WHO BENCHMARKS FOR THE PRACTICE OF AYURVEDA

World Health Organization

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Contents

Foreword

The World Health Organization (WHO) is currently implementing its 13th General Programme of Work (GPW13) to support countries in reaching all health-related Sustainable Development Goals (SDGs). GPW13 is structured around three interconnected strategic priorities: achieving universal health coverage; addressing health emergencies; and promoting healthier populations. These strategic priorities are supported by three strategic shifts: stepping up leadership; driving public health impacts in every country; and focusing global public goods on impact.
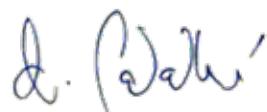
Traditional medicine has always had a role in this collective endeavour. The Declaration of Astana, renewed from the Declaration of Alma-Ata towards universal health coverage and the SDGs, reaffirms the role of traditional medicine in strengthening primary health care, a cornerstone of health systems, in pursuit of health for all. This has also been reflected in the *WHO global report on traditional and complementary medicine 2019*, in which 88% of WHO Member States acknowledge the use of traditional and complementary medicine in health care.

Taking note of the growing importance of traditional medicine in the provision of health care nationally and globally, WHO and its Member States have strived to explore ways to integrate, as appropriate, safe and evidence-based traditional and complementary medicine services within national or subnational health systems, as committed to in the Political Declaration of the High-level Meeting on Universal Health Coverage.

WHO aims to provide policy and technical guidance to Member States; promote the safe and effective use of traditional and complementary medicine through appropriate regulation of products, practices and practitioners; and support Member States in harnessing the contribution of traditional and complementary medicine to people-centred health care in implementing the *WHO Traditional Medicine Strategy 2014–2023*.

Setting norms and standards is a unique function of WHO. The normative work is driven by needs and could be translated into real impact in relevant countries through appropriate policy options. This series of benchmarks, covering various systems and interventions of traditional, complementary and integrative medicine, aims to provide a reference point to which actual practice and practitioners can be evaluated.

I am very pleased to introduce this series to policy-makers, health workers and the general public, and I firmly believe it will serve its purpose.

Zsuzsanna Jakab
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Preface

Integrated health services are essential for the World Health Organization (WHO) in the implementation of its 13th General Programme of Work, which aims to support countries in achieving universal health coverage and the health-related Sustainable Development Goals. The overarching mission for the Department of Integrated Health Services is to accelerate equitable access to good-quality health services that are integrated and people-centred, and that can be monitored and evaluated.

WHO is unique in its mandate to provide independent normative guidance. Its normative products encompass a wide range of global public health goods, including norms and standards. It is therefore the primary role of the Department of Integrated Health Services to generate and produce relevant global goods. Key to improving its work in this area is ensuring global public health goods are driven by country needs and can deliver tangible impacts at the country level.

As of 2018, when 88% of WHO Member States acknowledged the use of traditional and complementary medicine, WHO's support in evaluating the safety, quality and effectiveness of traditional and complementary medicine has continuously ranked in the top areas of need, according to the *WHO global report on traditional and complementary medicine 2019*.

WHO prioritizes normative products based on an assessment of demands. To address increasing needs and to drive impact in countries, this series of benchmarks captures the main systems and interventions of traditional, complementary and integrative medicine by setting up required norms and standards on training and practice.

These benchmarks documents have been prepared following existing WHO methodology and processes. They consider consumer protection and patient safety as core to professional practice and reflect the consensus of what the community of practitioners of traditional medicine disciplines considers to be reasonable practice in the respective discipline. They provide a reference point to which the practice and practitioners of traditional medicine can be compared and evaluated. These documents will support countries to establish appropriate legal and regulatory frameworks for the practice of traditional medicine. WHO will not only assess the quality of these normative products but also streamline systems and plans for monitoring and evaluation.

I am pleased to present this series of benchmarks and invite you to join us in measuring and documenting their impact.

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Acknowledgements

Glossary

Aṣṭāṅga āyurveda

Aṣṭāṅga āyurveda includes eight specialized domains of clinical practice. These describe in detail the principles and methods of diagnosis and treatment in the clinical domains of internal medicine (*kāya-cikitsā*); obstetrics and maternal, neonatal and paediatric health (*kaumārabhṛtya*); mental illness and diseases due to external influences invisible to the naked eye (*graha cikitsā*); diseases of the head and neck (*śālākya-tantra*); diseases requiring surgical or parasurgical interventions (*śalya-tantra*); diseases due to external toxins (*agada-tantra*); care of elderly people and regenerative medicine (*rasāyana-cikitsā*); and reproductive and sexual health (*vājīkaraṇa-cikitsā*).

Mahābhūta (basic elements)

There are five basic elements, or *mahābhūta*: space (*ākāśa*), which allows room for materials to exist; gaseous state (*vāyu*), which is the basis for motion; heat (*agni*), which allows energy exchange; liquid state (*āpa*), which allows materials to bond together; and solid state (*pṛthvī*), which allows materials to have mass.

Doṣa

Doṣa are biological factors formed as a result of the synchronized interplay between the five basic elements (*mahābhūta*) within a living system. They evolve through the processes of life and simultaneously influence its course. They are embodied in different structural elements of the body (*dhātu*) and metabolic products in a living system. The robustness of their function maintains the normal physiology of the body. Disturbance to their function is the basis for disease.

The *doṣa* are *vāta*, which maintains functional balance through the processes of motion; *pitta*, which maintains functional balance through the processes of transformation; and *kapha*, which maintains functional balance through the processes of cumulation.

Dhātu

Dhātu are structural elements of the body. The metabolic process involves functions such as providing energy, nourishment, binding/covering and shape, allowing for movement of structures, providing structure, replenishing lost tissues, and procreation. Structural elements of the body that take part in performing one set of these body functions are classified together as a specific *dhātu*.

Mala

Mala are substances of metabolism that, in normal physiology, are to be excreted naturally without further transformation (metabolism) in the body. *Mala* also have functions in the body. Solid faecal matter formed at the end of the correct digestive process supports the body functions, urine carries with it all the naturally formed internal metabolic wastes of the body, and sweat manages the external metabolic wastes of the body and maintains the health of the hair.

Prakṛti

Prakṛti is the discrete phenotype of an individual based on physical, psychological, physiological and behavioural traits, and independent of social, ethnic and geographical variables.

Pañcakarma

Pañcakarma is the five therapeutic methodologies that prepare and expel the vitiated (abnormal quality or quantity of) *doṣa* and *mala* and then re-establish normal metabolism. *Pañcakarma* includes therapeutically induced emesis (*vamana*) and purgation (*virecana*); administration of medicines through the nasal route (*nasya*); enemas using a mixture of medicinal substances, predominantly made up of herbal decoctions (*āsthāpanavasti/āsthāpanabasti,*[1] *kaṣāyavasti* or *nirūhavasti*); and enemas using lipid-based Ayurveda medicines (*anuvāsanavasti* or *snehavasti*). These five procedures are classified as the main (*pradhāna*) procedures (*karma*) of *pañcakarma*.

Procedures preceding the main procedure are classified as preparatory procedures (*pūrva karma*) and those following the main procedure as post-therapy procedures (*paścāt karma*). Preparatory and post-therapy procedures are also part of the processes denoted by the broad term *pañcakarma*.

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[1] The suffixes *–vasti* and *–basti* are used interchangeably in the literature but have the same meaning. This document uses *–vasti*.

Introduction

Why this benchmark?

In 2010 the World Health Organization (WHO) published *Benchmarks for training in Ayurveda*. This presented what professional experts and health regulators considered to be appropriate training programmes for Ayurveda practitioners.

A standardized protocol for Ayurveda, against which its actual practice can be compared and evaluated, has been lacking, however. With the increasing use of Ayurveda in clinical settings worldwide, there is an urgent need to develop benchmarks for the practice of Ayurveda to ensure its safety, quality and effectiveness.

Aligned to its objectives, this document serves as a reference to national authorities to establish or strengthen regulatory standards to ensure qualified practice of Ayurveda and to assure patient safety. It describes models of practice and the practice profile of providers, and provides consensus to practitioners, professional organizations, regulators, health system managers and patients on how the services should be organized.

This document will join *Benchmarks for the training of Ayurveda* to form an integral part of the serial benchmarks, targeting key modalities of traditional medicine intervention and contributing to the establishment of a reference toolkit for countries.

How was this benchmark prepared?

This document followed the established methodology of WHO to develop benchmarks in traditional, complementary and integrative medicine. To substantiate the update, a desk review of available information on formal licensure and established national standards and guidelines to assure good-quality health-care delivery of Ayurveda was conducted. As part of this exercise, the existing training benchmark document was also reviewed.

Data from 26 Member States, including the 16 that regulate Ayurveda practitioners, were reviewed.[2] Information from Argentina, Australia, Bahrain, Bangladesh, Brazil, Colombia, Cuba, Germany, Hungary, India, Italy, Malaysia, Mauritius, Nepal, Netherlands, Oman, Pakistan, Qatar, Serbia, Singapore, South Africa, Sri Lanka, Switzerland, the United Arab Emirates, the United Kingdom of Great Britain and Northern Ireland and the United States of America were examined. The information was collected from relevant websites of ministries of the respective Member States, and from direct communication with officials and experts associated with these Member States. We examined the relevant information on existing benchmarks, legislation, national standards and guidelines available in these countries.

From the information gathered, we did not find evidence of an existing benchmark covering the objectives holistically. We found considerable diversity of the practice, its prevalence and acceptance among the Member States. It became clear that the WHO benchmarks document should take into account this diversity and suggest regulations for practice, products and training, keeping in mind the different levels of social acceptance, community awareness and uptake, and availability of resources for practice across the Member States.

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[2]   WHO global report on traditional and complementary medicine 2019. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/312342).

We further scoped the Google Scholar, PubMed and AYUSH research portals to identify information on existing publications for Ayurveda that would substantiate and support the development of the Ayurveda benchmark documents. Using a combination of "safety, "quality" and "trial" along with "Ayurveda" presented more than 78 200 references. Owing to the broad nature of the enquiry, we further refined the search into two categories.

One category identified the publications related to "benchmarks", "regulations", "quality", "practice" and "training". Filtering out duplicates and those not specifically relevant to Ayurveda practice or training provided information on 884 publications. After studying their abstracts, this was narrowed down to 151 publications to be read in detail. Of these, 35 highlighted the need for a practice benchmark document for Ayurveda practice, and 61 for a benchmark document for Ayurveda training. A total of 63 and 113 publications, respectively, provided insights into the content requirements of practice and training benchmark documents. Fifty-six publications identified regulatory gaps and requirements, and 68 provided inputs on quality requirements of Ayurveda practice or training.

The second category refined the information for "Ayurveda and safety" and identified 3781 publications after exclusion of duplicates. The data were further cleaned using a combination of "medicine", "drug" or "trial" as additional filters. This provided information on 1228 publications. Another filtration added the terms "randomise/ze" or "safety" in the title or abstract of the publications. In this category, we identified and examined in detail 326 publications that were most relevant to the practice and training benchmarks of Ayurveda.

The first draft of the document was prepared based on the information gathered and directions identified through the desk review. As the basis for its development, the draft document used the existing regulatory frameworks in Member States; standard practices and processes adopted in Member States to guarantee safe, good-quality practice of traditional medicine; traditional textbooks of Ayurveda; and relevant information from WHO and other publications.

The first draft was reviewed and revised by the working group meeting in September 2018. The 39 experts, from 19 countries across the 6 WHO regions, of the working group reviewed the document for appropriateness in terms of its WHO-mandated objectives and its veracity with respect to the evidence considered. The experts also brought in new perspectives based on the current practice of the system in different Member States and evidence from publications. The second draft of the document, which evolved through the discussions in the working group, was sent for extensive international peer review.

A total of 87 experts from 27 countries covering all 6 WHO regions contributed to the peer review. They represented the range of expertise deemed essential in the development of the benchmarks and provided more than 3507 concrete suggestions encompassing every aspect of the document, from overall structural arrangement to specialized technical issues. The peer review provided perspectives from Australia, Bangladesh, the Islamic Republic of Iran, Italy, Malaysia, Mauritius, Nepal, the Netherlands, New Zealand, Oman, Serbia, Singapore, South Africa, Sri Lanka, Switzerland, the United Arab Emirates and United States of America based on respective national regulations and existing protocols. This valuable feedback supported the evolution of the second draft to the third draft, which was then readied for further review at the expert consultation meeting.

The expert consultation meeting conducted in November 2019 aimed to conclude the consulting process by inviting selected experts to finalize the document. A total of 49 experts from 22 countries across the 6 WHO regions joined the consultation and contributed to the development of the fourth draft. The resultant fourth draft became the last technical version of the benchmark before formatting and printing.

What does this benchmark cover?

This document is structured in nine parts:

- Background: gives a briefing on the objectives, domain, and scope of the document.
- Levels of practice in Ayurveda: describes the different levels of Ayurveda practice.
- Ayurveda health service providers: describes the different categories of providers.
- Infrastructure and facilities: describes requirements for infrastructure and facilities.
- Practice of Ayurveda health interventions: presents relevant requirements and considerations on practice of the interventions.
- Health products and medical devices used in Ayurveda practice: provides relevant requirements and considerations of the products and devices used in Ayurveda practice.
- Safety in Ayurveda practice: emphasizes key elements for the safe practice of Ayurveda.
- Regulatory, legal and ethical aspects of Ayurveda practice: presents the requirements and relevant considerations of these aspects.
- Health data: describes guidance on management of health data.

These nine parts constitute a complete set of benchmarks for the practice of Ayurveda.

Who is this benchmark for?

By setting norms and standards, this document helps to address the gap between the increased demands and the uncertified delivery of Ayurveda services. It offers a useful reference point to evaluate Ayurveda service providers, which will benefit policy-makers, health workers, education providers and the public in general.

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1 Background

The term Ayurveda literally means "knowledge of life". It encompasses the physical, psychological, spiritual, social and subtle dimensions of life, and the dynamic concepts of well-being, promotion of health, and prevention and management of diseases.

Documented history of Ayurveda from the Indian subcontinent dates back 3500 years, and the references therein suggest the oral tradition of Ayurveda is even older.

As a system of health care and medicine, Ayurveda reflects time-tested knowledge and applied aspects of health and illness during the human lifespan. It encompasses the scope of ensuring optimal longevity and quality of life.

The current form of Ayurveda is the result of inferences and logical conclusions drawn from fundamental concepts, practical experiences, continuous direct observations, experimental interventions and continual advancements with evidence-based inputs.

Owing to its recognition as a comprehensive system of traditional medicine for providing holistic health care, there has been a resurgence of demand for Ayurveda practice, practitioners and products in many Member States, and its use is spreading to new regions and populations.

Ayurveda is rooted in two basic doctrines (*siddhānta*). The doctrine of *pañca-mahābhūta* postulates that the manifestation of the entire physical universe, including the human body, is made possible by the combined attributes of the five basic elements (*pañca-mahābhūta*): space (*ākāśa*), which allows room for materials to exist; gaseous state (*vāyu*), which is the basis for motion; heat (*agni*), which allows energy exchange; liquid state (*āpa*), which allows materials to bond together; and solid state (*pṛthvī*), which allows materials to have mass.

The doctrine of *tridoṣa* postulates there are three *doṣa* (*vāta*, *pitta*, *kapha*), which maintain functional balance in the body. *Doṣa* are biological factors formed as a result of synchronized interplay among the *pañca-mahābhūta* (five basic elements) within a living system. *Vāta* is the *doṣa* that maintains functional balance through the processes of motion; *pitta* through the processes of transformation; and *kapha* through the processes of cumulation. The *doṣa* evolve through the processes of life and simultaneously influence its course. They are embodied in different *dhātu* (structural elements of the body) and metabolic products in a living system. The robustness of their functions maintains the normal physiology of the body. Disturbance to their function is the basis for disease.

The basic approach of Ayurveda towards health and disease is holistic. It takes into consideration the person's body–mind constitution, behaviour, lifestyle and interaction with the environment. In Ayurveda, the statuses of health and disease are attributed respectively to the balance and imbalance of *doṣa*, the digestive and metabolic processes (*agni*), the functional integrity of *dhātu* (structural elements of the body), the process of eliminating *mala* (excretable materials), and the harmonious coordination of the body (*śārīra*), senses (*indriya*), mind (*manas*) and consciousness (*ātmā*).

Clinical practice of Ayurveda is aimed at promotion and maintenance of health, prevention of diseases and treatment of diseases, with the eventual objective to sustain or restore the natural harmonious balance in the body–senses–mind–consciousness system.

In general, Ayurveda clinical practice (*cikitsā*) advocates three approaches – bio-cleansing therapy (*saṃśodhana* or *śodhana*), pacifying therapy (*saṃśamana* or *śamana*), and preventive interventions (*nidānaparivarjana*).

Ayurveda describes eight specialized domains of clinical practice (*aṣṭāṅga āyurveda*). These specialties describe in detail the principles and methods of diagnosis and treatment in the clinical domains of internal medicine (*kaya-cikitsā*); obstetrics and maternal, neonatal and paediatric health (*kaumārabhṛtya*); mental illness and diseases due to external influences invisible to naked eye (*graha-cikitsā*); diseases of the head and neck (*śālākya-tantra*); diseases requiring surgical or parasurgical interventions (*śalya-tantra*); diseases due to external toxins (*agada-tantra*); geriatrics and regenerative medicine (*rasāyana-cikitsā*); and reproductive and sexual health (*vaajeekarna-cikitsā*).

According to the classical texts of Ayurveda, successful clinical practice is built on four pillars (*cikitsā catuṣpāda*):

- the Ayurveda practitioner (*bhiṣak/vaidya*);
- therapeutic tools (*dravya*), including medicines (*auṣadha*) and medical equipment and instruments (*upakaraṇa*);
- paramedical and other support staff (*upasthāta* or *paricāraka*);
- the patient (*rogi*).

The success or failure of clinical practice depends on the qualities of each of these four pillars. Specific attributes for each of the four pillars are also described:

- The Ayurveda practitioner (*bhiṣak*) should be skilful, wise, clever, diligent, prompt, alert, experienced and hygienic, with a thorough textual knowledge and contextual intelligence and with high ethical and moral values.
- The medicines (*auṣadha*) should be suitable for use in different dosage forms, have multiple beneficial effects, have all the claimed effectiveness, and be of good quality.
- Paramedical and other support staff (*paricāraka*) should be compassionate, hygienic, skilful, wise, clever, diligent, prompt, alert and intelligent.
- The patient (*rogi*) should be supported with sufficient resources to afford the treatment, have confidence in the treating physician, comply with the treating physician's clinical advice and instructions, be able to communicate, and have a balanced mind and attitude.

The science of Ayurveda is based on universal principles and values that find their appropriate expression with respect to place (*deśa*) and time (*kāla*). The contemporary form of clinical Ayurveda practice has multiple variants and peculiarities that vary from country to country, region to region, practitioner to practitioner and specialty to specialty.

In the twentieth century, education and practice of Ayurveda spread globally. Ayurveda is now regulated and practised to varying extents by Member States in all WHO regions. The *WHO global report on traditional and complementary medicine 2019* records that in 2012, Ayurveda was practised in 93 Member States, 32 Member States acknowledged the presence of Ayurveda providers practising in their country, 16 Member States had frameworks to regulate Ayurveda practitioners, and 5 Member States had health insurance coverage for Ayurveda practices *(1)*.

Ayurveda is the predominant traditional medicine system in Bangladesh, India, Nepal and Sri Lanka. These countries train university-qualified Ayurveda practitioners, who are licensed to undertake clinical practice and research and are extensively involved in delivery of public health care.

