al 2015; Clarke et al 2015). This is not about higher preference for non-drug / non-food TCSM practices because the ‘nonvitamin, nonmineral dietary supplements’ category among complementary health approaches had the highest prevalence in these surveys among both US adults and children. According to US National Health Expenditure 2007 data, CAM out-of-pocket expenditures of USD 33.9 billion included USD 14.8 billion on nonvitamin, nonmineral, natural products (NVNMNP) alone, USD 11.9 billion on CAM practitioner visits and USD 7.2 billion on ‘other CAM’, which included Yoga, tai chi, qi qong classes; homeopathic medicine and relaxation techniques.18 Two suggestions can be made in this context. One, both ‘soft’ (drugless) and ‘hard’ (drug) TCSM should be promoted. Both are of practical benefit from different perspectives. Two, reasons for lower utilization of Ayurveda and other hard Indian TCSM should be explored. One possible reason could be that people are less inclined to ‘consume’ hard TCSM, given the challenges of evidence and the ensuing lack of confidence, while they might feel TCSM practices won’t really harm them. It is possible that there is much higher evidence available for TCSM practices like Yoga, if we are to go by the number of Yoga CTs (quoted above). If this is the case, evidence is key. And India should insist in the G20 and other forums that appropriate evidence frameworks of safety, quality and efficacy are developed for TCSM. If there is consensus among experts that science-based clinical evidence is essential and acceptable, the Government of India should promote developing scientific evidence for its TCSM. The G20 and other forums should provide technical and financial R&D support to developing countries in both cases. Not just UHC / PHC, but also R&D, as discussed in the G20 and other related forums, should encompass TCSM.

The challenge of an operational and positive definition

The WHO 2001 TM definition lists various types of TCSM and argues that the ‘comprehensiveness of the term “traditional medicine” and the wide range of practices it encompasses make it difficult to define or describe’ it. This has been a long-standing issue and continues to be one to this day. A clear, consistent and consensual definition is needed for a wide range of classificatory and

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operational purposes. However, it is equally important for the definition to be positive, which too has been quite a challenge so far. Several definitions and nomenclatures have been tried over time. Let us discuss some of the most prominent ones here.

Following the popularity of TM in the American public, the US Congress established the Office of Unconventional Therapies (OUT) in 1992 – renamed as the Office of Alternative Medicine (OAM), then as National Center for Complementary and Alternative Medicine (NCCAM), and finally as the NCCIH. The renaming of the organization over time reflects shifting understanding and search for a more acceptable nomenclature in the US. However, a negative conceptualization has continued, at least in some quarters, as we shall see. The term ‘unconventional therapies’ was conceptualized negatively, either vis-à-vis ‘conventional medicine’, or as ‘medical interventions’ that are not taught / offered widely in US medical schools / hospitals (table 1). This gave way to the term ‘alternative medicine’ (as reflected in the name, OAM), which was again negatively conceptualized in both the NCCIH and NCI definitions – ‘non-mainstream practice’ and ‘used instead of standard treatments’ respectively (table 1). Several scholars from University of Exeter (UK)’s Centre for Complementary Health Studies made a similar argument about ‘complementary medicine’ in 1995 – that prevalent definitions were negative, ‘the abundance of publications on the subject sharply contrasts with the lack of a valid definition’, and that ‘an inclusive, positive’ definition was required. They claimed that ‘a consensus definition was finally found’ (in table 1: Ernst et al 1995). While the NCCIH continues to define the term ‘complementary medicine’ (CM) negatively (‘non-mainstream practice’), the Exeter scholars offered a definition which seems to be very positive and reasonable, and among the best of all definitions of TM and related terms that we have today. It refers to health care as a ‘common whole’ – with possibly a common goal – rather than a competitive one, divided between conventional and unconventional / alternative / traditional camps. Quite significantly, and realistically, it refers to CM as ‘satisfying a demand not met by orthodoxy’. Although TM is historical and traditional in terms of its origins, its widespread revival and acceptance in recent times makes modern biomedicine ‘orthodox’ and TM ‘unorthodox’, called upon to fill a vacuum in the former or ‘diversifying the conceptual frameworks of medicine’. This is a positive rather than a negative, and should be celebrated and portrayed as such. The uniqueness of TM should not be compromised. However, evidence of their safety, efficacy, quality, etc.
should be absolutely non-negotiable. What type and process of evidence should be applied to TM remains a matter of acrimonious debate.  

Coming back to the US context, the further renaming of OAM as NCCAM seems to reflect change in the preferred nomenclature from alternative medicine to CAM. In April 1995, the erstwhile OAM organized a CAM Research Methodology Conference, with a Panel on Definition and Description, which accepted its combination of the terms ‘alternative’ and ‘complementary’ medicine as CAM, and came up with a definition of CAM (in table 1: OAM 1995 conference) in order to delineate the ‘research jurisdiction’ of the OAM. To avoid a negative definition, the panel started out its definition with a ‘positive wording’ (O’Connor 1997). Nevertheless, a sister institute of NCCIH, the NCI – the oldest and one of the 27 institutes / centers of the NIH, world’s largest biomedical research agency – continues to define alternative medicine as well as CAM negatively – as ‘used instead of standard treatments’ and ‘not considered standard medical approaches’ respectively. Celebratory of ‘standard’ conventional medicine, it argues that ‘less research has been done for most types of alternative medicine’, ‘less is known about most types of complementary and alternative medicine’ in

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19 An extreme group like Science-Based Medicine (SBM) refers to TM as ‘pseudomedicine’ and ‘pseudoscience’, given their ‘scientific implausibility’, and see research on them as ‘wasteful spending’. https://bit.ly/2ZhNnrn (27/8/2019, 18:59 hours), and clinical trials on them as ‘testing whether magic works’. They ‘argue that what is needed is science-based medicine rather than evidence-based medicine’ (Gorski and Novella 2014), closing the door for any source of evidence other than the scientific. Even a proponent of complementary medicine like Edzard Ernst, referred to above (University of Exeter), wrote a column in The Guardian, ‘There is no scientific case for homeopathy: the debate is over’ (12/3/2015). https://bit.ly/2qjYTuU (27/8/2019, 19:13 hours). He mentions that a UK House of Commons select committee report of 2010 concluded that homeopathy was no more than a placebo and that the NHS should stop funding it. UK government, nevertheless, ‘felt that, if patients want homeopathy, they must have it on the NHS’, which the author, in turn, felt was a waste of the taxpayers’ money. ‘Undeterred by the evidence, the public continue their long and intense love affair with homeopathy’, he regretted. In 2016, the US Federal Trade Commission ruled that homeopathic medicine manufacturers should add a disclaimer on their OTC drug packaging that – 1) ‘There is no scientific evidence that the product works’, and 2) ‘the product’s claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts’. https://bit.ly/2f71t3j (27/8/2019, 19:13 hours). Whose choice should medicine be remains a moral and practical concern – that of ‘experts’ or scientists or that of the people / users / consumers themselves, who are assumed to lack the technical knowledge and expertise to decide the safety, efficacy and quality of medicines on their own, hence the need for regulatory and medical experts? Lay people definitely lack the technical expertise to assess specific drugs, which is why we need drug regulators and doctors. However, they choose from among the different systems of medicine based on their individual preferences / assessments vis-à-vis their philosophies, epistemologies and approaches. And their choices in this regard should be considered utmost, not that their choice of specific drugs, especially in the OTC category, could be ignored, if they were to have a choice.
its respective definitions. Elsewhere, it states that ‘some CAM therapies have undergone careful evaluation and have been found to be safe and effective. However there are others that have been found to be ineffective or possibly harmful’, that ‘natural does not mean safe’ always.20 It needs to be mentioned here that the NCI has been evaluating information about CAM since the early 1940s, much before OUT came into existence, and established its own CAM office – the Office of Cancer Complementary and Alternative Medicine (OCCAM) – in 1998 in order ‘to coordinate and enhance’ its CAM activities21 for ‘prevention, diagnosis, and treatment of cancer, cancer-related symptoms and side effects of conventional cancer treatment’.22 There seems to be a lack of consensus within the NIH on CAM. The NCCIH has been heavily criticized by proponents of conventional medicine.

A decade after the 1995 OAM conference, the Health and Medicine Division of the US National Academies argued that ‘a lack of consistency in the definition of what is included in CAM is found throughout the literature’ (IOM 2005: 17), and that ‘no clear and consistent definition of CAM exists’ (19). It developed a modified version of the definition (table 1: IOM 2005) adopted at the 1995 OAM conference. Interestingly, both the OAM 1995 and the IOM 2005 CAM definitions refer to CAM as ‘other’ vis-à-vis the ‘dominant health system’, which hints at the political economy dynamics between modern and traditional medicine systems in modern times. In the past, though, ‘Western medicine was itself “complementary and alternative” to Ayurveda in 19th-century India’ (Jonas and Calabrese 2018: 1), for instance. We will discuss the history and political economy of medicine systems in some detail in the next section.

After IOM’s 2005 definition, the Cochrane Complementary Medicine published its own operational definition of CAM by classifying a list of therapies as ‘complementary, alternative or integrative’23 in a 2011 paper. Nevertheless, in 2017, one paper argued that ‘presently, there is no agreed upon definition of CAM or for its pattern of use. Increasingly, even the term itself, “complementary and alternative medicine,” has been replaced by newer descriptors such as “complementary health approaches,” “integrative medicine,” or “integrative health”. This inconsistent operationalization of CAM has and will continue to alter the core activities of public health practice. For example, surveillance and

benchmarking of key health indicators or the volume of services utilization could fluctuate depending on how CAM is defined or measured. This, in turn, affects local planning of health and human services’ (Robles, Upchurch and Kuo 2017: 2). We are back to zero, so it seems.

The G20 should call for the development / adoption of a clear, consistent and consensual theoretical and operational definition of TCSM which can be used for international, regional and national public policy and operational use (for example, for surveys, literature reviews, budgetary allocation, expenditure assessment, human resources, governance, UHC, PHC, health sector regulation, insurance, etc.).

We propose that one of the following or a new definition based on the following should be considered – a) the definition of ‘complementary medicine’ put forth by Ernst et al (1995), b) one of the definitions of ‘integrative medicine’, c) of ‘integrative health care’ by NCCIH, d) the definition of ‘holistic medicine’ offered by the American Holistic Health Association.

Nomenclature

The term ‘traditional’ renders itself vulnerable to the ‘traditional / modern’ or ‘traditional / scientific’ binary, as something which is ‘not’ modern / scientific. This is not always negative and detrimental, if overwhelming public interest in TCSM in the US and other developed countries is any indication. The word modern, on the other hand, has widespread acceptance, as something which relates ‘to the present or recent times as opposed to the remote past’, ‘characterized by or using the most up-to-date techniques, ideas, or equipment’ (Oxford dictionary). It also implies that it is ‘scientific’ and ‘rational’ – and, given the binary perception, the word ‘traditional’ is perceived to be otherwise. For instance, the Declaration of Astana 2018 refers to ‘scientific as well as traditional knowledge’ (scientific as well as non-scientific?) to strengthen PHCs and UHC and improve health outcomes. Figure 1 below depicts one of the widespread perceptions and portrayals of TM.

Modern science itself has ancient roots. ‘Western science is what it is because it successfully built upon the best ideas, data, and even equipment from other cultures’ (Teresi 2002: 7). ‘Chemical knowledge with regard to medicine pervades all ancient and indigenous cultures. The Chinese documented herbal cures beginning in around 3000 B.C.; the Assyrians collected some one thousand medicinal plants over their fifteen-hundred-year civilization; the Indians, Egyptians, and later the Greeks left the world a huge legacy of both herbal cures and techniques. Much of this knowledge has laid the foundation for Western medicine’
(Teresi 2002: 314). Despite this, science is widely seen as ‘modern’, while the contributions on which it was built and developed are termed as ‘traditional’, involving the perception of being unscientific. One of the major reasons for the success of science is that it built upon historical legacy and moved ahead – and continues to do so. Evidence and innovation are the defining features of science, which is not necessarily the case or general perception about the TCSM – with the limited exception of the Chinese.

Figure 1: A portrayal of traditional medicine

Source: WHO Regional Office for Africa website.

Through constant development and innovation as well as change of TM nomenclature, the ‘traditional / modern’ or ‘traditional / scientific’ binary could be addressed – and with it, the widespread perception of TM as something not modern / scientific. We do not necessarily have to accept the Western / natural scientific definition of science, but as ‘continuous and systematic progress’ (Patwardhan 2014: 2) in a generic sense.24

As far as nomenclature is concerned, we recommend two terms for traditional and modern systems of medicine – 1) ‘integrative health care’, and 2) ‘holistic health care’. One of these could be proposed by the Government

24 UK’s Science Council defines science as ‘the pursuit and application of knowledge and understanding of the natural and social world following a systematic methodology based on evidence’. https://bit.ly/2Mz4qyy (9/8/2019, 12:04 hours). We can take this as a working definition for our purpose here.
of India to be considered at G20 and other forums. The term ‘medicine’ refers to drugs, and does not quite capture the drugless systems and dimensions of TCSM, hence we recommend the term ‘health care’ instead. Although the term ‘holistic’ is widely used for TCSM, that is also a problem since it would give out the impression of it being only TCSM and not inclusive of modern medicine. On the other side, the term ‘integrative’ is already in wide use in the US and elsewhere, and would have more acceptability from these countries.

**Contexts**

In this section, we discuss certain contexts and related recommendations which it would be helpful to bear in mind for the promotion of TCSM. Since the report focuses on the G20 context, we begin with that. Subsequently, we discuss the SDG context, which has emerged as the broad framework for discussions on different dimensions of development in the G20 and other international forums. We have made references to the philosophy, epistemology and the political economy of traditional and modern medical systems. We discuss them in some detail here.

**G20**

G20 leaders and health ministers expressed their willingness towards the inclusion of ‘scientifically proven traditional and complementary medicine’ under UHC programs in their declarations during the Argentinian Presidency in 2018. Under Japanese Presidency this year, the G20 leaders’ summit has happened in Osaka on 28-29 June 2019, and a joint session of G20 health and finance ministers took place, for the first time, on the sidelines of the summit on 28 June to discuss financing of UHC. The session did not lead to any formal outcome document, so we do not know what was discussed. In his address, the UK Chancellor of the Exchequer, Philip Hammond, reemphasized the importance of focusing on antimicrobial resistance (AMR). India’s Union Minister for Health and Family Welfare, Harsh Vardhan, talked about the ‘plurality of pathways towards the achievement’ of UHC, an indirect reference to the inclusion of TCSM. G20 leaders argued for ‘traditional and indigenous knowledge’ in the context of climate change in their 2019 declaration. Although it does not specifically mention

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TCSM, it did refer to related themes such as UHC, PHC, ‘health promotion, prevention and control of communicable and non-communicable diseases … community-based integrated health’. What is of concern is the fact the 2019 G20 health ministers’ declaration makes no reference to TCSM at all, and if India has to make it a central focus of its G20 Presidency in 2022, it should start doing the groundwork during the upcoming Saudi Presidency in 2020 and the Italian Presidency in 2021.

**SDGs**

TCSM hold promise for the achievement of SDGs in several ways. At a specific level, they could help achieve SDG 3 – ‘ensure healthy lives and promote well-being for all at all ages’. Promotion of health and well-being and prevention of non-communicable diseases (NCDs) in particular are associated with TCSM much more than the treatment-oriented, modern system of medicine. SDG target 3.8 is about UHC. With their community networks, TCSM could help enhance the coverage of essential health services (SDG indicator 3.8.1), contain large population as well as government health care expenditure (SDG indicator 3.8.2), given their focus on health promotion / prevention as well as cost-efficacy. According to a World Bank report (2019), ‘3.6 billion people do not receive the most essential health services they need, and 100 million are pushed into poverty from paying out-of-pocket for health services’ (6). Global health care expenditure is projected to increase from USD 7.7 to 10.1 trillion during 2017-22 – at an annual rate of 5.4% compared to 2.9% during 2013-17 (Deloitte 2019). While out-of-pocket health care expenditures are pushing people into poverty, countries with high UHC coverage have long been concerned about rising health care expenditure – a lesson for those moving toward UHC. At the same time, most developing countries would miss their UHC and other SDG targets unless urgent steps are taken to strengthen their health financing (World Bank 2019). Affordable approaches to the achievement of UHC – and thereby of not only SDG 3, but also SDG 1 (poverty), 2 (zero hunger), 10 (reduced

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27 Coverage of essential services vis-à-vis 14 tracer indicators related to – 1) reproductive, maternal, newborn and child health, 2) infectious diseases, 3) NCDs, 4) service capacity and access, among the general and most disadvantaged populations (WHO, 9 May 2018). According to WHO Global Report on Traditional and Complementary Medicine 2019, TCSM could ‘make a significant contribution to the goal of UHC by being included in the provision of essential health services’ (WHO 2019: 10).

28 Proportion of population with large (greater than 10% and greater than 25% of total household expenditure or income) household expenditure on health (WHO, 9 May 2018).
inequalities) and others – are high on the global policy agenda. No wonder, there is a resurgence of interest in PHC – regarded as a cost-effective approach to UHC – at the international level, the Astana Declaration 2018 revisiting the Alma-Ata Declaration 1978 as well as G20 and G7 meetings of 2018 and 2019 being examples.

At a general level, TCSM tend to adopt a holistic approach to health and well-being, which is being increasingly appreciated and adopted, with the recognition of multiple morbidities and soft health challenges like musculoskeletal and mental disorders, whose burden has shot up from 82 million years lived with disability (YLDs) each in 1990 to 136 and 123 million respectively in 2017 globally (Global Burden of Disease / GBD). A holistic approach is in sync with the ‘integrated’, ‘indivisible’ and ‘balanced’ orientation of the 2030 Agenda vis-à-vis the economic, social and environmental dimensions of sustainable development. At the same time, the crisis of modern medicine from this perspective is clearly reflected in the challenge of AMR. However, while AMR continues to be the single most important health concern for G20 leaders, finance and health ministers, the potential of TCSM in this regard has not been discussed so far. The G20 continues to emphasize R&D vis-à-vis modern antimicrobials, and quite rightly. They have been of enormous support in reducing the burden of death and disease and enhancing life expectancy. Nonetheless, while ‘irrational use’ of antibiotics in humans and animals, for instance, has been widely regarded as the primary culprit for antibiotic resistance (ABR), the way in which antibiotics work seems to be a part of the problem, as illustrated in figure 2. In any case, AMR R&D should include research on the potential of TCSM in tackling and preventing AMR / ABR. Dr Tu Youyou won the Nobel Prize in Physiology / Medicine 2015 for extracting artemisinin, a substance that inhibits the malaria parasite, based on her studies of traditional Chinese herbal medicines. TCSM have been extensively used for dengue, including in India. Another example is a Dutch Research Consortium that came up in 2015 to ‘develop and investigate safe and effective CAM treatments for infectious diseases of humans (and animals)’ (Kok

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29 Multiple morbidities / multimorbidity is the ‘coexistence of several chronic diseases’. It has been argued that ‘one of the most important tasks in clinical medicine today is managing multimorbidity. This requires an evolution away from the single disease focus that has dominated [modern] medicine for centuries’ (Ording and Sørensen 2013: 199). In India, the issue of multimorbidity was highlighted when former Union Finance Minister, (Late) Arun Jaitley, was being attended by a multi-disciplinary team of doctors at AIIMS, New Delhi. https://bit.ly/33CVUUF (19/8/2019, 12:21 hours).

et al 2015). The G20 has not taken cognizance of these developments so far vis-à-vis AMR.

- There is very little discussion / reference to TCSM in the context of SDGs. India should call for exploring the potential and promotion of TCSM vis-à-vis SDGs in general – including the protection and promotion of medicinal plants – and SDG 3 in particular. Environmental concern and a holistic approach are at the core of SDGs – these defining features of TCSM, especially herbal medicines, should be highlighted in international forums and included in the global environmental movement.

- India should call for the inclusion of TCSM under the ambit of AMR R&D in the G20 as well as elsewhere.

- With regard to SDG 3 on health and SDG 3.8 on UHC in particular, India should encourage the optimal – rather than the optional (as is presently the case) – leveraging of TCSM.

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31 The Association of Academies and Societies of Sciences in Asia, South Korea and the Pakistan Academy of Sciences jointly organized a regional workshop themed, ‘Complimentary medicine as an answer to challenges faced in achieving Sustainable Development Goals’ (19-21 August 2019, Islamabad).

32 SDG 2.5 talks about maintaining ‘the genetic diversity of seeds, cultivated plants’ as well as the promotion of access to and ‘fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge’. However, SDG indicator 2.5.1 refers to plant genetic resources ‘for food and agriculture’, but not medicinal purposes. A UNDP project, ‘Mainstreaming conservation and sustainable use of medicinal plants in three Indian states’, in partnership with the Ministry of Environment and Forests, Government of India, funded by the Global Environmental Finance (GEF) tried to prevent biodiversity loss in Arunachal Pradesh, Chhattisgarh and Uttarakhand and avert the loss of a major source of affordable health care at the national and international levels. Further information about the project can be accessed at: https://bit.ly/33AjHEu (15/8/2019, 15:29 hours). Medicinal plants should also be covered under the SDG indicator 2.5.1. The National Medicinal Plants Board (NMPB), Ministry of AYUSH, should be consulted on this issue.

Science and regulatory concerns are often raised vis-à-vis TCSM – ‘scientifically proven traditional and complementary medicine, assuring the safety, quality and effectiveness of health services’ (G20 leaders’ and heath ministers’ declarations 2018), for example. One could argue that the scientific epistemological and drug regulatory frameworks, used extensively in the case of modern medicine, may not be justifiably applied to TCSM that are rooted in a different philosophy and epistemology. One of the early documents of the WHO on traditional medicine is reflective of this epistemological / methodological dilemma. ‘Long historical use of many practices of traditional medicine, including experience passed on from generation to generation, has demonstrated the safety and efficacy of traditional medicine. However, scientific research is needed to provide additional evidence of its safety and efficacy. In conducting research and evaluating traditional medicine, knowledge and experience obtained through the long history of established practices should be respected’ (WHO 2000: 1).

