FORM 1: PROPOSAL FOR A NEW FIELD OF TECHNICAL ACTIVITY

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Proposer BIS, INDIA	ISO/TS/P TS/P 306

A proposal for a new field of technical activity shall be submitted to the ISO Central Secretariat, which will assign it a reference number and process the proposal in accordance with the ISO/IEC Directives Part 1, Clause 1.5. The proposer may be a member body of ISO, a technical committee, subcommittee or project committee, the Technical Management Board or a General Assembly committee, the Secretary-General, a body responsible for managing a certification system operating under the auspices of ISO, or another international organization with national body membership. Guidelines for proposing and justifying a new field of technical activity are given in the ISO/IEC Directives Part 1, Annex C.

Proposal (to be completed by the proposer)		
Title of the proposed new committee (The title shall indicate clearly yet concisely the new field of technical activity which the proposal is intended to cover).		
Ayush systems		
Scope statement of the proposed new committee (The scope shall precisely define the limits of the field of activity. Scopes shall not repeat general aims and principles governing the work of the organization but shall indicate the specific area concerned).		
Standardization in the field of Ayush systems including Ayurveda, Yoga, Naturopathy, Unani, Siddha, Sowa rigpa and Homoeopathy. Both traditional and modern aspects of products and services of these systems are covered.		
Excluded from its scope are products and services covered by ISO/TC 54 'Essential oils', ISO/TC 215 Health Informatics, and ISO/TC 249 'Traditional Chinese Medicine'.		
∑ The proposer has checked whether the proposed scope of the new committee over- laps with the scope of any existing ISO committee		
 If an overlap or the potential for overlap is identified, the affected committee has been informed and consultation has taken place between proposer and committee on modification/restriction of the scope of the proposal to eliminate the overlap, potential modification/restriction of the scope of the existing committee to eliminate the overlap. 		
☐ If agreement with the existing committee has not been reached, arguments are presented in this proposal (under question 7) as to why it should be approved.		

Proposed initial programme of work. (The proposed programme of work shall correspond to and clearly reflect the aims of the standardization activities and shall, therefore, show the relationship between the subject proposed. Each item on the programme of work shall be defined by both the subject aspect(s) to be standardized (for products, for example, the items would be the types of products, characteristics, other requirements, data to be supplied, test methods, etc.). Supplementary justification may be combined with particular items in the programme of work. The proposed programme of work shall also suggest priorities and target dates.)

The initial Programme of Work of the proposed ISO/TC shall focus on Standardization in the field of Ayush systems, but not limited to the following:

- Glossary of Terminology;
- Quality and Safety of raw herbs and extracts, herbo-mineral products, medicinal products and dietary supplements / nutraceuticals;
- Health and Wellness service requirements;
- Processing of medicinal ingredients and products;
- -Diagnostic and therapeutic procedures and practices
- -Panchakarma (Ayurvedic way of rejuvenation by detoxification) equipment and Yoga accessories like Yoga Mats, Yoga props, Yoga attire etc.;
- -Yoga postures and practices;

For all the Ayush systems (<u>Annexure 1</u>), domain-wise subcommittees will take up the task of formulation of standards for the identified priority areas.

Indication(s) of the preferred type or types of deliverable(s) to be produced under the proposal (This may be combined with the "Proposed initial programme of work" if more convenient).

- ISO Standards
- ISO/ TS Technical Specifications
- ISO/TR Technical Reports
- ISO Guides

A listing of relevant existing documents at the international, regional and national levels. (Any known relevant document (such as standards and regulations) shall be listed, regardless of their source and should be accompanied by an indication of their significance.)

WHO

- WHO Traditional Medicine Strategy 2014- 2023, WHO, 2013 (ISBN 978 92 4 150609 0);
- Benchmarks for training in Ayurveda. Geneva, WHO, 2010 (ISBN 978 92 4 159962 7);
- WHO benchmarks for the practice of Ayurveda. WHO, 2022, (ISBN: 9789240042674);
- WHO benchmarks for the practice of Unani Medicine. WHO, 2022, (ISBN: 9789240042698);
- WHO Global report on Traditional and Complementary Medicine, 2019, WHO (ISBN 978-92-4-151543-6);
- WHO benchmarks for the training of Unani medicine, WHO 2022 (ISBN: 9789240042735)
- Key technical issues of herbal medicines with reference to interaction with other medicines, WHO 2021 [ISBN: 9789240019140 (electronic version) 9789240019157 (print version)]
- Pharmaco-vigilance and Traditional and Complementary Medicine in South-East Asia, WHO 2019 (ISBN: 978-92-9022-725-0)
- Traditional and complementary medicine in primary health care, WHO 2018 (WHO/HIS/SDS/2018.37)
- TRS 1003 51st report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, WHO 2017 (ISBN: 978 92 4 121003 4)
- WHO guidelines for quality assurance of traditional medicine education in the Western Pacific Region, WHO 2013 (ISBN: 9290611995)
- The Regional Strategy for Traditional Medicine in the Western Pacific (2011-2020), WHO 2012 (ISBN: 9789290615590)
- Quality control methods for herbal materials, WHO 2011 (ISBN: 9789241500739)
- Traditional herbal remedies for primary health care, WHO 2010 (ISBN: 9789290223825)
- Benchmarks for training in traditional / complementary and alternative medicine: benchmarks for training in naturopathy, WHO 2010 (ISBN: 9789241599658)
- Safety issues in the preparation of homeopathic medicines, WHO 2009 (ISBN: 9789241598842)
- WHO guidelines on good manufacturing practices (GMP) for herbal medicines, WHO 2007 (ISBN: 9789241547161)
- WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues, WHO 2007 (ISBN: 9789241594448)
- WHO monographs on selected medicinal plants, WHO 2006 (ISBN: 9241545178)
- Guidelines on minimum requirements for the registration of herbal medicinal products in the EMR, WHO 2006 (WHO-EM/EDB/048/E)
- WHO global atlas of traditional, complementary and alternative medicine, WHO 2005 (ISBN: 9241562862)
- National policy on traditional medicine and regulation of herbal medicines: report of a WHO global survey, WHO 2005 (ISBN: 9241593237)
- WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants, WHO 2003 (ISBN: 9241546271)
- The WHO strategy for traditional medicine: Review of the global situation and strategy implementation in the Eastern Mediterranean Region, WHO 2002 (EM/RC49/13)
- Legal status of traditional medicine and complementary/alternative medicine: a worldwide review, WHO 2001 (WHO/EDM/TRM/2001.2)
- General guidelines for methodologies on research and evaluation of traditional medicine, WHO 2000 (WHO/EDM/TRM/2000.1)