There is much diversity in the training and practice of Ayurveda, outside the Indian subcontinent. There is a need for guiding principles and norms for coherent, streamlined practice of Ayurveda, which will help to define the attributes of Ayurveda practitioners and requirements in health-care facilities for general and specialty practice. There is also a need to bring uniformity in training and practice of Ayurveda to ensure its safe and effective use in Member States.

It is in this context that the World Health Organization (WHO) has developed this document. The document provides guiding principles to establish and regulate safe and effective Ayurveda clinical practice in Member States.

Basic technical contents of this document are mainly derived from the classical treatises – *Caraka saṃhitā*, *Suśruta saṃhitā*, *Aṣṭāṅga saṃgraha* and *Aṣṭāṅga hṛdaya*. The operational aspects of practice are based on contemporary requirements, including information from WHO publications on traditional medicine.

Readers are encouraged to read other relevant publications referred to in this document for details and further clarifications.

1.1 Domain and scope of Ayurveda practice

1.1.1 Domain of Ayurveda practice

Ayurveda practice covers the areas of:

- maintenance and promotion of health or well-being;
- prevention of diseases;
- diagnosis and management of diseases.

Ayurveda practice delivers health care in these domains by:

- undertaking personalized, customized or categorized health assessment of individuals, categorized groups of individuals or whole populations;
- providing personalized or generalized interventions for health maintenance, including consultation, advice, counselling, guidance and preventive procedures;
- administering personalized or categorized interventions for general or specific prevention of diseases in individuals, categorized groups of individuals or whole populations;
- performing diagnosis, prognosis, treatment, management and documentation of medical conditions through application of Ayurveda approaches, techniques, methodologies and modalities.

1.1.2 Scope of Ayurveda practice

The major scope of Ayurveda practice is to administer appropriate Ayurveda health interventions for the maintenance and promotion of health or well-being, prevention of diseases, and diagnosis and management of diseases.

Ayurveda health intervention is an act performed for, with or on behalf of a person or population, with the purpose to assess, improve, maintain, promote or modify health, functioning or health conditions.

Major components of Ayurveda health interventions are consultation, Ayurveda medicine-based interventions, Ayurveda therapies, hospitalized care and pharmacy services. These are also the major components of Ayurveda clinical practice. The components of Ayurveda health interventions are defined in Annex 1.

As a part of community health-care services, Ayurveda practice offers health services by monitoring, assessing and predicting health problems of the individuals of a community or a specific population within a community, and provides individualized or community-based Ayurveda health interventions to prevent and manage diseases, and promote health, wellness and longevity.

This scope of Ayurveda practice may be undertaken by appropriate integration of Ayurveda in the health system, which is enabled to assess the relative benefits of Ayurveda in well-defined unmet health needs of the community.

In functional terms, clinical practice of Ayurveda may adopt any of the following progressive models as scope of practice:

- consultation and counselling: the following two formats are not exclusive of each other, and both may be used in clinic-based and community medicine settings, according to situation-based needs and possibilities, in the most efficient manner:
  - enabling practitioner–patient interaction and diagnostic assessment (clinical examination), and providing prescriptions for medicines and diet and lifestyle modifications, or giving a treatment regimen; this is usually part of clinic-based Ayurveda practice;
  - facilitating practitioner–health seeker interaction and assessment, and providing health advice or lifestyle and diet counselling; this is mainly part of community-based Ayurveda practice;
- consultation and counselling plus administration of Ayurveda health interventions at the outpatient level;
- consultation and counselling plus administration of Ayurveda health interventions plus hospitalization.

Consultations and counselling sessions should be conducted with the patient and Ayurveda practitioner at the same physical location, involving direct one-to-one interaction between them in real time. In unavoidable situations when the patient and the Ayurveda practitioner cannot be in the same location at the same time, telemedicine may be used to facilitate the consultation or counselling, allowing direct personal interaction between the two in real time. The relevant patient documents and diagnostic data, including imagery, essential to support clinical decision-making should be shared electronically. If needed, another Ayurveda practitioner may undertake the necessary physical examination of the patient and report the details to the consultant practitioner.

Ayurveda pharmacy services are an essential part of Ayurveda practice. Pharmacy services may be made available to the clinical establishment through practical arrangements, including co-locating services within the practice facility. Ayurveda pharmacy may also be an outsourced service functionally associated with the clinical facility but not physically co-located within it.

It is appropriate to have in-house pharmacy services attached to facilities that offer hospitalization.

Ayurveda practice should adhere to the regulatory and management practices that exist in the Member State.

2 Levels of practice in Ayurveda

Based on the qualifications and professional experience of the health service providers engaged, the infrastructure and facilities of the clinical establishment, and the services provided, Ayurveda practice can be qualified as basic, advanced or specialty.

Services provided by the basic, advanced and specialty levels of practice cover all three domains of Ayurveda practice – maintenance and promotion of health or well-being, prevention of diseases, and diagnosis and management of diseases.

Ayurveda practitioners are categorized as basic-level, advanced-level and specialty-level practitioners based on their level of training and professional experience. Chapter 3 describes the criteria used to categorize Ayurveda practitioners.

Ayurveda clinical establishments should have adequate infrastructure and be appropriately furnished, equipped and maintained to ensure safe and good-quality Ayurveda practice. Chapter 4 describes the infrastructure needed at the basic, advanced and specialty levels of Ayurveda practice.

In general, basic, advanced and specialty levels of Ayurveda practice should use the services of appropriately qualified Ayurveda health service providers and should have facilities required to meet the standards of the corresponding level of practice. The services that may be provided at the basic, advanced and specialty levels of Ayurveda practice are detailed below.

2.1 Services provided at the basic level of Ayurveda practice

The basic level of Ayurveda practice should achieve its goal through the appropriate administration of the following interventions, using the services of an Ayurveda practitioner who holds a minimum qualification as a basic-level practitioner after successfully completing the type I (basic-level) practitioner training programme:

- consultation;
- prescription and dispensing of Ayurveda medicines (*auṣadha*);
- Ayurveda therapies;
- Ayurveda protocols for promotion of health and modalities for prevention of noncommunicable diseases and known seasonal infections;
- Ayurveda health interventions for prevention of diseases and preservation of health according to seasonal regimens (*rtucaryā*) and daily regimens (*dinacaryā*);
- specific supportive care for pregnant woman, and antenatal and postnatal care;
- disease-specific Ayurveda interventions for preservation of health and prevention of diseases, according to public health guidelines issued by the Member State;
- activities supporting mental health and well-being, and prescription of well-established Ayurveda diet and lifestyle programmes, including yoga for health maintenance and disease management;
- identification of patients with health conditions and diseases requiring expert or technically advanced care and appropriate referral;
- Ayurvedic management of diseases;
- administration of Ayurveda medicines;
- "dos and don'ts" (*pathya* and *apathya*), including disease- and person-specific diet modifications, physical activity and behaviour.

2.2 Services not provided at the basic level of Ayurveda practice

The following Ayurveda procedures, processes, medicines and medical conditions must not be undertaken at the basic level of practice in Ayurveda:

- all Ayurveda services defined as permissible only at the advanced or specialty level of practice (see Section 2.3);

- all Ayurveda services falling under the category of unique clinical situations and health interventions requiring specialty-level facilities and training (see Section 2.5).

2.3 Services provided at the advanced level of Ayurveda practice

A clinical establishment offering advanced-level practice can provide the following services using the services of a type II (advanced level) practitioner:

- all services permissible at the basic level of Ayurveda practice;

- treatment for all diagnostic conditions described in Ayurveda, except those defined as permissible only at the specialty level of Ayurveda practice (see Section 2.5);

- all Ayurveda health interventions mentioned in classical textbooks of Ayurveda, including therapeutic procedures and medicines that are part of the management of diseases, as required in the practice of *aṣṭāṅga āyurveda*, except those mentioned in Section 2.4;

- pharmacy services (these may also be a part of basic-level practice);

- stimulation of vital points of the body (*marma*) as a therapeutic intervention (*marmacikitsā*) (this can be undertaken at the basic level of practice if the basic-level practitioner undertakes specific training in *marmacikitsā*);

- the following services, which are defined as permissible only at the advanced or specialty level of Ayurveda practice:

    - customized community health interventions to prevent and manage noncommunicable and infectious diseases;

    - secondary and tertiary tiers of Ayurveda health-care services;

    - hospitalization and treatment and care of inpatients;

    - management of patients requiring long-term care and inpatients with infections and infectious diseases;

    - palliative care;

    - appropriate prescription and administration of all Ayurveda medicines, considering the customized requirements of the patient, and addressing safety of medicines and the patient;

    - administering lipid-based medicines (oils and ghee) in titrated quantities over a specific period (*accha-snehapāna*);

    - rectal administration of liquid medicines prepared according to the disease or health condition, with specific combinations of herbal decoctions, oil or ghee, herbal pastes, salts, and honey or jaggery (*āsthāpanavasti* or *kashayavasti*);

    - infusing powdered medicinal herbs through the nose for medicinal benefits (*pradhamananasya*);

    - counselling, including psychological counselling (*satvāvajayacikitsā*);

    - leech therapy (*jalaukāvacaraṇa*);

    - bloodletting by making numerous cutaneous wounds with a sharp needle (*pracchāna*);

- bloodletting by applying vacuum suction over surgically inflicted cutaneous wounds (*alābu/ śṛṅga*);

- thermal cautery (*agnikarma*);

- infusing liquid medicines into the urinary bladder or uterus for medical benefits (*uttharavasti karma*) (NB: uterine infusion is permitted only at the specialty level of practice);

- retaining specially prepared medications in the eye for a specified period (*tarpana* and *puṭapāka*);

- dilation of the anal canal;

- urethral dilation and meatotomy (*mūtramārgavivardhana*).

2.4 Services not provided at the advanced level of Ayurveda practice

Any Ayurveda services falling under the category of unique clinical situations and health interventions that require specialty-level facilities and training (see Section 2.5) are not provided at the advanced level of Ayurveda practice.

During regular clinical practice, situations may arise when such medical conditions are encountered, and procedures and processes are required in view of patient safety and practicality. In these cases, essential and appropriate support, to the extent and duration required, may be provided at the advanced level of practice. After providing the essential support to ensure necessary management and patient safety, the patient should be referred to the appropriate specialty-level practice at the earliest practical time.

2.5 Services provided at the specialty level of Ayurveda practice

To undertake specialty-level management of certain clinical conditions or administer certain Ayurveda interventions requires specialized and precise skills. A specialty-level clinical establishment may offer a specific specialty service by using the services of a type III (specialty-level) Ayurveda practitioner who has undertaken specialty training in the clinical specialty or skill.

Type III (specialty-level) nurse training is the preferred qualification for Ayurveda nurses assisting type III (specialty-level) practitioners at the specialty level of Ayurveda practice.

Details of training requirements for type III (specialty-level) Ayurveda practitioners and type III (specialty-level) Ayurveda nurses are described in *WHO benchmarks for the training of Ayurveda (2)*.

A specialty-level Ayurveda clinical establishment may require special facilities, infrastructure and equipment specific to the specialty care being offered or the specialty intervention being administered. These clinical conditions and specialized interventions may be totally or selectively adopted and included as specialty Ayurveda interventions by the Member State, based on existing rules and regulations and practical applicability.

A specialty-level clinical establishment is eligible to offer all services permissible at the basic and advanced levels of Ayurveda practice.

Specialized interventions that may be provided at the specialty level of Ayurveda practice are listed in Annex 2.

2.6 Ayurveda practice in public health

The levels of Ayurveda practice in a health-care system are defined by the scope of services offered. Primary, secondary and tertiary care levels are equivalent to basic, advanced and specialty levels of Ayurveda practice, respectively.

2.7 Co-located Ayurveda facilities

Ayurveda clinical facilities may be co-located with clinical facilities of other systems, with many of the facilities of the clinical establishment shared between the co-located systems. Such a clinical Ayurveda facility may be designated basic, advanced or specialty level, depending on the criteria to fulfil the requirements as a basic-, advanced- or specialty-level practice.

2.8 Integrated Ayurveda practice

Ayurveda health interventions may be integrated with interventions of other systems of medicine and offer person-specific personalized integrated care.

As and when appropriate, Ayurveda health interventions may be integrated with the clinical management protocols for specific conditions of other medical systems or public health intervention protocols involving other medical systems to obtain specific health outcomes in a defined population.

The integration process may be initiated and implemented by appropriately qualified and certified Ayurveda practitioners in conjunction with practitioners of other systems of medicine.

Regardless of the model adopted, an integrated Ayurveda practice may be designated basic, advanced or specialty level, depending on the criteria to fulfil the requirements as a basic-, advanced- or specialty-level practice. Thus, an integrated Ayurveda practice facility may be basic, advanced or specialty level, depending on the level of Ayurveda practice offered in the clinical establishment, regardless of the general classification of the whole facility as a primary-, secondary- or tertiary-level centre within the health-care system.

3 Ayurveda health service providers

The health workforce in Ayurveda practice includes Ayurveda practitioners, Ayurveda nurses, Ayurveda therapists, Ayurveda community health workers and Ayurveda pharmacists. All Ayurveda health service providers other than Ayurveda practitioners are subclassified as associate Ayurveda service providers.

Details of training requirements, knowledge, essential skills and professional competence required for Ayurveda health service providers involved in the practice of Ayurveda are detailed in *WHO benchmarks for the training of Ayurveda (2)*.

Ayurveda health service providers should be licensed, registered, certified and accredited in accordance with the regulations and quality control provisions of the Member State.

3.1 Ayurveda practitioners

An Ayurveda practitioner is a person who is formally trained, certified and appropriately authorized by the regulatory and accreditation bodies in the Member State to perform the duties of an Ayurveda physician through administration of appropriate Ayurveda health interventions, such as consultation and counselling, use of Ayurveda medicines and Ayurveda therapies, preparation of clinical records, assessment of individual and community health, and management of health-seeking individuals at outpatient clinics, hospitals or in the community, to achieve the goals of promotion of health, prevention of diseases and management of diseases.

To provide services at the basic level of Ayurveda practice, the Ayurveda practitioner should have successfully completed the type I (basic-level) Ayurveda practitioner training programme. After completing the type II (advanced-level) Ayurveda practitioner training programme, the Ayurveda practitioner can independently deliver services at the advanced level of Ayurveda practice.

Successful completion of the appropriate type III (specialty-level) Ayurveda practitioner training programme is essential for a practitioner to independently offer specific specialty-level services.

The training requirements, knowledge, essential skills and professional competence required for basic-, advanced- and specialty-level practitioners are detailed in *WHO benchmarks for the training of Ayurveda (2)*. Professional categories, types of training and corresponding levels of Ayurveda practice for Ayurveda practitioners are presented in Annex 3.

3.2 Associate Ayurveda service providers

There are four professional categories of associate Ayurveda service providers: Ayurveda therapists, Ayurveda nurses, Ayurveda community health workers and Ayurveda pharmacists.

The training programmes for associate Ayurveda service providers are detailed in *WHO benchmarks for the training of Ayurveda (2)*. Professional categories, types of training, and corresponding levels of Ayurveda practice for associate Ayurveda service providers are presented in Annex 4.

3.2.1 Ayurveda therapists, nurses and community health workers

Ayurveda therapists, Ayurveda nurses and Ayurveda community health workers are trained and skilled Ayurveda health service providers who support Ayurveda practitioners, clinical establishments or health centres to organize and administer various Ayurveda therapies according to instructions

from an Ayurveda practitioner, or who support delivery of Ayurveda-based community health care according to protocols and procedures established by the health system.

In clinical practice, Ayurveda therapists, Ayurveda nurses and Ayurveda community health workers support Ayurveda practitioners to perform the duties of Ayurveda physicians, and support patient care, patient safety, medicines management, diet administration, and management of clinical records.

After essential training and acquiring the necessary skills and competencies, Ayurveda therapists, Ayurveda nurses and Ayurveda community health workers can also assist Ayurveda practitioners in the administration of surgical and parasurgical procedures and specific therapies, at appropriate levels of practice.

The minimum qualification to work as an Ayurveda therapist, Ayurveda nurse or Ayurveda community health worker at the basic level of practice is successful completion of the type I (basic-level) Ayurveda therapist, nurse and community health worker training programme.

Qualification through the type II (advanced-level) Ayurveda therapist, nurse and community health worker training programme is preferred to support the functioning of an advanced-level Ayurveda practice.

Qualifications, skills and competency, preferably acquired by successfully completing the specialty-specific type III (specialty-level) Ayurveda nurse training programme, is preferred to undertake the roles and responsibility of a specialty nurse for a specific specialty.

3.2.2 Ayurveda pharmacists

Ayurveda pharmacists are trained and skilled Ayurveda health service providers responsible for Ayurveda pharmacy services. Ayurveda pharmacists collect, prepare, store and dispense Ayurveda health products and manage supplies, stocks and distribution of Ayurveda medicines and preparations. They may also be responsible for compounding of primary medicinal formulations in clinical practices.

They support Ayurveda practices by being responsible for quality control, safety and regulatory compliance, and managing operations by procuring, storing, manufacturing, labelling, stocking and dispensing of Ayurveda health products, at all levels of clinical practice.

They may also be responsible for management of medicines and medicinal ingredients with an addictive or harmful nature, and recording and reporting adverse reactions related to the use of Ayurveda health products, according to the regulations of the Member State.

The minimum essential qualification to work as an Ayurveda pharmacist at the basic level of practice is successful completion of the type I (basic level) Ayurveda pharmacist training programme.

Training and certification as a type II (advanced-level) Ayurveda pharmacist is preferred to work as an Ayurveda pharmacist at the advanced level of practice.

Type II (advanced-level) Ayurveda pharmacist training is required to provide pharmacy services at the specialty level of Ayurveda practice.

3.3 Limitations in practice

Ayurveda therapists, Ayurveda nurses, Ayurveda community health workers and Ayurveda pharmacists can independently work within the framework of eligibility, as described in *WHO benchmarks for the training of Ayurveda (2)*.

They may not practise Ayurveda at any level of clinical establishment to diagnose, treat or prescribe Ayurveda medicines. They may not independently make clinical decisions or administer Ayurveda health interventions without the guidance, supervision and responsibility of an Ayurveda practitioner.

They may not perform any function in the Ayurveda domain other than those in which they are trained, qualified and eligible, according to *WHO benchmarks for the training of Ayurveda (2)* and within the limits of authority and permission accorded by the competent authority in the Member State. When performing duties that they are not permitted to practise independently, they are required to work under the supervision and direction of a qualified Ayurveda practitioner.

An Ayurveda practitioner may administer all Ayurveda health interventions with or without the assistance of an Ayurveda therapist, Ayurveda nurse or Ayurveda community health worker, but the Ayurveda practitioner may independently administer only those Ayurveda health interventions they are permitted to, according to their type and level of qualification.

For details of Ayurveda interventions permitted for different types of Ayurveda practitioner qualifications, see *WHO benchmarks for the training of Ayurveda (2)*.

4 Infrastructure and facilities

The infrastructure and facilities for Ayurveda practice should be suitable to fulfil the requirements of the scope of the clinical establishment. Consideration should be paid to the components of patient care envisaged in the clinical establishment, such as consultation, counselling, administration of Ayurveda health interventions, hospitalization and pharmacy services.

The infrastructure and facilities should correspond to the level of practice, with advanced and specialty levels requiring more specific clinical infrastructure and equipment, according to their needs.

4.1 General considerations

The following apply to all levels of Ayurveda practice:

- Space: there should be adequate space to accommodate various sections, according to the type, level and specialty of services being offered, in buildings complying to the regulatory requirements of the Member State.