34 According to Dr Bhushan Patwardhan, Vice-Chairman of University Grants Commission (UGC), ‘continuous research on safety, quality and efficacy of Ayurvedic drugs and procedures is needed. … No tradition is a static entity … while accepting modern tools and technologies, it is equally important to respect epistemological value of knowledge system like Ayurveda. Embracing modernity by Ayurvedic community does not mean blind acceptance of Western logic and reductive methodologies … Evidence-based Ayurveda needs appropriate blends of modern science, rigorous trial methods and observational studies. Arguably, the nature of evidence in case of Ayurveda may be different from that of Western biomedicine’ (Patwardhan 2014: 2). He further says: ‘certainly, there is a need to develop appropriate research methodology for complex whole system, whole-person-centered clinical trials as an alternative to RCTs’ [randomized controlled clinical trials]. Nevertheless, the ‘non-suitability of RCTs should not be used as an excuse for avoiding rigorous scientific research and clinical documentation’ (Patwardhan 2014: 4). This seems
It appears to be trying to please both the advocates of traditional medicine and science, but ends up raising several questions – and probably displeasing both. For instance –

1) How does ‘long historical use’ and inter-generational ‘experience’ demonstrate ‘the safety and efficacy of traditional medicine’? Was any evidence gathered vis-à-vis their safety and efficacy pre- or post-use?

2) If their safety and efficacy has already been historically and inter-generationally demonstrated, why do we need ‘additional evidence’?

3) How can ‘scientific research’ yield such evidence when ‘traditional’ medicine, by the very term, belongs to the pre-modern / pre-scientific period and is probably not amenable to the scientific epistemology / methodology or to the scientific notion of humans and their health, its causes, ways of tackling ill-health, etc.?

4) Why – and how – exactly should science respect ‘the long history of established practices’ in ‘evaluating traditional medicine’?

Although epithets like ‘complementary’ and ‘integrative’ are widely used for traditional medicines to characterize the role they are supposed to play vis-à-vis modern medicine, there are conceptual and operational challenges involved. Lakshmi et al (2015) argue that ‘the coexistence of numerous systems of medicine … is often fraught with tensions related to the coexistence of philosophically disparate, even opposed, disciplines, with distinct and unaligned notions of evidence and efficacy, and ethical and operational challenges of the administration of a plural workforce’ (1067). This is not just a theoretical concern, but has played out in the open in India as well as elsewhere – the protests by doctors of modern medicine against mainstreaming traditional medicine practitioners. The ‘integrative management’ of a particular disease is a ‘far bigger challenge’ than realized, with potentially fatal implications. Drug-drug interaction (DDI) studies are done in the case of modern medicine, and modern medicine practitioners are cautious about potential DDI while prescribing medicines. However, there is little to almost no discussion, research, understanding and guidelines on DDIs involving traditional and modern medicines. Many patients who use both

35 It has been argued with reference to Ayurveda, but applies to other TCSM too, that the ‘basic concepts of Ayurveda should not be distorted to suit convenience or availability of biomedical research models … However, the onus of developing suitable models to build necessary evidence must be voluntarily accepted by the Ayurveda sector. Some efforts in the direction to conduct the whole system clinical trials are already in progress’ (Patwardhan 2014: 5).
do not inform their doctors and tend to buy the TM particularly over the coun-
ter (OTC) for self-medication with incomplete information and care about po-
tential risks. According to Dr Markus Joerger (Cantonal Hospital, St. Gallen, Switzerland), ‘the low risk perception associated with CAMs among patients is a big issue’. In this context, Dr Audrey Bellesoeur (University Paris Descartes, France) feels that a better understanding of DDIs is ‘necessary today for a real personalised medicine’.36

We propose a 7-principle framework to enhance wider acceptability and practice of TCSM, and strengthen their complementary / integrative capac-
ity vis-à-vis modern medicine.

1) While countries and civilizations can lay historical claims to their respective TCSM, they should desist from exclusionary attitudes,37 and make them open to all to make them evolutionary, resilient and universal. Civilizations grow and progress building upon developments in and borrowing from other civilizations. For instance, though the Unani system had its origins in ancient Egypt and Babylon, the Greeks owned and built upon it, and so did the Arabs and Persians in the medieval period. ‘During its journey wherever it passed, the system enriched its repository by imbibing which was best of the healthcare systems in vogue in those countries. The system after getting further developed in the Arab and Persian lands came to India around the 8th century and took deep roots in the Indian civilization. The Indian scholars and physicians have made significant contributions to the further advance-
ment of this system’ (Ministry of AYUSH 2016: iii). An open and universal rather than a parochial and exclusionary approach to TCSM is needed for their own health and well-being. Of 612 Yoga CTs (footnote 16), less than 3% are / were being conducted in India. Its universal popularity and research uptake would perhaps not have been possible without an open attitude to-
wards it. Such openness is, first and foremost, needed in the origins, and only then be expected from a wider set of potential stakeholders.

2) TCSM should be supported by G20 and other forums to revisit / modernize aspects of their philosophy, epistemology, understanding of humans, health,
well-being and disease, diagnostics, etc. than can be revisited / modernized without compromising on what is reasonably regarded as their essential and eternal aspects.38

3) A framework of evidence for TCSM should be developed, which is sensitive to their essential and eternal aspects while being cognizant of later / recent developments.39

4) India should call for developing harmonized conceptual and operational frameworks so that TCSM and modern medicine can work within a complementary / integrative framework, without – or at least, minimizing – the ‘tensions’ referred to above.40

5) Rigorous systematic reviews of TCSM41 should be promoted to facilitate evidence-based TCSM health care decision-making at policy, point-of-care and other levels.

38 ‘Ayurveda was meant to be open for new ideas, principles and knowledge for continuous and systematic progress. However, its progression seems to be stalled during the last several centuries resulting in chronic stagnancy of today. Heritage pride and past glory-based emotional attitudes seem to be predominant among practitioners as against evidence-based quest of scientific research. There seem to be an evident complacency, defensive and dogmatic attitude and often pure sentimentalism rather than a pragmatic scientific outlook’ (Patwardhan 2014: 2).

39 ‘The clinical evaluation of herbal remedies within the specific framework of rigorous clinical pharmacological principles, done without trampling on the concepts of traditional systems of medicine, is an important challenge’. And, ‘There is an urgent need to develop … research methods that can be used to assess the value of traditional medicines’ (Chaudhury et al 2007: 389 and 400).

40 According to Patwardhan et al (2015), ‘the true spirit of integration is in avoiding the temptation of taking any sides—be it modern medicine, Ayurveda, Yoga, or any other system. True integration is about a scientific and unbiased attempt to strike a mutual, trust-based balance between the various systems in the best interest of the people’ (331). Elsewhere, Patwardhan (2014) mentions that ‘the need to define a common model of health and disease between the western and eastern knowledge systems has been pointed out earlier’ (4). Concrete work is needed in this direction.

41 Cochrane defines systematic reviews as ‘attempts to identify, appraise and synthesize all the empirical evidence that meets pre-specified eligibility criteria to answer a specific research question’. Those who conduct these reviews ‘use explicit, systematic methods that are selected with a view aimed at minimizing bias, to produce more reliable findings to inform decision making’. https://bit.ly/2L76ifZ (30/8/2019, 11:05 hours). Cochrane is a global network of researchers, professionals, patients, carers and people interested in health. It owns Cochrane Library (CL) of databases with ‘different types of high-quality, independent evidence to inform healthcare decision-making’; Cochrane Database of Systematic Reviews (CDSR), ‘the leading resource for systematic reviews in health care’; Cochrane Clinical Answers (CCAs), which ‘provide a readable, digestible, clinically-focused entry point to rigorous research from Cochrane Reviews … designed
6) TCSM-related indicators should be included in existing health and related surveys. Alternatively, there should be dedicated TCSM surveys on TCSM use, reasons for use / non-use, background characteristics and health status of users, expenditures, etc. regularly.\(^42\) Desirably, these indicators and surveys should be standardized as much as possible and also have a qualitative dimension, given the subjective nature of non-physical aspects of health, well-being as well as health-seeking behaviors.\(^43\)

7) There should be well-defined regulatory frameworks for TCSM products, practices, practitioners, etc. as well as a Health Technology Assessment (HTA) methodology for TCSM inclusion in health programs, taking above proposals into consideration.

**Political economy**

Behind the philosophical and practical is the problem of political economy. WHO Director-General, Tedros A Ghebreyesus, tweeted ahead of joining G20 leaders at the 2019 Osaka Summit – ‘health is a political choice’.\(^44\) Health care is not just a political, but a political economy choice. The OAM 1995 and the

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\(^{42}\) The existing ‘International Complementary and Alternative Medicine Questionnaire’ (I-CAM-Q) could be considered.

\(^{43}\) Cochrane reviews integrate quantitative and qualitative evidence. ‘A synthesis of evidence from qualitative research can explore questions such as how do people experience illness, why does an intervention work (or not), for whom and in what circumstances? In reviews addressing healthcare delivery, it may be desirable to draw on qualitative evidence to address questions such as what are the barriers and facilitators to accessing healthcare, or what impact do specific barriers and facilitators have on people, their experiences and behaviours?’, etc. \(\text{https://bit.ly/2Lfwlk6}\) (30/8/2019, 12:03 hours).

\(^{44}\) \(\text{https://twitter.com/DrTedros/status/1144493529009254403}\) (27/6/2019, 23:31 hours).
IOM 2005 definitions, discussed in the previous section, referred to CAM as ‘other’ than the ‘dominant health system’.

It has been argued that traditional systems of medicine were ‘subjugated, devalued, co-opted, and in some cases decimated across the globe within the context of European colonization’ (Ijaz and Boon 2018: 308). In India, the British colonizers ‘obstructed’ Indian medicine, even as ‘the revival of local medical traditions was a source of national pride, and Indian independence was linked with reinvigorating Indian traditions and knowledge’. It has also been argued that, though indigenous and international efforts at modernization, professionalization and regulation of traditional systems and practitioners of medicine led to the inclusion of some, they excluded other, traditional systems and practitioners of medicine. Certain practitioners of traditional medicine wanted their drugs and therapies to be used as complementary with modern medicine, yet others wanted to do away with ‘highly individualized medicine’ of traditional systems and follow the modern Fordist model of mass production and consumption, even as some others argued for distinctive systems of medicine. Now that modern medicine is moving towards the post-Fordist model of personalized / precision medicine, the question for traditional medicine is whether it would want to continue with the OTC, self-medication, mass consumption Fordist model, or revert back to its roots of service-intensive, practitioner-focused form of ‘highly individualized’ diagnosis and treatment?

In the present, the predominance of modern medicine is said to be ‘far less the result of biomedical science’s evidenced efficacy than it is a feature of the

45 ‘From the 1830s the British government no longer tolerated Indian medicine. Only those trained in Western medicine could be registered as doctors. However, local traditions continued. They adapted and became more professional to compete with medicine introduced by the British administration’. British Science Museum’s History of Medicine website: https://bit.ly/2LWmORU (2/8/2019, 12:18 hours).


48 Since most TCSM are not covered by health insurance / universal health programs (for e.g. the NHS in the UK), their sales are largely in the OTC rather than the prescription drug category.

49 A report by the American National Academy of Sciences states that ‘many conventional [modern] treatments have not been supported by rigorous testing. For example, a review of 160 Cochrane systematic reviews of the effectiveness of conventional biomedical procedures found that 20 percent showed no effect, whereas insufficient evidence was available for another 21
ongoing sociopolitical subordination of precolonial indigenous knowledge systems and related healthcare practices’. And although TCSM have been widely used in developed countries for quite some time now – and in the developing, obviously, for a much longer period – ‘considerable political, research, economic, and institutional capital continues to sustain biomedicine’s pre-eminence in state healthcare systems worldwide’ (Ijaz and Boon 2018: 308). TCSM continue to be largely in the OTC rather than the prescription, insurance-covered category. Their formal / institutional inclusion in the governmental and medical systems will not be easy, not just apparently for scientific, but also for reasons of political economy. TCSM have also benefited in some contexts due to a similar set of reasons (for e.g. Berger 2013).

® We are living in a post-Fordist (marked by transition from mass production / consumption to more individualized patterns) and post-industrial (transition from a manufacturing-based to a service- and knowledge-based economy) world in which holistic TCSM have a natural advantage, given their individual, practitioner-oriented focus. The very fact that there has been widespread acceptance of TCSM by the general public – despite lack of institutional support – is reflective of a certain level of disillusionment with modern scientific medicine (post-modernity). Once relegated to the margins with the ascendance and domination of modern medicine, TCSM have been in vogue. Strategies to promote TCSM should keep such ecosystemic trends – post-Fordism, post-industrialism and post-modernity – in mind.

® India should promote TCSM drugs (both personalized and generic) as well as practitioners (practices) at the international level. International recognition of degrees and accreditation mechanisms will be crucial to promote the migration of traditional practitioners.

® A political economy strategy needs to be devised to promote and facilitate the institutional uptake of TCSM, especially from the perspective of UHC, PHC, financing, manpower, etc.

percent’. Conversely, ‘some CAM manufacturers adopt higher standards than are currently required in the United States and rigorously test their CAM products’ (IOM 2005: 17-18).

50 ‘The history of the relationship between complementary medicine (CM) and mainstream health care has shifted from the early days of pluralism, through hostility and exclusion, to one of grudging acceptance. The current situation is one of a tacit acknowledgement and in some cases open endorsement by biomedicine for a number of forms of CM practice, largely driven by the popularity of CM to consumers in our increasingly market driven health care system’ (Wiese, Oster and Pincombe 2010).
Market size

Given the definitional challenges and TCSM expenditures being largely out-of-pocket, we do not have very reliable estimates of TCSM industry or market size in India or internationally. Known estimates are listed in table 2 below. India is considered as one of the top exporters of traditional medicines – major export destinations being US and EU countries like Germany and France (Research and Markets 2017). To boost AYUSH exports, International Arogya conferences have been organized annually since 2017 jointly by Ministry of AYUSH, Ministry of Commerce and Industry, Pharmexcil and FICCI, even as the Government of India has allowed up to 100% FDI in the AYUSH sector.

Table 2: Market size estimates of traditional medicines

<table>
<thead>
<tr>
<th>Market research company</th>
<th>Geography</th>
<th>Category</th>
<th>Estimated market size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Markets</td>
<td>India</td>
<td>AYUSH and alternative medicine industry</td>
<td>USD 10 billion in 2017; USD 15 billion by 2020</td>
</tr>
<tr>
<td>CII</td>
<td>India</td>
<td>Ayurveda industry</td>
<td>USD 3 billion in 2016; USD 9 billion by 2022</td>
</tr>
<tr>
<td>Market Research Future</td>
<td>Global</td>
<td>Herbal pharmaceuticals, herbal functional foods, herbal beauty products and herbal dietary supple-</td>
<td>USD 129.7 billion by 2023</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ments</td>
<td></td>
</tr>
<tr>
<td>Research and Markets</td>
<td>Global</td>
<td>Botanicals, acupuncture, mind, body, and yoga, magnetic intervention</td>
<td>USD 196.9 billion by 2025</td>
</tr>
<tr>
<td>Grand View Research</td>
<td>Global</td>
<td>Botanicals, acupuncture, mind, body and Yoga, magnetic intervention</td>
<td>USD 210.8 billion by 2026</td>
</tr>
</tbody>
</table>

1. International discourse on TCSM

The international discourse on TCSM has largely been conducted under the aegis of WHO and, to some degree, the BRICS forum. We provide an overview of the evolution of international TCSM narrative below, and eventually the direction that it is taking/expected to take in the days to come.

1970s

Despite sporadic attempts to recognize TCSM internationally, it was only in the 1970s that WHO’s official engagement with TM actually began through World Health Assembly (WHA) resolutions of 1976 and 1977. However, it is important to highlight that the WHA resolution of 1969 (WHA 22.54), which focused on the establishment of pharmaceutical production in developing countries, acknowledged the ‘widespread use of various TMs in many countries’ and ‘differences in the development of therapeutic practices in the countries of the world.’ Moreover, the WHA expressed concern about the ‘hazards and economic wastage connected with the empirical use of such drugs as long as their efficacy and safety have not been established.’ While the WHA of 1969 ambivalently promoted TCSM, international declarations highlighting the promise of TM gained impetus in the mid-1970s.

In 1975, a landmark study jointly carried out by WHO and UNICEF on Alternative Approaches to Meeting Basic Health Needs in Developing Countries played a crucial role in strengthening the TCSM agenda. The report highlighted the potential of local resources in developing more sustainable and equitable approaches to meet unmet health care needs of populations in developing countries. It criticized developing countries for prioritizing the creation of vertical disease programmes as it had ‘hindered the development of basic health services in these countries’ (WHO 1975: 7). The report officially acknowledged that relying exclusively on health care services was insufficient to achieve desired health outcomes and alternative approaches embedded in ‘prevailing human attitudes and values’ were required to dramatically revolutionize health care in developing countries (WHO 1975: 8).

The resolution of 1976 (WHA 29.72) drew attention to the challenge of ‘absolute and relative shortage of health manpower and the often inadequate and irrelevant training of such manpower.’ It made a cursory reference to TM and called for development of a manpower ‘reserve constituted by those practicing TM.’ The resolution of 1977 (WHA 30.49), marked the formal beginning of
WHO’s endorsement of TCSM, and emphasized on the advancement of training and research in TM. In line with the recommendations of the 1975 report, the resolution recognized the importance of using ‘local health resources’ to provide access to PHC to a considerable section of the population in developing countries. It further noted that ‘immediate, practical and effective measures to utilize traditional systems of medicine fully are necessary and highly desirable.’ Unlike its precedents, it was the first time that an international agreement highlighted the need to investigate the ‘technological procedures related to traditional indigenous systems of medicine.’

During this period, two major meetings of the WHO paved way for global recognition of TM and thus merit attention in this discussion. First, the expert committee meeting on selection of essential drugs blatantly criticized the interests of pharmaceutical companies and remarked that despite an increase in the number of pharmaceutical companies, proportionate improvement in population health had not been achieved. It recognized that both developed and developing countries spend considerable proportions of their health care budgets on drugs, and hence needed to adopt an essential list of therapeutically effective drugs. Since cost was an important criterion for including drugs in this list, the report of the meeting directed countries to evaluate the ‘cost of non-pharmaceutical therapeutic modalities’ (WHO 1977: 12). It further remarked that ‘for the treatment of certain conditions, nonpharmacological forms of therapy, or no therapy at all, may be preferable’ (WHO 1977: 13). Second, while recognizing the untapped potential of PHC in health care service delivery, the well-known Alma Ata Declaration of 1978 reaffirmed the principles endorsed by WHO in the 1970s – utilizing local resources, promoting national self-reliance and identifying cost-effective approaches outside the ambit of existing biomedical systems. The declaration explicitly acknowledged the potential role TM practitioners may assume in delivering PHC (WHO 1978a: 63). It also recommended the inclusion of ‘proved traditional remedies’ in the list of essential drugs (WHO 1978a: 29). Anchored in PHC, TM systems could uphold the internationally acknowledged principles of the 1970s.

In 1978, WHA passed another resolution (WHA 31.33) which categorically focused on the significant role that medicinal plants assume in health care systems in developing countries. However, unlike the earlier resolution, the resolution of 1977 was carefully articulated and it recognised that even though medicinal plants ‘contain substances which may be of therapeutic value’, they ‘may also possibly show potential toxicity when improperly used.’ Compiling ‘inventory’ and ‘therapeutic classifications’, standardizing ‘botanical nomenclature’, reviewing ‘scientific data’ on the efficacy of medicinal plants, developing and applying ‘scientific criteria’ and methods for proof of ‘safety and efficacy’, developing
international standards and specifications for ‘identity, purity and strength’, and identifying methods for ‘safe and effective use’ of medicinal plant products (including labelling, directions for use, etc.) were hence considered essential. Despite acknowledging the remedial strength of medicinal plants, this particular resolution brought to the fore certain contradictions associated with how TM was perceived at that time.

First, the suggestion to formulate international standards for ‘identity, purity and strength’ failed to consider important differences within and between systems of TM. Unlike biomedicine which can treat patients with similar symptoms more or less uniformly – thereby making mass production and standardization possible – TM systems treat every patient with a unique set of remedies by taking into consideration a range of factors such as an individual’s age, weight, gender, etc. Therefore, imposing international standards overlooked the individualized nature of treatment prescribed in such systems. Second, certain TM systems extensively make use of one or more plants as a whole and not isolated plant ‘substances’. In fact, selective molecular extraction may yield suboptimal levels of efficacy in such systems (Foran 2007). Third, in many indigenous systems of medicine, knowledge of identification and preparation of plants is verbally inherited for generations and protecting its secrecy is of fundamental importance to ensure the potential and efficacy of administered medicine. Unlike biomedical systems where therapeutic formulations may be interpreted as biological and physiological compositions, it was important for TM systems to thrive in their social and cultural contexts. The resolution of 1978 evidently neglected such aspects of TM systems.

It is important to mention that in 1978, WHO launched a technical report on Promotion and Development of TM which sought to achieve ‘effective collaboration of different practitioners and their integration into an overall national health care delivery system’ (WHO 1978b: 7). The objective to achieve integration of TM within mainstream health care systems was crucial from the perspective of realizing WHO’s ‘Health for All’ goal, which it had endorsed in 1975. The rationale behind integration was thus obvious – resources in biomedical systems were insufficient to fulfil the health care needs of the masses and had to be supplemented with TM. As mentioned in its 1978 report, ‘the most cogent reason for the radical development and promotion of TM is that it is one of the surest means to achieve total health care coverage of the world population, using acceptable, safe, and economically feasible methods, by the year 2000’ (WHO 1978b: 14). Further, given the emphasis of international discourse on medicinal plants, the report asserted that understanding of TM should not be limited to medicinal plants and instead be augmented to include other systems of TM in actual practice.
In the 1980s, a number of resolutions were passed to reiterate the role of TM in ‘preventive, promotive and curative aspects of health’ (WHA 40.33 of 1987) and urge member states to intensify efforts to integrate TM systems into health care delivery. However, unlike resolutions of the previous decade, resolutions of the 1980s were less cautiously worded. The resolutions were also less obscure in their requests to member states and reflected stronger international commitment to promote and protect TM. For instance, resolution of 1988 (WHA 41.19) expressed apprehension about the rapid increase in deforestation activities and appealed to member states to take measures to preserve their medicinal plants and promote sustainable utilisation. Similarly, the resolution of 1989 (WHA 42.43) asserted that increase in national and international funding was indispensable to achieve significant strides in the field of TM. It may thus be inferred that compared to the 1970s, international discourse on TM evolved in a far more positive light in the 1980s and connected itself with mainstream global issues such as environmental conservation and sustainable development.

Despite consistent attempts to influence national health care policies, international deliberations on TCSM had limited impact on transforming the biomedical, curative focus of health care systems. This led several international policy analysts to doubt the commitment of the WHO to the TCSM agenda (Foran 2007). A number of issues were identified to explain the slow pace of progress at national levels. First, even though PHC and integration of TM seemed promising notions, absence of lucid guidance documents in international circles hindered the formulation of actionable policies at the national level.51 Second, hostile competition within TM systems and between biomedical and TM systems prevented translation of global agreements to national policies and programmes. Third, reorienting health care systems in light of the recommendations of international discussions required major overhauls in existing health care systems. For instance, traditional remedial therapies had to undergo scientific scrutiny before being incorporated in PHC programmes, which would have entailed significant costs. Although TM offered cost-effective strategies to improve

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51 In order to execute the implementation of TM in primary health centres, the WHO published two guides in 1990s – Guidelines for Training Traditional Health Practitioners in Primary Health Care (WHO 1995a) and Traditional Practitioners as Primary Health Care Workers (WHO 1995b). Although both the guides contained step-by-step procedures for training traditional practitioners for delivering health care at primary health centres, their practical use was contested and they seemed long-overdue.
population health in the long run, it required countries to make exorbitant investments in the short run.