Europe

- The European Academy of Ayurveda: 20 years of Ayurvedic education in Germany, Anc Sci Life. 2012 Jul-Sep; 32(1): 63–65, doi: 10.4103/0257-7941.113797, PMCID: PMC3733211, PMID: 23929998.
- Legal status and regulation of CAM in Europe (https://cam-europe.eu/wp-content/up-loads/2018/09/CAMbrella-WP2-part 1final.pdf)
- Complementary and Herbal medicine in Switzerland (https://www.swissmedic.ch/swissmedic.ch/swissmedic.ch/swissmedic/en/home/kpa.html)

USA

 Complementary and Alternative Medicine Products and their Regulation by the Food and Drug Administration (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/)

Australia

 Australian regulatory guidelines for complementary medicines (https://www.tga.gov.au/sites/default/files/australian-regulatory-guidelines-complementary-medicines-argcm.pdf)

<u>Asia</u>

- Regulation of Herbal Medicinal Products in Russia, April 2012, Planta Medica 78(05), DOI:10.1055/s-0032-1307488 (https://www.researchgate.net/publication/315047635_Regulation_of_Herbal_Medicinal_Products_in_Russia)
- Regulation of herbal medicines in Japan, June 2000Pharmacological Research 41(5):515-9 DOI: 10.1006/phrs.1999.0645 (https://www.researchgate.net/publication/12561959)
- HAAD Standard for Scope of Practice for Traditional Complementary and Alternative Medicine (TCAM) Practitioners- Department of Health-Abu Dhabi (https://www.doh.gov.ae/en/)
- The Drugs and Cosmetics Act, 1940 and Rules there under;
- The Ayurvedic Pharmacopoeia of India (API);
- The Siddha Pharmacopoeia of India (SPI):
- The Unani Pharmacopoeia of India (UPI);
- The Homoeopathic Pharmacopoeia of India (HPI);
- Indian Standards IS 17424 part 1:2020; IS 17424 part 2:2020; IS 17424 part 3:2020; IS 17424 part 4:2020; and IS 17424 part 5:2021;
- https://globalwellnessinstitute.org/press-room/statistics-and-facts/

A statement from the proposer as to how the proposed work may relate to or impact on existing work, especially existing ISO and IEC deliverables. (The proposer should explain how the work differs from apparently similar work, or explain how duplication and conflict will be minimized. If seemingly similar or related work is already in the scope of other committees of the organization or in other organizations, the proposed scope shall distinguish between the proposed work and the other work. The proposer shall indicate whether his or her proposal could be dealt with by widening the scope of an existing committee or by establishing a new committee.)

There will be no direct overlap of scope of work or conflict between this proposal and other exiting technical committees or subcommittees within ISO and IEC.

Presently, the International Standards related to few domains of Traditional Medicine are being taken care of in a scattered manner in the ISO through ISO/TC 54 'Essential oils'; ISO/TC 215 (WG 10) Health Informatics (Traditional Medicine); and ISO/TC 249 'Traditional Chinese Medicine'. The scope of ISO TC 54 is confined to standardization of methods of analysis and specifications for essential oils.

ISO TC 215 exclusively deals with the subject of 'Health Informatics' whereas, the proposed TC on 'Ayush Systems' aims to cater to the subjects including, but not limited to Terminology in Ayush systems; Quality and Safety of raw herbs and extracts, herbo-mineral products, medicinal products and dietary supplements used in Ayush; Health and Wellness service requirements in Ayush sector; Processing of medicinal ingredients and products in Ayush systems; Diagnostic and therapeutic procedures and practices used in Ayush systems; Panchakarma (Ayurvedic way of rejuvenation by detoxification) equipment and Yoga accessories like Yoga Mats, Yoga props, Yoga attire specific to Ayush systems; Yoga postures and practices, etc. It categorically excludes the work being done in ISO TC 215 from its scope. Hence, the instant proposal does not overlap with the ongoing work of ISO TC 215.

There is no overlap with the scope of ISO TC 249 which exclusively deals with Traditional Chinese Medicine only. Since Ayush systems have a unique philosophy that is discrete from the TCM, it is required to have a dedicated TC for formulation of International Standards in Ayush systems in the wake of the fact that as per World Health Organization (WHO) survey {WHO Global report on Traditional and Complementary Medicine, 2019, WHO (ISBN 978-92-4-151543-6)} more than 90 WHO member states use Ayurveda; more than 100 use Homoeopahy; and more than 82 use Unani. Also, the UN General Assembly on 11 December 2014 adopted a resolution declaring June 21 as 'International Day of Yoga', recognising that "Yoga provides a holistic approach to health and well-being." The resolution had 175 nations joining as co-sponsors, the highest number ever for any General Assembly resolution. Ayurveda is recognized as System of Medicine in Nepal, Sri Lanka, Pakistan, Bangladesh, UAE, Oman, Saudi Arabia, Bahrain, Malaysia, Mauritius, Hungary, Serbia, Tanzania, Switzerland, Cuba and Brazil. Romania, Hungary, Latvia, Serbia and Slovenia are 5 countries of European Union (EU), where Ayurvedic Practices is regulated. Unani system is recognized in Bangladesh, Sri Lanka, Malaysia, Pakistan, Bahrain, UAE and Tanzania. Siddha system is recognized in Sri Lanka and Malaysia. Sowa Rigpa system is recognized in Bhutan and Mongolia. Homoeopathy system is recognized in Sri Lanka, Bangladesh, Pakistan, Oman, UAE, Russia and Tanzania. It is well regulated in Ghana, Chile, Colombia, Romania, Turkey, Ontario (Canada) and is integrated into National Health Policy in UK (Annexure 4). It is noteworthy that Ayush products is being exported to more than 100 foreign countries either as Medicine or as Food Supplement.