- Ventilation and lighting: there should be adequate ventilation and lighting, with temperature control mechanisms if appropriate.

- Accessibility: the clinical establishment should be easily accessible for all groups of people, including assisted patients, people who use wheelchairs, and patients on stretchers. There should be adequate space for movement of patients and staff. There should be sufficient and easily identifiable emergency exits. Mechanized facilities such as lifts may be needed to support access and movement.

- Waiting facilities: the clinical establishment should have adequate waiting facilities for patients.

- Toilet facilities: there should be adequate, easily accessible toilet facilities segregated by gender. It is preferable to have separate toilet facilities for patients and clinical and non-clinical staff to reduce the risk of infection. Toilet and bathroom facilities that cater to the therapy sections should be attached or nearby.

- Personal storage space: the clinical establishment may have resting and personal storage space for caregivers.

- Maintenance of hygiene: there should be established measures and mechanisms for maintenance of hygienic conditions, prevention of cross-contamination and infection, risk management, and safety and security of the premises. The infrastructure, equipment and adopted procedures should support keeping the premises clean and preventing contamination and infection. Floors and walls should be easily washable, with appropriately installed drains. Adequate waste collection facilities should be available, and procedures for segregated and safe waste disposal adopted.

- Gender sensitivity and privacy: infrastructure, facilities and procedures should assure the privacy and safety of patients and employees in a gender-sensitive manner. This may be more relevant when offering specialized gender-specific consultations, other Ayurveda health interventions, and hospitalized care.

- Falls prevention: the infrastructure, equipment and adopted procedures should support preventing falls and related injuries in patients. Handrails on stairs, toilets and treatment rooms can support patients. Beds should be equipped with rails. Height-adjustable beds can prevent falls during transfers. Floors may be covered with anti-skid material.

- Fire prevention: the infrastructure, facilities and adopted procedures should support prevention and effective management of fire. Fire extinguishers should be easily accessible, and staff adequately trained to operate them. Areas where fire or heating equipment is used to support the therapeutic process should have firefighting equipment.

- Medicines safety: the adopted procedures of the clinical establishment should be supportive of medicines safety.

- Safety of clinical data: the infrastructure, facilities and adopted procedures should support appropriate modes of clinical data collection, storage and retrieval. The system should ensure safety of the data collected and confidentiality of patient information.

- Essential supplies: the clinical establishment should be equipped with tools, equipment, appliances, furniture and materials to support the type, level, specialty and volume of services it provides.

- Standard operating procedures: the clinical establishment may have predefined and documented guidelines and standard operating procedures to ensure their compliance. At all levels of practice, the processes to be followed, roles and responsibilities of patients and different types of staff, may be defined and adopted.

4.2 Requirements based on level of practice

4.2.1 Consultations

The basic level of consultation should have the minimum infrastructure, facilities, equipment and adopted procedures to fulfil the requirements of an Ayurveda consultation (see Section 1.1.2). There must be space, appropriate furniture and necessary equipment for the practitioner to interact with the patient, undertake clinical examination, and provide counselling, medical advice and prescriptions, while respecting the patient's privacy, safety and security. Annex 5 provides a list of general requirements for an Ayurveda clinic offering outpatient services.

Advanced- and specialty-level consultations may need additional infrastructure, specialized clinical examination facilities, diagnostic equipment and patient transportation. Examples include:

- an ophthalmoscope for specialties dealing with diseases of the head and neck (*śālākya-tantra*);

- a paediatric stethoscope for specialties managing children's diseases (*kaumārabhṛtya*);

- a lithotomy table and proctoscope for anorectal clinics (covered under the specialty that uses surgical or parasurgical interventions – *śalya-tantra*);

- ultrasonography equipment for specialties managing diseases of the liver, gallbladder or kidneys and for Ayurveda gynaecology services (*strīroga-viśeṣa*);

- specialized equipment to improve neuromuscular coordination for stroke rehabilitation clinics.

4.2.2 Ayurveda health interventions

Infrastructure, facilities, equipment and adopted procedures to provide Ayurveda interventions at the basic level should be adequate to attain the needs for that level.

The clinical establishment should provide accessible facilities for patients to rest after treatment, if needed. The therapy space and the space for post-therapy rest should have accessible toilets.

The therapy space should have associated facilities with easy access to store medicines, equipment, utensils and other consumables.

At the basic level of Ayurveda practice, the following are required:

- specialized treatment beds (*droṇi*);

- facilities for procedures that involve using cloth filled with Ayurveda medicines (*poṭalī*) or pouring medicated liquids over the body (*dhārā*, *seka*);

- facilities for heating;
- facilities to administer different methods of heat application to the body (*svedana*);
- accessible toilets and washrooms with running water;
- fire safety facilities;
- waste management facilities.

At the advanced or specialty level of Ayurveda practice, the therapy room may need additional space, equipment, materials and furniture, depending on the therapies offered, such as:

- an autoclave and surgical lights for invasive procedures involving excision and healing using specialized medicated threads (*kṣāra-sūtra*);
- a specifically designed building (*kuṭī*) according to the architectural indications prescribed in Ayurveda textbooks to administer regenerative therapy (*kuṭīpraveśikarasāyana*);
- a specific instrument (*agnikarma-śalākā*) to administer thermal cautery (*agnikarma*);
- specific surgical blades (*śastra*) to administer bloodletting (*raktamokṣaṇa*);
- a safe, secure, gender-sensitive post-intervention recovery room to keep patients under observation after treatment procedures using highly potent emetic and purgative agents such as *Hydnocarpus laurifolia* (*tuvarakarasāyana*) and surgical interventions, before being discharged or moved to a daycare or inpatient ward;
- separate washrooms and aseptic storage facilities, including facilities for fumigation of materials and instruments, in clinical establishments that provide surgical interventions.

4.2.3 Hospitals

Infrastructure, facilities, equipment and adopted procedures for providing basic-level hospitalization facilities in Ayurveda must be adequate to fulfil needed requirements (see Section 1.1.2).

Hospitalization in advanced and specialty-level practices may require intervention-specific infrastructure, facilities, equipment and procedures.

Daycare and inpatient spaces require an adequate number of washrooms, considering privacy, security and gender.

Clinical establishments with hospitalization facilities should have resting and personal storage space for the hospital staff, considering privacy, security and gender.

4.2.4 Pharmacies

Infrastructure, facilities, equipment and adopted procedures for providing pharmacy services must be suitable to support the specific functions (see Section 1.1.2). Clinical establishments providing Ayurveda therapies or hospitalization may have additional pharmacy facilities where fresh medicines and therapeutic combinations are prepared for immediate use.

4.3 Shared infrastructure and facilities

Each clinical establishment is a combination of infrastructure and facilities, depending on its scope and level of work. Where possible, and depending on the type, level, specialty and volume of services, infrastructure and facilities should not be duplicated, to avoid wasting resources.

For example, a post-therapy space may be shared by more than one therapy room, provided the treatments in the therapy rooms are timed so as not to conflict with patients' requirements.

5 Practice of Ayurveda health interventions

Ayurveda health interventions (*āyurveda cikitsā*) include medicinal therapy, nutrition therapy, and procedure-based interventions that involve internal medicines, diet-based therapies, manual therapies, heat-based therapies, *pañcakarma*, surgical and parasurgical interventions, yoga and other mental, spiritual and mind–body therapies.

The broad objectives of Ayurveda health interventions are the maintenance and promotion of health and well-being in healthy people (*svāsthyasyorjaskaraṃ*) and treatment of unwell people (*ārtasyaroganut*). These two objectives are not exclusive to each other and frequently overlap in practice. Treatment goals are achieved through interventions that have a logical causal effect on the outcome.

Ayurveda practice should aim to achieve and promote health (*svāsthya*) and prevent diseases through the use of appropriate Ayurveda interventions. These interventions include daily regimens (*dina-caryā*), seasonal regimens (*ṛtu-caryā*) and appropriate self-, interpersonal and social conduct (*sadvṛtta*). Ayurveda medicines (*auṣadha*), *pañcakarma* and rejuvenating and regenerative Ayurveda interventions, behaviours and conduct (*rasāyana*) are also used to maintain and promote health.

It is important for Ayurveda practitioners to study, analyse and understand a disease before intervening to correct it and restore health. This process includes understanding the cause of the disease (*nidāna*), distinguishing its early (prodromal) signs and symptoms (*pūrvarūpa*), recognizing its full-blown spectrum of manifestation (*rūpa*), and understanding the paths by which the causative factor has affected and altered the body to result in disease (pathology, *saṃprāpti*).

Sometimes it is necessary to observe the minute positive and negative responses of the patient to specific treatment interventions (*upaśaya* and *anupaśaya*) to deduct the accurate pathology (*saṃprāpti*) of the disease.

In general, a disease is understood by its cause and the signs and symptoms it manifests (*vyādhi*).

Broadly, the pathology of a disease is understood as the dimensions of its effect on the *doṣa* (biological factors that maintain functional balance), the functional integrity of the *dhātu* (structural elements of the body), and the process of eliminating the *mala* (excretable materials) – the triad of the body functions (generally termed the *doṣa* basis of the disease).

When managing a patient, the Ayurveda practitioner should plan interventions to restore health after understanding the disease correctly. Based on the stage of the pathology (*saṃprāpti*), the objective of the intervention may be to purge the vitiated *doṣa* (*doṣa śodhana*) or to pacify the vitiated *doṣa* (*doṣa śamana*) to its original state. Depending on the cause, location, type and extent of suffering caused by the disease, or the expected individualized prognosis, the objective of the interventions may also be to disassociate the patient from the causative factors of the disease (*nidānaparivarjana*) and to manage the signs and symptoms (*vyādhi śamana*). These two approaches are not exclusive to each other and are often administered together.

The methods of intervention adopted to achieve these objectives are internal medicines (*antaḥparimārjanaṃ*), external medicines (*bahiḥparimārjanam*) and surgical or parasurgical methods (*śastra praṇidhānam*) achieved through the use of surgical instruments.

Preventive interventions (*nidānaparivarjana*) may also fall under the broad category of purging or pacifying the *doṣa*. Therefore, treatment methods are generally classified under interventions for purging the *doṣa* (*doṣa śodhana*) or for pacifying the *doṣa* (*doṣa śamana*).

Śodhana means cleaning. An intervention used to physically expel or remove the cause of suffering or disease is a cleaning procedure (*śodhana*). Cleaning wounds, washing the eyes, vaginal douches, gargles, emesis and enemas are examples of cleaning processes.

Emesis (*vamana*) is the cleaning procedure used to expel disease-causing material from the stomach and upper part of the body, including the respiratory organs and tracts. Purgation (*virecana*) is the cleaning procedure used to expel disease-causing material from the intestines and lower part of the body, such as with the use of enemas (*vasti*).

Administration of medicines through the nose (*nasya*) is the cleaning procedure used to expel disease-causing materials from the nasopharynx and head.

Bloodletting (*raktamokṣaṇa*) is the cleaning procedure used to facilitate the removal of blood of abnormal quantity or quality, which can cause disease.

5.1 Pañcakarma

Pañcakarma is a combination of two Sanskrit words – *pañca* meaning "five", and *karma* meaning "work, action or procedure". *Pañcakarma* refers to the five therapeutic methodologies that prepare and expel the vitiated *doṣa* and *mala* and then re-establish normal metabolism.

Pañcakarma includes therapeutically induced emesis (*vamana*) and purgation (*virecana*), administration of medicines through the nose (*nasya*), use of enemas with a mixture of medicinal substances (predominantly made up of herbal decoctions – *āsthāpanavasti, kaṣāyavasti* or *nirūhavasti*), and use of enemas with lipid-based Ayurveda medicines (*anuvāsanavasti* or *snehavasti*).

These five procedures are classified as the main (*pradhāna*) procedures (*karma*) of *pañcakarma*.

The procedures preceding the main procedure are classified as preparatory procedures (*pūrva karma*), and those following the main procedure are classified as post-therapy procedures (*paścāt karma*). The preparatory procedures and the post-therapy procedures are also part of the processes denoted by the broad term *pañcakarma*.

Although the *doṣa* (biological factors that maintain functional balance) are spread all over the body, the main *kapha* organs are in the chest, the *pitta* organs in the umbilical area, and the *vāta* organs in the lower part of the intestine where the digestive process is completed. To regulate a *doṣa*, carefully planned processes are undertaken, specifically focused on the organs in these parts of the body.

Excessive *kapha* may be reduced by expelling it from the region of the chest through the upper gastrointestinal tract, the nasopharynx and the mouth. This is done by inducing medical emesis (*vamana*) using carefully selected medicines.

Excessive *pitta* may be reduced by expelling it from the organs in the umbilical region through the intestines, rectum and anus. This is done by inducing medical purgation (*virecana*).

For emesis and purgation, it is essential that the vitiated *kapha* or *pitta* physically moves from its seat of accumulation to the corresponding excretory channels for expulsion. This is achieved through preparatory procedures (*pūrva karma*) involving administration of lipid-based medicines in titrated quantities and maintaining the person in an environment with controlled air, temperature, food and water for a specific period of time to pharmaceutically achieve the extrusion of the vitiated/excess *doṣa* from the *dhātu* and ready it for physical displacement. This preparatory procedure is called *snehapāna*.

This is followed by the application of heat to the body to raise the temperature in a controlled manner that results in controlled sweating (*svedana*). Different types of sweating procedures are used to administer a variety of heat (e.g. dry, wet) and focus on different parts of the body or the body as a whole. The process of sweating mobilizes the vitiated *doṣa* to the corresponding excretory channels.

Since emesis and purgation use the gastrointestinal tract to enact the work of expelling the vitiated (impaired in quality, quantity or function) *doṣa*, the function of the gastrointestinal tract (digestion) is considerably disturbed and reduced immediately after these *pañcakarma* procedures. To overcome this, gastrointestinal health must be built back systematically through controlled diet and activities of life. This post-therapy process (*paścāt karma*) is called *saṃsarjana*.

Vitiated *doṣa* accumulated in the head and neck region can be expelled through the nasopharyngeal, nasal and oral routes. This is achieved by administration of specific medicines through the nose (*nasya*).

Excessive *vāta* is regulated using a medicated enema (*vasti*). Medicated enemas include a mixture of medicinal substances predominantly made up of herbal decoctions (*āsthāpanavasti*, *kaṣāyavasti* or *nirūhavasti*) or lipid-based Ayurveda medicines (*anuvāsanavasti* or *snehavasti*). Appropriate and controlled drastic reduction (*śodhana*) of *vāta* is achieved through the judicious use of enemas. Since the enema acts on the seat of *vāta* directly, and there is a natural exit for the contents of the enema, it is not always essential to undertake elaborate preparatory or post-therapy procedures.

5.2 Pacifying therapies (*śamana*)

Most of the methods adopted in preparatory (*pūrva karma*) and post-therapy (*paścāt karma*) procedures are also independent pacifying therapies and interventions (*śamana*), with specific and independent therapeutic endpoints.

If the *doṣa* is not extensively vitiated, or the disease is mild and with less chance of progression and complications, or the patient's health condition is not suitable for cleansing therapies (*śodhana*), pacifying therapies are used.

Regular clinical practice of Ayurveda aimed at day-to-day disease management mostly uses pacifying methods (*śamana*). Pacifying therapies also use internal and external interventions.

In pacifying therapies, interventions are designed and administered to correct metabolism. This includes interventions for improving the digestive process (*jaṭharāgni*), metabolic functions (*agni*), functional integrity of the *dhātu* (structural elements of the body), tissue metabolism (*dhātu-agni*) and the processes of elimination of *mala* (excretable materials). The process is initiated by controlling and reducing the external inputs (*laṅghana*) to reduce the complexity of the metabolic imbalance.

In a healthy person, mild *doṣa* imbalances can be managed through diet control (medically advised fasting and thirst, *kṣut* and *pipāsā*) or by increasing the natural metabolic process of the body through physical exercise or exposure to sunlight or wind. These can be further supported by methods that enhance the extent of reach of the metabolic process to several layers of the metabolic process (*dīpana*) and by strengthening the metabolic process itself to support the digestion of metabolites resistant to normal digestive processes (*pācana*).

A variety of pacifying interventions are used when treating diseases with more intense disturbances of the *doṣa*. These include internal medicines; interventions administered through the nose (*nasya*) and the rectum (*vasti*); fumigation (*dhūmana*); external therapies, such as sweating induced through application of heat (*svedana*), local application of medicines, and different types of massage (*abhyaṅga*); and mind–body techniques, including yoga and meditation.

Pacifying therapies settle the vitiated *doṣa* and prevent their increase. Pacifying therapy methods are also used to manage the signs and symptoms of disease (*vyādhiśamana*).

Some interventions are classified as both cleansing (*śodhana*) and pacifying (*śamana*) procedures, depending on the intended purpose of the intervention, the ingredients and dose of the medicines used, and the method of application.

The effect of an intervention depends on the properties and qualities of the interventions or materials used. Materials with similar properties (*sāmānya*) cause an increase in materials with the

same properties in a living system. Materials with dissimilar properties (*viśeṣa*) cause a reduction in materials that are not similar.

Several pharmaceutical preparations are used in Ayurveda interventions. Care and precautions must be taken when preparing medicines for this purpose. The outcome of Ayurveda interventions mainly depends on the use of appropriate medicines in optimal doses to ensure desired results without untoward effects.

Each Ayurveda intervention has specific indications, contraindications, operative procedures, "do's and don'ts" and outcome indicators that determine its optimal, insufficient or excessive effects, possible complications and remedial measures.

A list of commonly used Ayurveda health interventions in the category of Ayurveda therapies is provided in Annex 6.

5.3 Promotion of health and prevention and management of diseases

Ayurveda interventions for the promotion of health focus on preserving and improving health (*svāsthya*). Interventions focus on improving the health-related knowledge of individuals in a community and support individualized behavioural actions by taking into consideration the routine and daily life of the person and seasonal and environmental factors.

Ayurveda interventions for the promotion of health involve dissemination of proper knowledge related to health preservation and administration of timely and appropriate action based on Ayurvedic advice on daily routines (*dinacaryā*), seasonal regimens (*ṛtu-caryā*) and appropriate conduct (*sadvṛtta*). This makes use of methods such as preventive interventions (*nidānaparivarjana*), pacifying interventions (*śamana*), cleansing interventions (*śodhana*) and *pañcakarma*, as appropriate.

Although Ayurveda interventions are most beneficial as individualized therapies, they can be used to support the requirements of the seven categories of humans comprising the population, according to the Ayurvedic concept of *prakṛti* (*vāta*, *pitta*, *kapha*, *vāta-pitta*, *vāta-kapha*, *kapha-pitta* and *vāta-pitta-kapha*), and may be administered as community-level Ayurveda interventions.

Prakṛti is defined as "the discrete phenotype of an individual and it is determined based on physical, psychological, physiological and behavioral traits, and independent of social, ethnic and geographical variables. Though all three *doṣa* exist in every human being, in most cases one is dominant based on which an individual's *prakṛti* is determined" *(3)*.

Further subcategorization of interventions is possible considering the environment (*deśa*), age (*vayaḥ*), special conditions of health such as pregnancy and old age, and existing or predisposition to chronic diseases.