1990s

In 1991, resolution WHA 44.34 reiterated the importance of TM to essential health care and cautioned against the damages that medicinal plants may face due to environmental and ecological changes. The resolution encouraged member states to strengthen cooperation between providers of TM and modern health care, specifically with respect to the 'use of scientifically proven, safe and effective traditional remedies to reduce national drug costs.' Another aspect that deserves mention in context of this particular resolution is that it urged member states 'to introduce measures for the regulation and control of acupuncture methods.' While all the earlier resolutions had exclusively recognized the use of medicinal plants, an additional indigenous therapy (acupuncture) had featured for the first time in a WHA resolution. Global health experts considered the abrupt inclusion of acupuncture in an international resolution as the victory of Chinese government as it had taken important measures to prove the clinical efficacy of acupuncture internationally. In fact, WHO's acceptance of acupuncture as an effective TM strategy was more pronounced in the *TM Strategy 2002-2005* as it asserted that, 'the efficacy of acupuncture in relieving pain and nausea has been conclusively demonstrated and is now acknowledged worldwide' (WHO 2002: 23). Nevertheless, the resolution of 1991 established a very important point – even though international dialogues to integrate TCSM in health care systems failed to bear fruit, people were increasingly relying on TCSM for addressing their health care needs. This may further be established by the sharp rise of a gigantic TCSM industry in the 1990s, which significantly propelled the TCSM agenda. In addition to the use of TCSM in developing countries, demand for TCSM products proliferated in developed countries as people looked for holistic, unconventional therapies for treating chronic diseases like diabetes, obesity and depression. The rampant use of such products in developed countries validated the fact that TCSM was not only relevant for resource-constrained settings but offered a pragmatic solution to ageing-related challenges which developed countries of that time were faced with. For instance, between 1991 and 1994, the market for herbal products in Japan increased two-fold from USD 1 billion to USD 2 billion. In the US, market for herbal products expanded from USD 1.6 billion in 1994 to USD 5.4 billion in 2000 (WHO 2002). It is also worthwhile to mention here that this was also the time when indigenous knowledge and resources were recognized as prized assets in international forums. For instance, in 1990, the United Nations General Assembly announced
the year 1993 as the *International Year of the World’s Indigenous Peoples*. Subsequently, the General Assembly proclaimed 1995-2004 as the first and 2005-2014 as the second International Decade of the World’s Indigenous Peoples. This was done with the objective of achieving increased global cooperation for addressing challenges faced by indigenous peoples in areas such as human rights, the environment, development, education, health, economic and social development.\(^{52}\) Likewise, the theme of World Bank’s World Development Report for 1998-99 was *Knowledge for Development* and it recognized that in 1990, global sales of modern medicine extracted from medicinal plants discovered by indigenous people were estimated at USD 43 billion (World Bank 1998: 146). This marked World Bank’s first ever contribution to the international discourse on TCSM.

**21st century**

In view of the unabated consumption of TCSM products in developing as well as developed countries, WHO launched the first *TM Strategy 2002-2005* in 2002. Prior to the release of this report, two international reviews on regulatory status of herbal medicines (WHO 1998) and legal status of TM / CAM (WHO 2001) were released to provide an overview of activities at the national level. Both these reports revealed significant differences between countries with respect to their regulatory and legal environments related to TCSM. The *TM Strategy 2002-2005* was an outcome of discussions on *Methodologies for Research and Evaluation of Traditional Medicine* and repeated requests by member states for more assistance on TM / CAM issues. The four objectives of the *TM strategy* were policy development for integrating TM / CAM within national health care systems; promoting safety, efficacy and quality of TM / CAM; increasing availability and affordability of TM / CAM; and promoting rational use of TM / CAM. While these objectives addressed some of the core issues relevant in the context of TCSM, they could be applied more specifically to biomedicine. For instance, there is ample evidence to show that TM / CAM yield adverse impact when used in places other than their place of origin. This is commonly observed when TM / CAM are produced in large quantities or using alternative methods of production, and consumed as a mixture of allopathic and traditional medicines (Foran 2007). For instance, *Kava*, a crop native to the Western Pacific Islands, has been used in the Pacific Islands for over two millennia in the treatment of stress, anxiety and insomnia with no reported adverse impact. However, users of *Kava* in Europe reportedly developed liver toxicity (Moulds and Malani 2003). Similarly, while *Ma Haung* (*Ephedra sinica*) is widely used in China

for the treatment of asthma and other conditions, its use in the United States resulted in nervous system problems, seizure, stroke and heart attack (Shekelle et al 2003). Further, since the nature of treatment in TM / CAM is personalised, industrial production of such medicines in large quantities is often associated with reduced level of efficacy (Thorne et al 2002). Therefore, while ensuring safety, efficacy and quality of TM / CAM is important, it is difficult to develop scientific measures of evaluation for these indicators.

The critical indicators identified by the TM strategy showed that in terms of official recognition, little progress had been achieved since the formal inception of TM in 1970s until the end of the century. Out of 191 member states, only 25 (13%) had a TM / CAM policy, 65 (34%) had laws and regulations on herbal medicines and 19 (10%) had a national research institute for TM / CAM. However, the TM Strategy acknowledged that the use of TM / CAM had increased manifold and in certain countries, spending on TM / CAM was higher than expenditure incurred on allopathic medicine. The global market for herbal medicines manufactured on the basis of indigenous knowledge was estimated at USD 60 thousand million (WHO 2002). Unprecedented rise in the use of TM / CAM in the 1990s necessitated a range of regulatory, legal and public health concerns to be resolved at the global level.

According to the WHO, health care systems exclusively providing biomedical care had ceased to exist by 2002. Based on the extent to which TM / CAM had been recognized and incorporated, the WHO defined three types of health care systems:

1) Integrative systems, which officially recognize and incorporate TM and CAM into all aspects of health care delivery, including drug policy, regulation and registration of practitioners and products, public and private provision of therapies, health insurance, and education. China, the Democratic People’s Republic of Korea, Republic of Korea and Vietnam were identified as countries with integrative systems of health care.

2) Inclusive systems were defined as those which recognize TM / CAM but have not yet included it into all dimensions of formal health care. Countries with inclusive health care models included developing countries such as Equatorial Guinea, Nigeria and Mali which have a national TM/CAM policy, but little or no regulation of TM / CAM products and developed countries such as Canada and the United Kingdom which do not offer significant university-level education in TM / CAM, but which are taking serious measures to ensure the quality and safety of TM / CAM.

3) Tolerant systems are representative of complete biomedical systems, but where some TM / CAM practices are accepted by law.
The WHO concluded that ‘countries operating an inclusive system can be expected to attain an integrative system’ (WHO 2002: 9). However, it is important to note that this assumption may not always hold true as development of integrative systems is determined by the relationship between biomedical and TM / CAM systems. The state plays an integral role in mediating this relationship and has the responsibility to assess the regulatory and legal dimensions of medicine before officially recognizing formal practice. Countries that have integrative systems have not necessarily transitioned from inclusive or tolerant systems, and have had socialist / communist regimes which have safeguarded the economies from global market forces. Moreover, the criterion of fully integrating TM / CAM into all aspects of health care services may not be realistic and neglects the aspect of informal integration that is quite prevalent at the levels of both consumers and practitioners. (Foran 2007). It is also worthwhile to bring to the fore that the *TM Strategy 2002-2005* made only a passing reference to PHC in the context of activities being undertaken in certain countries and did not include PHC in its objectives and components.

In May 2008, the sixty-first WHA adopted resolution WHA 61.21 on ‘global strategy and plan of action on public health, innovation and intellectual property’. In view of the high incidence of communicable diseases and its disproportionate impact on impoverished population particularly in developing countries, the resolution urged member states to support novel thinking in health-related innovation. In the context of TM, member states were encouraged to ‘promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities’ (WHA 2008: 13). The resolution laid the foundation for the Beijing Declaration, which was passed by the first-ever WHO Congress on TM in November 2008. In addition to recognizing the role of TM in PHC services, the Declaration urged governments ‘to establish systems for the qualification, accreditation or licensing of traditional medicine practitioners’ and ‘upgrade their knowledge and skills based on national requirement’ (WHO Congress 2008). It further called for strengthened communication between conventional and TM providers. The Beijing Declaration was widely appreciated because unlike previous WHA resolutions, it addressed both clinical and practical challenges associated with integration of TM in health systems.

Building on the work introduced in the Beijing Declaration, resolution WHA 62.13 of the sixty-second WHA (2009) appealed to the WHO Director General to revise the *TM Strategy 2002-2005* to take into account the progress made, and challenges being faced by countries in the field of TM. The *WHO TM Strategy 2014-2013* was thus launched in 2013 to help member states realize the potential of TM and CAM by building the knowledge base of TM and CAM in these countries and formulating national policies, ensuring safety, efficacy and quality
of TM / CAM through better regulation, and advancing universal health coverage (UHC) by integrating TM / CAM and self-health care into national health systems (WHO 2013). The strategy reiterated that ‘achieving UHC has been set as one of the overarching goals in WHO’s 12th General Programme of Work 2014-2019’ and UHC is indispensable for achieving ‘highest attainable standard of health’ (WHO 2013: 35). It further noted that lack of patient-centeredness and existing geographical (e.g. distant health care services), organizational (e.g. poorly staffed health care systems leading to long waiting hours for patients) and cultural (e.g. health care systems may be incompatible to consider patients’ cultural / gender preferences) barriers must be overcome to achieve UHC. The 2014-2023 TM Strategy also highlighted that inefficiencies in health care systems predominantly emanate from disease-oriented, curative and hospital-based nature of health care services. It acknowledged that partnership between TM and conventional health sectors is necessary to tackle the rising burden of chronic diseases as an increasing number of patients in many advanced economies were resorting to TM / CAM for managing certain chronic conditions like musculoskeletal, gastrointestinal and neurological disorders. In order to tackle the rising burden of chronic diseases, the TM Strategy 2014-2023 suggested member states to engage ‘qualified’ TM / CAM professionals in health systems, particularly PHC. Such an engagement was positively associated with ‘(improved) patient accessibility to health services, and greater awareness of health promotion and disease prevention’ (WHO 2013: 53). Integration of TM / CAM in UHC plans was also expected to reduce health care costs and ease the existing financial burden of health care systems. Another significant recommendation offered in the TM strategy was to develop a knowledge-based integration policy depending on the national context in every member state (WHO 2013: 39). Although the TM Strategy 2014-2023 did not address many important challenges that such integration approaches may entail, for instance, the inherent conflict between biomedicine and TM / CAM, it recognized the potential of these indigenous systems of medicine in responding to the threat posed by chronic diseases.

As part of 2014-2023 TM Strategy, the Ministry of AYUSH in India and the WHO had signed a Project Collaboration Agreement to develop practice benchmark documents for Ayurveda, Panchakarma and Unani, and international terminologies documents in Ayurveda, Siddha and Unani. In addition to strengthening the safety requirements for practicing Ayurveda, Panchakarma and Unani, these documents are expected to serve as reference texts for national regulatory authorities to ensure safe and ethical practice of TM systems. In this regard, the Ministry of AYUSH recently hosted two important meetings of the WHO at the Institute of Post Graduate Teaching and Research in Ayurveda, Jamnagar (Gujarat) and at the Morarji Desai National Institute of Yoga and
Naturopathy, New Delhi. The first of the two meetings – the WHO-International Experts Consultation Meeting (IECM) – was organised from 26 November to 29 November 2019 and hosted a group of international experts working on different TM systems, health policy and regulations from all six WHO regions. The second meeting – the WHO Working Group Meeting (WGM) was held from 2 December to 4 December 2019 – to review and give suggestions on the draft versions of documents on Standard Terminologies of Ayurveda, Unani and Siddha, and achieve consensus on the structure and content of these documents, including meanings and definitions of terms used in these systems. The consultation hosted a group of international experts working on TM literary research and other academic streams, including language experts with substantial experience of working in TM languages (such as Sanskrit, Arabic, Persian, Urdu and Tamil) and literature from all six WHO regions.\(^53\)

\(^{53}\) [https://pib.gov.in/PressReleseDetailm.aspx?PRID=1593447 (24/12/2019, 13:30 hours).]
Figure 3: International TCSM timeline, 1969-2019

1992
- Resolution WHA 33.49 noted the importance of using local health resources to provide access to PHC to a considerable section of the population in developing countries.
- Highlighted the need to investigate 'technological procedures' related to TM.

1993
- Alma Ata Declaration acknowledged the role that TM practitioners may assume in PHC and recommended inclusion of 'proved traditional remedies' in the list of essential drugs.
- Report on Promotion and Development of TM sought to achieve effective collaboration of different practitioners and their integration into national health care delivery system.

1994
- Resolution WHA 44.34 encouraged member states to strengthen cooperation between providers of TM and modern health care to reduce national drug costs.
- Urged member states to introduce measures for regulation and control of acupuncture.

1998
- World Bank's World Development Report (1998-99) recognized that in 1990, global sales of modern medicine extracted from medicinal plants discovered by indigenous people were estimated at USD 43 billion.

2002
- WHO TM strategy 2002-05 was launched to provide more assistance to member states on integrating TM / CAM into national health care systems, promoting its safety, efficacy and quality, enhancing its affordability and rational use.

2003
- Beijing Declaration urged governments to establish systems for the qualification, accreditation or licensing of TM practitioners and called for strengthened communication between conventional and TM providers.

2010
- WHO TM strategy 2014-2013 was launched to build knowledge base of TM and CAM, advance UHC by integrating TM / CAM and self-health care into national health systems, etc.
- BRICS Health Ministers urged BRICS countries for increased knowledge-sharing and cooperation on TM.
- Adoption of Delhi Declaration by South-East Asian countries to engage in collaborative efforts for mutual recognition of TM, regional cooperation for capacity building of TM experts, etc.

2018
- G20 Leaders and Health Ministers argued for inclusion of 'scientifically proven TM / CAM, assuring the safety, quality and effectiveness of health services' as part of UHC.
- Declaration of Astana emphasized that using 'traditional and scientific knowledge' was important to strengthen PHC and improve health outcomes.

2019
- WHO Global Report on T&CM noted that improving equitable access to safe, quality and effective T&CM services can potentially meet communities' needs and build sustainable and culturally sensitive PHC.
- By being included in the provision of essential health services, T&CM could significantly contribute to UHC.
2. TCSM in major G20 countries

As indicated above, TCSM hold special relevance in the context of chronic disease morbidity and disability. Figure 4 below illustrates how the disability burden of chronic diseases has always been high in G20 countries – and has only increased over time. In addition to their human costs, chronic diseases impose significant economic costs on individuals and governments. If UHC is viewed as the mitigation of financial burden on individuals arising out of access to health care, the economic implications for governments also need to be borne in mind. According to the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), 90% of the USD 3.3 trillion annual health care expenditure in the US was on chronic and mental health conditions. Additionally, heart diseases and stroke alone led to USD 131 billion in lost productivity.54

Figure 4: Years lived with disability (YLDs) in G20 countries by cause, 1990-2017

Source: Global Burden of Disease.

The global economic burden of chronic diseases has been estimated to be approximately USD 47 trillion during 2010 and 2030, affecting economic outcomes through reduced labor supply, productivity, investments, incomes, savings, etc. (Bloom et al 2017). People in the West have taken recourse to TCSM over the past few decades for mitigating some of these burdens, especially that of mental and musculoskeletal disorders, which were together responsible for more than 31% of all YLDs in 2017.

India should call for a rigorous international study on the potential of TCSM in the mitigation of the human and economic costs of chronic diseases, especially in the context of the G20. Box 1 below presents some evidence in this direction.

| Box 1 – Health and human benefits of TCSM use: A case study from Northern Ireland |
|---|---|
| In Northern Ireland, the Department of Health, Social Services and Public Safety set up a pilot project which provided patients with access to a range of complementary therapies through their GP practice. Overall, 713 patients, presenting with musculoskeletal and mental health conditions, were referred to the project by their GPs for a range of complementary therapies. The project was implemented by Get Well UK, a complementary therapy service run by a practitioner on the British Acupuncture Council’s register in 2 primary care centres in Northern Ireland. The evaluation was conducted independently by Social & Market Research. It found a significant level of health gain for the vast majority of patients. Additionally: |
| 24% of patients who used other health services prior to treatment (e.g. other primary care services, secondary care services and Accident and Emergency), said they now use these services less often |
| 64% of patients in employment said that following treatment they now take less time off work |
| Among patients not in employment, 16% said that having the complementary therapy treatments had encouraged them to think about going back into employment |
| 65% of GPs reported an improvement in health outcome and said they saw the patient less often |
| Half of GPs reported prescribing less medication and half said it had reduced their workload |
| 99% of GPs said they would refer to the service again and 98% said they would recommend it to other GPs. |


Let us now briefly review the approaches and strategies of selected G20 countries vis-à-vis TCSM.
India

With the objective of development and promotion of TCSM, the Government of India created the Department of Indian Systems of Medicine and Homeopathy under the Ministry of Health & Family Welfare in 1995. It was later renamed as the Department of Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH) in 2003, and eventually elevated to the status of an independent ministry, the Ministry of AYUSH in 2014. Several Memorandums of Understanding (MoU) have been signed by the Government of India at the international level to promote AYUSH (table 3). Various inter-ministerial / organisational MoUs have also been signed between the Ministry of AYUSH and other ministries / institutions of the Government of India. One such prominent MoU was signed between the Ministry of AYUSH and Council of Scientific and Industrial Research (CSIR), New Delhi in April 2019 for cooperation in research and education in the traditional systems of medicine and their integration with modern science. As part of this MoU, both organisations agreed to focus and collaborate in the areas of R&D covering fundamental research; AYUSH specific diagnostic tools; linking microbiome, gene expression and prakriti; multi-ingredient herbal formulations, including their standardization; exploring modern scientific methods for integration with traditional Indian Systems of Medicine (ISM); linking disease signatures, etc. Earlier, CSIR and Ministry of AYUSH had collaborated to develop the Traditional Knowledge Digital Library (TKDL), a globally recognised proprietary database to prevent biopiracy and misappropriation of ISM knowledge. TKDL contains 0.29 million medicinal formulations of ancient texts of ISM available in five international languages (English, Japanese, French, German and Spanish). Under its Access (Non-disclosure) Agreement, TKDL database can be accessed by 9 patent offices around the world (the European Patent Office, the United States Patent & Trademark Office, Japan Patent Office, United Kingdom Patent Office, Canadian Intellectual Property Office, German Patent Office, Intellectual Property Australia, Indian Patent Office and Chile’s Patent Office). Given its global recognition, an international conference was organized by the World Intellectual Property Organization (WIPO) in collaboration with CSIR, themed ‘Utilization of Traditional Knowledge Digital Library as a Model for Protection of Traditional Knowledge’, in New Delhi in 2011.

Another successful initiative which positioned India globally in the field of traditional medicine was the adoption of ‘Delhi Declaration on Traditional Medicine for the South-East Asian countries’ by the Hon’ble Health Ministers of Bangladesh, Bhutan, India, Nepal, Minister of Indigenous Medicine of Sri Lanka, Vice Minister of Timor-Leste and representatives of DPR Korea, Indonesia, Myanmar, Maldives and Thailand during the ‘International Conference on Traditional Medicine for South-East Asian Countries’ in New Delhi in 2013. Through this conference, these countries committed to collaborative efforts in developing institutionalised mechanisms for the exchange of information, expertise and knowledge with the cooperation of WHO; harmonised approach for the education, practice and regulation of TMs; mutual recognition of educational qualification, pharmacopoeias, monographs and relevant databases of TMs; regional cooperation for training and capacity building of TM experts; common reference documents of TMs for Southeast Asian countries, etc.58

In 2017, India organised the first-ever international summit on AYUSH and wellness – the ‘Arogya 2017’ – which was attended by approximately 1500 delegates from India and 60 other countries. The summit’s second edition was organized from 5-8 December 2019 in New Delhi. One of the prime objectives of these summits has been to showcase the strength and scientific validation of AYUSH at the global level and promote international cooperation and collaboration opportunities at bilateral, multilateral, regional and global levels. At the first summit, the Minister of Commerce and Industry, Suresh Prabhu, said that ‘the Indian domestic market of AYUSH is estimated to be INR 500 crore, while exports amount to INR 200 crore. Young entrepreneurs planning a start-up could find a lot of opportunities in holistic healthcare. The Government has allowed 100% FDI in AYUSH. The AYUSH industry is expected to grow in double digits and provide direct employment to 1 million people and indirect employment to 25 million people by 2020’.

In 2019, ‘World Integrated Medicine Forum on the Regulation of Homeopathic Medicinal Products’ with the theme, ‘Advancing global collaboration’, was organised by Central Council for Research in Homeopathy (CCRH) in collaboration with the Homoeopathic Pharmacopoeia Convention of the United States (HPCUS), the European Coalition on Homeopathic & Anthroposophic Medicinal Products (ECHAMP), Pharmacopoeia Commission of Indian Medicine and Homoeopathy and the Central Drugs Standard Control Organization.60

event was successful in bringing stakeholders together for strategic discussions on the effective regulation of homoeopathic medicinal products.