Though Ayush systems are being practised in many countries across the globe and several countries are engaged in collaborative research for promotion of Ayush systems, the traditional

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medicine systems of Ayurveda, Siddha, Sowa rigpa, Unani and Homoeopathy and the non-pharmacological systems like Yoga and Naturopathy per-say are not covered in the scope of any of the existing Technical Committee in the ISO/ IEC.

Hence, creation of an ISO TC for Ayush systems will catalyse the formulation of international standards to augment the quality, safety and effectiveness of the Ayush products and practices used by people across the globe.

A listing of relevant countries where the subject of the proposal is important to their national commercial interests.

As per a WHO survey, 107 Member States have a national office for traditional medicine and 75 Member States have a national research institute of traditional medicine. A total of 34 Member States across the six WHO regions include traditional or herbal medicines in their national essential medicines lists. Also, out of nine traditional & complimentary medicine practices surveyed (acupuncture, Ayurvedic medicine, chiropractic, herbal medicine, homeopathy, naturopathy, osteopathy, traditional Chinese medicine, and Unani medicine), more than 110 WHO member states use herbal medicine and more than 90 WHO member states use of Ayurveda; more than 100 use Homoeopathy; more than 82 use Unani {WHO Global report on Traditional and Complementary Medicine, 2019, WHO (ISBN 978-92-4-151543-6)}.

WHO has also stated in the "WHO Traditional Medicine Strategy 2014-2023" that "For many millions of people, herbal medicines, traditional treatments, and traditional practitioners are the main source of health care, and sometimes the only source of care. This is care that is close to homes, accessible and affordable. It is also culturally acceptable and trusted by large numbers of people. The affordability of most traditional medicines makes them all the more attractive at a time of soaring health-care costs and nearly universal austerity."

Appreciating the role of traditional medicines in healthcare, WHO is setting up a Global Centre for Traditional Medicine (WHO GCTM) in Gujarat, India.

Recognising that "Yoga provides a holistic approach to health and well-being", on 11th Dec 2014, the UN General Assembly adopted a resolution declaring June 21 as 'International Day of Yoga', The resolution had 175 nations joining as co-sponsors, the highest number ever for any General Assembly resolution. In 2021, the International Day of Yoga (IDY) was celebrated in 192 out of total 193 UN member countries.

Further, according to the Global Wellness Institute (GWI) report, 2020, the global wellness economy having 11 sectors was valued at \$4.9 trillion in 2019 and continue to be above \$4.4 trillion in 2020 despite of world health crisis. The important sectors those would be directly linked to the proposed committee are Healthy Eating, Nutrition, & Weight Loss (\$946 billion); Physical Activity (\$738 billion); Wellness Tourism (\$436 billion); Traditional & Complementary Medicine (\$413 billion); Public Health, Prevention, & Personalized Medicine (\$375 billion).

As per the report, the traditional & complementary medicine (T&CM) services/practitioners represent 54% of the market (\$222 billion in 2020), while T&CM medicines/products represent 46% (\$191 billion). Asia-Pacific is by far the largest regional market for T&CM (\$295 billion in 2020).

It is also relevant to mention that Ayurveda is recognized/ regulated in India, Nepal, Bangladesh, Pakistan, Sri Lanka, UAE, Colombia, Malaysia, Switzerland, South Africa, Cuba, Tanzania, Romania, Hungary, Latvia, Serbia and Slovenia.

To have detailed information about the countries where Ayush systems are being practiced and which are encouraging collaborative research for promotion of Ayush systems, please refer to Annexure 2. The list is illustrative and not exclusive.

The standardization endeavour is therefore intended to involve all countries, considering the numerous sectors covered in the proposed scope.

A listing of relevant external international organizations or internal parties (other ISO and/or IEC committees) to be engaged as liaisons in the development of the deliverable(s). (In order to avoid conflict with, or duplication of efforts of, other bodies, it is important to indicate all points of possible conflict or overlap. The result of any communication with other interested bodies shall also be included.)

The following ISO Technical Committees / sub-committee(s) may be considered for engagement as liaisons in the development of the deliverable(s) in the proposed new TC:

- ISO/TC 54 'Essential oils',
- ISO/TC 215 'Health Informatics',
- ISO/TC 249 'Traditional Chinese Medicine',
- ISO/TC 34/SC 7, Spices, culinary herbs and condiments;

The proposal would seek contact with the following international organizations in the study of standardization:

- WHO (World Health Organization);
- UNESCO (UN Economic and Social Council):
- UN (United Nation) in reference to SDG (sustainable development goal) 3: Ensure healthy lives and promote well-being for all at all ages;

A simple and concise statement identifying and describing relevant affected stakeholder categories (including small and medium sized enterprises) and how they will each benefit from or be impacted by the proposed deliverable(s).

Globally, the landscape for Traditional & Complementary Medicine (T&CM) has been improving and augmenting consistently. Traditional medical systems including Ayush systems are important and often underestimated health resource with many applications, especially in the prevention and management of lifestyle-related chronic diseases, and in meeting the health needs of ageing populations. Given the unique health challenges of the 21st century, interest in Ayush Systems is undergoing a revival.