At the individual level, Ayurveda interventions may be further finetuned based on the increasing granularity of the information available. Interventions or intervention protocols may be tailormade by taking into consideration the season; the person's place of birth and residence; the diet, nutrition and quantity of food consumed (*mātrā*); sleep; sexual health; regularity of physical activity; relative predominance and strength (*sāra*) of *dhātu* (structural elements of the body); robustness of the metabolism (*agni*); process of eliminating *mala* (excretable materials); management of natural urges (*vega*); adaptation owing to regular use of or continuous exposure to materials or environment (*sātmya*), or maladaptation to materials or environment despite continuous exposure (*asātmya*); regularity of use of improper combinations of food causing food–food interactions (*viruddhāhāra*); mental health, mental occupation and addictive habits; ease in succumbing to or recovering from infectious or seasonal diseases; and family history of hereditary diseases.

Seasonal cleansing procedures (*śodhana*) performed in healthy people to eliminate vitiated *doṣa* that would otherwise cause seasonal diseases owing to their accumulation is an example of a preventive

Ayurveda intervention. For example, emesis (*vamana*) is administered at the beginning of spring (*vasanta*) and purgation (*virecana*) at the beginning of autumn (*śarad*) to prevent season-specific diseases caused by accumulated *kapha* and *pitta*.

Examples of disease-specific preventive Ayurveda interventions include appropriately selected *pañcakarma* interventions administered to people susceptible to diseases such as bronchial asthma, urticaria, allergic dermatitis, diabetes mellitus and psoriasis at periodic intervals to prevent recurrence of disease.

Ayurvedic interventions to treat unwell people are aimed at management and prevention of recurrence of a disease. Deviation from the state of health (*svāsthya*) is disease. To correct a condition of disease and bring a person back to health (*svāsthya*) requires well-planned administration of interventions. This is the work of an Ayurveda practitioner (*bhiṣak/vaidya*) who attempts to manage diseases.

Such interventions should be planned after carefully analysing and understanding the afflicted structural elements of the body; the person's excretory processes, innate strength, and ability to resist diseases and rebound to the state of health (*vyādhi-kṣamatvaṃ*); the strength of the disease to cause further imbalance in the person or to sustain the existing imbalance (*vyādhibala*); the stage of the disease (*vyādhiavasthā*); the strength of the metabolic processes in the body (*agnibala*); the person's *prakṛti*, age (*vayaḥ*), mental attitude and resilience (*satvaṃ*); the person's regular habits, lifestyle, food and environment (*sātmyaṃ*); the environment in which the disease developed (*deśa*); and the impact of seasons and time of day (*kāla*) on the disease.

5.4 General considerations when administering Ayurveda health interventions

A clinical establishment can administer Ayurveda interventions according to its corresponding level of practice, available infrastructure and facilities, and the knowledge, skills and competencies of its human resources.

For successful treatment, the Ayurveda practitioner must have comprehensive knowledge acquired through training in the interventions they plan to administer. All interventions should be carried out according to the principles and processes explained in the following and other classical Ayurveda texts:

- *Caraka saṃhitā (4)*;
- *Suśruta saṃhitā (5)*;
- *Aṣṭāṅga saṃgraha (6)*;
- *Aṣṭāṅga hṛdaya (7)*;
- *Madhava nidāna (8)*;
- *Chakradatta (9)*;
- *Śāraṅgadhara-saṃhitā (10)*.

The Ayurveda practitioner must:

- review the patient's condition before, during and after administration of the therapeutic procedure, and prescribe necessary and timely instructions for the patient, therapists and health workers involved in treatment;
- examine the patient's health status, including vital signs and other parameters also using appropriate laboratory investigations, to confirm the patient's eligibility to undertake the intervention;

- assess the patient for indications and contraindications for the specific procedure before planning and administering an intervention, and comprehensively assess the patient's condition, strength and tolerance level to determine the appropriate course of the necessary interventions;

- consider special conditions, such as menstruation, pregnancy, the perinatal and postnatal period, paediatric and elderly age groups, compromised immunity, debility and friability, mental illness, medical emergencies and non-cooperative patients, before prescribing and administering an intervention;

- examine the patient and record the information after the therapeutic intervention to assess the patient's health status and to observe the expected optimal signs of benefits;

- make a post-therapy plan and offer the patient advice on improving nutritional status and behaviour to facilitate recovery from illness and restore health;

- observe for contraindications and follow standard procedures, processes and safety precautions, as required, when planning and administering any intervention; the practitioner should be knowledgeable managing risks and adverse events associated with various Ayurveda therapies.

The patient must be prepared in accordance with the Ayurveda practitioner's instructions. All practitioners and supporting staff involved in administering the procedure should be knowledgeable about the patient's condition, the therapeutic procedure, and the mode and site of its administration.

The Ayurveda practitioner or designated responsible person of the clinical establishment should ensure the availability of all the equipment, materials, medicines and other facilities that may be required before, during and after administration of the therapeutic procedures. The designated responsible person should ensure the therapy rooms, equipment, utensils, materials and environment are clean, neat and safe, and aseptic measures are in place.

The Ayurveda practitioner and supporting clinical staff should ensure the cleanliness and maintenance of the equipment and therapy room after use, including disposal of waste. They should be aware of the likelihood of risk and safety compromise during therapy, and actions needed in such an event. Knowledge and skills related to risks and patient safety should be checked at regular intervals. New staff members should receive orientation training before they take on assigned tasks.

The patient or their attendant should be briefed about the intended procedure, modalities of administration, expected benefits, possible complications and impact. The Ayurveda practitioner should ensure the patient's physical and mental condition is favourable for the smooth administration of the prescribed therapy and observance of the related instructions. Appropriate written informed consent should be obtained from the patient or responsible person, as required by law in the Member State, before administering the intervention.

Standard operating procedures, if available, should be followed carefully when administering Ayurveda therapy to ensure correctness of the intervention and effective outcome, without causing untoward signs of discomfort or pain to the patient.

During administration of the therapeutic procedure, the patient should be encouraged to cooperate with the clinical staff and supported to overcome anxiety and discomfort arising from the intervention. Appropriate positioning of the patient, the correct site (body part) for administering the intervention, and proper procedures in administering the therapy must be ensured, with necessary instructions given to the assisting Ayurveda therapists and nurses. Adequate support must be provided to make the patient receptive and responsive to the instructions and advice.

The attending practitioner should be observant of optimal effects (*samyakyoga*), erratic or adverse effects (*mithyāyoga*), excessive effects (*atiyoga*) and suboptimal effects (*hīnayoga*) of the procedure and manage the abnormal effects or ensuing complications with appropriate remedial measures.

After the intervention, the patient should be kept under supervision if necessary until their vital signs are stabilized. Instructions about food, physical activity, behaviour change, lifestyle modulation,

further treatments, "do's and don'ts" related to the medicines, clinical condition and disease, and information on follow-up should be given to the patient.

The Ayurveda practitioner and clinical service providers should follow safety protocols to nullify all likely risks associated with the administration of therapies to themselves and patients. Maintaining hygiene and sanitation in the clinical establishment and ensuring cleanliness and decontamination of materials, equipment and tools form part of standard safety protocols.

All Ayurveda health service providers should be aware of their roles, responsibilities and duties within the clinical establishment. They should know their reporting line and support resources. They should be aware of their location of work and the equipment they work with, including their personal time schedules and facility arrangements within the clinical establishment. They should be aware of the cleaning requirements and schedules of the equipment and facility. They should demonstrate professionalism and interpersonal communication skills while interacting with patients, patient attendants and co-workers.

Details of the case, including the patient's demographic data, diagnosis, health condition, diagnostic procedures administered, treatments provided, clinical outcomes and follow-up instructions, should be documented and recorded properly (see Section 9).

Adverse events requiring remedial treatment or referral in Ayurveda practice are listed in Annex 7, and their common signs and symptoms in Annex 8.

6 Health products and medical devices used in Ayurveda practice

Health products and medical devices (*dravya*) used in Ayurveda treatment (*ayurveda cikitsā*) form an important quadrant (*pāda*) of the four components essential for the success (*cikitsā catuṣpāda*) of Ayurveda practice *(4)*. Health products and medical devices include Ayurveda medicines, instruments, equipment, and specific furniture used in Ayurveda practice. Availability of good-quality Ayurveda health products and medical devices is essential for the success of Ayurveda practice.

Ayurveda health products and medical devices should be of good quality, have defined safety parameters, be appropriate to the requirements, be affordable and be accessible. Using modifiable medical devices or health products with diverse purposes can offer more value to clinical establishments.

6.1 Ayurveda medicines (*auṣadha*) and food (*āhāra*)

Ayurveda medicines (*auṣadha*) comprise herbs, herbal materials, herbal preparations and finished herbal products that contain parts of plants, other plant materials, natural organic or inorganic active ingredients of animal or mineral origin, and combinations thereof as ingredients.

In this document, Ayurveda medicines are defined as single or compound substances of herbal, animal or mineral origin that balance Ayurveda pathophysiological parameters to promote health or positively influence disease conditions.

Ayurveda food (*āhāra*) denotes the use of food and nutrition for therapeutic purposes. Ayurveda food is used for health promotion and preservation and to support unwell people to regain health.

6.2 Quality assurance of Ayurveda medicines

According to Ayurveda classical texts, an Ayurveda medicine should be useable in different dosage forms and preparations, have multiple beneficial effects, have all the effectiveness it proclaims, and be of good quality. It should be available, accessible and safe for appropriate use.

The composition of elements in Ayurveda medicines is studied in terms of various properties, referred to as taste (*rasa*), properties of the material (*guṇa*), potential for pharmacological action (*vīrya*), alteration in composition and property of the material after digestion (*vipāka*), and special properties of some medicines that cannot be explained by their elemental composition (*prabhāva*). According to Ayurveda, the effects and actions of medicines depend on these properties *(6)*.

The manufacturing processes for Ayurveda medicines should follow the procedures as described in the following and other classical Ayurveda texts and relevant publications:

- *Caraka saṃhitā (4)*;
- *Suśruta saṃhitā (5)*;
- *Aṣṭāṅga saṃgraha (6)*;
- *Aṣṭāṅga hṛdaya (7)*;
- *Chakradatta (9)*;
- *Śāraṅgadhara-saṃhitā (10)*;
- *Bhaiṣajya-ratnāvali (11)*;
- *Sahasrayogam (12)*;

- A*yurvedic formulary of India (13)*;
- A*yurvedic pharmacopoeia of India (14)*.

Ayurveda medicines should be processed in facilities with good manufacturing practices and follow other regulations of manufacturing and sales of such medicines, as relevant to the Member State.

Ayurveda medicines should comply with all existing regulatory requirements of licensing, registration and approval from responsible regulatory authorities in the Member State. To ensure safety, quality and efficacy, Member States should follow the regulatory provisions they have established to assure quality of Ayurveda medicines. If specific regulations are not established in the Member State, they should adopt the corresponding regulations for traditional medicines or herbal medicines available within their regulatory framework or follow the various quality assurance guidelines for herbal medicines suggested below.

Adhering to the processes and guidelines discussed in the following WHO documents and other guidelines can ensure the quality of Ayurveda medicines:

- *WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants (15)*;
- *Quality control methods for herbal materials (16)*;
- *WHO guidelines on good manufacturing practices (GMP) for herbal medicines (17)*;
- *WHO guidelines on good herbal processing practices (GHPP) for herbal medicines (18)*;
- *WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues (19)*;
- *WHO guidelines for marker substances of herbal origin for quality control of herbal medicines (20)*;
- *Guidelines for inspection of GMP compliance by Ayurveda, Siddha and Unani drug industry (21)*.

Ayurveda medicines must be stored carefully to maintain their quality and shelf-life. The clinical establishment must maintain records pertaining to the quality and procurement of the Ayurveda medicines and any other requirements and regulations of the Member State.

The clinical establishment should have necessary quality control mechanisms in place and must ensure the Ayurveda practitioners, Ayurveda nurses and therapists, Ayurveda pharmacists, staff undertaking laboratory investigations and other support staff associated with the practice are skilled and capable to identify medicines used or present in the facility, including patent and proprietary medicines, prescription medicines, over-the-counter medicines, and allied health products such as home remedies and self-care preparations.

Quality control mechanisms should be robust enough to ensure proper storage and documentation of the medicines, appropriate shelf-life, identification and management of expired or near-expired medicines, and an infection-free environment.

6.3 Ayurveda medical devices

Ayurveda medical devices include equipment, instruments and special furniture used in Ayurveda practice.

The clinical establishment should proactively establish and implement policies to ensure the safety of patients and staff when using these devices. All precautionary processes must be undertaken to prevent infection when reusable devices are used.

The responsible staff of the clinical establishment must be competent and skilled in managing, using and maintaining the devices according to the needs of their individual work and the needs of the clinical establishment.

Ayurveda medical devices should comply with the quality standards and regulatory licensing, registration and approval of the Member State.

7 Safety in Ayurveda practice

Due care is required in the practice of Ayurveda to ensure the safety of patients and risk management.

7.1 Essential knowledge for practitioners

The Ayurveda practitioner and other support staff should be aware of personal hygiene and sanitation measures to ensure patients' and personal safety.

The practitioner should be knowledgeable about the safe use of Ayurveda medicines. The practitioner should be aware of the signs of potential adverse effects of Ayurveda medicines, and be able to provide immediate relief to the patient, and report such events to the relevant authorities following pharmacovigilance procedures.

The practitioner should have the skills to manage medical emergencies that might occur, whether during treatment or otherwise. The practitioner and other support staff at the establishment should undertake regular basic life support training.

The practitioner should be clinically competent to identify the need for timely referral of patients to other or higher centres of health care with appropriate medical expertise and facilities.

The practitioner should have the knowledge to manage various other safety and facility management requirements, including handling of potential hazards (e.g. biomedical waste) and emergency procedures (e.g. fire safety).

7.2 General considerations

Safety considerations in Ayurveda practice are similar to those in the practice of conventional medicine and other systems of medicine. In general, to ensure safety, the following aspects should be considered:

- appropriate training, qualification, skills and competencies of staff engaged in the functioning of the clinical establishment;
- safe and secure environment and infrastructure;
- adequate fire exits and fire management equipment, with enough staff trained in fire safety;
- safe drinking water;
- adequate ventilation;
- uninterrupted power supply;
- safety plan for fire and non-fire emergencies, including regular staff training in basic life support;
- staff with knowledge and skills to manage medical and non-medical emergencies;
- safe storage, management and use of medicines, devices and hazardous materials in the clinical establishment;
- staff trained in recognition and management of hazardous materials, and processes to clearly identify hazardous materials;
- special safety concerns for individual procedures;
- processes in place for appropriate maintenance of medical equipment, and staff qualified and trained to operate and maintain the equipment.

- infection prevention and control measures;
- waste management facilities, with staff trained to execute waste management work;

7.3 Crucial elements in patient safety and risk mitigation

Due care is required in Ayurveda practice to ensure the safety of patients and risk management. Safety concerns may be related to:

- the structure of the health-care facility;
- clinical errors;
- the use of equipment and tools;
- the nature and dose of medicines;
- drug–drug or drug–herb interactions;
- drug–food interactions;
- food–food incompatibilities;
- medicinal or therapeutic incompatibility;
- improper administration of therapeutic procedures;
- morbidity of the patient;
- falls and associated injury.

All possible risk factors in the clinical establishment should be assessed for preventive, remedial or mitigative measures. Risk implications resulting from any compromise to a patient's safety must be managed effectively. Important considerations include:

- procedures to avoid injuries to staff and patients caused by, for example, heating devices, hot substances, sharp instruments or falls;
- minimizing use of hazardous materials, technologies and situations;
- preventing injuries to patients due to medical interventions and clinical errors, and accidents such as falls;
- steps to prevent faulty administration of clinical interventions;
- training and educating staff in management and prevention strategies against all identified risks.

7.4 Safety related to Ayurveda medicines

Ensuring the safety of patients taking medicines and undergoing interventions is of the utmost importance. While framing the clinical establishment's patient safety policies, the nine WHO Patient Safety Solutions may be considered *(22)* with suitable and appropriate modifications, to include special requirements for Ayurveda practice:

- lookalike and soundalike medicine names;
- patient identification;
- communication during patient handovers and referral;
- performance of the correct procedure at the correct body site;
- control of concentrated electrolyte solutions;
- control of toxic and hazardous medicines, substances and materials used in the clinical establishment;

- accuracy of medicines during care transitions;
- avoiding catheter and tubing misconnections;
- single use of injection and invasive devices;
- improved hand hygiene to prevent health care-associated infection;
- measures to prevent falls and associated injury.

See also *Medication errors: technical series on safer primary care (23)* and *Guidelines for the appropriate use of herbal medicines (24)*.

Ayurveda medicines may cause adverse events and harm through contamination, adulteration, misidentification, inappropriate use of herbal species, or prescribing above accepted dosages.

When using food as an intervention, the practitioner should be aware of incompatible food combinations.

The quality and safety of Ayurveda medicines must be ensured by using manufacturing processes that adhere to the traditional Ayurveda texts or according to approved industrial processes. Improperly prepared medicines can be unsafe.

Ayurveda medicine practitioners and pharmacists should be able to recognize adverse effects of Ayurveda medicines and know the procedures to deal with them. The Ayurveda practitioner or pharmacist should inform the patient of the expected effects of the administered medicines, caution about any possible adverse effects, advise on how to identify such effects, and recommend emergency or appropriate responses, including ways to report incidents to the practitioner.

Medicines that are toxic, poisonous, narcotic or potentially harmful should be labelled, stored, used and disposed of under the guidance and responsibility of an Ayurveda practitioner or a staff member specifically assigned and recorded as responsible for such medicines.

The clinical establishment should have appropriate provision for recording and managing adverse events, according to the level of its practice.

7.5 Safety related to Ayurveda interventions

Knowledge of contraindications of Ayurveda interventions is important. Generally, if Ayurveda therapies are performed according to the Ayurveda texts, incidences of adverse events and emergencies are likely to be reduced. Nevertheless, the following measures are suggested.

Potentially harmful Ayurveda interventions should be administered under the guidance and responsibility of the Ayurveda practitioner or staff member specifically assigned and recorded as being responsible for administering such interventions.

The clinical establishment should have a plan to address adverse events, communicated to all staff. Staff should be periodically trained in preparedness for and mitigation of adverse events. Ayurveda practitioners and paramedical staff should have a basic knowledge of cardiopulmonary resuscitation, basic life support and primary management of burns.

The facility should have a well-defined policy on when to refer patients. Ayurveda practitioners and other health service providers should have adequate knowledge of the conditions that require urgent treatment or referral to another hospital.

7.5.1 General precautions when administering Ayurveda interventions

- Informed consent of the patient must be obtained before administering the intervention.
- Assure proper functioning and safety standards of specific medical devices to conduct the planned therapeutic intervention.

- Medical devices must be periodically calibrated and monitored for quality.

- Availability and accessibility of appropriate Ayurveda medicines must be ensured.

- The patient must be assessed before the procedure to confirm their necessary fitness to undergo the procedure:

    - The patient's history of other ailments, concomitant medicines, and known allergies and intolerances should be recorded clearly.

    - The patient's vital signs and general condition must be monitored before, during and after each procedure.

- Establish processes to identify the patient, the type of procedure and the site of the procedure or intervention before starting the procedure.

- Establish safe surgical and intervention processes for invasive interventions, and ensure appropriate training of practitioners and support staff to undertake and document such processes, in a timely manner *(25)*.

- Use disposable instruments such as surgical blades and needles for invasive procedures to avoid infections, and put in place necessary operating procedures to assure safe disposal of such instruments *(25)*.

- Put in place operating processes to ensure reusable invasive instruments and equipment are cleaned and sterilized following appropriate procedures.

7.5.2 Precautions when treating people with special requirements

Special precautions should be taken when administering Ayurveda interventions to people with special requirements, such as pregnant and postnatal women, elderly people, children, people with mental disorders, and people with special needs.