‘Promotion of international cooperation in AYUSH’ was one of the prime themes as part of Central Sector Scheme of the Government of India implemented since 9th Five Year Plan. It was amended in 2015 to widen its scope. The 6 major components of the scheme that also reflect priority-areas of the government as far as international cooperation in traditional medicines is concerned are –

1) International exchange of experts and officers;

2) Incentive to drug manufacturers, entrepreneurs and AYUSH institutions for international propagation of AYUSH by participating in international exhibitions, trade fairs, road shows, etc. and registration of AYUSH products (market authorisation) with regulatory bodies of different countries such as United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), UK’s Medicines and Healthcare products Regulatory Agency (MHRA), Canada’s Natural and Non-prescription Health Products Directorate and Australia’s Therapeutic Goods Administration (TGA) for exports;

3) Support for international market development and AYUSH promotion-related activities;

4) Translation and publication of AYUSH literature / books in foreign languages;

5) Establishment of AYUSH information cells and strengthening of health centres / institutions in foreign countries with AYUSH equipments, etc.;

6) International fellowship / scholarship programmes for foreign nationals for undertaking AYUSH courses in premier institutions in India.61

**TCSM in Five Year Plans (FYPs)**

Post-independence, the Government of India made several efforts to revive the ISM. In the early FYPs, ISM did not get much attention. It is only from the 6th FYP that ISM were emphasised upon (James 2014). In particular, the 6th FYP emphasised on adequate financial support for improving the quality of teaching and research and standardisation of pharmacopoeia to ensure production of quality drugs. The 7th FYP envisioned integration of TCSM at suitable levels

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within the national healthcare architecture, with special focus on integration at the PHC level. The 8th and 9th FYPs emphasised R&D aimed at standardisation of drugs, new drug formulations, clinical trials for new-promising potential drugs. The 9th Plan talked about patenting of formulations in ISM for the first time. It highlighted that the Department of ISM&H, originating during 8th FYP, established a patent cell to keep a track of patents filed in India and elsewhere vis-à-vis Ayurveda, Siddha and Unani (ASU) drugs as well as to provide financial and professional assistance to scientists filing patents. The 10th FYP thrust areas included plans to mainstream ISM&H systems, the promotion of health tourism for the prevention and management of lifestyle-related disorders, the enforcement of good manufacturing practices (GMPs) and improving availability and export potential of ISM&H drugs.

Efforts were made to integrate AYUSH in the National Rural Health Mission (NRHM) during 10th FYP. The 11th FYP planned to further mainstream AYUSH in national healthcare delivery system by establishing AYUSH facilities in primary healthcare networks; promoting scientific validation of AYUSH principles, remedies and therapies; documentation and validation of local health traditions; digitising TCSM manuscripts; and promotion of international cooperation in research, education, health services, trade and market development vis-à-vis TCSM. The 12th FYP emphasised upon cross-disciplinary learnings between AYUSH and modern medicine practitioners, recommending integration of relevant AYUSH modules into the medical, nursing and pharmacy course curricula. Another priority area of the 12th FYP was to ensure robust systems for quality certification of raw materials, accreditation of educational programs, health services and manufacturing units. The National AYUSH Mission (NAM) was also established during the 12th FYP to provide affordable, accessible and sustainable health care.

In addition to the FYPs, the National Policy on Indian Systems of Medicine and Homeopathy, 2002 emphasised development of TCSM and revival of their past glory. It emphasised the preservation of ancient ISM literature through the creation of a digital library for each system, promotion of ISM industry and

medical tourism (for instance, Yoga and Panchakarma), and introduction of Ayurveda and Yoga modules in curricula of medical institutions abroad.

**Recent initiatives towards national integration of AYUSH**

In order to integrate AYUSH in the existing public health system, a pilot project has been initiated by Ministry of AYUSH with the Directorate General of Health Services in 2019 to include AYUSH in National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), a component of the National Health Mission (NHM) through three research institutes – the Central Council for Research in Ayurvedic Sciences (CCRAS), the Central Council for Research in Unani Medicine (CCRUM) and the Central Council for Research in Homoeopathy (CCRH) – in select districts for health promotion and patient management services, including the integrated Yoga programme at NCD clinics. AYUSH is also being promoted as part of *Ayushman Bharat* – 10% of the existing sub-centres will be upgraded as AYUSH health and wellness centres (HWCs) and will exclusively provide AYUSH services.

**Table 3: Memorandums of Understanding / Cooperation (MoU) for promotion of TCSM between India and other countries, 2018 and 2019 (Jan – July)**

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<th>Country</th>
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<tr>
<td>Israel</td>
<td>MoU between CCRH and the Centre for Integrative Complementary Medicine, Shaare Zedek Medical Center for research cooperation in the field of homeopathic medicine</td>
<td>Jan 15, 2018</td>
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<tr>
<td>Iran</td>
<td>MoU for cooperation in traditional systems of medicine (TSM)</td>
<td>Feb 17, 2018</td>
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<tr>
<td>Mauritius</td>
<td>MoU between University of Mauritius and CCRAS for establishing AYUSH Academics Chair in Ayurveda</td>
<td>Mar 14, 2018</td>
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<tr>
<td>Equatorial Guinea</td>
<td>MoU between Ministry of AYUSH and Ministry of Health and Social Welfare, Government of Equatorial Guinea on cooperation in TSM</td>
<td>Apr 8, 2018</td>
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<th>Country</th>
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<tr>
<td>UK</td>
<td>MoU between All India Institute of Ayurveda (AIIA) and the College of Medicine, UK for the development of evidence-based guidelines for integrating Ayurvedic principles and practices with modern medicine, and develop Ayurvedic medical education guidelines for Ayurveda education in UK</td>
<td>Apr 18, 2018</td>
</tr>
<tr>
<td>Cuba</td>
<td>MoU between Ministry of AYUSH and Ministry of Public Health, Republic of Cuba on cooperation in TSM and homoeopathy</td>
<td>Jun 22, 2018</td>
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<tr>
<td>Austria</td>
<td>MoU between AIIA and the Medical University of Graz for cooperation and collaboration in Ayurveda</td>
<td>Sep 26, 2018</td>
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<tr>
<td>Japan</td>
<td>MoC between Ministry of AYUSH and Kanagawa Prefectural in the field of healthcare and wellness</td>
<td>Oct 29, 2018</td>
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<tr>
<td>Zimbabwe</td>
<td>MoU between the Republic of India and the Republic of Zimbabwe on Cooperation in the field of Traditional Systems of Medicine and Homeopathy</td>
<td>Nov 3, 2018</td>
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<tr>
<td>Bangladesh</td>
<td>MoU on cooperation in the field of Medicinal Plants between National Medicinal Plant Board (NMPB), Ministry of AYUSH and Directorate General of health Services, Ministry of Health &amp; Family Welfare, Bangladesh</td>
<td>Feb 8, 2019</td>
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<tr>
<td>Bolivia</td>
<td>MoU between Government of India and the Government of Plurinational State of Bolivia to strengthen, promote and develop cooperation in the fields of traditional systems of medicine and Homeopathy between the two countries on the basis of equality and mutual benefit</td>
<td>Mar 30, 2019</td>
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**Regulatory framework for TCSM in India**

The TCSM regulatory framework is, by and large, modelled on the lines of allopathic medicines. ASU drugs are regulated in India as per the Drugs and

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70 Information provided by the Minister of State (Independent Charge) for AYUSH, Shripad Yesso Naik, in a written reply on 2/1/2018 to a question raised in the Rajya Sabha. [https://bit.ly/34e1mO8](https://bit.ly/34e1mO8)
Cosmetics Act 1940 (DCA 1940), the Drugs and Cosmetics Rules 1945 (DCR 1945) and any amendments made in them from time to time. ASU drugs are defined in chapter 1, section 3, clause (a) of DCA 1940 as – ‘all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of [disease or disorder in human beings or animals, and manufactured] exclusively in accordance with the formulae described in, the authoritative books of [Ayurvedic, Siddha and Unani Tibb systems of medicine], specified in the First Schedule’. As defined in clause (h), ASU ‘patent or proprietary medicine’ means – ‘all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a)’. Chapter IV A of DCA 1940 has exclusive provisions for ASU drugs, while the First Schedule, as indicated above, specifies the authoritative books of ASU medicines. Ayurveda books are listed under section A, serial numbers 1 to 54C, including part 1 of the Ayurvedic Formulary of India and Ayurvedic Pharmacopoeia of India. Siddha books are listed under part A, serial numbers 55 to 84, including part 1 of the Siddha Formulary of India, while section b lists Unani Tibb books from serial numbers 1 to 13, including part 1 of the National Formulary of Unani Medicine. The Second Schedule lists standards to be complied with for homeopathic medicines.

Part XVI of DCR 1945 contains provisions for the manufacture for sale of ASU drugs; while Part XVI A deals with the approval of institutions for carrying out tests on ASU drugs and raw materials used in their manufacture. Part XVII provides details regarding labelling, packing and alcohol limits in ASU drugs. Part XVIII makes provisions for government analysts and inspectors for ASU drugs. Part XIX outlines standards to be complied with in the manufacture and distribution of ASU drugs. Schedule E (1) lists poisonous substances under ASU systems of medicine of vegetable, animal and mineral origins. Schedule T prescribes GMP for ASU drugs.

The CDSCO is India’s central drug regulatory authority, responsible for discharging the functions assigned to Central government under DCA 1940. It has 6 zonal, 4 sub-zonal and 13 port offices as well as 7 laboratories in its jurisdiction. Its functions include – approval of new drugs and clinical trials, regulatory control over drug imports, meetings of Drugs Consultative Committee (DCC)
and Drugs Technical Advisory Board (DTAB), and approval of licenses of specified categories of drugs like blood and blood products, I. V. fluids, vaccines and sera as central license approving authority. As per DCA 1940, the regulation of manufacture, distribution and sale of drugs is primarily the responsibility of State Drug Regulatory Authorities (SDRAs). In addition to above-stated functions, the CDSCO coordinates the activities of the SDRAs, and provides expert advice in order to ensure consistency in the enforcement of DCA 1940. The CDSCO functions under the Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare (MoHFW), Government of India, and SDRAs likewise function under their respective health ministries / departments.71

The Drug Control Cell (DCC) in the Ministry of AYUSH is the AYUSH vertical of the CDSCO since February 2018, to administer regulatory issues as per the provisions of DCA 1940 and DCR 1945. The DCC coordinates with SDRAs for effective and consistent implementation of these provisions. Technical Officers / Central Drug Inspectors of the Ministry of AYUSH undertake joint inspections with the SDRAs. The DCC also coordinates with the Directorate General Foreign Trade (DGFT) in the Union Ministry of Commerce and Industry, with the Union Ministry of Environment, Forest and Climate Change (MoEFCC) as well as other regulatory agencies for WHO-GMP and Certificate of Pharmaceutical Product (CoPP) certification and issues related to exports / imports, clinical trials, availability of raw materials, quality certification of ASU&H drugs and industry. The DCC provides regulatory guidance and clarifications, manages quality control of ASU&H drug-related part of the National AYUSH Mission (NAM), under which grant-in-aid is provided for improving infrastructural and functional capacity of State drug-testing laboratories and pharmacies for production, testing and quality enforcement of ASU&H drugs. The DCC also houses the secretariats of the Ayurvedic, Siddha and Unani Drug Technical Advisory Board (ASUDTAB) and Ayurvedic, Siddha and Unani Drugs Consultative Committee (ASUDCC), constituted as per sections 33C and 33D respectively of DCA 1940.72

71 For a detailed discussion on the administrative structure and functionings as well as related challenges of the CDSCO and SDRAs, refer to ICRIER working paper # 309. https://icrier.org/pdf/Working_Paper_309.pdf (1/9/2019, 10:10 hours). The paper also reviews drug regulatory frameworks in 4 international domains (US, EU, China and Indonesia) and draws lessons for the Indian context.

72 http://e-aushadhi.gov.in/ayush/aboutus#gsc.tab=0 (31/8/2019, 16:51 hours).
There is lack of clarity, to say the least, regarding the establishment of efficacy, safety and quality of ASU&H drugs. Chapter IV A, section 33, clause EED of the DCA 1940 outlines that 'if the Central Government is satisfied on the basis of any evidence or other material available before it that the use of any Ayurvedic, Siddha or Unani drug is likely to involve any risk to human beings or animals or that any such drug does not have the therapeutic value claimed or purported to be claimed for it and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug'. What type of evidence or material is not specified. Any misbranded, adulterated and spurious ASU drug or in contravention of any provisions under chapter IV A can be prohibited for manufacture and sale by State governments (section 33, clause EEC). The said chapter also provides 'for the establishment of laboratories for testing and analysing’ of ASU drugs (33N(2)(a)). On 2nd January 2018, the Minister of State (Independent Charge) for AYUSH, Shripad Yesso Naik, said that there are no 'explicit provisions for the clinical trials of Ayurvedic medicines’ as of now under DCA 1940 or DCR 1945; that Rule 158B of DCR 1945 ‘does provide the requirement of pilot study to generate proof of safety & effectiveness of certain categories of Ayurvedic medicines’, and that his Ministry ‘has published Good Clinical Practice Guidelines for conduct of clinical trials on Ayurvedic, Siddha and Unani medicines on voluntary basis’. He added that the Pharmacopoeia Commission of Indian Medicine and Homoeopathy (PCIM&H) and the Ayurvedic Pharmacopoeia Committee (APC) are in place to develop quality standards and Standard Operating Procedures (SOPs) for Ayurvedic (and Siddha, Unani and homeopathy (SUH)) medicines, which manufacturers have to comply with. The Central and State governments have established drug testing laboratories for Ayurvedic (and other SUH) drugs and their raw materials – 55 laboratories were approved / licensed in the country (until 2.1.2018) as per DCR 1945. Quality certification schemes for Ayurvedic (as well as the SUH) medicines are administered as per WHO guidelines and international standards by CDSCO and the Quality Council of India (QCI). Like allopathic medicines, Ayurvedic (as well as SUH) medicines are covered under Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder.

73 The Siddha (SPC), Unani (UPC) and Homoeopathic (HPC) pharmacopeia committees are also in place. The PCIM&H serves as an umbrella organization for these committees. [https://bit.ly/2ZJEPB8](https://bit.ly/2ZJEPB8) (31/8/2019, 14:21 hours).

A Central Sector Scheme for promoting pharmacovigilance\textsuperscript{75} of ASU&H medicines was rolled out towards the end of financial year 2017-18. It aims to develop the culture of documenting adverse effects and undertaking the safety monitoring of ASU&H medicines and surveillance of misleading advertisements in the print and electronic media by means of a three-tiered network of national, intermediary and peripheral pharmacovigilance centres. The All India Institute of Ayurveda (AIIA), an autonomous institution under Ministry of AYUSH, is the designated National Pharmacovigilance Centre (NPvCC). 100 peripheral centres are being targeted by 2020.\textsuperscript{76} Interestingly, in the context of this scheme, the AIIA website states that ‘the common myth regarding herbal medicines is that these medicines are completely safe and can therefore be safely consumed by the patient on his/her own, without a physician’s prescription. This belief has led to large-scale self-medication by people all over the world, often leading to disappointing end-results, side effects, or unwanted aftereffects. Hence, AYUSH practitioners and consumers now need to be vigilant about the safety monitoring of drugs in the interest of Public Health’.\textsuperscript{77}

In another set of information provided by AYUSH Minister of State (Independent Charge), Shripad Yesso Naik, he claimed that analytical techniques and equipments used for the testing of ASU&H drugs and interventions are ‘same

\textsuperscript{75} WHO defines pharmacovigilance (PV) as ‘science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem’.\url{https://bit.ly/2FtIYX5} (22/7/2019, 11:20 hours). The Pharmacovigilance Program of India (PvPI) was approved by MoHFW in July 2010 ‘to create a nation-wide system for patient safety reporting’. There are 250 functioning adverse drug monitoring centres (AMCs) (medical colleges and corporate hospitals) in India under PvPI. The Indian Pharmacopoeia Commission (IPC), MoHFW is National Coordination Centre (NCC), launched as WHO Collaborating Centre (WHO-CC) for Pharmacovigilance in Public Health Programmes and Regulatory Services on 30 October 2017. The PvPI was initiated by the CDSCO in July 2010, with AIIMS New Delhi as the NCC and 22 AMCs. AMCs report adverse drug reactions (ADR) to NCC-PvPI, which works in collaboration with the global ADR monitoring WHO Uppsala Monitoring Centre (WHO-UMC) in Sweden, and contributes to the global ADR database. The NCC-PvPI helps CDSCO take decisions for safe drug use.\url{https://bit.ly/2ZEUGsS} (1/9/2019, 10:38 hours). India has been a full member of WHO-UMC since 1998.\url{https://www.who-umc.org/} (1/9/2019, 11:09 hours). The PvPI collates and analyses data to ‘recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public’. The broadened scope of pharmacovigilance also includes ‘the detection of medicines of substandard quality as well as prescribing, dispensing and administration errors’. Drug counterfeit, AMR and ‘the need for real-time surveillance in mass vaccinations are other pharmacovigilance challenges which need to be addressed’.\url{https://bit.ly/2ZEUGsS} (1/9/2019, 11:13 hours).

\textsuperscript{76} \url{https://bit.ly/2LFZz2e} (31/8/2019, 16:16 hours).

\textsuperscript{77} \url{https://aiia.gov.in/pharmacovigilance/} (31/8/2019, 16:20 hours).
as applicable in modern system of medicine’. Their respective research councils and pharmacopoeia committees work for standardization and quality testing of drugs. Good Clinical Practice (GCP) ‘guidelines, ICMR’s ethical guidelines and WHO guidelines are followed, as and where required, for clinical validation of AYUSH interventions and evaluation of efficacy & safety of drugs. Research & Development interventions in AYUSH are by and large done on the basis of integrated protocols and methodologies involving both AYUSH and modern scientific parameters of analysis and assessment. In this direction, collaborative research activities in AYUSH are being promoted involving premier medical and scientific institutions and registration of clinical research studies for ASU&H drugs is done in Clinical Trials Registry of India (CTRI)’. He also added that ‘regulatory provisions are laid down prescribing conditions required to be fulfilled for grant of license to manufacture’ ASU&H drugs that include compliance to GMP, proof of safety and effectiveness prescribed in DCR 1945 and ‘adherence to quality standards of identity, purity and strength of drugs’ prescribed in the respective pharmacopoeias. ‘Quality standards of identity, purity and strength of about 2600 ASU&H drugs are published in the respective pharmacopoeias, which are mandatory for the industry to manufacture drugs under license’. The WHO-GMP / CoPP ‘guidelines are applicable for quality certification of ASU herbal drugs intended for export and international trade’. ‘AYUSH Research Portal has also been created to place scientific inputs and interventions in public domain’.78 It is clear that AYUSH policymakers have taken note of prevalent concerns vis-à-vis safety and efficacy of ASU drugs as well as initiatives to address them. To what extent have they been successful in doing so needs to be systematically reviewed and assessed.

**Guidelines and regulations on insurance coverage of AYUSH services**

As per regulation 5, clause 1 (‘AYUSH coverage’) of the Insurance Regulatory and Development Authority (Health Insurance) Regulations, 2013, ‘insurers may provide coverage to non-allopathic treatments provided the treatment has been undergone in a government hospital or in any institute recognized by government and / or accredited by Quality Council of India / National Accreditation Board on Health or any other suitable institutions’. The Insurance Regulatory and Development Authority of India (Health Insurance) Regulations, 2016

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explicitly refer to ‘AYUSH treatment’\(^{79}\) and ‘general insurers and health insurers’ (regulation 18) vis-à-vis the generic terms ‘non-allopathic treatments’ and ‘insurers’ used in the 2013 regulations. Regulation 19 of 2016 Regulations, right after ‘AYUSH coverage’, is about ‘wellness and preventive aspects’, but does not refer to AYUSH in this context. If AYUSH is covered under insurance only for curative – that too, hospitalization – contexts, their primordial appeal of disease prevention and health promotion is ignored, and so is their practical utility in promoting health and well-being.

\(^{®}\) AYUSH should be covered under regulation 19 of the 2016 IRDA regulations pertaining to ‘wellness and preventive aspects’. This will not only lead to improved health and well-being of insured beneficiaries, but also reduced curative claims benefiting insurance companies. This will help leverage the primordial potential of AYUSH in the most appropriate manner.

**Challenges in the global promotion of ISM**

1) Limited / lack of scientific evidence vis-à-vis the efficacy, safety and quality of ISM is the most significant constraint for the global promotion of ISM. Wide variations in quality of raw materials and lack of proper quality control procedures lead to differences in the quality of final products and make ISM uncompetitive in the international market. Several traditional Indian medicines – as well as other TCSM – have come under scrutiny due to the presence of toxic metal traces, which is one of the biggest concerns as far as safety of TCSM is concerned. As stated earlier, India should call for the development of an appropriate framework of evidence of efficacy, safety and quality for TCSM in the G20 as well as in other international forums.

\(^{79}\) There were 15 insurance companies in India in 2017 covering one or more AYUSH systems. [https://bit.ly/2MMMRLu](https://bit.ly/2MMMRLu) (1/9/2019, 11:58 hours). There are no insurance products that offer standalone AYUSH cover; it is only available as part of standard health insurance policies, premiums for which are ‘significantly’ higher vis-à-vis those policies not offering it. Furthermore, ‘one must be hospitalized for more than 24 hrs in a recognized hospital to claim for the treatment taken’; there is a cap on the amount covered, ‘which usually ranges from 7.5% to 25% of Sum Assured’, while body rejuvenation programs are not covered. [https://bit.ly/2ZIBu9B](https://bit.ly/2ZIBu9B) (1/9/2019, 11:58 hours). Guidelines for reimbursement / settlement of AYUSH expenditure claims – including for drugless Yoga and Naturopathy – under insurance cover have been notified. As per IRDAI’s ‘Draft guidelines on standardization of individual health product’ (February 2019), expenses on AYUSH treatments ‘shall be covered subject to fixed and standard sub-limits based on Sum Insured’. [https://bit.ly/2NTLMBB](https://bit.ly/2NTLMBB) (1/9/2019, 12:49 hours).
2) Shortage of raw materials is another challenge. There are very few ISM industries which invest adequately in the cultivation of herbal plants and in value chain components such as collection, storage, distribution, processing and marketing of medicinal plants or follow good agricultural practices (GAP) and GMP for standardisation in final product. Most of the small manufacturing industries rely on local market sources, which are not able to provide quality raw materials.

3) Manufacturers of Ayurvedic medicines in India have pointed out to lack of product traceability as a major deterrent for exports (CII 2018). The Government of India’s track-and-trace system – Drug Authentication and Verification Application (DAVA) portal – for pharmaceutical exports from India should be leveraged for AYUSH too, or an alternative system acceptable to various stakeholders should be developed, since DAVA has been a cause of concern for the industry. The DGFT, CDSCO and Ministry of AYUSH can coordinate with various national / international stakeholders in this regard.

4) Given the high cost of clinical R&D / trials and drug registration, Ayurvedic products from India are generally exported as food / dietary supplements. Lack of provisions to register poly-herbal formulations in many countries is also a major deterrent for export of Ayurvedic medicines as most of them are made with multiple herbs (CII 2018). The preventive and promotive aspects of TCSM in general, AYUSH in particular, should be promoted since this is an area where they have competitive advantage over allopathic medicines vis-à-vis both health / well-being as well as financial outcomes. At the same time, global efforts should be made to develop appropriate frameworks of evidence, R&D, clinical trials, drug registration, etc. for TCSM / AYUSH drugs so that they maintain their primordial preventive and promotive appeal among the masses and not lose out on their cost-efficacy competitive advantage.