Today, as many as 80% of the world's people depend on traditional medicine for their primary health care needs, according to the World Health Organization (WHO). Hence, all stakeholders, including consumers, industries, governments/regulatory organizations, national and international traders, academia and researchers across the globe dealing with Traditional systems of medicine including Ayush systems will benefit from and be affected by the proposed deliverables.

An expression of commitment from the proposer to provide the committee secretariat if the proposal succeeds.

If the proposal is accepted, BIS, India is willing to undertake the work of secretariat of the new TC, and is committed to provide all resources to successfully run the secretariat as per ISO norms.

Purpose and justification for the proposal. (The purpose and justification for the creation of a new technical committee shall be made clear and the need for standardization in this fieldshall be justified. Clause C.4.13.3 of Annex C of the ISO/IEC Directives, Part 1 contains a menu of suggestions or ideas for possible documentation to support and purpose and justification of proposals. Proposers should consider these suggestions, but they are not limited to them, nor are they required to comply strictly with them. What is most important is that proposers develop and provide purpose and justification information that is most relevant to their proposals and that makes a substantial business case for the market relevance and the need for their proposals. Thorough, well-developed and robust purpose and justification documentation will lead to more informed consideration of proposals and ultimately their possible success in the ISO IEC system.)

Purpose:

It is the need of the hour to move towards Sustainable Development Goal 3 (SDG 3) – ensuring healthy lives and promoting well-being for all at all ages – by achieving universal health coverage (UHC), addressing health emergencies and promoting healthier populations. Ayush systems can make a significant contribution to the goal of UHC by being included in the provision of essential health services.

The Declaration of Astana of the World Health Organization (WHO), adopted at the Global Conference on Primary Health Care in October 2018, made clear that the success of primary health care will be driven by applying scientific as well as traditional knowledge, and extending access to a range of health care services, which include traditional medicines. It is reported that 88% Member States have acknowledged use of traditional medicines which corresponds to 170 Member States in WHO.

Ayurveda is recognized as System of Medicine in Nepal, Sri Lanka, Pakistan, Bangladesh, UAE, Oman, Saudi Arabia, Bahrain, Malaysia, Mauritius, Hungary, Serbia, Tanzania, Switzerland, Cuba and Brazil. Romania, Hungary, Latvia, Serbia and Slovenia are 5 countries of European Union (EU), where Ayurvedic Practices is regulated. Unani system is recognized in Bangladesh, Sri Lanka, Malaysia, Pakistan, Bahrain, UAE and Tanzania. Siddha system is recognized in Sri Lanka and Malaysia. Sowa Rigpa system is recognized in Bhutan and Mongolia. Homoeopathy system is recognized in Sri Lanka, Bangladesh, Pakistan, Oman, UAE, Russia and Tanzania. It is well regulated in Ghana, Chile, Colombia, Romania, Turkey, Ontario (Canada) and is integrated into National Health Policy in UK (Annexure 3).

Ayush products are being traded into more than 100 countries either as Medicine or as Food Supplement.

With a view to promote the safety, quality and effectiveness of Ayush systems, it is envisaged to formulate International Standards. Such an endeavour is poised to not only augment the International trade but also building confidence among the consumers.

Signature of the proposer

Rachna Sehgal, Head (International Relations), Bureau of Indian Standards

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Further information to assist with understanding the requirements for the items above can be found in the <u>Directives, Part 1, Annex C.</u>

Annexure 1

Introduction to Ayush systems

'Ayush' is a term which connotes all the traditional Indian systems of medicine comprising of Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-rigpa and Homoeopathy.

Earlier, the word 'AYUSH' was used as an acronym for Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-rigpa and Homoeopathy. To emphasise the underlying commonalities and hence unity of all these holistic systems of healing, in May 2018, the Government of India has defined the word 'ayush'/'Ayush' as 'Traditional and Non-Conventional Systems of Health Care and Healing which include Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-rigpa, Homoeopathy etc.'

Ayurveda -the science of life is one of the oldest medical systems which integrally incorporates the concepts of health and disease and aims at achieving homeostasis of the body, mind, and spirit- referred to as the holistic approach. The objectives of Ayurveda are - to maintain the health of the healthy; and to treat the ailing mankind. Ayurveda primarily guides regarding prevention of disease, promotion and preservation of health through diet, lifestyle rules and other interventions. Therapeutic modalities in the form of herbal / herbo-mineral drugs and detoxification procedures play an important role in restoring health in the ailing mankind.

Yoga is an art and science for healthy living that brings harmony in all walks of life and thus, is known for disease prevention, health promotion and management of many lifestyle related disorders. The practice of Yoga leads to the union of an individual consciousness with the universal consciousness. The eightfold components of Yoga advocate certain restraints and observances which have the potential to improve physical health and induce tranquility of mind. The benefits of this ancient practice go far beyond increased flexibility and muscle tone as the study and practice of Yoga incorporates mindfulness-based practices such as mindful breathing techniques, focused concentration, meditation and self-reflection.

Naturopathy is the science of health and healing. It is a drug-less system of medicine that advocates harmonious living with constructive principles of Nature on physical, mental, moral and spiritual planes. It has health promotive, health restorative, disease preventive as well as curative potential. According to Naturopathy, the primary cause of disease is violation of Nature's laws which lead to decreased vitality, impaired body constituents and accumulation of toxins in the body. Naturopathy believes that the disease is Nature's effort to eliminate the morbid matter from the body to restore the health, hence, we must not try to suppress the symptoms and cooperate with Nature in the process.