7.5.3 Safety criteria for regulating Ayurveda interventions

Ayurveda interventions may be regulated and monitored on the basis of prescribed standards and quality control parameters with regard to:

- training and professional competence of Ayurveda practitioners;

- infrastructure facilities, hygienic and sanitary conditions, and safety measures adopted in clinical settings;

- location where therapeutic procedures are administered;

- safety, efficacy and quality of products used;

- knowledge and skills of assistants and therapists;

- compliance with professional codes of conduct, etiquette and medical ethics by staff.

7.6 Safety related to health-care facilities and workplaces

Safety at health facilities and workplaces should have appropriate infrastructure, equipment, furniture, storage facilities and medicine dispensing areas to support the services offered. Signage should be used effectively to reduce the chances of error and unnecessary delays for patients, staff and others.

Proper safety at health-care facilities and workplaces may be ensured by:

- using standard-quality structural elements, including building design and construction materials;

- periodically checking non-structural components, such as equipment, furniture, storage facilities and dispensing areas;

- proper use of signage to reduce the chances of error and unnecessary delays for patients and staff;
- adhering to standard operating procedures in all operations of the clinical establishment;
- adhering to the rational prescription of medicines, therapies and precautions;
- training all health workers in the clinical establishment in aspects of safety and adverse events.

Establishing and adhering to standard operating procedures is very supportive for maintaining high standards of patient safety. It is important that Ayurveda practitioners follow rational prescription of medicines, therapies and precautions to support patient safety.

All health workers should have orientation training on safety and adverse events. A safety culture should be promoted to eliminate risks to patients during the care process and to ensure the safety of other patients, staff and family members.

Challenges and constraints in prevention and control of infection in the Ayurveda clinical establishment should be known and addressed appropriately.

7.7 Cleaning and sterilization

The best possible measures and methods should be applied for regular cleaning of the clinical facility to keep it free from contamination, infection and hazardous material. Air flow, floors, walls and water resources must be kept clean and disinfected.

Equipment, instruments and tools used in diagnostic procedures and therapeutic interventions should be appropriately sterilized with autoclaving, antiseptic reagents, disinfectants, fumigation and other approved conventional techniques and procedures.

Disposable gloves, clothing, syringes, surgical-blades, gauze, cotton pieces, and single-use sets for enemas should be used.

Appropriate contemporary relevant methods and agents should be used for cleaning and disinfecting the patient's body and body parts where any therapeutic procedure is to be applied.

7.8 Waste management

In this document, medical waste is defined as any discarded biological (e.g. blood, body fluids, body tissues) or non-biological (e.g. laboratory disposables, bandages, plaster of Paris casts, syringes) products that have been used and are no longer required.

Waste management is the process of collecting waste material, including proper collection and segregation of different types of waste in colour-coded containers, storage, and transportation to the site of treatment or disposal within stipulated time limits, in an appropriate manner.

Waste management should follow the regulations, guidelines and provisions prevailing in the Member State.

A robust waste management system should be in place according to standard processes and protocols. Degradable and non-degradable wastes must be separately disposed. Wastes classified as biohazards must be handled according to protocols of the Member State.

Workers handling wastes must be properly trained, and their skills and work performance monitored at regular intervals.

7.9 Infection prevention and control

Appropriate hand hygiene procedures and relevant guidelines should be implemented in the Ayurveda facility. All staff should be educated and trained in these procedures. Detailed guidelines are available in the WHO information note on hand hygiene *(26)*.

The risk of infection should be reduced or eliminated by adopting appropriate antiseptic and disinfectant measures and careful handling of infected patients. Potential infection risks should be identified and addressed promptly.

A safety culture should be promoted to eliminate risks to patients during treatment and to ensure the safety of other patients, staff and family members.

Challenges and constraints in prevention and control of infection in the facility should be known and addressed appropriately.

Annex 9 provides additional information on staff health programmes and other basic infection control methods.

8 Regulatory, legal and ethical aspects of Ayurveda practice

Ayurveda practice needs to be regulated and monitored on the basis of prescribed standards and quality control parameters with regard to:

- the training and professional competence of the Ayurveda practitioner;
- the infrastructure, hygienic and sanitary conditions, and safety measures adopted in the clinical setting;
- the place of administering therapeutic procedures;
- the safety, efficacy and quality of products used in the practice;
- the knowledge and skills of assistants and therapists;
- compliance with professional codes of conduct, etiquette and medical ethics by staff of the clinical establishment.

Ayurveda practice in a Member State may be facilitated by setting up an appropriate quality control mechanism. Desirable qualities of Ayurveda practice, practitioners, medicines, therapeutic devices and professional conduct based on specified benchmarks should be notified and placed in the public domain for the purpose of compliance by stakeholders.

Ayurveda practice should be monitored by regulators or administrators. Quality checks or technical audits should be carried out periodically to ensure compliance with prescribed standards and to take regulatory or corrective measures in cases of deviation.

Necessary provisions are required to prevent and rectify unwanted omissions, commissions and violation of norms in the practice of Ayurveda. A system should also be in place to take cognizance of public complaints and incidences of irregularities and poor-quality services in Ayurveda practice and to issue alerts or warnings to such defaulters.

8.1 Licensing and registration of Ayurveda practitioners and clinical establishments

Ayurveda practitioners and Ayurveda clinical establishments should obtain licensing, registration and accreditation with the appropriate regulatory or certifying body according to the regulatory provisions of the Member State, provided such provisions are available and implemented in the Member State.

8.2 Referral and cross-referral

Ayurveda practitioners should be able to identify critical and emergency conditions that may arise during practice. In such a case, when their clinical skills are not enough to manage clinical emergencies, they should be able to refer the patient in a timely manner to an appropriate higher-level medical establishment with enough facilities and expertise to manage such cases.

Ayurveda practitioners and members of regulatory and accreditation organizations are encouraged to read the following publications to get more insights on the subject:

- T*wo-way communication mechanism between T&CM practitioners and registered medical practitioners (RMPs) in Ministry of Health (MoH) hospitals (27)*;
- A*yurveda and conventional medicine: cross referral approach for select disease conditions (28)*.

8.3 Notifiable diseases

Any notifiable disease encountered during Ayurveda practice should be notified to the appropriate authorities according to the prevalent regulations and health advisories in the Member State. The Ayurveda practitioner should be aware of, and adhere to, the observations, instructions and guidelines issued by health authorities, state administration and professional bodies.

8.4 Pharmacovigilance

Appropriate precautions and measures must be taken to support the detection, evaluation, understanding and avoidance of adverse effects or any other medicine-related problem in Ayurveda practice.

Adverse effects must be reported within the specified timeframe to local health authorities, pharmacovigilance centres and other relevant organizations in the Member State, according to the prevalent regulatory provisions. This may also include the data and analysis report of safety of commonly used Ayurveda medicines in the practice and the dosages and duration of their use by individual patients.

Ayurveda practitioners and members of regulatory and accreditation organizations are encouraged to read the following WHO publications for more insight:

- *The importance of pharmacovigilance (29)*;
- *Safety monitoring of medicinal products: reporting system for the general public (30)*;
- *The safety of medicines in public health programmes: pharmacovigilance, an essential tool (31)*;
- *WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems (32)*;
- *Key technical issues of herbal medicines with reference to interaction with other medicines (33)*;
- *Medication errors: technical series on safer primary care (23)*.

8.5 Regulatory requirements for research

Ayurveda practitioners engaged in clinical research activities should be knowledgeable about methodologies, guidelines and ethics of research. Research in Ayurveda should adhere to the general principles of Ayurveda medicine and follow internationally accepted modules and rules and regulations for medical research.

In addition to consulting with learned Ayurveda researchers and scholars, Member States may refer to the following WHO documents and other relevant guidelines and prevalent laws pertaining to medical research in the Member State:

- *General guidelines for methodologies on research and evaluation of traditional medicine (34)*;
- *Handbook for good clinical research practice (GCP): guidance for implementation (35)*;
- *Guideline for good clinical practice: ICH harmonised guideline (ICH GCP) (36)*;
- *Standards and operational guidance for ethics review of health-related research with human participants (37)*;

- *Good clinical practice guidelines for clinical trials in Ayurveda, Siddha and Unani medicine (GCP-ASU) (38);*
- *General guidelines for drug development of Ayurvedic formulations (39);*
- *General guidelines of safety/toxicity evaluation of Ayurvedic formulations (40);*
- *General guidelines for clinical evaluation of Ayurvedic interventions (41).*

8.6 Principles of ethics relating to practice

Ayurveda practitioners should have knowledge of general principles of ethics to be followed in clinical practice. For more on ethics in clinical practice, see the documents referenced in Section 8.5 and the following:

- *Code of conduct for registered health practitioners (42);*
- "Putting ethical principles into clinical practice" *(43);*
- "Ethical aspects of clinical practice" *(44).*

Practitioners should refer to relevant guidelines describing requirements for regulatory compliance with prevalent laws of the Member State pertaining to ethics in clinical practice.

8.7 The practitioner–patient relationship, rights and privacy, and information for patients

The regulatory aspects relevant to the practitioner–patient relationship should be governed according to the laws and regulations prevalent in the Member State.

The Ayurveda practitioner should *(45)*:

- be aware of the rights of patients and respect the individual rights of all people who come to the clinical establishment for care;
- protect the rights of the patient and their family and inform them about their responsibilities during Ayurveda medicine care;
- respect individual beliefs and values and involve the patient and their family in decision-making processes;
- be aware that the patient and their family have the right to be informed about their health-care needs, proposed treatment and intervention plans, and the related costs and time.

The clinical practice should establish a documented process for obtaining the informed consent of the patient or their family at appropriate times during treatment, as laid down by the prevalent laws of the Member State.

The practice should provide correct and appropriate information to the patients. Ayurveda practitioners and members of regulatory and accreditation organizations are encouraged to read the following WHO and other relevant documents while developing information for patients:

- *Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicines (46);*
- *Consumer guideline for proper use of traditional and complementary medicine in Malaysia (47);*
- *Patient rights and responsibility (48);*
- *Public notice to consumers and stakeholders for promoting safe use of ASU drugs (49).*

See Annex 10 for more suggestions on processes to disseminate appropriate information to patients.

9 Health data

Health data are an important resource providing comprehensive information on the health of an individual or population and enabling effective and efficient health-care delivery, while supporting its continued improvement.

Ayurveda practice includes data on:

- health conditions and status of health, including well-being and mental and spiritual health;
- health-related habits and activities of daily life;
- morbidity, births and mortality, including reproductive health and causes of death;
- health interventions, including interventions for health promotion, interventions for general and specific prevention, interventions tailored to specific health conditions and stages of life, and related outcomes observed on an individual or population.

Multiple data streams are generated when individuals interact with health-care systems, and these streams need to be captured. Health system data should include records of health-care services rendered, clinical conditions encountered, health interventions undertaken, and information about the outcomes of the interventions.

Health systems may also record information on socioeconomic and environmental factors that might influence health and wellness outcomes in the community and for individuals.

The goal of health data management in Ayurveda practice is to ensure the required information is provided in an authenticated, secure and accurate manner at the right time, in the right place and to the right person. The system should be able to collect, store, analyse, use, transmit and retrieve health data, and generate specific reports, as and when required to improve clinical outcomes, individual health, and overall health system performance.

Health information management systems in Ayurveda practice are similar to those used in conventional and other systems of medicine. In an Ayurveda clinical establishment, relevant data of every patient attending the facility should be recorded and stored and should include:

- demographic data;
- unique identification and contact details connecting the dataset to the specific patient;
- data on clinical conditions;
- diagnostic data;
- data on interventions and outcomes at different stages of interaction of the patient with the clinic throughout the timeline of the entire treatment process;
- referral data, post-treatment advice and follow-up.

Data on referral should contain information about the reasons for referral and the name of the hospital or centre to which the patient is being referred.

Member States may use Ayurveda-specific terminology to describe and record diagnostic criteria, diagnostic terms, Ayurveda health interventions, prognosis, and outcomes of health conditions while collecting and managing health data involving Ayurveda practice in clinical establishments and health systems.

Member States may use *International statistical classification of diseases and related health problems* (ICD) *(50)* or other nationally endorsed and accepted standard terminologies and codes. It is advisable that such records use a dual coding system in which codes from other sections of ICD and *International classification of health interventions (51)* or other national terminology or coding documents are used concurrently with Ayurvedic terms to bring clarity to health data, especially in pluralistic health system environments.

Confidentiality of clinical data should be maintained at all levels with due ethical considerations. Privacy, confidentiality and safety of medical records must be maintained in accordance with national law and directives of the Member State. In general, patient information may be shared in medicolegal cases only when asked for officially and specifically.

Dedicated space to secure and store data for the time period specified by the regulations of the Member State, and with due measures to protect data from damage or corruption or theft, may be provided by the clinical establishment. After the stipulated period required by the laws of the Member State, the data may be destroyed following due processes to maintain its confidential nature.

Although digitizing and storing improves efficiency in health data management, and is preferred, the basic principles of a good information management system apply equally to a manual or paper-based system. Member States are encouraged to use electronic health records where appropriate and plausible, but there should always be sound processes in place to protect the privacy and confidentiality of patients.

References

1. WHO global report on traditional and complementary medicine 2019. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/312342).

2. WHO benchmarks for the training of Ayurveda. Geneva: World Health Organization; 2022 (https://apps.who.int/iris/handle/10665/351480).

3. Govindaraj P, Nizamuddin S, Sharath A, et al. Genome-wide analysis correlates Ayurveda Prakriti. Sci Rep. 2015;5:15786.

4. Caraka saṃhitā. Delhi: Central Council for Research in Ayurveda and Siddha (https://niimh.nic.in/ebooks/ecaraka/index.php).

5. Suśruta saṃhitā. Delhi: Central Council for Research in Ayurveda and Siddha (https://niimh.nic.in/ebooks/esushruta/index.php).

6. Aṣṭāṅga saṃgraha. Bangalore: Indian Institute of Ayurveda and Integrative Medicine (http://ayurvidya.net/shastra/sangraha/?mod=read).

7. Kunte AM, Navare KS, Shastri H, editors. Vagbhata's Aṣṭāṅga hṛdayam, with Arunadatta's Sarvangasundara interpretation and Hemadri's Ayurveda rasāyana commentary. Mumbai: Panduranga Javaji; 1938.

8. Madhava nidāna. Delhi: Central Council for Research in Ayurveda and Siddha (https://niimh.nic.in/ebooks/madhavanidana/?mod=home&con=fore).

9. Vidyasagara PJ, editor. Chakrapanidatta's Chakradatta, second edition. Kolkata: Saraswathi Press; 1888.

10. Śāraṅgadhara-saṃhitā: translated by KR Srikantha Murthy. Varanasi: Chaukhambha Orientalia; 2016.

11. Baghavathpadacharya G. Bhaiṣajya-ratnāvali: Vidyotini Hindi commentary by Kaviraj Ambikadatta Shastri – XIII edition. Varanasi: Chowkhamba Sanskrit Series Office; 1997.

12. Vidyanath R. Sahasrayogam: text with English translation – vol. 18. Varanasi: Chowkhamba Sanskrit Series Office; 2006.

13. Ayurvedic formulary of India. Ghaziabad: Pharmacopoeia Commission for Indian Medicine and Homoeopathy; 2000 (https://pcimh.gov.in/show_content.php?lang=1&level=1&ls_id=56&lid=54).

14. Ayurvedic pharmacopoeia of India. Ghaziabad: Pharmacopoeia Commission for Indian Medicine and Homoeopathy; 1986 (https://pcimh.gov.in/show_content.php?lang=1&level=1&ls_id=56&lid=54).

15. WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants. Geneva: World Health Organization. 2003 (https://apps.who.int/iris/handle/10665/42783).

16. Quality control methods for herbal materials. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/handle/10665/44479).

17. WHO guidelines on good manufacturing practices (GMP) for herbal medicines. Geneva: World Health Organization; 2007 (https://apps.who.int/iris/handle/10665/43672).

18. WHO guidelines on good herbal processing practices (GHPP) for herbal medicines. Geneva: World Health Organization; 2017 (https://www.who.int/medicines/areas/quality_safety/quality_assurance/V-2ndGlobalReview-RevisedDraft-WHO-GHPP-March2017.pdf?ua=1).

19. WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues. Geneva: World Health Organization; 2007 (https://apps.who.int/iris/handle/10665/43510).

20. WHO guidelines for marker substances of herbal origin for quality control of herbal medicines. Geneva: World Health Organization; 2017 (https://www.who.int/traditional-complementary-integrative-medicine/publications/trs1003_annex1.pdf).

21. Guidelines for inspection of GMP compliance by Ayurveda, Siddha and Unani drug industry. Delhi: Department of AYUSH, Ministry of Health and Family Welfare; 2014 (http://www.e-aushadhi.gov.in/ayush/download/external/Notification/File779%20%20%204201902121950.pdf).

22. Patient safety solutions. Geneva: World Health Organization; 2007 (https://www.who.int/news-room/fact-sheets/detail/patient-safety).

23. Medication errors: technical series on safer primary care. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/bitstream/handle/10665/252274/9789241511643-eng.pdf).

24. Guidelines for the appropriate use of herbal medicines. Geneva: World Health Organization; 1998 (https://apps.who.int/iris/handle/10665/207021).

25. Van Wicklin SA. Safe injection practices. Plast Surg Nurs. 2021;41(2):105–7.

26. Hand hygiene: why, how and when? Geneva: World Health Organization; 2009 (https://www.who.int/gpsc/5may/Hand_Hygiene_Why_How_and_When_Brochure.pdf).

27. Two-way communication mechanism between T&CM practitioners and registered medical practitioners (RMPs) in Ministry of Health (MoH) hospitals. Putrajaya: Ministry of Health Malaysia; 2020 (https://tcm.moh.gov.my/en/upload/garispanduan/mekanisma-dua-hala.pdf).

28. Ayurveda and conventional medicine: cross referral approach for select disease conditions. Delhi: Central Council of Indian Medicine; 2021 (http://ccras.nic.in/sites/default/files/viewpdf/15112021_Cross_Referral_Approach_for_Selected_Disease_Conditions.pdf).

29. The importance of pharmacovigilance. Geneva: World Health Organization; 2002 (https://apps.who.int/iris/handle/10665/42493).

30. Safety monitoring of medicinal products: reporting system for the general public. Geneva: World Health Organization; 2012 (https://www.who.int/publications-detail-redirect/9789241503198).

31. The safety of medicines in public health programmes: pharmacovigilance, an essential tool. Geneva: World Health Organization; 2006 (https://apps.who.int/iris/handle/10665/43384).

32. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Geneva: World Health Organization; 2004 (https://apps.who.int/iris/bitstream/handle/10665/43034/9241592214_eng.pdf).

33. Key technical issues of herbal medicines with reference to interaction with other medicines. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/341406).

34. General guidelines for methodologies on research and evaluation of traditional medicine. Geneva: World Health Organization; 2000 (https://apps.who.int/iris/handle/10665/66783).

35. Handbook for good clinical research practice (GCP): guidance for implementation. Geneva: World Health Organization; 2005 (https://apps.who.int/iris/handle/10665/43392).

36. Guideline for good clinical practice: ICH harmonised guideline (ICH GCP). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; 2016 (https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf).

37. Standards and operational guidance for ethics review of health-related research with human participants. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/handle/10665/44783).

38. Good clinical practice guidelines for clinical trials in Ayurveda, Siddha and Unani medicine (GCP-ASU). Delhi: Department of AYUSH, Ministry of Health and Family Welfare; 2013 (https://health.ncog.gov.in/ayush-covid-dashbaord/assets/Classified/GCP_ASU.pdf).