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<td><strong>NFHS-4 (2015-16)</strong></td>
<td>Households seeking care when they get sick by 'traditional healer' and 'vaidya / hakim / homeopath (AYUSH)' by place of residence (urban / rural) and wealth index</td>
<td>Public health sector (AYUSH) – R: 0.2%, U: 0.2%, T: 0.2%  Private health sector (AYUSH) – R: 0.3%, U: 0.2%, T: 0.3%  Traditional healer – R: 0.6%, U: 0.1%, T: 0.4%</td>
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<tr>
<td><strong>NFHS-3 (2005-06)</strong></td>
<td>Households seeking care when they get sick by 'traditional healer' and 'vaidya / hakim / homeopath (AYUSH)' by place of residence (urban / rural) and wealth index</td>
<td>Private health sector (AYUSH) – R: 0.4%, U: 0.7%, T: 0.5%  Traditional healer – R: 0.3%, U: 0.0%, T: 0.2%</td>
</tr>
<tr>
<td><strong>NFHS-2 (1998-99)</strong></td>
<td>Diarrheal treatment with a solution made from ORS packets for children under 3 years of age</td>
<td>0.6%</td>
</tr>
<tr>
<td><strong>NFHS-2 (1998-99)</strong></td>
<td>Sought advice / treatment of reproductive health problems by vaid / hakim / homeopath</td>
<td>2%</td>
</tr>
<tr>
<td><strong>NSS (2014)</strong></td>
<td>Average out-of-pocket expenditure (in INR) on AYUSH medicines and other (non-AYUSH) medicines per treated person in the last 15 days by residence  (Also see tables 5 and 6 below for usage statistics)</td>
<td>R: AYUSH (270), Other (392); U: AYUSH (378), Other (454)</td>
</tr>
<tr>
<td><strong>NCAER household survey of healthcare utilisation and expenditure (1995)</strong></td>
<td>1. Individuals seeking treatment (includes data from faith healer / religious person) for non-hospitalised illness episodes by state, gender, place of residence, nature of illness (acute, chronic, serious communicable, injuries)  2. Reasons for choice of treatment by type of treatment</td>
<td>1. R: Male (0.7%), Female (0.3%), Total (0.5%); U: Male (0.3%), Female (0.2%), Total (0.2%)  2. R: Inexpensive / free (18.7%), no other facility nearby (4.8%), time suitable (2.1%), good reputation (19.5%), close by (0%), others (55%); U: Inexpensive / free (11.3%), no other facility nearby</td>
</tr>
</tbody>
</table>
### Surveys Variables Key statistics

| Singh et al (2004) | (including faith healer / religious person) | (3.2%), time suitable (0%), good reputation (0%), close by (0%), others (85.6%) |

1. Preference for various indigenous systems of medicine for common and serious ailment
2. Sick persons availing various indigenous systems of medicine

1. Common ailments: Ayurveda (18.71%), Homeopathy (12.66%), Unani (0.37%), Siddha (0.63%), Allopathy (67.63%)
2. Serious ailments: Ayurveda (5.02%), Homeopathy (11.41%), Unani (1.02%), Siddha (0.53%), Allopathy (82.02%)

2. Ayurveda (7.08%), Homeopathy (6.25%), Unani (0.19%), Siddha (0.66%), Allopathy (85.82%)

---

**Note – R: Rural, U: Urban, T: Total.**


**Table 5: Percentage patients (persons reporting illness during reference period of last 15 days) receiving medical treatment (excluding hospitalization) by nature of treatment and background characteristics, Rural India, 2014**

<table>
<thead>
<tr>
<th>Rural India</th>
<th>Allopathy</th>
<th>ISM</th>
<th>Homoeopathy</th>
<th>Yoga &amp; Naturopathy</th>
<th>Other</th>
<th>AYUSH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 5 years</td>
<td>95.7</td>
<td>1.0</td>
<td>2.3</td>
<td>0.1</td>
<td>0.9</td>
<td>3.5</td>
</tr>
<tr>
<td>5 to 14 years</td>
<td>95.0</td>
<td>2.7</td>
<td>1.1</td>
<td>0.9</td>
<td>0.3</td>
<td>4.7</td>
</tr>
<tr>
<td>15 to 59 years</td>
<td>92.7</td>
<td>3.8</td>
<td>3.3</td>
<td>0.5</td>
<td>0.4</td>
<td>7.5</td>
</tr>
<tr>
<td>60 years &amp; above</td>
<td>93.0</td>
<td>4.1</td>
<td>2.9</td>
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<td>0.1</td>
<td>7.6</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
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<tr>
<td>Male</td>
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<td>1.9</td>
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<td>0.3</td>
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<td>Female</td>
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<td>7.6</td>
</tr>
<tr>
<td>Rural India</td>
<td>Allopathy</td>
<td>ISM</td>
<td>Homoeopathy</td>
<td>Yoga &amp; Naturopathy</td>
<td>Other</td>
<td>AYUSH</td>
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<td><strong>Caste / tribe</strong></td>
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</tr>
<tr>
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<td>1.4</td>
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<tr>
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<tr>
<td>OBC</td>
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<td>2.8</td>
<td>0.4</td>
<td>0.1</td>
<td>6.3</td>
</tr>
<tr>
<td>Others</td>
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<td>3.8</td>
<td>4.1</td>
<td>0.4</td>
<td>0.5</td>
<td>8.1</td>
</tr>
<tr>
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<td></td>
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<td>1.3</td>
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<tr>
<td><strong>Education of household head</strong></td>
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<tr>
<td><strong>MPCE quintile</strong></td>
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<td>Lowest</td>
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<td>2.7</td>
<td>1.0</td>
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<td>6.9</td>
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<td>Middle</td>
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<tr>
<td>Highest</td>
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<td>0.4</td>
<td>8.2</td>
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<tr>
<td><strong>Type of illness</strong></td>
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<td>5.3</td>
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<tr>
<td>Rural India</td>
<td>Allopathy</td>
<td>ISM</td>
<td>Homoeopathy</td>
<td>Yoga &amp; Natur-</td>
<td>Other</td>
<td>AYUSH</td>
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</tbody>
</table>


Table 6: Percentage patients (persons reporting illness during reference period of last 15 days) receiving medical treatment (excluding hospitalization) by nature of treatment and background characteristics, Urban India, 2014

<table>
<thead>
<tr>
<th>Urban India</th>
<th>Allopathy</th>
<th>ISM</th>
<th>Homoeopathy</th>
<th>Yoga &amp; Natur-</th>
<th>Other</th>
<th>AYUSH</th>
</tr>
</thead>
<tbody>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Below 5 years</td>
<td>92.2</td>
<td>2.9</td>
<td>4.3</td>
<td>0.3</td>
<td>0.4</td>
<td>7.4</td>
</tr>
<tr>
<td>5 to 14 years</td>
<td>93.8</td>
<td>1.6</td>
<td>3.8</td>
<td>0.9</td>
<td>0.0</td>
<td>6.3</td>
</tr>
<tr>
<td>15 to 59 years</td>
<td>93.5</td>
<td>3.8</td>
<td>3.2</td>
<td>0.2</td>
<td>0.5</td>
<td>7.2</td>
</tr>
<tr>
<td>60 years &amp; above</td>
<td>93.8</td>
<td>4.8</td>
<td>2.4</td>
<td>0.1</td>
<td>0.1</td>
<td>7.2</td>
</tr>
</tbody>
</table>

| Gender       |          |     |             |                 |       |       |
| Male         | 93.2     | 4.4 | 2.4         | 0.3             | 0.5   | 7.1   |
| Female       | 93.8     | 3.2 | 3.7         | 0.2             | 0.2   | 7.1   |

| Caste / tribe |          |     |             |                 |       |       |
| ST           | 94.5     | 3.5 | 1.7         | 0.6             | 0.0   | 5.8   |
| SC           | 94.5     | 4.1 | 2.0         | 0.2             | 0.2   | 6.3   |
| OBC          | 93.6     | 4.0 | 3.0         | 0.2             | 0.3   | 7.3   |
| Others       | 93.0     | 3.3 | 3.7         | 0.3             | 0.5   | 7.3   |

<p>| Religion     |          |     |             |                 |       |       |
| Hinduism     | 93.5     | 3.8 | 3.1         | 0.3             | 0.3   | 7.2   |</p>
<table>
<thead>
<tr>
<th></th>
<th>Allopathy</th>
<th>ISM</th>
<th>Homoeopathy</th>
<th>Yoga &amp; Naturopathy</th>
<th>Other</th>
<th>AYUSH</th>
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**Education of household head**

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<tr>
<th></th>
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<th>Primary or below</th>
<th>Secondary education</th>
<th>Higher education</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>94.3</td>
<td>94.1</td>
<td>93.6</td>
<td>91.6</td>
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**MPCE quintile**

<table>
<thead>
<tr>
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<th>Lowest</th>
<th>Second</th>
<th>Middle</th>
<th>Fourth</th>
<th>Highest</th>
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</thead>
<tbody>
<tr>
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<td>94.9</td>
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<td>93.6</td>
<td>94.9</td>
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</table>

**Type of illness**

<table>
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<tr>
<th></th>
<th>Chronic</th>
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</tr>
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<tbody>
<tr>
<td></td>
<td>93.1</td>
<td>94.1</td>
<td>4.4</td>
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**Total**

<table>
<thead>
<tr>
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<th>Urban India</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>93.5</td>
<td>3.7</td>
<td>3.2</td>
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</tr>
</tbody>
</table>


**Saudi Arabia**

Saudi Arabia is the country with highest number of scientific TCSM publications in the Arab world. However, it does not have a unique traditional system of
medicine like India or China.\textsuperscript{81} Although there is no nationally representative survey on TCSM use in the country, several regional surveys indicate prevalence as high as 75 percent\textsuperscript{82} – ‘religious healing, herbal medicine, cupping therapy and healing with honey’ being most used therapies. A 2013 study indicated that TCSM was largely used in Saudi Arabia, as elsewhere, for chronic illnesses, and ‘was more common among females and middle-aged people’. ‘Highly educated and high-income people preferred to use wet cupping and honeybee therapies’. According to a 2010 study, acupuncture was used largely for joint pains (22.4%) and headaches (18.6%). Nevertheless, while Saudi Arabia provides universal health care, its UHC does not cover TCSM – TCSM expenses have to be paid out-of-pocket (Khalil et al 2018).

The National Center for Complementary and Alternative Medicine (NCCAM), established in 2008 as part of Saudi Ministry of Health (MOH), ‘is the Saudi national reference for all activities related to complementary medicine’. It is responsible for setting ‘rules and criteria for regulating, monitoring and supervising complementary medicine practices’. NCCAM also promotes research, training, public awareness and authentication of Islamic medicine (Khalil et al 2018). Among its top priorities is the ‘evaluation of other complementary medicine approaches for their suitability, establishing licensing requirements for new complementary practice modalities’, and promotion of ‘integration between complementary and modern medicine’. As per Saudi MOH’s Health Professions Act and its Executive Regulations (2017-09), ‘alternative and complementary medicine may be practiced only with’ NCCAM’s authorization, ‘in accordance with the specific conditions and requirements’ – penal action is taken against unauthorized practitioners. Among currently regulated and licensed TCSM are cupping therapy, acupuncture, osteopathy, chiropractic and naturopathy – practitioners are required to possess training / formal degree from approved institutions for registration. Herbs, food supplements and complementary medicine devices, on the other hand, are regulated by the Saudi Food and Drug Authority (Aboushanab, Khalil and Al Ahmari 2019).

\textsuperscript{81} Islamic medicine and Prophetic medicine are commonly used terms to refer to traditional medicines in Saudi Arabia. Islamic medicine refers to a group of healing therapies practiced in Arab and Islamic world within the context of religious influences of Islam, and is open to all practices that do not contradict the Islamic faith. Prophetic medicine is restricted to practices included in the traditions and sayings of the Prophet of Islam (Khalil et al 2018). According to WHO (2019), Islamic and Prophetic medicines, hijaama, honey and other bee products are used by 60–79% of the population, while Acupuncture, chiropractic, naturopathy and traditional Chinese medicine are used by 1–19% each and herbal medicines by 40–59% of the population.

\textsuperscript{82} According to Abuelgasim et al (2018), TCSM varies between 33–93.3%, with most of it (both dietary and non-dietary) being ‘of a religious nature’ (2).
A study on understanding the attitude of medical students in Saudi Arabia towards TCSM reveals that while majority of students do not have sufficient knowledge about these systems of medicines, they were willing to learn more about TCSM. Furthermore, 60 percent of students surveyed in a sample of 399 medical students supported inclusion of TCSM courses in their medical curriculum, while more than 50 percent of students were in favour of TCSM being taught as a separate course (Albadr et al 2018). An integrative health care model has not been adopted in any of the medical institutions / hospitals, except for a few clinics of complementary therapies which were established for research in medical universities and military hospitals (Khalil et al 2018).

India should try to convince Saudi Arabia to include TCSM as part of health agenda during its G20 Presidency in 2020. It could build on the leads above in doing so.

Italy will have the G20 Presidency in 2021. India can start working with it from now on itself for including TCSM in its G20 health agenda. This would enable India to take up TCSM in a big way during its G20 Presidency in 2022.

Italy

TM is commonly known as non-conventional medicine (NCM) in Italy. The Italian Republic upholds the principles of scientific pluralism in health care. It ensures that individuals are free to choose between different treatment therapies and professionally qualified health care providers use their discretion to choose between different treatment approaches. While use of NCM has dramatically increased over the past three decades, there is no national law to regulate professional training, education and practice of NCM in Italy (di Sarsina and Iseppato 2009).

NCM use in Italy

A number of surveys have been conducted to estimate the use of NCM among Italian population. In 2010, a study undertaken by EURISPES estimated that more than 11 million people in Italy use NCM. In 2008, a CENSIS survey revealed that 23.4 percent of Italian population had used NCM, particularly homeopathy and phytotherapy previous year. In 2005, a survey conducted by ISTAT revealed that eight million people had used NCM in the last three years. Among different NCM therapies, homeopathy was the most popular form of NCM, followed by osteopathy, chiropractic, physiotherapy and acupuncture.
The popularity of homeopathy in Italy was also highlighted in the results of a 3-year longitudinal study carried out by Menniti-Ippolito et al (2004) on 52,332 families. It concluded that, in comparison to manual therapy, phytotherapy, acupuncture and other NCMs, homeopathy was most preferred NCM among Italians. The 2005 ISTAT survey also found a strong correlation between higher education and NCM use. It also revealed that women between 35 and 44 years of age have a higher tendency to use NCM vis-à-vis their male counterparts. Further, an online survey conducted by Health Monitor CompuGroup in 2011 established that almost 52 percent of general practitioners in Italy prescribe homeopathic medicines to patients (Bordogna 2011; di Sarsina and Iseppato 2011).

Legal status of NCM in Italy

Before 2002, sporadic attempts were made to grant legal recognition to NCM in Italy. For instance, Ministry of Health Decree (22/7/96) included acupuncture and other therapies among specialized services which could be administered by clinics under the National Health Service. Presidential Decree (271/2000) included acupuncture as part of additional services that could be administered by specialists (Bordogna 2011). In 2002, the National Federation of Councils of MDs and Dentists (FNOMCeO) recognised 9 NCMs (acupuncture, traditional Chinese medicine, Ayurvedic medicine, homeopathy, anthroposophical medicine, homotoxicology, phytotherapy, chiropractic, osteopathy) and mandated that these NCMs could be practiced only by MDs or dentists (Bordogna 2011; di Sarsina and Iseppato 2011). In Italy, chiropractic and osteopathy are recognised as primary health disciplines, which implies that they are independent. Chiropractic and osteopathy may also be practiced by doctors / physiotherapists after undergoing the internationally recommended training for these disciplines. In 2006, the revised Italian Code of Medical Ethics reiterated that only medical and dental surgeons who have attended specified training courses are eligible to practice NCM. Time and again, rulings of the Supreme Court of Italy (for instance in 1982, 1999, 2003, 2005 and 2007) have upheld that acupuncture is a medical practice, homeopathic medicines must be prescribed by a doctor, and it is illegal for individuals without a medical degree to practice NCM (di Sarsina and Iseppato 2011). Further, education in NCM is not a mandatory part of graduation curriculum in Italian medical schools (Bordogna 2011). Non-professionalizing courses are offered at the post-graduation level, and these courses often remain outside the purview of mainstream medical departments (di Sarsina and Iseppato 2009).
Health care is a shared responsibility between the national and regional governments in Italy – the national government sets health care standards, while regions have the responsibility to establish organizational and regulatory structures for regional health care services. This has led to regional differences in the level of integration between modern medicine and NCM. Some regions such as Tuscany have incorporated a chapter on NCM in their regional health plans. In fact, the regional government of Tuscany guarantees access to acupuncture therapy as part of approved regional health care standards and requires patients to make a nominal co-payment for homeopathy, phytotherapy, acupuncture and traditional Chinese medicine. In Emilia-Romagna, a NCM regional observatory was set up in 2004 to conduct and promote experimental projects in acupuncture, homeopathy and phytotherapy. In 2008, the Piemonte region established the first regional reference centre for acupuncture and scientific coordination for NCM (di Sarsina and Iseppato 2009). Therefore, while several regional initiatives have been taken to achieve formal integration of NCM with modern medicine, demand for a nationwide law to acknowledge and regulate NCM has not yet been met by the Italian national government.

Regulatory situation of NCM pharmaceuticals

Italy had specific regulations for homeopathy and anthroposophic medicines (WHO 2001). In 2006, the European Directive on Pharmaceuticals (2004/27/CE) comprising of 5 articles on homeopathic and anthroposophical medicines was enforced in Italy. For the first time in 2009, the Italian Medicines Agency (AIFA) issued guidelines for ensuring the quality of homeopathic medicines. However, registration of new homeopathic medicines in Italy has been suspended since 1995. Moreover, Italy has stringent laws that prohibit printing of instructions and dosages on homeopathic medicine packets or advertising them in any form (di Sarsina and Iseppato 2009).

Japan

The history of traditional Japanese medicine can be traced back to 6th century AD when Chinese medicine was imported in Japan through the Korean Peninsula. While Chinese medicine was initially practiced in its original form in Japan, Japanese practitioners gradually modified it to meet local health care needs (Arai and Kawahara 2018). This altered form of Chinese medicine came to be known as Kampō (also written as Kanpo), literally referring to the herbal system of medicine that developed in China during the Han dynasty from 206 BC to 220 AD. Between 1868 and 1912, the Japanese government mandated all
prospective physicians to study Western medicine even if they aspired to practice Kampo. Thus, Japan became one of the first developed countries where Western and traditional medicine coexisted within the same health care system. However, this period is often referred to as the ‘period of repression’ for Kampo and for the first time, three of its components – herbal medicine, acupuncture and acupressure – came to be distinctly recognized. Since the onset of the 20th century, Kampo mainly refers to herbal medicine (Yu et al 2006). Despite being based on traditional Chinese medicine, traditional Japanese medicine has developed uniquely, and it is worthwhile to highlight differences between the two systems of medicine.

1) **Diagnosis**: In traditional Chinese medicine, the first step is to identify a patient’s Zheng (literal meaning ‘syndrome’ which encompasses aetiology, pathology and disease location). Practitioners confirm the treatment ‘principle’ after comprehensively analyzing a patient’s medical history and symptoms. The treatment principle may entail selecting a particular treatment formula or making a new formulation based on the patient’s condition. On the other hand, practitioners of traditional Japanese medicine treat patients based on Sho (symptoms) and prescribe the most suitable treatment formula. The diagnosis and prescription method is often regarded as similar to that of a lock and key. Although the concept of Sho is derived from Zheng, it is much simpler as practitioners tend to prescribe treatment based on symptoms. Instead of developing a theoretical medical background of a patient and then prescribing medicines, Japanese practitioners are trained to focus on treatment (Yu et al 2006).

2) **Treatment methods**: While decoctions, powdered herbs and tablets prescribed in traditional Chinese medicine are based on a single herb, Kampo medicines are mostly based on formulations, which are combinations of several herbs known as ‘crude drugs’. Unlike traditional Chinese medicine, Kampo prescriptions maintain the combination ratios of classical formulations and new prescriptions are not usually created by practitioners (Arai and Kawahara 2018; Yu et al 2006).

3) **Physician licensing**: In China, departments of traditional Chinese medicine exist in every Western medicine school and prospective practitioners can either choose to specialize in Western medicine or traditional Chinese medicine. In contrast, as mentioned before, Japan exclusively recognizes physicians licensed in Western medicine and a separate license in Kampo medicine does not exist (Arai and Kawahara 2018). An allopathic physician can use either Western or Kampo procedures for diagnosis and prescribe biomedical and / or Kampo medicines, depending on the nature of the
disease. However, acupuncture is practiced by non-physicians and remains outside the purview of official health care system (Scheid and MacPherson 2012).

Let us also highlight some major occurrences that marked the evolution of TCSM in Japan.

1) **Realization of national health insurance system:** Even before the realization of national health insurance system in 1961, the insured Japanese population was usually reimbursed for Kampo therapies. In 1959, 20 types of crude drugs and in 1965, 43 types of crude drugs were included in the drug price list, also referred to as the ‘drug tariff’, which implied that patients could make insurance claims for the listed drugs. In 1976, 42 types of Kampo extract products were listed under the ‘ethical Kampo products’ classification in the drug list (Akiba 2011). As Kampo medicines gained official recognition for the first time as therapeutic drugs, physicians extensively started prescribing Kampo medicines to their patients. Currently, 148 formulations are listed as ‘ethical Kampo products’, while official approval standards for over-the-counter (OTC) Kampo products exist for 294 formulations (Arai and Kawahara 2018).

2) **Deletion of OTC Kampo products from drug tariff:** By the 1980s, provision of free health care to the elderly led to rapidly increasing health care costs in Japan. In 1983, the Japanese government declared that OTC Kampo products would be removed from the drug tariff because certain OTC Kampo products were as efficacious as ethical Kampo medicines and hence their inclusion in the drug tariff was not required (Akiba 2011). Moreover, even though traditional Japanese medicines were being extensively used as therapeutics, consciousness to demonstrate clinical safety and efficacy of Kampo medicines was gradually emerging in Japan.

3) **Adverse reactions and establishing clinical safety of Kampo medicines:** In 1996, the Ministry of Health, Labour and Welfare (MHLW) declared that the use of shosaikoto, a Kampo extract which was widely prescribed for treating viral hepatitis, had led to interstitial pneumonia in 88 patients and death of 10 patients since 1994. The news triggered a nationwide outrage. Kampo medicines were no longer considered safe and there was an unprecedented demand to establish clinical safety and efficacy of these medicines. Subsequently, research institutions proactively took measures to establish clinical efficacy of Kampo medicines. For instance, an Evidence-based Medicine (EBM) Committee was constituted in Japanese Association for Operative Medicine (JAOM) to demonstrate that clinical treatment with Kampo medicines is safe and effective. The foremost objective of the Committee was
to collect a substantial amount of evidence by categorizing research papers by clinical fields and outcomes. At the end of this process, 93 papers were submitted to the Board of Directors at JAOM, and final EBM report was submitted to the MHLW in 2005. Novel evidence to support the quality, safety and efficacy of Kampo medicines has increased considerably since then (Akiba 2011).