Unani system of medicine emphasises the use of naturally occurring substances, mostly herbal medicines and also uses some medicines of animal, marine and mineral origin. This system is based on the humoral theory i.e. the presence of blood, phlegm, yellow bile and black bile in every person. The temperament of a person can accordingly be Sanguine, Phlegmatic, Choleric and Melancholic depending on the presence and combination of the Humors. The treatment consists of four components, namely, Preventive, Promotive, Curative and Rehabilitative. According to Unani theory, the humors and the drugs themselves are assigned temperaments. Any change in

quantity and quality of the humors brings about a change in the status of the health of the human body. A proper balance of humors is required in the maintenance of health.

Siddha system of Medicine emphasises on the patient, environment, age, sex, race, habits, mental framework, habitat, diet, appetite, physical condition, the physiological constitution of the diseases for treatment that is individualistic. Diagnosis of diseases is done through examination of pulse, urine, eyes, study of voice, the colour of body, tongue and status of the digestion of individual patients. The system has a unique treasure for the conversion of metals and minerals as drugs.

Sowa-rigpa meaning 'knowledge of healing'. Sowa Rigpa mainly emphasises on maintaining a healthy balance on both the physical and mental level. The diagnosis in this system is done by observation, palpation and questioning. The diagnosis is supplemented with pulse examination. The Sowa-rigpa system utilizes various forms of treatment such as medicinal plants, medicinal bath, vein puncturing, moxibustion, and massage depending upon the nature and severity of the ailment.

Homoeopathy is a method of treating diseases by administering drugs which have been experimentally proved to possess the power to produce similar symptoms on healthy human beings. Treatment in Homoeopathy, which is holistic in nature, focuses on an individual's response to a specific environment. Homoeopathic medicines are prepared mainly from natural substances, such as plant products, minerals and from animal sources, nosodes, sarcodes etc. Homoeopathy is based on the assumption that the causation of a disease mainly depends upon the susceptibility or proneness of an individual to the incidence of the particular disease in addition to the action of external pathogens. The first principle of Homoeopathy 'Similia Similibus Curentur', says that a medicine which could induce a set of symptoms in healthy human beings would be capable of curing a similar set of symptoms in human beings actually suffering from the disease. The second principle of 'Single Medicine' says that one medicine should be administered at a time to a particular patient during the treatment. The third principle of 'Minimum Dose' states that the bare minimum dose of a drug which would induce a curative action without any adverse effect should be administered.

Annexure 2

International activities pertaining to Ayush systems

(A) <u>Country to Country Memorandum of Understanding (MoUs) for Cooperation in Ayush systems</u>

The following countries/ organizations have entered into MoU with one or more countries for promotion of Ayush systems and mutual cooperation in the field of traditional medicine:

- 1. Nepal
- 2. Bangladesh
- 3. Bolivia
- 4. Brazil
- 5. China
- 6. Colombia
- 7. Cuba
- 8. Equatorial Guinea
- 9. Gambia
- 10. Germany
- 11. Guinea, Republic of
- 12. Hungary
- 13. India
- 14. Iran
- 15. Japan
- 16. Malaysia
- 17. Mauritius
- 18. Mongolia
- 19. Myanmar
- 20. Sao Tome & Príncipe
- 21. St. Vincent & The Grenadines
- 22. Suriname
- 23. Trinidad & Tobago
- 24. Turkmenistan
- 25. Zimbabwe

(B) <u>Institutional arrangements for undertaking Collaborative Research in Ayush systems</u>

The following institutes have entered into collaborative arrangements for conducting research in and promotion of Ayush systems:

- 1. National Centre for Natural Product Research (NCNPR), University of Mississippi, USA
- 2. Royal London Hospital for Integrated Medicine, United Kingdom.
- 3. College of Homoeopathy (COH), Ontario
- 4. United States Pharmacopoeia Convention.
- 5. University of Maimonides, Argentina.
- 6. Health Sciences Fund of the Tel Aviv Sourasky Medical Center (TASMC), Israel.
- 7. University of Alberta, Canada
- 8. Universiti Tunku Abdul Rahman, Kaula Lumpur, Malaysia
- 9. Homoeopathic Pharmacopoeia Convention of the United States (HPCUS)
- 10. Scientific Society for Homoeopathy (WissHom), Germany

- 11. Federal University of Rio De Janerio (FURJ), Brazil
- 12. European Academy of Ayurveda (Birstein), (REAA) Germany
- 13. Centre for Integrative Complementary Medicine, ShaareZedek Medical Center, Jerusalem, Israel
- 14. National Institute of Integrative Medicine (NIIM), Australia
- 15. College of Medicine, United Kingdom
- 16. Medical University of Graz, Graz Austria
- 17. State Educational Establishment "Tajik State Medical University named Abualilbn Sino".
- 18. Spaulding Rehabilitation Hospital, USA
- 19. Department of Neurology and Complementary Medicine, Lutheran, Hospital Hattingen, Germany
- 20. National Cancer Institute, NIH, Dept. of Health & Human Services, Government of the USA
- 21. Leaders Development Institute (LDI), Ministry of Sports, Saudi Arabia for Cooperation in the field of Yoga.
- 22. Western Sydney University Australia.
- 23. Divine Values School, Ecuador (DVSE) on establishment of an Academic Collaboration in Yoga.
- 24. Frankfurter Innovationszentrum Biotechnologie GmbH FIZ, Germany.
- 25. The London School of Hygiene and Tropical Medicine (LSHTM), United Kingdom.
- 26. Shimane University, Japan
- 27. Universitas Hindu (UNHI), Indonesia.
- 28. Centre Hospitalier Universitaire Felix Guyon, Reunion Island, France.
- 29. Harvard Medical School, Boston.
- 30. Future Vision Institute and University of Sao Paulo, Brazil.
- 31. American Herbal Pharmacopoeia.
- 32. Ministry of Ayush, Government of India