39. General guidelines for drug development of Ayurvedic formulations. Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (https://www.ayush.gov.in/docs/guideline-drug-development.pdf).

40. General guidelines of safety/toxicity evaluation of Ayurvedic formulations. Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (https://www.ayush.gov.in/docs/guideline_safety_toxicity.pdf).

41. General guidelines for clinical evaluation of Ayurvedic interventions. Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (https://www.ayush.gov.in/docs/clinical_evaluation.pdf).

42. Code of conduct for registered health practitioners. Canberra: Pharmacy Board of Australia; 2010 (https://www.pharmacyboard.gov.au/documents/default.aspx?record=WD10%2F2677&dbid=AP&chksum=nB64XbJXJk306oLyBehEGQ%3D%3D).

43. Bowman D, Green M. Putting ethical principles into clinical practice. BMJ. 2012;344:e1311.

44. Nandi PL. Ethical aspects of clinical practice. Arch Surg. 2000;135(1):22–25.

45. Goold SD, Lipkin M. The doctor–patient relationship: challenges, opportunities, and strategies. J Gen Intern Med. 1999;14(Suppl. 1):S26–S33.

46. Guidelines on developing consumer information on proper use of traditional, complementary and alternative medicines. Geneva: World Health Organization; 2004 (https://apps.who.int/iris/handle/10665/42957).

47. Consumer guideline for proper use of traditional and complementary medicine in Malaysia. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/ms/upload/garispanduan/consumer/BukuPanduan_BI.pdf).

48. Patient rights and responsibility. New Delhi: All India Institute of Ayurveda (https://aiia.gov.in/patient-info-education-section/patient-rights-and-responsibility/).

49. Public notice to consumers and stakeholders for promoting safe use of ASU Drugs. New Delhi: Ministry of AYUSH (https://main.ayush.gov.in/acts-rules-and-notifications/public-notice-to-consumers-and-stakeholders-for-promoting-safe-use-of-asu-drugs/).

50. International statistical classification of diseases. Geneva: World Health Organization (https://www.who.int/standards/classifications/classification-of-diseases).

51. International classification of health interventions. Geneva: World Health Organization (https://www.who.int/classifications/ichi/en/).

Bibliography

Ajanal MN, Nayak SU, Kadam AP, Prasad BS. Pharmacovigilance study of Ayurvedic medicine in Ayurvedic teaching hospital: a prospective survey study. Ayu. 2015;36(2):130–137.

Ajanal M, Nayak S, Prasad BS, Kadam A. Adverse drug reaction and concepts of drug safety in Ayurveda: an overview. J Young Pharma. 2013;5(4):116–120.

Alostad AH, Steinke DT, Schafheutle EI. A qualitative exploration of Bahrain and Kuwait herbal medicine registration systems: policy implementation and readiness to change. J Pharm Policy Pract. 2019;12(1):1–20.

AlRawi SN, Khidir A, Elnashar MS, et al. Traditional Arabic and Islamic medicine: validation and empirical assessment of a conceptual model in Qatar. BMC Complement Altern Med. 2017;17(1):1.

Azaizeh H, Saad B, Cooper E, Said O. Traditional Arabic and Islamic medicine (TAIM) now joins TCM CAM, Kampo and Ayurveda. eCAM. 2008;5(3)363–364.

Amendment regulations. Delhi: Central Council of Indian Medicine; 2020 (https://www.ccimindia.org/latestupdate/193695.pdf).

Bhavaprakasha nighantu. Delhi: Central Council for Research in Ayurveda and Siddha (https://niimh.nic.in/ebooks/e-Nighantu/bhavaprakashanighantu/?mod=read).

Madanapala nighantu. Delhi: Central Council for Research in Ayurveda and Siddha (https://niimh.nic.in/ebooks/e-Nighantu/madanapalanighantu/?mod=read).

Bernardini S, Del Prete M, Morandi A, et al. La FNOMCeO e le medicine "non convenzionali" nel codice di deontologia medica: criticità, attualità e proposte – una analisi documentale 1996–2020. Prima parte. Bollettino Notiziario, 10 October 2020 (https://www.odmbologna.it/wp-content/uploads/2020/11/BOLLETTINO_N_10_OTT_20.pdf).

Bernardini S, Del Prete M, Morandi A, et al. La FNOMCeO e le medicine "non convenzionali" nel codice di deontologia medica: criticità, attualità e proposte – una analisi documentale 1996–2020. Seconda parte. Bollettino Notiziario, 11 November 2020 (https://www.odmbologna.it/wp-content/uploads/2020/12/BOLLETTINO_N_11_NOV_20.pdf).

Berra JL, Molho R. Ayurveda in Argentina and other Latin American countries. J Ayurveda Integr Med. 2010 Jul;1(3):225–230.

Brar BS, Norman RG, Dasanayake AP. Involvement of Ayurvedic practitioners in oral health care in the United States. J Am Dent Assoc. 2012;143(10):1120–1126.

Ayurveda-based diet and lifestyle guidelines for prevention of cardiac disorders. Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (http://ccras.nic.in/sites/default/files/ebooks/24052018_CCRAS_Cardiac_disorders.pdf).

Ayurveda-based diet and lifestyle guidelines for prevention and management of skin diseases. Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (http://ccras.nic.in/sites/default/files/ebooks/24052018_CCRAS_HQ_Ayurvedabaseddiet&lifeStyleGuidelinesSkinDiseases.pdf).

Ayurveda-based dietary guidelines for mental disorders. Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (http://ccras.nic.in/sites/default/files/ebooks/Ayurveda-Based_Dietary_Guidelines_Mental_Disorders.pdf).

Website guide: guide to navigate Charak Samhita new live edition. Charak Samhita (https://www.carakasamhitaonline.com/index.php?title=Website_guide&oldid=36016).

Conboy LA, Edshteyn I, Garivaltis H. Ayurveda and panchakarma: measuring the effects of a holistic health intervention. Sci World J. 2009;9:272–280.

Dixon A. Regulating complementary medical practitioners: an international review. London: King's Fund; 2008 (https://www.kingsfund.org.uk/publications/regulating-complementary-medical-practitioners).

Elaheebocus N, Mahomoodally MF. Ayurvedic medicine in Mauritius: profile of Ayurvedic outlet, use, sale, distribution, regulation and importation. J Ethnopharmacol. 2017;197:195–210.

Furst DE, Venkatraman MM, Krishna Swamy BG, et al. Well controlled, double-blind, placebo-controlled trials of classical Ayurvedic treatment are possible in rheumatoid arthritis. Ann Rheum Dis. 2011;70(2):392–393.

Gewali MB, Awale S. Aspects of traditional medicine in Nepal. Japan: Institute of Natural Medicine, University of Toyama; 2008.

Katiyar C, Gupta A, Kanjilal S, Katiyar S. Drug discovery from plant sources: an integrated approach. Ayu. 2012;33(1):10–19.

Katoch D, Sharma JS, Banerjee S, et al. Government policies and initiatives for development of Ayurveda. J Ethnopharmacol. 2017;197:25–31.

Khan MA, Chowdhury SK. Traditional medicine in Bangladesh. Trad Med Asia. 2002:275–278.

Kretchy IA, Okere HA, Osafo J, et al. Perceptions of traditional, complementary and alternative medicine among conventional healthcare practitioners in Accra, Ghana: implications for integrative healthcare. J Integr Med. 2016;14(5):380–388.

Lavekar G, Menon T, Bharti, et al. A practical handbook of panchakarma procedures. Delhi: Central Council for Research in Ayurveda and Siddha; 2010 (https://www.researchgate.net/publication/257358254_A_PRACTICAL_HANDBOOK_OF_PANCHAKARMA_PROCEDURES).

Lim MK, Sadarangani P, Chan HL, Heng JY. Complementary and alternative medicine use in multiracial Singapore. Complement Ther Med. 2005;13(1):16–24.

Luketina-Šunjka M, Rančić N, Subotić S, Jakovljević M. Complementary and alternative medicine in Serbia. Acta Med Median. 2020;98–104.

Annual report 2018–2019. Delhi: Ministry of AYUSH; 2019 (https://main.ayush.gov.in/tenders-vacancies/annual-reports/ministry-of-ayush/).

National AYUSH morbidity and standardized terminologies electronic portal. Delhi: Ministry of AYUSH (http://www.namstp.ayush.gov.in).

Morandi A. Ayurvedic medicine (general considerations). Proceedings of National Symposium on NHS, Equal Health Rights and Traditional, Complementary and Non Conventional Medicine. Adv Ther. 2016;10:50–55.

Morandi A, Sartori G, Tosto C. [Training in Āyurveda in Italy: actuality, needs, criticalities, perspectives.] In Roberti di Sarsina P, Tognetti M, Gensini G, editors. La formazione nelle medicine tradizionali e non convenzionali in Italia: attualità, esigenze, criticità, prospettive. [Training in traditional and non-conventional medicine in Italy: actuality, needs, criticalities, perspectives.] Milan: Franco Angeli; 2015:110–133.

Morandi A, Tosto C, Roberti di Sarsina P, Dalla Libera D. Salutogenesis and Ayurveda: indications for public health management. EPMA J. 2011;2(4):459–465.

Narayanasamy A, Narayanasamy M. Ayurvedic medicine: an introduction for nurses. Br J Nurs. 2006;15(21):1185–1190.

Accreditation standards for panchakarma clinics. Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2017 (https://nabh.co/Images/PDF/PanchakarmaClinic_Standards1stEdition.pdf).

Accreditation standards for Ayurveda hospitals. Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2016 (https://nabh.co/Images/PDF/AyurvedaStandard_2ndEdition.pdf).

Obeyesekere G. The impact of Ayurvedic ideas on the culture and the individual in Sri Lanka. In: Leslie C, editor. Asian medical systems. Berkeley, CA: University of California Press; 2020:201–226.

Patwardhan B. Strategic cooperation with WHO. J Ayurveda Integr Med. 2016;7(1):1–2.

Patwardhan B. Traditional medicine: modern approach for affordable global health. Geneva: World Health Organization; 2005 (http://www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf).

Patwardhan B, Tillu G. Universal health coverage and AYUSH systems. J Ayurveda Integr Med. 2018;9(1):1–2.

Patwardhan K, Pathak J, Acharya R. Ayurveda formulations: a roadmap to address the safety concerns. J Ayurveda Integr Med. 2017;8(4):279–282.

Peterson C, Lucas J, John-Williams L, et al. Identification of altered metabolomic profiles following a panchakarma-based Ayurvedic intervention in healthy subjects: the self-directed biological transformation initiative (SBTI). Sci Rep. 2016;6:32609.

Roberti di Sarsina P, Alivia M, et al. [Traditional and non-conventional medicines in Italy: considerations on a social choice for person-centred medicine.] Adv Ther. 2012;1(1):3–29.

Rohilla P, Naik R, Acharya RN. A look into the contribution of Raja nighantu, an Ayurvedic Nighantu (lexicon) of 14th century AD, towards drug safety. Drug Safety. 2016;39(10):1036.

Rudra S, Kalra A, Kumar A, Joe W. Utilization of alternative systems of medicine as health care services in India: evidence on AYUSH care from NSS 2014. PLoS One. 2017 May 4;12(5):e0176916.

Satow YE, Kumar PD, Burke A, Inciardi JF. Exploring the prevalence of Ayurveda use among Asian Indians. J Altern Complement Med. 2008;14(10):1249–1253.

Sen S, Chakraborty R. Revival, modernization and integration of Indian traditional herbal medicine in clinical practice: importance, challenges and future. J Trad Complement Med. 2016;7(2):234–244.

Shaikh BT, Hatcher J. Complementary and alternative medicine in Pakistan: prospects and limitations. eCAM. 2005;2(2):139–142.

Singh RH. Pancha karma therapy (ancient classical concepts, traditional practices, recent advances and guidelines of standard practice), 2nd edition. Varanasi: Chowkhamba Sanskrit Series Office; 2002.

Siti ZM, Tahir A, Farah AI, et al. Use of traditional and complementary medicine in Malaysia: a baseline study. Complement Ther Med. 2009;17(5–6):292–299.

Srikanth N, Bandi V, Sharma SK, et al. Guidelines on basic training and safety on panchakarma. Delhi: Department of AYUSH, Ministry of Health and Family Welfare; 2008 (https://www.researchgate. net/publication/215554092_Guidelines_on_Basic_Training_and_safety_on_Panchakarma).

Sujatha V. The universal and the global: contextualising European Ayurvedic practices. Soc Cult South Asia. 2020;6(1):52–73.

Suroowan S, Mahomoodally MF. A comparative ethnopharmacological analysis of traditional medicine used against respiratory tract diseases in Mauritius. J Ethnopharmacol. 2016;177:61–80.

Thirthalli J, Zhou L, Kumar K, et al. Traditional, complementary, and alternative medicine approaches to mental health care and psychological wellbeing in India and China. Lancet Psychiatry. 2016;3(7):660–672.

Thomas V, Nair SNV, Ved DK, Shankar D. Controversial identities of medicinal plants in classical literature of Ayurveda. J Ayurveda Integr Med. 2020;11(4):565–572.

Wiesener S, Falkenberg T, Hegyi G, Hök J, Roberti di Sarsina P, Fønnebø V. Legal status and regulation of complementary and alternative medicine in Europe. Forsch Komplementmed. 2012;19(Suppl. 2):29–36.

WHA67.18. Traditional medicine. In: Sixth-seventh World Health Assembly, Geneva, 24 May 2014 (https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R18-en.pdf?ua=1).

WHA54.11. WHO medicines strategy. In: Fifty-fourth World Health Assembly, Geneva, 21 May 2001 (https://apps.who.int/iris/handle/10665/78786).

Guideline on self-care interventions for health and well-being. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/342741).

Operational framework for primary health care: transforming vision into action. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/337641).

Consolidated guideline on self-care interventions for health: sexual and reproductive health and rights. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/325480).

A vision for primary health care in the 21st century: towards universal health coverage and the Sustainable Development Goals. Geneva: World Health Organization; 2018 (https://apps.who. int/iris/handle/10665/328065).

Fifty-second report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/handle/10665/272452).

Traditional medicine strategy: 2014–2023. Geneva: World Health Organization; 2013 (https://apps. who.int/iris/handle/10665/92455).

Patient safety curriculum guide: multi-professional edition. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/handle/10665/44641).

Benchmarks for training in traditional/complementary and alternative medicine: benchmarks for training in Ayurveda. Geneva: World Health Organization; 2010 (https://apps.who.int/iris/handle/10665/44352).

Traditional medicine strategy 2002–2005. Geneva: World Health Organization; 2002 (https://apps.who.int/iris/handle/10665/67163).

Legal status of traditional medicine and complementary/alternative medicine: a worldwide review. Geneva: World Health Organization; 2001 (https://apps.who.int/iris/handle/10665/42452).

Medicines strategy 2000–2003. Geneva: World Health Organization; 2000 (https://apps.who.int/iris/handle/10665/66694).

Quality control methods for medicinal plant materials. Geneva: World Health Organization; 1998 (https://apps.who.int/iris/handle/10665/41986).

Regulatory situation of herbal medicines: a worldwide review. Geneva: World Health Organization; 1998 (https://apps.who.int/iris/handle/10665/63801).

The use of traditional medicine in primary health care. Geneva: World Health Organization; 1990.

Traditional medicine and health care coverage: a reader for health administrators and practitioners. Geneva: World Health Organization; 1983.

Patient safety assessment manual, 2nd edition. Cairo: World Health Organization Regional Office of the Eastern Mediterranean; 2016 (https://apps.who.int/iris/handle/10665/249569).

Traditional herbal remedies for primary health care. Delhi: World Health Organization Regional Office for South-East Asia; 2010 (https://apps.who.int/iris/handle/10665/206024).

Research guidelines for evaluating the safety and efficacy of herbal medicines. Manila: World Health Organization Regional Office for the Western Pacific; 1992 (https://apps.who.int/iris/handle/10665/207714).

Annex 1. Components of Ayurveda health interventions

A health intervention is "an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions", as defined by the World Health Organization in the International Classification of Health Interventions.

Consultation is the process by which a practitioner interacts with a person for health-related needs, and that facilitates appropriate communication, clinical examination, diagnosis, and prescription of suitable clinical advice, procedures and remedies.

Ayurveda medicine-based interventions involve interventions using Ayurveda medicinal products administered internally (through the oral, nasal, conjunctival, anorectal, vaginal, vesical or uterine routes) or externally (through the extradermal or transdermal routes). Any Ayurveda medicine-based intervention other than oral administration implies Ayurveda therapy according to the standard operating procedure of the therapy being administered.

Ayurveda therapies are procedure-based interventions that involve manual therapies, heat-based therapies, *pañcakarma*, and surgical (*śastra karma*) and parasurgical (*anuśastra karma*) interventions. They often use Ayurveda medicines, diet-based therapies, nutritional therapy, and interventions such as yoga and other mental, spiritual and mind–body therapies. Ayurveda therapies also use Ayurveda medicines as part of the procedure and administer them through the mouth, nose, conjunctiva, anal canal, vagina, urinary bladder, uterus, or extradermal or transdermal routes, according to the standard operating procedure of the therapy being administered.

Ayurveda hospitalization refers to the act of admitting a person to an Ayurveda medical care facility to administer Ayurveda health interventions for disease management, disease prevention or health promotion. Two kinds of hospitalization are possible in Ayurveda practice: daycare and inpatient care. In daycare, the patient is admitted for a period between the morning and the evening and is discharged on the same day. In inpatient care, the patient is managed at the facility overnight and sometimes for several days.