International efforts to promote traditional medicine

Compared to traditional Chinese medicine, the demand for Kampo products in international markets is still low and most Kampo products are used domestically. In the United States, for instance, Kampo products are only available in the form of non-prescription or OTC products and have to fulfil Japanese GMP norms (Watanabe et al 2011). The value of Kampo exports is quite low vis-à-vis export value of Chinese herbal products and was estimated at ¥ 8 million (~USD 80,000) for 2015 (Arai and Kawahara 2018). While national policies in China and South Korea have consistently promoted their systems of traditional medicine, the Japanese government has made limited progress in this regard. Unlike China and South Korea, Japan does not have government departments or public institutes focusing exclusively on Kampo (Fuyuno 2011). In fact, Japan does not have a holistic policy or law to promote or regulate all aspects of traditional medicine. However, in order to develop a framework for standardization of terminologies on traditional medicine and natural pharmacological ingredients (which may differ across countries even when they have the same name), the Japan Liaison of Oriental Medicine (JLOM) was established in 2005 by four academic associations (Japan Society for Oriental Medicine, Japanese Society of Pharmacognosy, Medical and Pharmaceutical Society for Wakan-Yaku, and Japan Society of Acupuncture and Moxibustion) and two WHO Collaborating Centers for Traditional Medicine (Kitasato University’s Oriental Medicine Research Center and University of Toyama’s Department of Japanese Oriental Medicine). JLOM is playing a pivotal role in promoting cooperation on standardization across national borders (Ishikawa 2013). Moreover, with a view to upgrade the existing status of Kampo medicine, the Japanese Ministry of Education, Culture, Sports, Science and Technology included Kampo education into the core curriculum of medical students in 2001 (Watanabe et al 2011).

Evaluation and re-evaluation of traditional Japanese medicines

Despite low international popularity, Kampo products are recognised worldwide for being based on updated scientific standards. Moreover, Japanese
regulations for evaluating Kampo and allopathic medicines are not very different from each other and regulations specified in Pharmaceutical Affairs Law of 1960 are uniformly applicable to both Kampo and Western medicines. Since 1980, new Kampo drugs are considered as a form of combined drug and their approval requires the same data that is required for the approval of allopathic medicines. Expensive and time-consuming tests such as tests for mutagenicity, carcinogenicity and teratogenicity are mandatory, depending on the possible duration of treatment and indications applicable to them. Drug approvals for Kampo products also require three-phase clinical trials (Arai and Kawahara 2018). Further, since 1971, the Japanese government started the practice of re-evaluation of all drugs marketed before 1967. For drugs approved prior to 1967, results of clinical efficacy were made public in several phases since 1973, and for drugs approved between October 1967 to March 1980, results have been published in the public domain since 1988. More importantly, a new system for re-evaluation of safety and efficacy of all ethical drugs in every 5 years was instituted in 1988 (WHO 2019; 1998).

As quality of Kampo products depends on the quality of crude drugs, it is important to ensure that crude drugs are of stable quality. The Japanese Pharmacopoeia (JP) consists of monographs which specify legally binding standards on a majority of crude drugs used for manufacturing Kampo products. The 17th edition of the JP contains monographs on 224 crude drugs. The following aspects of crude drugs are stated in each article of the JP monograph: name, origin, medicinal part, preparation process, content of specific constituents, description, identification, purity (including heavy metals, arsenic, residual pesticides), loss on drying, total ash, acid-insoluble ash, extract content and assay (Arai and Kawahara 2018). In 2008, a guidebook on non-binding approval standards for OTC Kampo products was issued and later updated (WHO 2019).

Ensuring quality and safety of Kampo medicines

1) **Decoction protocol**: Most Kampo products in the Japanese market are manufactured by decocting all crude drugs together in hot water. However, in China and Korea, crude drugs are individually decocted and dry extracts of decocted drugs are subsequently mixed to manufacture herbal medicines (Arai and Kawahara 2018). Since mixing individual decocted extracts stimulates interactions between extracts which may influence the composition of the herbal medicine, the practice of manufacturing Kampo medicines by mixing individual decocted extracts is not permitted in Japan.
2) **GMP norms:** Since Kampo products are manufactured in the same way as Western medicines, the Pharmaceutical GMP is applicable to them. However, as Pharmaceutical GMP was developed from the perspective of manufacturing Western drugs and is inadequate to manufacture Kampo products which contain crude drugs, the Japan Kampo Medicines Manufacturers Association (JKMA) formulated self-imposed standards called ‘GMP for Kampo products’ (Kampo GMP) in 1988. Kampo GMP mandates that a crude drug control manager possessing adequate expertise in crude drug identification be appointed at every manufacturing plant. It also describes certain aspects of manufacturing Kampo products, such as cutting crude drugs, sampling method for crude drugs, order of mixing crude drugs, deploying quality control methods, verifying conditions feasible for extraction, etc. In 2012, the Kampo GMP was updated to the present version by the Federation of Pharmaceutical Manufacturers’ Associations of Japan (Arai and Kawahara 2018).

3) **GMP standards and safety measures:** In 2014, Japan became a member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme which specify GMP standards for manufacturing herbal medicines. Manufacturers of Kampo products now adhere to these standards for manufacturing Kampo products. Further, to ensure that safe crude drugs are procured for manufacturing Kampo medicines, Japan has enforced additional standards to test for residual pesticides and heavy metals (Arai and Kawahara 2018).

4) **Post-marketing surveillance:** The MHLW has established three major systems for collecting data on adverse reactions caused by Western and Kampo medicines. The first is the Adverse Drug Reaction Monitoring System in which designated hospitals report adverse reaction cases to the MHLW. The second system is known as the Pharmacy Monitoring System, which is a consortium of pharmacies authorized to gather data on adverse reactions caused by OTC drugs. The third system is the Adverse Reaction Reporting System in which manufactures are required to report cases of severe adverse reactions to the MHLW (WHO 1998).

**Usage and users of Kampo medicine**

Although Kampo medicine is prescribed to 1 out of 10 patients in Japan, limited evidence exists on its use and users. In order to address this lacuna, independent surveys have been conducted. For instance, an internet survey based on the International Complementary and Alternative Medicine Questionnaire (I-CAM-
Q) was conducted among the Japanese population in February 2016. Of the 3,208 participants, 411 (12.8%) reported CAM use in the past 12 months. The use of CAM was more common among females in their 40s and 50s with university level education and ‘tolerable’ chronic diseases like hypertension, mental and musculoskeletal diseases. The I-CAM-Q survey concluded that OTC Kampo medicines, prescribed Kampo medicines, dietary supplements, massage and other physical services were the most widely used CAM therapies in Japan (Motoo et al. 2019).

A more elaborate questionnaire-based survey with 354 participants was carried out in three Japanese outpatient clinics in 2013. More than two-thirds of patients participating in the survey were females and almost all participants were at least high school graduates. Around three-fourth of survey participants were users of Kampo medicines and most patients had used Kampo in the past for treating chronic conditions, which usually coexisted with other morbidities. The most frequent indications for earlier Kampo use were common cold, gastrointestinal complaints, over-sensitivity to cold, stress / anxiety, shoulder stiffness, gynaecological diseases, allergies, hay fever, headache / migraine, disturbed sleep, low back pain and dermatological diseases. For most indications, around half of the patients preferred to be treated with a combination of Kampo and Western medicines. Users of Kampo medicines believed in the underlying Asian philosophies of traditional medicine and felt that Kampo treatment is more holistic and natural and is associated with fewer side effects. Some users also felt that use of Kampo medicines stimulates self-healing (Hottenbacher et al. 2013). The findings of this survey were similar to the results of a web-based physicians’ survey conducted by JKMA in 2011, which concluded that participating physicians had mostly prescribed Kampo medicines for muscle cramps, acute upper respiratory tract inflammation, gastrointestinal and gynaecological conditions. Further, for almost 83% of patients, physicians had prescribed Kampo medicines in combination with modern medicines (Arai and Kawahara 2018).

**Challenges**

1) **Differences in quality of crude drugs and Kampo products.** Unlike biomedical products, it is difficult to impose stringent quality checks on Kampo products. This is because plants of different origin are used to manufacture a crude drug and a combination of several crude drugs is used to manufacture a particular Kampo formula. Although information about plants like place of origin must be obtained, the quality of such plants is often different, and composition of Kampo products is hence different across different manufacturers. Moreover, since different manufacturers use their own reference
texts to manufacture Kampo products, certain products with the same name may be manufactured using a different formula (Kiuchi and Makino 2011).

2) **Adverse reactions:** Although it is widely believed that traditional Japanese medicine has no / minimum side effects, consumption of certain crude drugs is associated with adverse reactions. For instance, Glycyrrhiza, a crude drug present in many Kampo formulae, may cause high blood pressure, hot flashes and dizziness. Adverse reactions are also likely due to interactions between crude drugs / Kampo products and allopathic medicines. Effects other than therapeutic effects are also observed if combinations of crude drugs / Kampo products are consumed (Kiuchi and Makino 2011). Therefore, patients are advised to consume traditional Japanese medicine only if they are prescribed to do so by their physicians.

3) **Lack of incentives for pharmaceutical companies:** Since applications for approval of ethical Kampo formulations need to be supported by the same data that are required to approve applications for allopathic medicines, Japanese pharmaceutical companies are reluctant to invest in research and development of Kampo medicines as estimated drug development costs are often higher than expected sales and prices listed on the national health insurance. Moreover, in order to make modifications to dosage forms and additions to generic Kampo medicines, pharmaceutical companies are subject to rules that are applicable to new drugs. In addition, pharmaceutical companies also find it difficult to identify all active ingredients in crude drugs (Arai and Kawahara 2018). For these reasons, changes or additions to existing Kampo formulations have lately occurred at a slow pace in Japan.

4) **Inaccurate diagnosis and treatment:** It is often argued that since Japanese practitioners are better trained in Western vis-à-vis traditional Japanese medicine, they tend to prescribe Kampo formulations based on Western diagnoses. The results of a web-based survey of physicians conducted in 2011 also highlighted that even though Japanese doctors used combinations of Western and Kampo medicines for treating a majority of their patients, they mostly relied on Western medical diagnoses (Arai and Kawahara 2018). While this is acceptable for certain indications in which Kampo formulae are close to Western prescriptions, there is a high degree of probability that prescribed Kampo medicines are based on inaccurate diagnosis (Watanabe et al 2011).

5) **Scarcity of raw materials:** Since Kampo medicines are based on traditional Chinese medicine, most Kampo products are manufactured by making use of imported Chinese herbs. In recent years, prices of Chinese herbs have
significantly increased due to rising domestic and international demand, and supply shortages caused due to a shrinking rural population (Ishikawa 2013). According to estimates provided by JKMA, while the average price of home-grown Japanese herbs has increased from ¥ 2,494 per kilogram to ¥ 3,019 per kilogram between 2006 and 2016, the average price of Chinese herbs more than doubled from ¥ 690 to ¥ 1,570 during this period. Although Chinese herbs are still cheaper, people fear that significant increases in price of Kampo medicines due to rising prices of Chinese ingredients may compel the Japanese government to exclude these medicines from national health insurance coverage. However, Japanese drug manufacturers are dealing with this ordeal by domestically producing alternatives to Chinese herbs and making them as affordable as authentic Chinese ingredients. For instance, Tsumura, which is the largest manufacturer of herbal medicines in Japan, is expanding its domestic procurement network by signing contracts with local farmers and providing them technical assistance and practical advice to produce medicinal herbs. Other manufacturers of Kampo medicine, such as Takeda Consumer Healthcare, are also adopting similar practices in anticipation of Chinese herb shortages in the future (Nishioka 2018).

Indian traditional systems of medicine in Japan

The history of Ayurveda in Japan can be traced to the introduction of Buddhism in Japan in the 6th century. During that time, Ayurveda was perceived as ‘Buddhist medicine’ among the Japanese. Despite India’s close geographical proximity and frequent cultural exchanges with Japan, Ayurveda could not receive significant attention in Japan until 1970. In 1970, a group of scholars led by Prof Hiroshi Maruyama from Osaka University visited the Gujarat Ayurveda University in India. Upon their return to Japan, they established the ‘Research Association of Ayurveda in Japan’ and introduced an annual journal on ‘Studies on Ayurveda in Japan’. Few years later, Research Institute of Traditional Oriental medicine (RITOM) was founded to promote integrated treatment with Western and Oriental medicine. Dr UK Krishna, an Indian Ayurvedic practitioner who came to Japan to pursue his doctorate studies in the medical school at Okayama University, assumed charge as the Vice President of RITOM in the 1980s and took important measures to popularize the original form of Ayurveda in the country. For instance, RITOM introduced educational programmes in Ayurveda and self-healing in 1994. In 2001, RITOM established the ‘Japan Ayurveda School’, an international branch of Gujarat Ayurveda University (Uebaba 2002). Although propagation of Ayurveda in Japan is still in its infancy vis-à-vis Kampo medicine, acceptance to the traditional Indian medicine system has reportedly been rising
and according to certain estimates, almost 12% of the Japanese population uses Ayurveda (Kumar 2011). It is worthwhile to mention here that in order to promote bilateral cooperation in Indian traditional systems of medicine such as Ayurveda and Yoga, Ministry of AYUSH in India and the Kanagawa Prefectural Government in Japan signed a Memorandum of Cooperation in October 2018. This agreement marked the official commencement of mutual cooperation in Indian traditional systems of medicine between the two countries (MEA 2018).

China

In recent years, Traditional Chinese Medicine (TCM) has gained a lot of traction at the global level. TCM practices of acupuncture and moxibustion have been included in the Representative List of the Intangible Cultural Heritage of Humanity by UNESCO, and the Yellow Emperor’s Inner Canon (Huang Di Nei Jing) and Compendium of Materia Medica (Ben Cao Gang Mu) listed in the Memory of the World Register (WHO 2019). 130 TCM elements have been included in the Representative List of National Intangible Cultural Heritage. In 2018, the World Health Assembly adopted the 11th version of the International Classification of Diseases (ICD-11) and included details about traditional medicines in it for the very first time in the form of a supplementary chapter, ‘Traditional Medicine Conditions – Module 1 (TM1)’. Inclusion of TM in ICD-11 is believed to be the result of persistent and strategic efforts of stakeholders who have a strong-base of traditional healthcare system – China and Japan are mostly credited with the success of TCM being covered under ICD-11. This step has been welcomed by the TCSM community as before this there was no agreed international standard for collection of comparable data, health status of TM users or for testing efficacy of interventions and monitoring data related to patient safety. Historically, one can trace the efforts for inclusion of TM in the conventional global healthcare narrative to the establishment of Department of Traditional Medicine at WHO in 1972. Alma-Ata declaration (1978) also proposed that the use of TM should be promoted further at the level of primary health care. Further, in order to deal with escalating health care costs, WHO recommended TCM as a possible intervention. Based on this, a study was initiated by WHO to study the feasibility of using TCM from a cost perspective, which resulted in two publications – ‘Standard Acupuncture Point Locations in the Western Pacific Region’ (2008) and ‘WHO International Standard

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Terminologies on Traditional Medicine in the Western Pacific Region' (2007). In order to standardise disease classification and for formulating diagnostic codes for TMs with regional descriptions, International Classification of Traditional Medicine was developed. China, Japan and Korea played a very important role at this stage.

According to Xu et al 2013, China’s TCM expansion phase can be classified into three phases – Phase I (1950s-1970s): developing TCM higher education, research and hospital networks in China; Phase II (1980s-2000s): developing legal, economic & scientific foundations and international networks for TCM; and Phase III (2011 onwards): further consolidating the scientific basis and clinical practice of TCM. As per these authors, in the first phase, China tried to modernise TCMs and create an extensive network of universities, research institutes and hospitals. This period also marked the award-winning discoveries of the anti-malarial drug (Artemisinin), drugs for cancer treatment and leukaemia treatment. In the second phase, ‘State Administration of Traditional Chinese Medicine’ was established which played a very crucial role in promoting TCM at the international level. Apart from integrating TCM within China’s health system, China started focusing on establishing universities, hospitals and research institutes in Europe and other parts of the world. Funding also played a critical role in popularising TCM during this phase. Funding organisations outside China also supported further research on TCM. For instance, National Institutes of Health in the United States established the ‘National Center for Complementary and Alternative Medicine’ in 1998, Australia established ‘National Institute of Complementary Medicine’ in 2007 for dedicated research into traditional, complementary and alternative systems of medicine. During this period, WHO also emphasised on TCM through efforts in standardising terms used in TCM and provided a platform for exchange of knowledge related with TMs. During this phase, acupuncture gained a lot of recognition in developed countries as well – for instance, in 2006, German health authorities decided to incorporate reimbursement for acupuncture treatment (for chronic low back pain and osteoarthritis) in social health insurance funds (Cummings 2009) and in 2009, the UK National Institute for Health and Clinical Excellence (NICE) guideline on ‘early management of non-specific low back pain’ also recommended acupuncture therapies (course of up to 10 sessions) as one of the treatment options (Savigny et al 2009). Third phase marked the dissemination of outcomes of the Good Practice in Traditional Chinese Medicine Research in the Post-genomic Era (also known as GP-TCM), the first EU-funded Seventh Framework Programme (FP7) Coordination Action (started in 2009) focused on informing the best practice and harmonising TCM research through interdisciplinary exchanges among TCM experts and scientists. GP-TCM consortium consisted of
a collaborative-extensive network of almost 200 scientists from 24 countries and 110 institutions.85

In the spirit of 2030 Agenda, China formulated a strategic national health policy plan known as Healthy China 2030 in October 2016. The plan emphasised on adopting measures and policies for expediting development of TCM including innovation and capacity building and further enhancing its usage in preventive and disease management aspects of healthcare. Furthermore, the State Council in China also issued the 'Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016-30)', which serves as the national strategy for the development of TCM in China. In China, TCM has been integrated at all the levels of care including hospitals, clinics and health stations in urban and rural areas (WHO 2013). Almost 90% of the general hospitals include a traditional medicine department and provide both inpatient and outpatient TM services. Patients who are covered under insurance can freely choose TM or western medicine as both government and commercial insurance (including both state-owned and private insurance companies) fully cover all indigenous TMs, including Tibetan, Mongolian, Uygur and Dai variants, apart from covering allopathic medicines. Although Chinese policies on TCM have theoretically focused on ‘integration’ but it seems that it in practice, it has actually resulted in converging Chinese medicine towards modern medicine. (Leung 2016). Consequently, practitioners of TCM often fear that such ‘integration’ may lead to loss of distinct identity of these indigenous systems of medicine. On the other hand, users of health systems (i.e. healthcare seekers) have adopted a very practical approach – affordability becomes the most critical factor influencing the choice of users (ibid). Government of China has extended immense support to the protection and preservation of TCM practices – for instance, Chinese government strongly condemned the activities and petitions of a group of scientists who expressed concerns over the insufficient scientific evidence in TCM and demanded its elimination (Chang 2006, Leung 2008 as cited in Leung 2016).

With rapid globalisation of TCM, medical tourism industry in China is booming. Moreover, overseas centres have been created in many cities including Barcelona, Budapest and Dubai, leading to significant increase in sales of TMs (Cyranoski 2018). As part of its Belt and Road Initiative, China intends to create 30 centres for TCMs related medical services and education by 2020.86 Beijing and Hainan are taking lead in promoting medical tourism, targeting international

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travellers especially from Hong Kong, Macao and Taiwan. Further, China plans to build 15 TCM ‘model zones’ by 2020 based on the Hainan model.87

In terms of numbers, the total export of TCM commodities was estimated at USD 3.43 billion (Lin et al 2018). TCM export commodities mainly comprised of plant extracts, decoctions and Chinese patent medicines and other healthcare products. Most of the TCMs were exported to Asian nations and regions with targeted markets located in Hong Kong, Japan, Malaysia, South Korea and Indonesia. US is the next biggest market for TCMs after Asian countries, accounting for 15% share of the total TCMs export from China in 2016 (ibid).

However, there are several challenges that China needs to overcome for further promoting TCM in other countries. Some of them are discussed below.

Evidence of clinical efficacy

Clinical trials are critical to evaluate the effectiveness and safety of any new medications / medical devices by monitoring their effects on a large group of people. In cases where standard therapies are not working or health conditions become incurable, patients participate in these clinical trials in the hope of finding potential new therapies for curing their diseases. Permission for conducting a clinical trial is given only when the drug regulatory authority is confident about the quality of data for the following – safety and efficacy of the drug, need for the trial, detailed study protocol and capacity of the sponsor. Generating adequate and reliable evidence base is an indispensable requirement for any TM to be accepted for wider use. Randomised controlled trials (RCTs), which are considered to provide the most reliable evidence on the effectiveness of interventions, indicate favouring results only for very few TCM and including some specific uses of acupuncture, herbal medicines and manual therapies. Another concern is that very few selected out of the thousands of medicinal plants used worldwide have been put to rigorous testing in RCTs. Several traditional medicine experts also argue that randomised placebo-controlled model might not gauge the true effects of TCM and needs an entirely different methodology to evaluate its effectiveness.

With the objective of providing access to trial information from various national registry sites, WHO established International Clinical Trials Registry Platform (ICTRP) in 2005, which included three primary registries – ClinicalTrials.gov

(launched in the year 1997 in USA), ISRCTN (launched in the year 2000 in UK) and ANZCTR (launched in the year 2005 in Australia). In July 2007, WHO ICTRP identified Chinese Clinical Trial Registry (ChiCTR) as the fourth primary registry — a major milestone for promotion of clinical research in China (Zhang et al 2019). In May 2007, the WHO Trial Registration Data Set (TRDS) was announced, specifying a minimum of 20 items for trial registration. Given the increasing recognition of TCMs, the number of Clinical Trial Registration (CTR) in TCMs has increased rapidly — for instance, in ClinicalTrials.gov, 95 trials were registered between 2000-2005 which improved dramatically to more than 1,150 trials between 2005-2015 (Chen et al 2017 as cited in Zhang et al 2019). China has the highest number of CTRs for TCMs followed by US. Zhang et al 2019 point out several challenges which affect the quality of clinical trials. Untimely registration is one of the major issues — out of 3,339 registered TCM trials, 39% were retrospective in nature. Another major concern is that the resulting publications are not linked with the registry. Ideally, results should be made available in the public domain after trial registration. Inadequate reporting of WHO TRDS is another major cause along with insufficient information on TCM characteristics including TCM theory, diagnostic criteria, interventions and outcomes.