(C) Ayush Academic Chairs

The following universities/ institutes across various countries have set up Ayush Academic Chairs to augment academic partnership and disseminate authentic knowledge about Ayush systems:

- 1. University of Debrecen, Hungary (Ayurveda Chair)
- 2. University of the West Indies, Trinidad & Tobago (Ayurveda Chair)
- 3. University of the Western Cape, South Africa (Unani Chair)
- 4. Rangsit University, Thailand (Ayurveda Chair)
- 5. Peoples' Friendship University, Russia (Ayurveda Chair)
- 6. Udayana University, Indonesia (Ayurveda Chair)
- 7. University of Primorska, Slovenia (Ayurveda Chair)
- 8. Yerevan State Medical University (YSMU), Armenia (Homoeopathy Chair)
- 9. University of Latvia, Latvia (Ayurveda Chair)
- 10. The Government of *Instituto Universitario del Gran Rosario* and The Government of *Fundacion de Salud Ayurveda Prema*, Argentina
- 11. University Tunku Abdul Rahman (UTAR), Malaysia.

- 12. Hamdard University Bangladesh, Bangladesh (Unani Chair)
- 13. University of Mauritius, Ministry of Education and Human resource (Ayurveda chair)
- 14. Western Sydney University, Australia

(D) Ayush systems in the World Health Organization (WHO)

The WHO has published several documents and undertaken many collaborative projects for disseminating authentic information on Ayush systems including:

- cooperation on promoting the quality, safety and effectiveness of traditional and complementary medicine;
- cooperation on integration of traditional and complementary medicine into health care system;
- publication on standard terminology in Ayurveda, Unani, and Siddha;
- agreement towards developing the 2nd module in the Traditional Medicine (TM) Chapter of the International Classification of Diseases -11 (ICD-11) Revision;
- deputation of an Ayush expert for WHO's regional traditional medicine programme in World Health Organization South East Asia Regional Office (WHO SEARO);
- conducting the research Project/study entitled "Assessment of integration of AYUSH into the public health system for combating COVID-19";
- developing M-Yoga- app, a Health Program for Yoga;
- establishment of the first WHO Global Centre for Traditional Medicine (GCTM) in India.

(E) Ayush systems related activities at International Forums

BRICS (comprising of 05 member states including Brazil, Russia, India, China and South Africa)

- a BRICS Wellness Workshop and exhibition in Bengaluru, India during 10-11 Sept, 2016 to deliberate on the shared concerns in the domain of traditional medicine and wellness;
- a BRICS High Level Meeting on Traditional Medicinal Knowledge on 16 Dec 2016 in New Delhi as part of the 6th BRICS Health Minister's Meeting;
- a BRICS Health Minister's Meeting and High-Level Meeting on Traditional Medicine and BRICS Senior Health Official Meeting held in Tianjin, China during 6-7 July, 2017;
- the first meeting of BRICS Sherpas held on 24-26 February 2021 in New Delhi, India for constitution of BRICS Forum on Traditional Medicine (BFTM) and MoU on BRICS co-operation in Traditional Medicines;
- a meeting of the BRICS Experts in Traditional Medicines held on 25th March 2021;
- a Webinar on Harmonization of Regulation of Standardization of Traditional Medicinal Products of BRICS Countries on 28th May 2021; and

- BRICS Senior Officials Meeting (SOM) on Health on 26th- 27th July, 2021 to discuss Traditional medicine.
- **❖** IBSA (comprising of 03-member states including India, Brazil and South Africa)
 - a tripartite MoU on mutual co-operation for promotion of Health including Traditional Medicine has been signed between the member states;
 - a joint working group has been formed for sharing information on the subject; and
 - role of Ayush systems in tackling with the CoVID-19 Pandemic was discussed during a Webinar organized by IBSA partners in October, 2020;
- ASEAN (The Association of Southeast Asian Nations comprising of 10 member states including Brunei; Cambodia; Indonesia; Laos; Malaysia; Myanmar; Philippines; Singapore; Thailand; and Vietnam)
 - ASEAN Secretariat on 2nd September, 2021 held discussion to explore possibilities of mutual cooperation in Traditional Medicine;
 - ASEAN Secretariat on 9th September, 2021 held discussion to consider the roadmap for mutual cooperation in Traditional Medicine
- CICA (The Conference on Interaction and Confidence-Building Measures in Asia comprising of 27 member states including Afghanistan; Azerbaijan; Bahrain; Bangladesh; Cambodia; China; Egypt; India; Iran; Iraq; Israel; Jordan; Kazakhstan; Kyrgystan; Mongolia; Pakistan; Palestine; Qatar; Russia; South Korea; Sri Lanka; Tajikistan; Thailand; Turkey; United Arab Emirates; Uzbekistan; and Vietnam)
 - a Workshop on Ayush systems is envisaged under the framework of CICA in 2022.
- ❖ <u>BIMSTEC</u> (The Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation comprising of 07 member states including Bangladesh; Bhutan; India; Myanmar; Nepal; Sri Lanka; and Thailand)
 - BIMSEC Task Force on Traditional Medicine held meetings in October 2017 in New Delhi, Myanmar in January, 2018 and Nepal in February, 2019; and
 - as a follow up to the meeting of the BIMSTEC Network of National Centers of Coordination in Traditional Medicine held in Nonthaburi, Thailand from 20-22 July 2015, the BIMSTEC secretariat published a report including a chapter on Ayush systems
- SCO (The Shanghai Cooperation Organization comprising of 08 member states including China; India; Kazakhstan; Kyrgzstan; Pakistan; Russia; Tajikistan; and Uzbekistan)
 - SCO member states are discussing modalities for imparting training to the Yoga Teachers;
 - a Webinar on Traditional Medicine was held on 22 September, 2020

(F) Establishment of Ayush Information Cells

Ayush Information Cells are functioning in the following countries to take up awareness building and disseminating authentic information about these systems:

- 1. Argentina
- 2. Australia
- 3. China
- 4. Cuba
- 5. Croatia
- 6. Dubai
- 7. Egypt
- 8. Finland
- 9. Hungary
- 10. India
- 11. Indonesia
- 12. Italy
- 13. Israel
- 14. Kuwait
- 15. Kyrgyzstan
- 16. London
- 17. Malaysia
- 18. Mauritius
- 19. Mexico
- 20. Mongolia
- 21. Peru
- 22. Romania
- 23. Russia
- 24. Serbia
- 25. Slovenia
- 26. Sweden
- 27. Switzerland
- 28. Taiwan
- 29. Tajikistan
- 30. Tanzania
- 31. Trinidad & Tobago
- 32. Venezuela

Annexure 3

International status of recognition of Ayush systems

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

The WHO's Declaration of Astana, adopted at the Global Conference on Primary Health Care in October 2018, made clear that the success of primary health care will be driven by applying scientific as well as traditional knowledge, and extending access to a range of health care services, which include traditional medicines.

As per the WHO global (updated) survey on T&CM during 2016 - 2018, 88% Member States have acknowledged their use of T&CM which corresponds to 170 Member States. These are the countries that have, for example, formally developed policies, laws, regulations, programmes and offices for T&CM, and the actual number of countries using T&CM is likely to be even higher.

Out of total 194 member states, 179 member states participated in the survey. A gist of the survey {WHO Global report on Traditional and Complementary Medicine, 2019, WHO (ISBN 978-92-4-151543-6)} is recapitulated as follows:

S. No.	WHO region	Attribute of Traditional and Complimentary Medicine (T&CM)	Number of Member States with Affirma- tive Response
1	African region	National Policy	40
	(47 countries)	Regulations on T&CM	39
		National Programme	34
	Algeria, Angola, Benin,	National Office	39
	Botswana, Burkina	Expert Committee	34
	Faso, Burundi, Came-	National Research Institute	29
	roon, Cabo Verde,	Regulation of Herbal medicines	20
	Central African Repub-	Registration of herbal medicines	23
	lic, Chad, Comoros, Congo, Cote d'Ivoire, Democratic Republic of the Congo, Equatorial Guinea, Eritrea, Eswatini, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal,	% population using T&CM	87

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2 Recall (3 Ar Ar Ba via (P Br Co Co m Ec G	ntigua and Barbuda, rgentina, Bahamas, arbados, Belize, Bolia Plurinational State of), razil, Canada, Chile, olombia, Costa Rica, uba, Dominica, Doinican Republic, cuador, El Salvador, renada, Guatemala,	National Policy Regulations on T&CM National Programme National Office Expert Committee National Research Institute Regulation of Herbal medicines Registration of herbal medicines % population using T&CM	11 15 13 17 12 9 18 19
ra Ni Pa Ki Lu ar Su ar To of	tuyana, Haiti, Hondu- as, Jamaica, Mexico, icaragua, Panama, araguay, Peru, Saint itts and Nevis, Saint ucia, Saint Vincent and the Grenadines, uriname, Trinidad and obago, United States f America, Uruguay, enezuela (Bolivarian epublic of)		
3 Ea re (2 Af Dj (Is Ira Jo no Oi ta m Ar sia	astern Mediterranean egion 21 countries) fghanistan, Bahrain, jibouti, Egypt, Iran slamic Republic of), aq, ordan, Kuwait, Lebann, Libya, Morocco, man, Pakistan, Qanalia, Sudan, Syrian rab Republic, Tunia, United Arab Emirtes, Yemen	National Policy Regulations on T&CM National Programme National Office Expert Committee National Research Institute Regulation of Herbal medicines Registration of herbal medicines % population using T&CM	9 12 4 13 11 10 18 17 90
	uropean region 3 countries)	National Policy Regulations on T&CM National Programme	11 21 7

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	Albania, Andorra, Ar-	National Office	15
	menia, Austria, Azer-	Expert Committee	15
	baijan, Belarus, Bel-	National Research Institute	11
	gium, Bosnia and	Regulation of Herbal medicines	45
	Herzegovina, Bulgaria,	Registration of herbal medicines	45
	Croatia, Cyprus,	% population using T&CM	89
	Czech Republic, Den-		
	mark, Estonia, Finland,		
	France, Georgia,		
	Germany, Greece,		
	Hungary, Iceland, Ireland, Israel, Italy, Ka-		
	zakhstan, Kyrgyzstan,		
	Latvia, Lithuania,		
	Luxembourg, Malta,		
	Monaco, Montenegro,		
	Netherlands, Norway,		
	Poland, Portugal, Re-		
	public of Moldova,		
	Republic of North Mac-		
	edonia, Romania, Rus-		
	sian Federation, San		
	Marino, Serbia, Slo-		
	vakia, Slovenia, Spain, Sweden, Switzerland,		
	Tajikistan, Turkey,		
	Turkmenistan,		
	Ukraine, United King-		
	dom of Great Britain		
	and		
	Northern Ireland, Uz-		
	bekistan		
5	South-East Asia region	National Policy	10
	(11 countries)	Regulations on T&CM	9
	Bangladesh, Bhutan,	National Programme National Office	10
	Democratic People's	Expert Committee	10 10
	Republic of Korea, In-	National Research Institute	7
	dia, Indonesia, Mal-	Regulation of Herbal medicines	10
	dives, Myanmar, Ne-	Registration of herbal medicines	10
	pal, Sri Lanka, Thai-	% population using T&CM	91
	land, Timor-Leste		
6	Western Pacific region	National Policy	17
	(27 countries)	Regulations on T&CM	13
	Austrolia Druma: Da	National Programme	11
	Australia, Brunei Da-	National Office	13
	russalam, Cambodia, China, Cook Islands,	Expert Committee	11
	Fiji, Japan,	National Research Institute	9
	Fiji, Japan, Kiribati, Lao People's	Regulation of Herbal medicines	13
	Democratic Republic,	Registration of herbal medicines	11
	Time or date i top dono,	% population using T&CM	93