Ayurveda pharmacy services in this document relate to activities undertaken to collect, prepare, store and dispense Ayurveda health products. This includes ensuring safety and regulatory compliance according to the prevalent laws in the Member State regarding packaging, labelling, storing, preparing, dispensing and managing medicines, medicinal ingredients of an addictive or harmful nature, and recording and reporting of adverse reactions related to the use of Ayurveda health products.
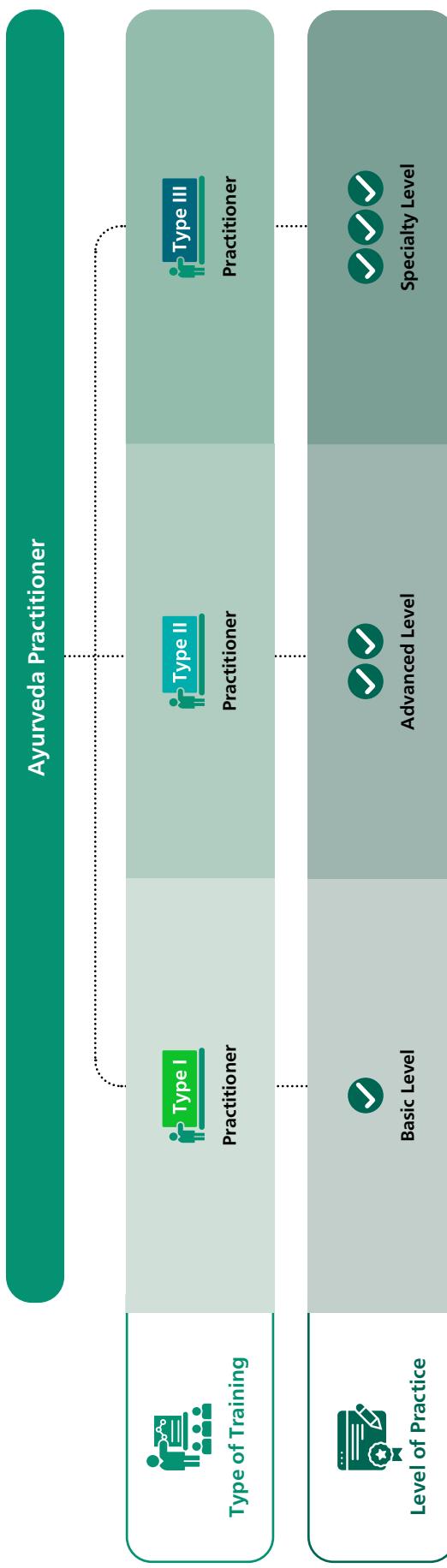
Annex 2. Specialized interventions that may be provided at a specialty-level Ayurveda practice

- invasive procedures involving excision and healing using specialized medicated threads (*kṣārasūtra karma*);
- bloodletting by venesection (*sirāvedha*);
- sling surgery for ptosis (*vātahata-vartma śastra karma*);
- ectropion and entropion correction surgery (*vartma-vikṛti śastra karma*);
- cataract surgery (*kaphajaliṅganāśa śastrakarma*);
- tonsillectomy (*gilāyu-nirharaṇa śastrakarma*);
- tooth extraction (*dantanirharaṇa*);
- removal of metallic and non-metallic foreign bodies from non-vital organs (*pranaṣṭaśalyanirharaṇa*);
- diagnostic and surgical (*śalya tantra*) interventions to remove urinary calculi (*aśmarī-nirharaṇa*);
- incision and drainage (*bhedana*) of glaucoma (*adhimanthaḥ*) (trabeculectomy);
- incision and drainage of peritonsillar abscess (*āśukārigilāyu vṛddhi*) and acute suppurative otitis media (*āśukārī madhya-karṇaśotha*);
- incision and drainage (*bhedana*) of abscess, such as perianal abscess (*gudavidradhi*) and breast abscess (*stanavidradhi*);
- incision and drainage (*vedhana-visrāvana*) of internal abscess (*ābhyantara vidradhi*); drainage of spermatocele, chylocele, pyocele and haematocele;
- incision and drainage (eversion of sac) (*vedhana-visrāvana*) of hydrocele (*mūtra-vṛddhi*);
- incision (*bhedana*) and drainage/curettage (*lekhana*) of cysts of the eyelids (chalazion);
- debridement/fasciotomy/curettage (*lekhana/ chedana*) of suppurative ulcers (*duṣṭanijavraṇa*);
- excision (*chedana karma*) of cysts (*granthi*), such as sebaceous cysts, dermoid cysts, mucosal cysts and retention cysts;
- excision (*chedana karma*) of benign tumours (*arbuda*), such as lipomas, fibromas and schwannomas of non-vital organs;
- excision/amputation (*chedana karma*) of gangrene (*sirā-snāyukotha*);
- various methods of haemorrhoidectomy (*chedana of arśa*);
- fistulectomy and fistulotomy (*chedana of nāḍīvraṇa*), such as excision of pilonidal sinus (*bhagandarachedana* using *kṣārasūtra*);
- excision and management (*chedana*) of pterygium (*arma*) and nasal polyps (*nāsārśa*);
- incision and drainage (*bhedana* and *chedana*) of dacrocystitis (*pūyālasa*);
- appendicectomy (*chedana* and *saṃdhāna* of *uṇḍukapucchaśotha*);
- circumcision and management (*chedana* and *saṃdhāna*) of phimosis (*niruddhaprakāśa*) and paraphimosis (*parivartikā*);
- ligation and repair (*saṃdhān karma*) of tendons and muscles (*sirā-kaṇḍara-snāyu*);

- various rectopexies (*saṃdhān karma* of *gudabhraṃśa*);

- all types of suturing and ligatures (*sīvana karma*), such as haemostatic ligatures, ligation of haemangioma, vascular ligation, ligation of varicocele, varicose veins/stripping surgery and varicocele high ligation;

- diagnostic and surgical (*śalya tantra*) interventions for management of hernia (*vriddhi roga cikitsā* and *saṃdhān karma*);

- laparotomy and paracentesis (*udarrognidancikitsā/udakodarvisravan*);

- placing and changing intercostal drain (chest drain/pleural drain), laryngeal mask airway, intubation, bag/mask ventilation, and urinary catheterization;

- critical or severe traumatic wound (*sadhyo-vraṇa*) management; complex/comminuted/open fracture management (*bhagna cikitsā*), including close reduction (*āñcana*), immobilization (*pīḍana*), splint/cast of compound fractures (*saṃkṣepa*, *kuśābandhana*); correction/reduction of dislocation and subluxation (*sandhimokṣa*);

- reconstruction surgery/grafting (*saṃdhān karma*), including ear lobe repair (lobuloplasty, *karṇapālī saṃdhāna*), nose repair (rhinoplasty, (*abhighātaja nāsāvikṛti saṃdhān karma*), repair after lip trauma (*oṣṭhāghāta*), hair lip repair (*oṣṭhabheda*), and deviated nasal septum surgery (septoplasty, *nāsā-yavānika-vakratā śastra karma*);

- obstetric and gynaecological surgery, including management of labour/delivery, caesarean section, hysterectomy, tubectomy, pelvic floor repair, dilation and curettage, complicated labour, surgical management of obstetric emergencies (malpresentation, prolonged or obstructed labour/dystocia, contracted pelvis, cephalopelvic disproportion, multiple pregnancy, cord abnormalities, antepartum haemorrhage, third-stage complications), management of complicated pregnancies (ectopic pregnancy, gestational trophoblastic disease, medical and surgical illness complicating pregnancy and labour), management of puerperal complications, medical termination of pregnancy, obstetric/gynaecological surgery, and neonatal care;

- interventions for medical termination of pregnancy;

- interventions for emergency management of severe trauma;

- administration of general anaesthesia (*saṃjñā-haraṇa*) and local anaesthesia (*sthānika-saṃjñā haraṇa*);

- infusion of liquid medicines into the uterus for medical benefits (*uttaravasti*);

- chemical cauterization (external and internal) (*kṣārakarma*);

- regenerative/rejuvenating medical procedures for patients from specific age groups and with diseases requiring long-term treatment and intensive care (*kuṭīpraaveshika rasāyana*); treatment using *Semecarpus anacardium* as the main medicine (*bhallātakarasāyana* – *rasāyana* treatment using *bhallātaka*); treatment using *Hydnocarpus laurifolia* as the main medicine (*tuvarakarasāyana* – *rasāyana* treatment using *tuvaraka*);

- interventions for radio-diagnosis, proctoscopy and sigmoidoscopy; investigations such as pap smear, colposcopy and endometrial biopsy;

- interventions for prenatal diagnosis and counselling; assessment of pelvic and fetal factors favourable and unfavourable for normal labour;

- critical care interventions;

- occupational therapy interventions;

- speech therapy interventions;

- sports medicine and sports rehabilitation interventions;

- interventions to manage non-traumatic emergencies.

Annex 3. Ayurveda practitioner professional categories, types of training and levels of practice

This shows the broad professional categories of Ayurveda practitioners, the training programmes in each category, and the corresponding levels of practice for each type of training.

Ayurveda Practitioner

Type of Training

| Type I Practitioner | Type II Practitioner | Type III Practitioner |

Level of Practice

Basic Level | Advanced Level | Specialty Level

Annex 4. Ayurveda service provider professional categories, types of training and levels of practice

This shows the broad professional categories of associate Ayurveda service providers, the training programmes in each category, and the corresponding levels of practice for each type of training.

Associate Ayurveda Service Provider

Professional Category	Type of Training	Level of Practice
Ayurveda Therapist	**Type I** — Ayurveda Therapist / Nurse / CHW	Basic Level
	Type II — Ayurveda Therapist / Nurse / CHW	Advanced Level
Ayurveda Nurse	**Type I** — Ayurveda Therapist / Nurse / CHW	Basic Level
	Type II — Ayurveda Therapist / Nurse / CHW	Advanced Level
	Type III — Ayurveda Nurse	Specialty Level
Ayurveda Community Health Worker (CHW)	**Type I** — Ayurveda Therapist / Nurse / CHW	Basic Level
	Type II — Ayurveda Therapist / Nurse / CHW	Advanced Level
Ayurveda Pharmacist	**Type I** — Ayurveda Pharmacist	Basic Level
	Type II — Ayurveda Pharmacist	Advanced / Specialty Level

Annex 5. General requirements for an Ayurveda clinic offering outpatient services

A5.1 Clinical equipment and furniture

The following equipment is essential for the Ayurveda clinic:

- facilities for the Ayurveda practitioner to work comfortably;
- appropriate seating for the patient and their attendant;
- examination couch with clean linen, and with adequate facilities to ensure the patient's privacy;
- appropriate stepladder to assist the patient on to the examination couch;
- stethoscope;
- sphygmomanometer;
- thermometer;
- clock;
- weighing scale;
- measuring tape;
- tongue depressor;
- torch;
- percussion hammer;
- disposable gloves;
- handwashing facilities;
- adequate washroom facilities, with access for disabled people;
- emergency trolley with equipment for use in emergencies;
- necessary medicines;
- necessary consumables;
- equipment for waste collection and disposal;
- fire extinguisher;
- other essential equipment depending on the specialty of the practice, such as:
    - instruments for minor surgery;
    - instruments for gynaecological examinations, normal delivery and simple gynaecological procedures;
    - ear, nose and throat examination set;
    - proctoscope.

A5.2 Infrastructure

The clinical establishment should:

- have adequate space and facilities for waiting patients and for clinical consultations;
- be adequately ventilated or air-conditioned and well illuminated;
- have proper facilities for easy access and exit for all patients;
- be maintained with proper hygienic measures and regular cleaning with disinfectants;
- have easily accessible drinking water facilities;
- have adequate, accessible and clean washroom facilities;
- have appropriate safety and security facilities, equipment and expertise according to regulations of the Member State;
- have necessary additional provisions of infrastructure, equipment, furniture and expertise if it is an advanced-level practice;
- have any other facilities according to the prevalent requirements and regulations of the Member State.

Annex 6. Commonly used Ayurveda health interventions in the category of Ayurveda therapies

- internal administration of lipid-based Ayurveda medicines (*snehapāna*):
- massage using Ayurveda techniques and oil (*abhyaṅga*);
    - smearing of medicated oil on the body parts for a specified period and then washing it off (*snehalepa*);
    - gentle massage (*saṃvāhana*);
    - deep massage with hands (*mardana*);
    - massage with foot (*pādāghāta*);
    - massage using paste of herbs moistened with oil (*utsādana*);
- massage with herbal powders in which the direction of massage is generally opposite to that used in *abhyaṅga* (*udvartana*);
- procedures to induce controlled sweating (*svedana*) – this process involves controlled application of heat to raise the body temperature, resulting in controlled sweating; various sweating procedures administer different types of heat and focus on different parts of or the whole body:
    - sweating induced through dry heat (*rūkṣasvedana*);
    - sweating induced through wet heat (*dravasvedana*) using materials of fluid (*drava*) nature, such as sweating induced in the lower half of the body using a medicated warm decoction while the person sits in a tub (*avagāha svedana*);
    - sweating induced using lipid-based Ayurveda medicines (*snigdhasvedana*);
    - steam bath (*bāṣpa svedana*) or sweating induced by administering steam to a specific body part using a tube (*nāḍīsveda*), or *nāḍī*sveda using steam from milk boiled with Ayurveda herbs (*kṣīradhūma*);
    - sweating induced using a poultice made of cloth filled with Ayurveda medicines or herbs (*poṭalīsvedana* or *piṇḍasvedana*); the poultice may be filled with medicinal leaves (*patra*; *patrapoṭalīsvedana*), medicinal powder (*cūrṇa*; *cūrṇasvedana*), sand (*vālukā*/*bālukā*; *vālukāsvedana*/*bālukāsvedana*), or *ṣaṣṭika* (a variety of rice) boiled in medicated milk (*ṣaṣṭikaśālipiṇḍasvedana*);
    - application of paste prepared from Ayurveda medicines to the affected body part, which is then covered with leaves of specific medicinal plants (*upanāhasvedana*); the medicine is heated before application;
    - application of thick paste prepared from Ayurveda medicines that increase body heat or metabolism to the affected body part (*pradehasvedana*); the medicine is not heated before application;
    - sweating induced using the heat generated by rubbing the palms together (*hasta svedana*);
    - application of medicated paste prepared from *ṣaṣṭika* (a variety of rice) and milk (*annalepana*);
- therapeutically induced vomiting (*vamana*);

- therapeutically induced purgation (*virecana*);
- administration of medicines through the nasal route (*nasya*);
    - instillation of two drops of lipid-based Ayurveda medicine through the nose (*pratimarśanasya*);
    - administration of Ayurveda medicine used in powder form for *nasya* (*pradhamananasya*);
    - administration of (expressed) juice of fresh herbs used as medicine for *nasya* (*avapīḍanasya*);
- enema – rectal administration of Ayurveda medicines (*vasti*);
    - mixture of medicinal substances predominantly made from herbal decoctions administered as enema (*nirūhavasti*, āsthāpanavasti or *kaṣāyavasti*); there are several types of *nirūhavasti*;
    - lipid-based Ayurveda medicine administered as enema (*anuvāsanavasti*);
- infusion of liquid medicines into the urinary bladder (*uttaravasti*);
- consistent pouring of liquids from a defined height and duration and with specific intensity on specified parts or the whole body (*dhārā*; also called *seka* or *pariṣeka*);
    - pouring of liquids on the whole body (*sarvāṅgadhārā*);
    - pouring of medicated oil and gentle massaging of the whole body (*kāyaseka*/*pizhichil*);
    - pouring of liquids on a specified part of the body (*ekāṅgadhārā*);
    - pouring of fermented liquid made from different grains (*dhānyāmla*);
    - pouring of liquid on the head (śirodhārā) and pouring of medicated oil (*taila*) on the head (*takraśirodhārā*);
    - pouring of medicated butter milk (*takra*) on the head (*takraśirodhārā*);
    - pouring of herbal decoction in a continuous stream over the eyes (*netradhārā*/ *pariṣeka*);
- application of oil over a part of the body by soaking a cloth in medicine (warm medicated oil) and keeping it over the defined body part (*picu*);
    - application of cloth soaked with warm medicated oil on the head (*śiropicu*);
    - insertion of a sterile tampon soaked with medicated oil in the vaginal canal (*yoni picu*);
- application of oil to the head (*mūrdhataila*):
    - application of oil to the scalp followed by massage (*śiro-abhyaṅga*);
    - pouring of medicated oil (*taila*) on the head using a special instrument (*dhārā yantra*) (śira-seka, popularly known as śirodhārā);
    - application of cloth soaked with warm medicated oil to the head (*śiropicu*);
    - retention of medicated oil over the head with the help of a specially designed head cap (*śiro-vasti*);
- instillation of Ayurveda medicine into the ear and retaining it for a specified period (*karṇapūraṇa*);
- instillation of medicated oil in the vaginal canal (*yoni pūraṇa*);
- instillation of liquid medicines as drops into an open eye (*āścyotana*);
- application of medicine to the lower conjunctiva or eyelid margin (*añjana*);
- retention of medicine (mainly *sneha* – lipid-based Ayurveda medicine) over the eyes while maintaining a specified temperature and duration (*tarpana*);
- retention of medicine prepared through a special process over the eyes while maintaining a specified temperature and duration (*puṭapāka*);
- retention of oil over the lower back or lumbosacral region (*kaṭivasti*);

- retention of oil over the chest region (*urovasti*);

- retention of warm oil inside a specially prepared frame made from black gram dough over the abdominal region (*udaravasti*);

- retention of warm oil inside a specially prepared frame made from black gram dough over the knee joint (*jānuvasti*);

- retention of warm oil inside a specially prepared frame made from black gram dough over the posterior part of the neck (*grīvavasti*);

- application of medicinal pastes (*lepa*):

    - application of medicinal paste covering the entire scalp (*śirolepa*/*thalapothichil*);

    - application of medicinal paste on the face (*mukhalepa*);

- gargling/mouth rinsing with liquid medicine (*kavalagraha*);

- holding liquid medicine in mouth for a certain period (*gaṇḍūṣa*);

- application of medicated paste with the intention of increasing secretions from nearby tissues (*pratisāraṇa*);

    - application of medicated pastes or powder in the mouth followed by soft massage of the surrounding tissue (*mukhapratisāraṇa*);

    - application of medicated pastes or powder on or near a wound to clean the wound and improve blood circulation (*vraṇapratisāraṇa*);

- inhalation of medicated fumes through the nose or mouth (*dhūmapāna*);

- use of a special medical substance of alkaline nature (*kṣāra*) to achieve desired effects of controlled cauterization/erosion of specific tissues (*kṣārakarma*) – for example, use of *kṣāra*-covered special medical threads to excise growths (e.g. haemorrhoids) or to cut through fistular wounds (e.g. fistula-in-ano) (*kṣārasutra karma*);

- direct thermal cauterization of the tissue surface using different materials (*agnikarma*);

- bloodletting (*raktamokṣaṇa*):

    - bloodletting (*raktamokṣaṇa*) through venesection specific to different clinical conditions (*sirāvedha*);

    - bloodletting (*raktamokṣaṇa*) by making numerous cutaneous wounds with a sharp needle;

    - bloodletting (*raktamokṣaṇa*) by applying vacuum suction over surgically inflicted cutaneous wounds (*śṛṅga*/*alābu*);

    - bloodletting (*raktamokṣaṇa)* by applying non-poisonous leeches (*jalaukāvacaraṇa*);

- surgical procedures (*śastra karma*):

    - incision (*bhedana*);

    - excision (*chedana*);

    - scraping (*lekhana*);

    - puncture (*vedhana*);

    - probing (*eṣaṇa*);

    - extraction (*āharaṇa*);

    - evacuating (*utpāṭana*);

    - suturing (*sīvana*).

Annex 7. Adverse events requiring treatment or referral in Ayurveda practice

Performing Ayurveda therapies according to the operative procedures explained in authoritative Ayurveda texts reduces the incidence of adverse events and emergencies. Nevertheless, the following measures are suggested.

The clinical establishment should have a plan to address adverse events, which needs to be communicated to all staff. Staff should be trained periodically for preparedness for and mitigation of adverse events.

Ayurveda health service providers should be knowledgeable about critical and emergency conditions that may arise, and their primary management. The clinical establishment should have a well-defined policy about when to refer patients. Ayurveda practitioners and paramedical staff should have basic knowledge of cardiopulmonary resuscitation, basic life support and primary management of burns.

Adverse events that Ayurveda health service providers should be aware of and observant for include:

- headache;
- fluid loss and dehydration;
- electrolyte imbalance;
- abdominal pain;
- persistent vomiting;
- diarrhoea;
- high fever;
- giddiness, fainting and loss of consciousness;
- hypertension;
- hypotension;
- chest pain;
- abdominal distension;
- hematemesis;
- bleeding (anorectal, oral, vaginal, nasal, urinary);
- hiccup;
- retention of urine;
- allergic reactions;
- anaphylactic reactions;
- adverse drug reactions;
- burns and scalds.

Annex 8. Common signs and symptoms of adverse effects of Ayurveda medicines

Ayurveda practitioners, Ayurveda pharmacists, Ayurveda nurses and Ayurveda therapists should be able to recognize the common signs and symptoms of adverse effects of Ayurveda medicines. They should know the appropriate procedures to deal with emergencies. Common signs and symptoms include:

- burning sensation of the skin;
- skin rash;
- itching;
- loss of lustre of the skin;
- loss of lustre of the eyes;
- constipation;
- diarrhoea;
- vomiting;
- pain and burning in abdomen/heartburn;
- bleeding haemorrhoids;
- restlessness;
- reduced sleep;
- giddiness and syncope;
- weakness.