Many proponents of TCMs also argue that TCM related remedies cannot be tested just like allopathic medicines as the former needs to be customised based on the interpretation of the patient’s needs by the doctor and are generally used in combination. Since drug approval processes for TMs are often resource-intensive and time-consuming, pharmaceutical companies have limited incentives to invest in their research and development. For instance, a single drug approval from United States Food and Drug Administration (USFDA) will involve expenditure to the tune of 100 million USD and will go on for at least 8 years (Lin et al 2018). Further, in case of herbal medicines, industry representatives argue that investing in research does not yield economic profits as herbal products cannot be patented as easily as new chemical entities (Satyanarayana 2014). Nevertheless, a number of TCM products are now in phase-2 and even phase-3 trials of USFDA’s new drug application process.

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88 https://go.nature.com/2OZol1S (8/7/2019, 15:34 hours).

Safety and quality concerns

Traditional medicines, particularly herbal medicines are generally considered to be relatively safer than synthetic drugs. However, there is substantial evidence to suggest that use of certain TMs has led to rapid kidney failure, other adverse reactions like oedema, hypertension, electrolyte imbalance, insomnia, irritability, etc. (Zhou et al 2019). Fear of such adverse effects has considerably hindered the promotion and acceptance of TM. Practitioners of western medicine argue that severe toxicities associated with their system are well-known and regulated while toxicities associated with TMs products are largely underestimated, especially in absence of regulations or in cases where it is being used as dietary supplements. Additionally, the precise data on toxicity for most Chinese herbal medicines are limited as compared to modern medicines. However, proponents of TCMs argue that the methods of verifying safety and efficacy of TMs are different from that of allopathic medicines: before testing toxicity of allopathic drugs on humans, it is being carried out on animals whereas TCMs toxicity tests directly start with experimenting on humans and relies completely on human experience. It is further argued that since these two are completely different systems of therapeutics, hence TMs efficacy and safety cannot be verified in a short duration with animal experimentation (Leung 2006). Moreover, documentation of safety and efficacy for TCMs have more than 3000 years of experience vis-à-vis allopathic medicines experience of 75 years — the process of documentation of toxicity of TMs is a dynamic process and has been carried out over many thousands of years and the updates and revisions are done whenever there is emergence of new data or relevant information based on human experiences of using these medicines (ibid). Even the Encyclopaedia of Materia Medica (1977) which is believed to be one of the most extensive modern records on TCMs, has categorised 495 out of the 5,767 medicinal herbs as toxic (Zhou et al 2019). Challenges arise in establishing safety and efficacy of TCMs at the global level as these regular updates are not available in non-Chinese literature and databases and hence remains inaccessible for the practitioners of modern medicine communities.

It has been cited in the literature that since toxic drugs played a crucial part in TCM practice in curing many diseases, TCM physicians in ancient times were well-respected for their skill and knowledge of using toxic drugs for treating illnesses. Cases of toxicity / adverse reactions arise mostly in cases of negligence on the part of the modern practitioners who do not follow the TCM principles religiously; part of this negligence also comes from the way modern days TCMs are trained (Fruehauf 1999 as cited in Leung 2006). The issue gets further
aggravated where partially informed public driven by the misconception of modernised TCM often use these medicines as dietary supplements (ibid).

**European Union**

*Legal and policy framework of CAM in EU*

Although EU Member States (MS) policies differ widely as far as regulation of CAM therapies is concerned, even then EU has made several steps towards EU-wide harmonisation of regulations associated with CAM therapies. In 1992, EU issued Directive 92/73/EEC which was the first legal instrument for CAM regulation, and it was repealed in 2001 by the Homeopathic Medicinal Products Directive. In furtherance to these directives, European Parliament and Parliamentary Assembly of the Council of Europe recommended harmonisation of non-conventional medicines in Europe and requested member states to support more comparative studies and research on CAMs. In 2004, EU adopted Directive 2004/24/EC for traditional herbal medicinal plants after amending Directive 2001/83 EC.

To quote from the Directive itself – ‘a significant number of medicinal products, despite their long tradition, do not fulfil the requirements of a well-established medicinal use with recognised efficacy and an acceptable level of safety and are not eligible for a marketing authorisation. To maintain these products on the market, the Member States have enacted differing procedures and provisions. The differences that currently exist between the provisions laid down in the Member States may hinder trade in traditional medicinal products within the community and lead to discrimination and distortion of competition between manufacturers of these products. The long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. Pre-clinical tests do not seem necessary, where the medicinal product on the basis of the information on its traditional use proves not to be harmful in specified conditions of use. However, even a long tradition does not exclude the possibility that there may be concerns with regard to the product’s safety, and therefore the competent authorities should be entitled to ask for all data necessary for assessing the safety. The quality aspect of the medicinal product

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is independent of its traditional use so that no derogation should be made with regard to the necessary physico-chemical, biological and microbiological tests. Products should comply with quality standards in relevant European pharmacopoeia monographs or those in the pharmacopoeia of a Member States’.91

On behalf of the European Medicines Agency, the Committee on Herbal Medicine Products (HMPC) issues scientific opinions on herbal substances and preparations including information on recommended uses and safety related aspects.92 In particular, HMPC focuses on – i) establishing EU monographs covering the therapeutic uses and safe conditions of well-established and / or traditional use for herbal substances and preparations and ii) drafting a EU list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products.93 Companies which are seeking a traditional use registration for their herbal product can refer to these EU monographs and list entries.94

‘Traditional use registration’ (governed by Article 16a (1) of Directive 2001/83/EC) does not require clinical trials as long as sufficient safety and efficacy are demonstrated. In order to be marketed in EU, the product must have been used for at least 30 years, including 15 years of use at least in EU itself.95 Another channel is through ‘well established use marketing authorisation’ (governed by Article 10a of Directive 2001/83/EC) where applicant has to demonstrate scientific literature establishing the fact that the active substances of the medicinal products have been in well-established medicinal use within the EU for at least ten years, with recognised efficacy and an acceptable level of safety.96 Traditional use registration is the most favourable route as the required level of research to validate market authorisations (clinical trials) is missing for most herbal medicines. Even through this route, just over 1,000 products have been registered throughout the EU in a decade’s time (2004-14). Out of these, UK, Poland, Germany and Austria granted majority of all registrations and few MS like France granted even less than 10 registrations (EUROCAM 2014).

94 No further evidence is required vis-à-vis the safety and traditional use of the product, if applicants can prove that their product complies with the EU list.
After being amended, Directive 2001/83/EC has simplified the registration procedure for homeopathic medicinal products as manufacturers are now required to follow a procedure defined in the European Pharmacopoeia. However, the registration procedure is not harmonised across EU-MS, and is decided by individual MS, resulting in different treatments given to the same registration application in different MS. Licensing is a cumbersome and economically unviable task as administrative burden might exceed economic benefits – there are many difficult requirements with respect to quality, safety and stability that need to be fulfilled (EUROCAM 2014).

Findings of the CAMbrella project

The CAMbrella project (2010-12) was funded by the Directorate-General Research and Innovation, European Commission with the objective of reviewing CAM provision in Europe and to suggest ways in which it could be integrated within the established EU healthcare system. Findings of the CAM suggest that there are 145,000 dual-trained doctors, trained in conventional medicine as well as a particular CAM modality (EUROCAM 2014). Apart from these, there are approximately 160,000 non-doctor CAM practitioners. Non-medical practitioners are not statutorily regulated in any EU-MS and it is not covered under Directive 2005/36/EC which deals with recognition of professional qualifications in EU (ibid).

In Europe, CAM treatments are provided as a complementary therapy along with conventional medicines or sometimes on a standalone basis as well, generally delivered in private practice settings. As per the findings of CAMbrella projects, there are no overall European legal framework for training in CAM modalities, most of the training in CAM is carried out by non-profit associations and private teaching / training centres. Universities are providing basic courses on CAM modalities as part of undergraduate medical curricula which is optional in most of EU-MS and compulsory in very few countries. Contrary to the narrative in developing countries, CAM therapies in EU are availed more by richer EU citizens who can afford to pay for these therapies or have better knowledge about them. Patients also have to be dependent upon their personal funds (out-of-pocket expenditure) or private health insurance companies in order to pay for CAM services as CAM modalities are not integrated in the public health care system.

97 CAM modalities comprise acupuncture, anthroposophic / ayurvedic / traditional Chinese / Tibetan / herbal medicine, phytotherapy, homeopathy, naturopathy, osteopathy, chiropractic, etc.

system. Out of all the CAM modalities, herbal medicine was the most frequently used by EU citizens and musculoskeletal problems were the most commonly reported conditions for which CAM therapies were used.99

**United Kingdom (UK)**

UK’s National Institute for Health and Care Excellence (NICE) produces evidence-based guidance, including clinical and cost effectiveness assessments of new health technologies (pharmaceutical products, procedures, devices and diagnostics), which can be used by the National Health Service (NHS) and anyone else ‘involved in delivering care or promoting wellbeing’.100 It has recommended the use of CAMs in a limited number of cases only. As such, the availability of CAMs as part of the NHS is also limited, and a patient is supposed to visit a General Practitioner (GP) first. ‘Do not visit a CAM practitioner instead of seeing your GP’, so goes the NHS advice.101 The limited inclusion of CAM in the NHS means that 95% of CAM practitioners registered with the Complementary and Natural Healthcare Council (CNHC), for instance, work privately under the self-employed or small business category.102 Nevertheless, UK’s Research Council for Complementary Medicine (RCCM) promotes research that would ‘widen the availability of and access to safe and effective’ CM within the ambit of the NHS.103

With the limited exception of osteopathy and chiropractic, governed by UK’s statutory professional regulation for conventional medicine, there is no regulation for other CAM providers, which means anyone can practice CAM, even without formal training or qualification. However, the government encourages CAM professions ‘to work towards voluntary regulation, if not under statute’.104 There are voluntary CAM organizations, some of which are accredited by the Professional Standards Authority (PSA), an independent body accountable to

UK Parliament that improves ‘the regulation and registration of people who work in health and care’. PSA-accredited organizations meet its ‘demanding standards, which are designed to help people make an informed choice when they’re looking for a practitioner’. They include the CNHC, the Federation of Holistic Therapists (FHT) and the British Acupuncture Council (BAcC). It is informative and interesting to note some of PSA’s observations in response to concerns raised about CAM

1) ‘Risks of harm in relation to complementary therapies is generally low and can be addressed by education and training’.

2) ‘Complementary therapies are used by approximately a quarter of the population’, and ‘people state that they derive benefit from them’. ‘Complementary therapies are widely used in cancer care and many people say they derive benefit from them alongside conventional treatments’.

3) ‘We concluded that we could not exclude complementary therapies or homeopathy from the Accredited Registers programme. Both fall within the definition of ‘health care’ as set out in the National Health Service Reform and Health Care Professions Act 2002, section 25E (8) as inserted by the Health and Social Care Act (2012)’.

4) ‘We decided that it was in the public's interests for them to be able to access such therapies from practitioners on registers that meet our high standards, and are subject to our oversight. This allows the public who wish to use complementary therapies to do so more safely’.

5) ‘We also introduced three particular standards to mitigate risks. Standard 6 requires the registers to explain clearly the extent of knowledge underpinning an occupation. Standard 8 requires registers to set standards of business practice, including advertising (and to comply with the Advertising Standards Authority’s requirements). Standard 9 requires registers to ensure that registrants are able to recognise and interpret clinical signs of ill-health and refer them to a doctor or other relevant health professional when necessary’.

Ayurvedic practitioners have also organized themselves. For instance, the British Association of Accredited Ayurvedic Practitioners (BAAAP) was established in 1999, as the ‘professional affiliate’ of British Ayurvedic Medical Council (BAMC),

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to promote Ayurveda in the west and to overcome regulatory restrictions and cultural prejudices that inhibit its integration within mainstream health care provision in the UK and elsewhere in Europe. It has been working in the areas of 'education and consumer protection', considering 'the practice of Ayurveda by unqualified practitioners and the dilution of the standards of Ayurvedic education and training to be unsafe, unethical and unprofessional'. Another initiative is MAYUR – the Ayurvedic University of Europe – established in London in 2004, which offers a BSc (Hons) degree approved by BAAAP and academics who teach its clinical modules accredited by it. Yet another example of Ayurvedic practitioners' association is the Ayurvedic Professionals Association (APA) – kindly refer to footnote 103 above for details.

**United States (US)**

In an institutional sense, the history of TCSM in the US dates back to October 1991 when the US Congress passed a legislation, mandating the establishment of an office within National Institutes of Health (NIH), to investigate and evaluate promising unconventional medical practices. Starting out as Office of Unconventional Therapies (OUT), it was soon renamed as the Office of Alternative Medicine (OAM) in 1993, then as the National Center for Complementary and Alternative Medicine (NCCAM) in 1998. NCCAM's first strategic plan (2001-2005), 'Expanding Horizons of Healthcare', outlined the motivation behind the institutional initiative of the US government.

*Frustrated by the inability of mainstream medicine to meet all their expectations and needs, many people have turned to complementary and alternative medicine (CAM) approaches. ... more and more Americans—as many as 42 percent of the public according to one recent estimate—are adopting CAM approaches to satisfy their personal healthcare needs. Between 1990 and 1997, the number of Americans using CAM increased by 38 percent from 60 million to 83 million. ... visits to CAM practitioners between 1990 and 1997 increased from an estimated 427 million to 629 million ... estimates put expenditures for alternative medicine professional services at $21.2 billion in 1997, with at least $12.2 billion paid out-of-pocket. Indeed, Americans spent more out-of-pocket for CAM than they paid out-of-pocket for all hospitalizations ...*

The plan also acknowledged that, 'among the first drugs for treatment of high blood pressure was reserpine from the herb *Rauwolfia serpentina*, described many centuries ago in Indian Ayurvedic monographs. Indeed, some of our most

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important drugs, while not originating as CAM therapies, are derivatives of the active ingredients identified in herbal remedies’ (NCCAM 2000).

Figure 5 highlights the increasing importance that the US government attached to CAM research. And this was the funding only to one institute of the NIH. Total funding to CAM research, including allocations to other NIH institutes and centers, went up to USD 161 million in the year 2000 alone (NCCAM 2000). In fact, as indicated earlier, that NIH’s NCI has been evaluating information about CAM since the early 1940s, much before OUT came into existence, and established its own CAM office – the Office of Cancer Complementary and Alternative Medicine (OCCAM) – in 1998. In May 2004, NCCAM and the National Center for Health Statistics (NCHS) of the US Centers for Disease Control and Prevention (CDC) released findings from the largest nationally representative survey till date – the NCCAM-funded supplement to the 2002 National Health Interview Survey (NHIS) – on the use of complementary health approaches among the Americans. The 2007 NHIS provided nationally representative data on CAM use among children for the first time as well as among the adults. It also provided the first nationally representative data on CAM spending by Americans. In December 2014, the US Congress renamed NCCAM as National Center for Complementary and Integrative Health (NCCIH). ‘The change is made to more accurately reflect the Center’s research commitment to studying promising health approaches already in use by the American public’.109

Figure 5: OUT / OAM / NCCAM funding, 1992-2000


NCCIH's mission is ‘to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative interventions and their roles in improving health and health care’. Among its top research priorities include the non-pharmacologic management of pain, prevention of disease and promotion of health across the lifespan and innovatively designed clinical trials to assess complementary approaches and their integration with health care. In September 2016, the Mayo Clinic published an NCCIH review of US clinical trials on the efficacy and safety of popular complementary health approaches used for chronic pains usually seen by primary health care providers. It found several complementary approaches effective. A year later, the US Department of Health and Human Services (HHS) – MoHFW’s counterpart – the Department of Defense (DoD) as well as the Department of Veterans Affairs (VA) announced the NIH-DoD-VA Pain Management Collaboratory, with NCCIH as the lead agency. To further its objective of disseminating objective evidence-based information on complementary and integrative health interventions, in June 2018, the NCCIH released its first mobile app, HerbList, which provides science-based information on safety and effectiveness of herbs and herbal products. With 9 major offices and divisions as well as 4 offices – the Office of Clinical and Regulatory Affairs (which plans, coordinates and monitors clinical trials and ensures compliance with US FDA regulations); the Office of Policy, Planning and Evaluation; the Office of Communications and Public Liaison; and lastly the Office of Administrative Operations – within the Office of its Director, the NCCIH is the world’s foremost scientific research agency as far as TCSM are concerned. Beyond research, it also coordinates 2 CAM surveys with other US agencies – the NHIS with the CDC and the survey on ‘Complementary and Alternative Medicine and People Aged 50+’ with the American Association of Retired Persons (AARP). There are 2 other CAM surveys in the US, both of which are managed by the CDC – National Health and Nutrition Examination Survey and the National Home and Hospice Care Survey.

Nevertheless, despite all such institutional measures, ‘there is no standardized national system for credentialing complementary health practitioners’. States decide credentials practitioners should have to work in their state and, therefore, the requirements vary widely by state and discipline. Likewise, ‘there is
no significant regulation of Ayurvedic practice or education in the United States, and no state requires a practitioner to have a license.113 National Ayurvedic Medical Association (NAMA) represents the Ayurvedic profession in the US. Association of Ayurvedic Professionals of North America (AAPNA), on the other side, aims ‘to bring the healing science of Ayurveda and its modalities to the forefront of integrative medicine in the West’.114 A third agency, the Council for Ayurveda Credentialing (CAC), aims to ‘create unifying educational standards, scopes of practice, and related lesson plans’ for accrediting and legitimizing the education and practice of Ayurveda, and become the ‘leading accrediting organization advancing excellence and quality in Ayurveda Medical Education programs’ in North America and Europe.115 According to CAC, the problem is that, ‘currently the practice of Ayurveda is not controlled or regulated by any licensing, on a state or national level, as allopathic medicine is’. Most education and practice in these countries using Ayurveda principles and philosophy remains an ‘ill-defined area of lifestyle management, nutrition, and health promotion. … Furthermore, clients seeking an Ayurveda consultation are unsure about how to ascertain the credential and competence of the practitioner’.116 There are already several US universities with centers of integrative medicine.117 The institutional promise already exists.118

Table 7: Status of TCSM in selected G20 countries

<table>
<thead>
<tr>
<th>Countries</th>
<th>Integration of TCSM in primary health care</th>
<th>Insurance coverage for TCSM</th>
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<tbody>
<tr>
<td>Argentina</td>
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<tr>
<td>Australia</td>
<td>✓</td>
<td>×</td>
</tr>
<tr>
<td>Brazil</td>
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<td>✓</td>
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118 One of them is the University of Arizona’s Andrew Weil Center for Integrative Medicine, a leading center for training of health professionals in ‘evidence-based, sustainable and integrative approaches’. It also conducts research on the cost-effectiveness of integrative primary care, and helps people find integrative health practitioners (its alumni) in many geographies – within and outside the US, but not India – and specialties. https://bit.ly/2UID63P (19/7/2019, 14:23 hours).
<table>
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<tr>
<th>Country</th>
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<tbody>
<tr>
<td>Canada</td>
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<tr>
<td>China</td>
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<tr>
<td>Germany</td>
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<tr>
<td>India</td>
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<tr>
<td>Indonesia</td>
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<tr>
<td>Japan</td>
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<td>Saudi Arabia</td>
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<td>South Africa</td>
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<td>South Korea</td>
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<td>UK</td>
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<td>US</td>
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Source: Authors’ compilation from official sources.
### Table 8: Status of TCSM / CAM in selected G20 countries

<table>
<thead>
<tr>
<th>Countries</th>
<th>National policy on TCSM</th>
<th>Regulator of traditional / herbal medicines</th>
<th>Regulations for traditional / herbal medicines</th>
<th>Practices, providers, education and health insurance</th>
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</thead>
</table>
| Argentina | No official policy       | National Administration of Drugs, Food and Medical Technology and National Institute of Medicines, Ministry of Health (MOH) | 1. Herbal medicines categorized as prescription, non-prescription, herbal medicines, dietary supplements and functional foods  
2. National legislation for herbal medicines updated in 2013  
3. Argentinian medicines codex (Codex Medicamentario Argentino, 6th ed., 1978) and United States pharmacopeia (2010) are used | 1. Only recognized CAM therapy is acupuncture  
2. No TCSM therapies are covered by public health insurance |
<p>| Australia | National policy for TCSM integrated into the National Medicines Policy 2000. The Therapeutic Goods Administration (TGA) | 1. Therapeutic Goods Act 1989 sets out legal requirements for import, export, | 1. Each Australian state has its own legislation - osteopathy and chiropractic are regulated in every state |</p>
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<tr>
<th>Countries</th>
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<th>Practices, providers, education and health insurance</th>
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<tr>
<td>Brazil</td>
<td>1. Integrative and Complementary Practices Policy (Política Nacional de Practicas Integrativas y Complementarias) is part of the unified health system (Sistema Unico de Saúde [SUS])&lt;br&gt;2. In 2017, the national policy was expanded to include 14 practices, additional to the original five</td>
<td>National Coordination Office on Integrative and Complementary Practices, administered under the MOH</td>
<td>manufacture and supply of therapeutic goods&lt;br&gt;2. British, European and US pharmacopoeias are used</td>
<td>2. Quality and accreditation requirements must be met by individual TCSM practices to receive insurance benefits&lt;br&gt;3. Bachelor’s and master’s degrees in TCSM along with training courses are available</td>
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*TCSM* stands for Traditional Complementary and Alternative Medicine.
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<th>Regulations for traditional / herbal medicines</th>
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| Canada    | No national policy      | The Natural and Non-Prescription Health Products Directorate under Health Canada looks after regulation of natural health products | 1. Definition of ‘natural health product’ includes homeopathic medicines and traditional medicines that make medical or health claims  
2. Manufacturers of natural health products are required to establish safety, quality and efficacy through clinical trials or traditional use claims | 1. Regulation for CAM practitioners is a provincial or territorial responsibility  
2. Some government agencies provide health insurance under which indigenous CAM services are covered |
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<th>Practices, providers, education and health insurance</th>
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<td>China</td>
<td>National policy documents for development of TCSM are ‘Outline of the Strategic Plan on the Development of Traditional Chinese Medicine’ (2016–2030) and ‘Outline of a Healthy China 2030 Plan’</td>
<td>Drug Administration Law provides the national regulatory system on herbal medicines</td>
<td>1. Pharmacopoeia of the People’s Republic of China (vol. 1) and Chinese materia medica and Standards for imported crude drugs are legally binding 2. There are regulations for protection of traditional Chinese medicines, administration of toxic drugs for medical use and protection of wild medicinal resources 3. Herbal products categorized as prescription or non-prescription medicines are sold in pharmacies and by licensed pharmacists</td>
<td>1. The state encourages exchanges between traditional Chinese medicine and Western medicine 2. Traditional Chinese Medicine hospitals have been encouraged to open specialized departments for specific diseases, in addition to general departments 3. Government and commercial insurance cover traditional Chinese medicine and partially cover acupuncture, herbal medicines and osteopathy</td>
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<tr>
<td>Germany</td>
<td>National policy for TM / CAM is integrated into Social</td>
<td>Federal Institute for Drugs and Medical Devices</td>
<td>1. Manufacturing regulations for herbal medicines are the</td>
<td>1. Licensed Heilpraktikers (‘healing practitioners’) may practice medicine with the exclusion</td>
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<td>Countries</td>
<td>National policy on TCSM</td>
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| India     | National Policy on Indian Systems of Medicine and Homeopathy issued in 2002 | Herbal medicines are regulated under Ayurveda, Siddha and Unani drugs provision in the Drugs and Cosmetics Act | 1. The Ayurveda pharmacopoeia of India, the Unani pharmacopoeia of India and the Siddha pharmacopoeia of India are legally binding  
2. Exclusive GMP regulations apply to the manufacturing of herbal medicines, separate from those for conventional pharmaceuticals | 1. National and state level regulations apply to providers of Ayurvedic, homeopathic and Unani medicine  
2. TCSM providers practice in both public and private sector clinics and hospitals. The national Government issues the TCSM license required to practice  
3. TCSM services are reimbursed by both public and private health insurance |