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Malaysia, Marshall Is-	
lands, Micronesia	
(Federated States of),	
Mongolia, Nauru, New	
Zealand, Niue, Palau,	
Papua New Guinea,	
Philippines, Republic	
of Korea, Samoa,	
Singapore, Solomon	
Islands, Tonga, Tu-	
valu, Vanuatu, Viet	
Nam	

STATUS OF PRESENCE OF AYUSH SYSTEMS IN THE WHO MEMBER STATES

S.No.	Member Country (participated in the WHO sur- veys regarding T&CM)	Presence of AYUSH systems (one or more out of Ayurveda- Yoga & Na- turopathy- Unani- Siddha- Sowa rigpa- Ho- meopathy)
WHO AFRICAN REGION		
1.	Benin	$\sqrt{}$
2.	Burkina Faso	$\sqrt{}$
3.	Burundi	$\sqrt{}$
4.	Cameroon	$\sqrt{}$
5.	Central African Republic	
6.	Chad	
7.	Comoros	V
8.	Congo	V
9.	Cote d Ivoire	V
10.	Democratic Republic of the Congo	
11.	Equatorial Guinea	
12.	Eritrea	
13.	Ethiopia	
14.	Gabon	
15.	Gambia	$\sqrt{}$
16.	Ghana	$\sqrt{}$
17.	Guinea-Bissau	$\sqrt{}$
18.	Liberia	
19.	Madagascar	
20.	Mali	$\sqrt{}$
21.	Mozambique	$\sqrt{}$
22.	Namibia	V
23.	Niger	
24.	Sao Tome and Principe	
25.	Senegal	V
26.	South Africa	V
27.	Uganda	V
28.	United Republic of Tanzania	

	WHO BECK	ON OF AMERICAS
20		IN OF AMERICAS
29.	Argentina	
30.	Bahamas	
31.	Barbados	
32.	Belize	
33.	Bolivia (Plurinational State of)	V
34.	Brazil	V
35.	Canada	V
36.	Chile	V
37.	Colombia	V
38.	Costa Rica	V
39.	Cuba	V
40.	Ecuador	V
41.	El Salvador	V
42.	Grenada	
43.	Guatemala	
44.	Guyana	
45.	Haiti	
46.	Honduras	
47.	Mexico	V
48.	Nicaragua	
49.	Panama	
50.	Paraguay	V
51.	Peru	V
52.	Saint Lucia	
53.	Saint Vincent and the Grenadines	$\sqrt{}$
54.	Trinidad and Tobago	$\sqrt{}$
55.	United States of America	
56.	Uruguay	
	EASTERN MEDI	TERRANEAN REGION
57.	Afghanistan	$\sqrt{}$
58.	Bahrain	$\sqrt{}$
59.	Iran (Islamic Republic of)	$\sqrt{}$
60.	Iraq	
61.	Jordan	
62.	Kuwait	$\sqrt{}$
63.	Lebanon	
64.	Morocco	
65.	Oman	V
66.	Pakistan	$\sqrt{}$
67.	Qatar	
68.	Saudi Arabia	
69.	Somalia	
70.	Sudan	
71.	Syrian Arab Republic	V
72.	Tunisia	V
73.	United Arab Emirates	V
74.	Yemen	
WHO EUROPEAN REGION		
75.	Albania	
76.	Andora	

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77.	Armenia		
78.	Armenia	V V	
78. 79.	Azerbaijan	V V	
80.	Belarus	V	
81.			
82.	Belgium Bosnia and Herzegovina	V	
83.	Croatia		
84.		√ V	
85.	Cyprus Czech Republic	V	
86.	Denmark Estonia	V	
87.		√ ./	
88.	Finland	. /	
89.	Germany	V	
90.	Hungary	V	
91.	Iceland		
92.	Ireland	V	
93.	Israel	V	
94.	Lithuania		
95.	Malta		
96.	Montenegro		
97.	Netherlands	V	
98.	Norway	V	
99.	Poland	V	
100.	Portugal	V	
101.	Republic of Moldova	V	
102.	Romania		
103.	Serbia	V	
104.	Slovakia	V	
105.	Slovenia	√	
106.	Spain	,	
107.	Sweden	V	
108.	Switzerland	V	
109.	Turkey	√	
110.	Ukraine	,	
111.	United Kingdom of Great Britain	$\sqrt{}$	
	and Northern Ireland		
		EAST ASIA REGION	
112.	Bangladesh	V	
113.	Bhutan		
114.	Democratic People's Republic of		
	Korea	,	
115.	India	V	
116.	Indonesia	V	
117.	Maldives	V	
118.	Myanmar	,	
119.	Nepal	V	
120.	Sri Lanka	V	
121.	Thailand	$\sqrt{}$	
122.	Timor-Leste		
WHO WESTERN PACIFIC REGION			
123.	Australia	$\sqrt{}$	

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124.	Brunei Darussalam	$\sqrt{}$
125.	Cambodia	V
126.	China	
127.	Cook Islands	
128.	Fiji	
129.	Japan	
130.	Kiribati	
131.	Lao People's Democratic Republic	V
132.	Malaysia	
133.	Marshall Islands	
134.	Micronesia (Federated States of)	
135.	Mongolia	
136.	Nauru	
137.	New Zealand	
138.	Niue	
139.	Palau	
140.	Papua New Guinea	
141.	Phillipines	
142.	Republic of Korea	
143.	Samoa	
144.	Singapore	
145.	Solomon Islands	
146.	Tonga	
147.	Tuvalu	
148.	Vanuatu	
149.	Vietnam	