2. German national pharmacopoeia (Deutsches Arzneibuch), European pharmacopoeia and EU’s Homeopathic pharmacopoeia are legally binding  
3. Both public and private insurance reimburse some CAM treatments (WHO 2001)
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| Indonesia | National Traditional Medicine Policy (Kebijakan Obat Tradisional Nasional) issued in 2007 | The Deputy of Traditional Medicines, Cosmetics and Complementary Product Control, National Agency of Drug and Food Control Indonesia (2001) serves as the point of contact for TM / CAM. The Directorate of Traditional, Complementary and Alternative Medicine, MOH, was established in 2011 | 1. Exclusive regulation for herbal medicines - Criteria and Procedure on Registration of Traditional Medicines, Standardized Herbal Medicines and Phytopharmaca  
2. Herbal medicines sold with medical and health claims  
3. The Indonesian herbal pharmacopoeia (4th ed., 1995) and its supplement (2009) are legally binding | 1. National, state and local regulations apply to indigenous TM providers, four types of TM practices and providers of acupuncture, chiropractic and herbal medicines  
2. The state or city government issues relevant licenses required to practice TM / CAM  
3. A student of TM / CAM can obtain a bachelor's and master's degree at the university level. Certified training programmes are also recognized |
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</table>
| Japan     | No single national law or regulation covers the entire area of TCSM | Japan Liaison of Oriental Medicine (JLOM) | 1. Japanese regulations for evaluating Kampo and allopathic medicines are not very different from each other and regulations specified in Pharmaceutical Affairs Law of 1960 are uniformly applicable to both Kampo and Western medicines  
2. Herbal medicines are regulated as prescription and non-prescription medicines and sold with medical claims  
3. The Japanese pharmacopoeia (17th ed., 2016) is legally binding | 1. Japan exclusively recognizes physicians licensed in Western medicine and a separate license in Kampo medicine does not exist  
2. Acupuncture is practiced by non-physicians and remains outside the purview of official health care system  
3. Patients can make insurance claims for 148 ethical Kampo formulations. Acupuncture is partially covered by national health insurance |
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<th>Regulations for traditional / herbal medicines</th>
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| Saudi Arabia    | No                      | 1. The Saudi Food and Drug Administration is responsible for registering and regulating TCSM products  
2. In 2008, the National Center for Complementary and Alternative Medicine (NCCAM) was established as a national reference point for all TM / CAM activities | 1. Specific regulation for herbal medicines - Regulation for registration of herbal preparations, health and supplementary food, cosmetics and antiseptics that have medical claims  
2. Herbal medicines are categorized as prescription medicines, non-prescription medicines, herbal medicines, dietary supplements and health foods; sold with medical, health and nutrient content claims  
3. US, British and European pharmacopoeias are used but are not legally binding | 1. Providers of acupuncture, osteopathy, chiropractic, naturopathy and cupping therapy must be licensed in Saudi Arabia  
2. A TCSM educational course for undergraduate medical students has been developed and introduced in three universities. The government recognizes TCSM training programmes at the postgraduate level  
3. Traditional and complementary medicine practices are not covered by national insurance policy |
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<th>Practices, providers, education and health insurance</th>
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<tr>
<td>South Africa</td>
<td>1. National policy on TCSM was issued in 1996</td>
<td>Directorate of Traditional Medicine</td>
<td>1. Under draft regulations, herbal medicines will at least in part be regulated in the same way as conventional pharmaceuticals</td>
<td>1. The Allied Health Professions Council of South Africa (AHPCSA), a statutory body, issues licenses required to practice TCSM</td>
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<td>2. Only national law for TM - Chiropractors, Homeopaths and Allied Health Service Professions Second Amendment Act of 1982</td>
<td></td>
<td>2. Depending on the discipline of the product, WHO monographs on selected medicinal plants, German pharmacopoeia, Chinese pharmacopoeia, Ayurveda and Unani pharmacopoeias of India, and EU’s European pharmacopoeia are used</td>
<td>2. Students of TCSM can obtain both bachelor’s and master’s degrees at university level. Government also officially recognizes a training programme for TCSM technicians</td>
</tr>
<tr>
<td>South Korea</td>
<td>National policy of TM / CAM was issued in 1993; in the same year, laws, regulations</td>
<td>1. Bureau of Traditional Korean Medicine was established in 1993 under the then Ministry of Health and</td>
<td>1. The Promotion of Korean Medicine and Pharmaceuticals Act, which provides overall strategic direction for</td>
<td>3. TCSM practices such as acupuncture, chiropractic, homeopathic medicines, naturopathy and osteopathy are partially covered by private health insurance</td>
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<th>Countries</th>
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<th>Practices, providers, education and health insurance</th>
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<td>and a national programme were also introduced</td>
<td>Social Affairs (now the Ministry of Health and Welfare [MoHW])</td>
<td>development of Korean medicine, was enacted in 2003. Under this Act, a national action plan on promotion and development of Korean medicine has been developed every 5 years since 2006</td>
<td>2. Two education tracks: Korean medicine universities providing 6-year medical education and graduate school of Korean medicine providing 4-year medical education</td>
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<td></td>
<td>2. The Bureau was expanded in 2008 to have two divisions: Division of Traditional Korean Medicine Policy and Division of Traditional Korean Medicine Industry</td>
<td>2. The Regulation on Quality Control of Herbal Materials and Distribution (Supply) was developed in 1995, under which the regulatory system for quality control of herbal materials was established in 1996</td>
<td>3. The Ministry of Food and Drug Safety (MoFDS) regulates processed herbal materials and herbal medicinal products</td>
<td>3. Graduates from accredited Korean medicine universities and graduate schools of Korean medicine can apply for the National Licensing Examination for traditional Korean medicine doctors</td>
</tr>
<tr>
<td></td>
<td>3. The Ministry of Food and Drug Safety (MoFDS) regulates processed herbal materials and herbal medicinal products</td>
<td>3. From 2012, the system was strengthened by requiring that all herbal materials used for Korean medicine</td>
<td></td>
<td>4. National health insurance has covered selected traditional Korean medicine services and some acupuncture, moxibustion and herbal medicinal products</td>
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<td>4. Korea Institute of Oriental Medicine oversees planning and implementation of R&amp;D of Korean medicine</td>
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<tr>
<th>Countries</th>
<th>National policy on TCSM</th>
<th>Regulator of traditional / herbal medicines</th>
<th>Regulations for traditional / herbal medicines</th>
<th>Practices, providers, education and health insurance</th>
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| **UK**    | TCSM policy is integrated into the national health policy | The Medicines and Healthcare Products Regulatory Agency and the Department of Health in England have several teams to develop policy on the safe use and practice of TCSM | must be processed by GMP-certified manufacturers | 1. The Complementary and Natural Healthcare Council (CNHC) is the voluntary regulator for a wide range of complementary therapies  
2. Although acupuncture, Ayurveda, naturopathy, Unani, etc. are used by the population, only chiropractors and osteopaths are officially regulated  
3. UK’s National Institute for Health and Care Excellence (NICE) has recommended the use of CAMs in a limited number of cases |
| **US**    | No national policy / national plan for integrating TCSM | 1. An Office of Alternative Medicine was formed within | 1. Licensed herbal medicines are licensed in the same way as conventional pharmaceuticals  
2. Herbal medicines are categorized as prescription medicines and non-prescription medicines, and sold with medical claims  
3. There is regulation of OTC herbal medicines under the Traditional Herbal Medicines Regulation (THMR) scheme | 1. TCSM practices and providers are regulated at the state level |
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<td>into mainstream health service delivery</td>
<td>the National Institutes of Health (NIH) Office of the Director in 1992 2. In 1999, the NCCIH was established</td>
<td>1994 forms the national regulation on herbal medicines 2. There is no registration of herbal medicines and they are not included in National Essential List of Medicines</td>
<td>2. TCSM services are reimbursed in some cases by private health insurance</td>
</tr>
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Source: Authors’ compilation from WHO 2019.
3. Major recommendations

Following are the major recommendations based on our desk research – some of them were also included in the chapters above. The overall tone is one of assertion (of our point of view) as well as accommodation (with the prevalent G20 point of view).

® There was a reference to TCSM, for the first and only time so far, in the G20 health ministers’ declaration in 2018 during Argentina’s G20 Presidency. The 2019 health ministers’ declaration made no reference to it, which is quite surprising given India’s and China’s commitment to the theme. If the Government of India wishes to make TCSM a central focus of its G20 Presidency in 2022, it should start some serious groundwork during the upcoming Saudi and Italian G20 Presidencies in 2020 and 2021 respectively – as well as in other international forums.

® One of the views is that the perception of traditional medicine (TM) as ‘accumulated wisdom’ has substantially contributed to its success in Western countries vis-à-vis the ‘seemingly fickle here-today-outdated-tomorrow approach of scientific medicine’. In this context, one can argue – from a practical perspective – that following the ‘scientific’ methodology of modern medicine (as called for in G20 and other forums – ‘scientifically proven’) could end up diminishing the popular appeal of TM in these countries. This should be weighed vis-à-vis the potential benefits of making TM ‘scientifically proven’ – for instance, higher acceptance of TM by policymakers, modern medicine practitioners, insurance companies, etc. leading to higher institutionalization and TM expense coverage. Institutionalization / mainstreaming of TM is presently quite low, despite their public acceptance being quite high. Many TM users do not inform their modern medicine doctors about TM use, and largely pay out-of-pocket (OOP) for their use, given their limited insurance coverage. A cost-benefit analysis of following / not following the scientific approach for TCSM needs to be done from a purely practical perspective. However, from the principled perspective of patient safety, regulatory requirements of safety, efficacy and quality should be of utmost priority and be absolutely non-negotiable.

® We are living in a world which could, at least partially, be characterized as post-Fordist (marked by a transition from mass production / consumption to more individualized patterns) and post-industrial (transition from a manufacturing-based to service- and knowledge-based economy), in which holistic TCSM have a natural advantage, given their individual, practitioner-
oriented focus. The very fact that there has been widespread acceptance of TCSM among the general public – despite lack of institutional support – is reflective of a certain level of disillusionment with modern scientific medicine. Relegated to the margins with the ascendance / domination of modern science / medicine, TCSM have moved from the phase of 'disenchantment' (to use the famous German thinker, Max Weber’s phraseology) to a phase of 're-enchantment', as we might characterize it. Strategies to promote TCSM should take such ecosystemic trends (post-Fordism, post-industrialism, post-modernity, etc.) into consideration.

The G20 should call for developing / adopting a clear, consistent and consensual theoretical and operational definition of TCSM which can be used for international, regional and national public policy and operational use (surveys, literature review, budgetary allocation, expenditure assessment, human resources, governance, UHC, PHC, health regulation, insurance, etc.). One of the following – or a new definition based on the following – could be considered – a) definition of ‘complementary medicine’ put forth by Ernst et al (1995); b) one of the definitions of ‘integrative medicine’; c) of ‘integrative health care’ by NCCIH; d) the definition of ‘holistic medicine’ offered by the American Holistic Health Association.

For evidence-based policy / prescription, we do need evidence for various health interventions. However, it is a matter of debate if evidence for non-drug and non-food practices – or, for that matter, more broadly for health and non-health sector policies and programs, including action on what is referred to as the ‘social determinants of health’ – should necessarily be scientific / clinical in nature. Health, as defined in WHO constitution (1948), and to which WHO ‘remains firmly committed’, ‘is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’. The WHO 1976 TM definition refers to its function in ‘diagnosis, prevention and elimination of physical, mental or social imbalance’, which is in sync with its definition of health. We recommend that this phrase from WHO’s 1976 definition be reinstated in the definition of TM, while insistence on scientific / clinical evidence for non-drug and non-food aspects of TM be reconsidered. G20 and other international forums should call for developing alternative evidence frameworks for at least such, if not all, aspects of TM.

At the same time, G20 / other forums should consider if TM’s ‘knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures’ (WHO’s 2019 definition) can be leveraged not only for complementary / integrative health practices, but also for
‘diversifying the conceptual frameworks of medicine’ (Ernst et al 1995: 506) in general, and making science itself more inclusive and ‘less homogeneous’. The insistence of the dominant medical / scientific frameworks on their own ‘indigenous’ Western methodology and approach – expecting all else to come up to their standards – is parochial, exclusionary / discriminatory. Since we are talking about fair representation of the developing world – in sync with its growing international stature – in international forums, we also need to think of their fair representation in the world of knowledge / academia / methodology as well. For far too long, knowledge and sciences have predominantly remained ‘Western’ – with all else viewed / classified as inferior, worthy of potential equal consideration only if they come up to Western standards. Discussions of health and medicine are – and should be – rooted in these larger considerations, and not merely the purely technical (scientific evidence, regulatory approvals, etc.). Different cultures and their manifestations (including systems of medicine) should be respected and evaluated on consensual – rather than purely Western – criteria. The realization of a multipolar world has been slow to come by in certain segments – health care being one of them.

While Yoga was the most highly used complementary health approach among US adults and children (footnote 13), Ayurveda use has been extremely low among both groups, as per NHIS surveys 2002, 2007 and 2012 (Black et al 2015; Clarke et al 2015). This is not about higher preference for non-drug / -food TCSM practices because the ‘nonvitamin, nonmineral dietary supplements’ category among complementary health approaches had the highest prevalence among both US adults and children. According to US National Health Expenditure 2007 data, CAM out-of-pocket expenditures of USD 33.9 billion included USD 14.8 billion on nonvitamin, nonmineral, natural products (NVNMNP) alone, USD 11.9 billion on CAM practitioner visits and USD 7.2 billion on ‘other CAM’ (Yoga, tai chi, qi qong classes; homeopathic medicine, relaxation techniques). Two recommendations can be made here – one, both ‘soft’ (drugless) and ‘hard’ (drug) TCSM should be promoted (both are of practical benefit from different perspectives); two, reasons for lower utilization of Ayurveda and other hard Indian TCSM should be explored. One possible reason could be that people are less inclined to ‘consume’ hard TCSM, given the challenges of evidence and the ensuing lack of confidence, while they might feel TCSM ‘practices’ won’t really harm them. It is possible that there is more evidence available for TCSM practices like Yoga, if we are to go by the number of Yoga clinical trials (CTs). If this is the case, evidence is key. And India should insist in the G20 and other forums that consensual evidence frameworks of safety, quality
and efficacy are developed for TCSM. The G20 and other forums should provide technical and financial R&D support for developing such evidence rather than just make it a precondition. TCSM should not only be discussed in the context of UHC / PHC, but also R&D – a core theme in G20 discussions, especially health. In particular, India should call for the inclusion of TCSM under the ambit of AMR R&D in the G20 as well as elsewhere.

The biggest challenge of TCSM is limited or lack of evidence. We have 4 recommendations in this regard –

1) Greater formalization / institutionalization – rigorous drug regulatory provisions, health technology assessment (HTA), harmonized credentialing of TCSM education / practice, etc. are needed to improve TCSM’s acceptance, especially in the developed world. The self-medication, over-the-counter (OTC), OOP model will not take it too far.

2) G20 countries should not only promote TCSM research in their own countries, but also facilitate the establishment of a global consortium of universities / institutions working on traditional / complementary / integrative / alternative medicine systems for exchange of ideas, students, faculty and researchers. This is in line with the BRICS communiques / declarations on health. India can generate consensus among its BRICS counterparts in the G20, to begin with. European CAM research network, Cambrella, is an example.

3) To promote TCSM R&D, the G20 should ask WHO to develop a ‘TCSM R&D Blueprint’ and, along with the World Bank, a ‘Sustainable TCSM R&D Financing Blueprint’, which should be used to establish a ‘Global TCSM R&D Hub’, with the membership of central public TCSM research agencies of G20 countries, with WHO and US’s NCCIH as lead institution. The G20 Leaders called for ‘a new international R&D Collaboration Hub’ for antimicrobials in their 2017 declaration and referred to ‘Global AMR R&D Hub’ in their 2018 and 2019 declarations. Why not a Global TCSM R&D Hub, models for which could be discussed and proposed by WHO and the World Bank to the G20?

4) There could be consortiums of drug and food regulatory authorities and HTA agencies of G20 countries – under the leadership of WHO – for mutual cooperation and capacity-building vis-à-vis TCSM. These consortiums can work with / support their counterparts in non-G20 countries as well, especially in Africa. From India, following agencies could be part of their respective consortiums – the CDSCO, the FSSAI, NHSRC (Division of Healthcare Technology for HTA) – all three under Ministry of Health and Family Welfare – and the Pharmacopoeia Commission for Indian Medicine
and Homoeopathy (PCIMH) under Ministry of AYUSH. The drug regulatory consortium could be led by FDA (USA), the food regulatory consortium by the European Food Safety Authority (EFSA) or the Food Standards Australia New Zealand (FSANZ), and HTA consortium by NICE (UK) from G20 members. The Joint Communiqué of BRICS on Health (Geneva, 2012) had recognized the need for cooperation among national drug regulatory agencies.

We propose a 7-principle framework to enhance the wider acceptability and practice of TCSM, and strengthen their complementary / integrative capacity vis-à-vis modern medicine.

1) While countries and civilizations can lay historical claims to their respective TCSM, they should desist from exclusionary attitudes, and make them open to all to make them evolutionary, resilient and universal. Civilizations grow building on developments in, and borrowing from, other civilizations. For instance, although the Unani system had its origin in ancient Egypt and Babylonia, the Greeks owned and built upon it, and so did the Arabs and Persians in the medieval era. ‘During its journey wherever it passed, the system enriched its repository by imbibing which was best of the healthcare systems in vogue in those countries. The system after getting further developed in the Arab and Persian lands came to India around the 8th century and took deep roots in the Indian civilization. The Indian scholars and physicians have made significant contributions to the further advancement of this system’ (Ministry of AYUSH 2016: iii). An open and universal rather than a parochial and exclusionary approach to TCSM is needed for their own health and well-being. Of the 612 Yoga clinical trials, less than 3% are / were being conducted in India. Its universal popularity and research uptake would perhaps not have been possible without an open attitude towards it. Such openness is, first and foremost, needed in the origins, and then be expected from a wider set of stakeholders.

2) TCSM should be supported by G20 and other forums to revisit / modernize aspects of their philosophy, epistemology, understanding of human beings, health, well-being and disease, diagnostics, etc. that could be revisited / modernized without compromising on what is ‘reasonably’ regarded as their essential and eternal aspects.

3) A framework of evidence for TCSM should be developed, which is sensitive to their essential and eternal aspects while being cognizant of later / recent developments.

4) India should call for developing harmonized conceptual and operational frameworks so that TCSM and modern medicine could function within a
complementary / integrative framework, without – or at least, minimizing – their tensions.

5) Rigorous systematic reviews of TCSM should be promoted to facilitate evidence-based TCSM health care decision-making at policy, clinical and other levels.

6) A TCSM Surveillance Strategy should be developed. TCSM-related indicators could be included in existing surveys, or there could be a dedicated TCSM survey, the latter being preferable – on TCSM use, health conditions for use, background characteristics and health status of users, expenditures, etc. Desirably, these indicators and surveys should be standardized as much as possible and have a qualitative dimension as well, given the subjective nature of non-physical aspects of health, well-being as well as health-seeking behaviors. The strategy should also include a TCSM Manpower Census as well as a pharmacovigilance strategy.

7) There should be well-defined regulatory frameworks for TCSM products, practices, practitioners, etc. as well as a Health Technology Assessment (HTA) methodology for TCSM inclusion in health programs / UHC / PHC.

® There is very little discussion or reference to TCSM in the context of SDGs. India should call for exploring the potential and promotion of TCSM vis-à-vis SDGs in general – including the protection and promotion of medicinal plants – and SDG 3 in particular. Environmental concern and a holistic approach are at the core of SDGs – these defining features of TCSM, especially herbal medicines, should be highlighted in international – especially environmental – forums.

® India should call for the optimal – rather than the optional (as is presently the case) – leveraging of TCSM in the context of SDG 3 (health) in general, SDG 3.8 (UHC) in particular.

® India should promote TCSM drugs (personalized / generic) as well as practitioners (practices).

® The quality of TCSM manpower and professional standardized practices are other challenges. The G20 could request the WHO to develop a ‘TCSM Education, Minimum Qualifications and Professional Standards Blueprint’, which should include a discussion about mutual recognition of educational qualifications of TCSM practitioners, at least within G20 countries, to begin with.

® Medical ethics and rationing could be part of the above blueprint or be taken up as a separate ‘TCSM Ethical Blueprint’. To begin with, the four principles
which are considered at the core of medical ethical reasoning – respect for autonomy, nonmaleficence, beneficence and justice (Beauchamp and Childress 2013; Gillon 1994; Ernst 1996) – can be adopted by potential joint WHO-World Bank Commission for this purpose as its conceptual framework. A discussion for rationing of health care resources should be included in this blueprint. Assessments of cost-efficiency of – and rationing of health care resources for (in conjunction with modern medicine) – TCSM need to be done. TCSM is said to be cost-effective, but there isn’t sufficient evidence regarding it. It is said that if TCSM were to conduct R&D (the way conventional medicine does) to meet the drug regulatory criteria, it might end up losing its assumed relative cost advantage vis-à-vis conventional medicine. ‘Complementary’ and ‘integrative’ are widely used terms than ‘alternative’ for traditional medicines, and in that case (i.e. in addition to rather than instead of conventional medicine), they would raise rather than contain total health care costs, hence the importance of addressing rationing issues. Given financing / budgetary implications, the World Bank should work with the WHO to develop such a blueprint at the global level, and likewise finance ministries with health ministries at national / subnational levels.