Annex 9. Staff health programmes and other basic infection control methods

General precautionary actions related to staff engagement:

- Pre-employment medical check-ups should be undertaken for all staff, including contractual staff.
- Annual medical check-ups should be undertaken for all staff.
- Vaccination for hepatitis B should be advised for all staff members.
- Records of medical fitness of staff and any proactive steps taken should be maintained by the facility's administrative office.

Handwashing:

- Frequent and appropriate handwashing is very important.
- Staff should be periodically trained in appropriate handwashing techniques.
- Checks should be in place to ensure compliance of staff with the clinical establishment's hand hygiene measures.

Personal protective equipment (PPE):

- Gloves, aprons, caps, masks and other appropriate PPE should be provided to staff, according to requirements, and monitored for correct and diligent use as and when needed.

Cleaning of equipment and articles:

- Contaminated disposable articles should be collected appropriately in leak-proof bags and disposed of properly.
- Reusable medical equipment must be disinfected or sterilized after use.

Laundry:

- Soiled linen should be handled with care and adequate precautions taken to prevent cross-contamination of the surroundings and of people handling it.
- All soiled linen should be collected in designated bags or stored separately. It should not be sorted or pre-rinsed in patient care areas.
- Linen soiled with blood or body fluids should be transported in leak-proof bags.

Periodic cleaning of the clinical establishment:

- Periodic general cleaning of the premises, including walls, blinds, curtains and the surrounding area, should be carried out.
- Housekeeping methods should be followed according to the requirement of services provided at the clinical establishment and the volume of people it cares for.

Housekeeping in the Ayurveda therapy room:

- The Ayurveda therapy room should be kept clean.

- Floors and other surfaces should be cleaned with soap solution.

- Procedure rooms should be cleaned daily, or after every procedure, depending on the level of possible contamination and level of sterility expected for the services offered in the room. If multiple rooms are connected, it is good practice to clean the entire complex thoroughly once a week.

- All instruments, equipment, furniture, *pañcakarma* tables (*droṇi*) and slabs should be wiped with soap solution.

Food handling:

- Standard guidelines should be followed to ensure food served to patients, visitors and staff is processed in a manner that avoids contamination.

Annex 10. Principles and processes for dissemination of information

- A written document on the type of services provided at the clinical establishment should be available to patients in booklet form in the local language and in other languages according to requirements.

- The available services should be displayed in the local language at a prominent place in the clinical establishment and should be available on the clinical establishment's website.

- Any change or increase or decrease in the services offered should be updated.

- A booklet in the local language covering basic information on Ayurveda, Ayurveda health interventions, Ayurveda therapies, "do's and don'ts", code of conduct, dietetic guidelines to be followed during Ayurveda health interventions, and time, duration and schedule for different Ayurveda therapies should be available to patients.

- Information on the safety of Ayurveda health interventions, including health advisories and other communications administered as part of public health programmes, should be developed with the utmost care and be disseminated in the most appropriate manner to reach the target population. There should be established checks to monitor and assess the benefits and risks of such public information instruments and their immediate and long-term impact on the target population, while also comparing them with possible unintentional outcomes in other sections of the population.

Annex 11. Human resources for Ayurveda practice

According to the requirements of the practice, the following may be required:

- Ayurveda practitioner;
- Ayurveda nurse;
- Ayurveda therapist;
- Ayurveda pharmacist;
- Ayurveda community health worker;
- medical recordkeeping staff;
- housekeeping staff.

Annex 12. Formal licensure and established national standards and guidelines available in Member States that supported the development of this document

Our enquiry on formal licensure and established national standards and guidelines available in Member States that can assure good-quality health-care delivery of Ayurveda and Unani systems of medicine provided the following information, which has supported the development of the content of this document. The information was collected from relevant websites of ministries of the respective Member States, and from direct communication with officials and experts associated with these Member States.

A12.1 Argentina

Argentina has Ayurveda medical training programmes that educate conventional doctors. Since 2000, postgraduate courses in Ayurveda have been held for physicians and other health professionals at various universities in Argentina. Since 2014, the Argentine Medical Association has conducted similar courses. Some insurance companies provide medical malpractice insurance to physicians covering the Ayurvedic medical care provided by these health-care professionals.

A12.2 Australia

The Australian Government officially recognized two training programmes in Ayurveda in 2015 – the Diploma in Ayurvedic Lifestyle Consultation, and the Advanced Diploma in Ayurveda. Each qualification has a clearly defined scope of practice for its graduates. This official recognition of Ayurveda allows qualified and certified Ayurveda doctors to practise in Australia without further qualification.

HLT52615 Diploma of Ayurvedic Lifestyle Consultation. Canberra: Industry Skills Council (https://training.gov.au/training/details/HLT52615).

HLT62615 Advanced Diploma of Ayurveda. Canberra: Industry Skills Council (https://training.gov.au/training/details/HLT62615).

A12.3 Bahrain

The Ministry of Health started to approve alternative medicine licences in 2003, including for Ayurveda and Unani. Since 2012, the licensing authority for regulating practice in Ayurveda and Unani has been the National Health Regulatory Authority.

A12.4 Bangladesh

The Unani and Ayurveda Practitioners Ordinance of 1983 provided for the regulation of qualifications and registration of Ayurvedic and Unani practitioners, formally acknowledging the Ayurvedic and Unani systems of medicine.

The Bangladesh Unani and Ayurvedic Practitioners Ordinance, 1983 (Ordinance No. XXXII of 1983) (http://bdlaws.minlaw.gov.bd/act-645.html).

Bachelor of Unani Medicine and Surgery. Munshiganj: Hamdard University (https://www.hamdarduniversity.edu.bd/department/bums).

General courses. Munshiganj: Hamdard University (https://www.hamdarduniversity.edu.bd/department/bums/program).

Bachelor of Ayurvedic Medicine and Surgery. Munshiganj: Hamdard University (https://www.hamdarduniversity.edu.bd/department/bams).

General courses. Munshiganj: Hamdard University (https://www.hamdarduniversity.edu.bd/department/bams/regular_program).

A12.5 Brazil

Ayurveda has been recognized within the framework of the National Policy of Integrative and Complementary Practices since 2017.

Ordinance 971 of 2006. Approves the National Policy of Integrative and Complementary Practices (PNPIC) in the Unified Health System. Brasilia: Ministry of Health; 2006 (https://bvsms.saude.gov.br/bvs/saudelegis/gm/2006/prt0971_03_05_2006.html).

Ordinance No. 849, 27 March 2017. Includes Art Therapy, Ayurveda, Biodanza, Circular Dance, Meditation, Music Therapy, Naturopathy, Osteopathy, Chiropractic, Reflexotherapy, Reiki, Shantala, Integrative Community Therapy and Yoga to the National Policy for Integrative and Complementary Practices. Brasilia: Ministry of Health; 2017 (https://bvsms.saude.gov.br/bvs/saudelegis/gm/2017/prt0849_28_03_2017.html).

A12.6 Colombia

There is no specific policy or law document for Ayurveda or Unani, but there is a regulatory framework that covers traditional and complementary medicine practice by health-care professionals; the inclusion of services in the health system; the provision of services, phytotherapeutic products; and health food stores. Ayurveda and Unani medicine are classified under complementary medicine in Colombia. Decree 2753 of 1997 (Article 4) limits complementary medicine practice to physicians. Resolution 2927 of 1998 defines and regulates different types of complementary medicine practices. Law 1164 of 2007 dictates provisions on the practice of traditional and complementary medicine, and Resolution 2003 of 2014 regulates all health-care services, including traditional and complementary medicine. It defines the minimum requirements for physical spaces where services are to be provided, equipment and training of professionals, and the standards for health professionals. The regulations on traditional and complementary medicine providers, enforced at the national level, are for acupuncture (2006), Ayurvedic medicine (2006), herbal medicines (2006) and homeopathic medicine (1962, 2006). Traditional and complementary medicine providers practise in private and public clinics. A traditional and complementary medicine licence or certificate issued by a relevant academic institution is required to practise. As a result of participatory work with the expert committees for traditional and complementary medicine, there is a proposal to define the profile and professional competencies of health professionals, to guide the formation and performance in each of the recognized systems.

Article 7 of Law 1164 of 2007. Bogotá: Subcommittee for Ayurveda Medicine, Committee for Alternative Medicine, Alternative and Complementary Therapies, National Council of Human Talent in Health.

A12.7 Cuba

Cuba regulates traditional medicine under the umbrella of the Natural and Traditional Medicine Program. In 2019, Cuba initiated the process of regulating Ayurveda and a pañcakarma department opened at a health centre operating within the national health system.

A12.8 Germany

There is no statutory recognition for Ayurveda or Unani, but there are increasing numbers of practitioners and their associations. Several courses have been conducted by private institutions, often under the aegis of medical associations, providing different levels of Ayurveda training.

A12.9 Hungary

Hungary officially recognized the Ayurveda medical system as a natural medicine through the 40/1997 Government Decree and the 11/1997 NM Order in 1997. According to the Decree, Hungarian medical doctors who have undertaken training of Ayurveda can practise it.

Decree 11/1997. (V.28.) NM of the Minister of Welfare on certain issues of the exercise of naturopathy activity and alternative medicaments (Ayurveda) (http://www.ayurveda.hu/doc/Decree_11-1997.pdf).

Government Decree 40/1997 (III.5.) Korm. on the Practice of Alternative Medicine (http://www.ayurveda.hu/doc/GovernmentDecree_40_1997.pdf?docid=99700040.KOR).

A12.10 India

India recognizes and regulates Ayurveda and Unani medicine as medical systems and has specific laws and frameworks in place to regulate training and practise of the systems. Ayurveda and Unani medicine are part of health system establishments. The services are delivered through government and private establishments. India has the world's largest number of registered Ayurveda and Unani practitioners who have completed the graduate medical training of the respective systems, which are of more than 5000 hours duration.

Apex manual. New Delhi: All India institute of Ayurveda; 2017.

Apex manual: biomedical waste management policy. New Delhi: All India Institute of Ayurveda; 2017.

Apex manual: hospital infection control manual. New Delhi: All India Institute of Ayurveda; 2017.

Apex manual: patients records department operation. New Delhi: All India Institute of Ayurveda; 2017.

Apex manual: patients right and education policy. New Delhi: All India Institute of Ayurveda; 2017.

Apex manual: safety policy. New Delhi: All India Institute of Ayurveda; 2017.

A practical handbook of panchakarma procedures. New Delhi: Central Council for Research in Ayurveda and Siddha; 2010 (https://www.researchgate.net/publication/257358254_A_PRACTICAL_HANDBOOK_OF_PANCHAKARMA_PROCEDURES).

Central Register of Indian Medicine (Amendment) Regulation 2016 (https://www.ccimindia.org/pdf/CCIM%20(Central%20Register%20of%20Indian%20Medicine)%20(Amendment)%20Regulation%202016.pdf).

Central Register of Indian Medicine (General) Regulations, 1976 (https://www.ccimindia.org/pdf/CCIM%20(General)Regulations%201976.pdf).

Ayurveda and conventional medicine: cross referral approach for selected disease conditions. New Delhi: Central Council for Research in Ayurvedic Sciences; 2021. (http://ccras.nic.in/sites/default/files/viewpdf/15112021_Cross_Referral_Approach_for_Selected_Disease_Conditions.pdf)

Ayurveda-based diet and life style guidelines for prevention of cardiac disorders. New Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (http://ccras.nic.in/sites/default/files/ebooks/24052018_CCRAS_Cardiac_disorders.pdf).

Ayurveda-based diet and life style guidelines for prevention and management of skin diseases. New Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (http://ccras.nic.in/sites/default/files/ebooks/24052018_CCRAS_HQ_Ayurvedabaseddiet�&lifeStyleGuidelinesSkinDiseases.pdf).

Ayurveda-based dietary guidelines for mental disorders. New Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (http://ccras.nic.in/sites/default/files/ebooks/Ayurveda-Based_Dietary_Guidelines_Mental_Disorders.pdf).

General guidelines for clinical evaluation of Ayurvedic interventions. New Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (http://ccras.nic.in/sites/default/files/viewpdf/Publication/CCRAS_Guideline%20of%20Clinical_Evaluation.pdf).

General guidelines for drug development of Ayurvedic formulations. New Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (https://www.ayush.gov.in/docs/guideline-drug-development.pdf).

General guidelines of safety/toxicity evaluation of Ayurvedic formulations. New Delhi: Central Council for Research in Ayurvedic Sciences; 2018 (https://www.ayush.gov.in/docs/guideline_safety_toxicity.pdf).

Good clinical practice guidelines for clinical trials in Ayurveda, Siddha and Unani medicine. New Delhi: Department of AYUSH, Ministry of Health and Family Welfare; 2013 (https://health.ncog.gov.in/ayush-covid-dashbaord/assets/Classified/GCP_ASU.pdf).

Guidelines on basic training and safety on panchakarma. New Delhi: Department of AYUSH, Ministry of Health and Family Welfare; 2008 (https://www.researchgate.net/publication/215554092_Guidelines_on_Basic_Training_and_safety_on_Panchakarma).

Indian Medicine Central Council (Post Graduate Ayurveda Education) Amendment Regulations, 2020 (https://www.ccimindia.org/latestupdate/223208-website.pdf).

Indian Medicine Central Council (Minimum Standards of Education in Indian Medicine) Amendment Regulations, 2019 (https://www.ccimindia.org/latestupdate/206002.pdf).

Indian Medicine Central Council (Postgraduate Unani Education) Regulations, 2019 (https://www.ccimindia.org/pdf/UNANI-PG-11-77-2018.pdf).

Indian Medicine Central Council (Minimum Standards of Education in Indian Medicine) Amendment Regulations, 2018 (https://www.ccimindia.org/latestupdate/193697.pdf).

Indian Medicine Central Council (Minimum Standard Requirements of Ayurveda Colleges and Attached Hospitals) Regulations, 2016 (https://www.ccimindia.org/pdf/rul-reg-msr-2016-9-7.pdf).

Indian Medicine Central Council (Minimum Standard Requirements of Unani Colleges and Attached Hospitals) Regulations, 2016 (https://www.ccimindia.org/pdf/UNANI-MSR-07-09-2016.pdf).

Indian Medicine Central Council (Minimum Standards of Education in Indian Medicine) Amendment Regulations, 2016 (https://www.ccimindia.org/rul-reg-mse-ay-2016-9.php).

Indian Medicine Central Council (Postgraduate Diploma Course in Unani medicine) Regulations, 2015 (https://www.ccimindia.org/rul-reg-mse-un-2015.php).

Indian Medicine Central Council (Postgraduate Diploma Course) (Ayurveda) Regulations 2010 (https://www.ccimindia.org/rul-reg-mse-ay-2010-1.php).

Indian Medicine Central Council (Election) Rules, 1975 (including amendments of 2012) (https://www.ccimindia.org/pdf/election_rule-1975.pdf).

Indian Medicine Central Council Act, 1970 (Act 48 of 1970) (https://www.ccimindia.org/actandammendment.php#).

Public notice to consumers and stakeholders for promoting safe use of ASU Drugs. New Delhi: Ministry of AYUSH; 2016 (https://main.ayush.gov.in/acts-rules-and-notifications/public-notice-to-consumers-and-stakeholders-for-promoting-safe-use-of-asu-drugs/).

Accreditation standards for Ayurveda hospitals, 2nd edition. New Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2016 (https://nabh.co/Images/PDF/AyurvedaStandard_2ndEdition.pdf).

Accreditation standards for Unani hospitals. New Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2009 (https://nabh.co/Images/PDF/UnaniStandards_1stEdition.pdf).

Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982 (https://www.ccimindia.org/pdf/Practitioners%20of%20Indian%20Medicine%20(Standards%20of%20Professional%20Conduct,%20Etiquette%20and%20Code%20of%20Ethics)%20Regulations,%201982.pdf).

Standard Unani treatment guidelines for common diseases: vol. I. New Delhi: Central Council for Research in Unani Medicine; 2014 (https://ccrum.res.in/writereaddata/UploadFile/Common%20Diseases,%20Vol%20I_1291.pdf).

Standard Unani treatment guidelines for common diseases: vol. II. New Delhi: Central Council for Research in Unani Medicine; 2016 (https://ccrum.res.in/writereaddata/UploadFile/Common%20Diseases,%20Vol%20II_1223.pdf).

CCRUM intra mural research policy. New Delhi: Central Council for Research in Unani Medicine; 2013 (https://ccrum.res.in/writereaddata/UploadFile/INTRAMURAL%20RESEARCH%20POLICY%20Final636994508003314440.pdf).

Entry level standards for Ayush hospitals. New Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2019.

Entry level standards for Ayush center. New Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2019.

National AYUSH morbidity and standardized terminologies portal (http://namstp.ayush.gov.in/#/index).

Apex manual. Lucknow: Ram Manohar Lohiya Combined Hospital; 2008.

Apex manual: biomedical waste management policy. Lucknow: Ram Manohar Lohiya Hospital; 2008.

Apex manual: patients records department operation. Lucknow: Ram Manohar Lohiya Hospital; 2008.

Apex manual: patients right and education policy. Lucknow: Ram Manohar Lohiya Hospital; 2008.

Apex manual: safety policy. Lucknow: Ram Manohar Lohiya Hospital; 2008.

A12.11 Italy

Ayurveda was recognized as a medical act in 2002 by the National Federation of Medical and Dental Orders, supervised by the Ministry of Health. This position, expressed by the highest body of the medical profession in the field of ethics, reiterates that doctors, surgeons and dentists, after appropriate certified training, are the only people qualified to practise clinical Ayurveda. In 2018, the first elective course of Introduction to Ayurveda was activated for fifth- and sixth-year medical students of the Faculty of Medicine of the State University of Milan.

In 2019, the Italian National Organization for Standardization issued the normative UNI 11756:2019 for the profession of technician (therapist) in Ayurveda, which has become an officially acknowledged and protected profession by the Italian Government under Law 4/2013. The recognition is subject to verification of the education, examination and certification by the Federazione delle Associazioni per la Certificazione, a body recognized by Accredia, the sole national accreditation body appointed by the Italian Government under the vigilance of the Ministry of Economic Development. The qualifying education programmes in Ayurveda for medical doctors and technicians (therapists) are private and preferably certified by third parties such as ISO 9001 certification for teaching quality.

Figura professionale: tecnico in Ayurveda. Cuneo: FAC Certifica (https://faccertifica.it/wp-content/uploads/2021/08/sk39.pdf).

FNOMCeO guidelines on non-conventional medicines and practices, approved in Terni 18 May 2002 and updated in 2009. Rome: Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri; 2010 (https://portale.fnomceo.it/la-proposta-fnomceo-in-tema-di-formazione-nelle-medicine-e-pratiche-non-convenzionali/).

Linee guida per la formazione nelle medicine e pratiche non convenzionali riservate ai medici chirurghi e odontoiatri della FNOMCeO. Rome: Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri; 2009 (https://portale.fnomceo.it/wp-content/uploads/import/201801/67825_linee-guida-fnomceo-formazione-nelle-medicine-e-pratiche-non-convenzionali.pdf).

Code of deontology. Article 15 non-conventional medicines. Rome: Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri (https://portale.fnomceo.it/wp-content/uploads/2020/04/CODICE-DEONTOLOGIA-MEDICA-2014-e-aggiornamenti.pdf).

The UNI Standard 11756:2019 (issued under Law 4/2013). Provisions relating to unorganized professions. Gazzetta Ufficiale, 26 January 2013 (https://www.gazzettaufficiale.it/eli/gu/2013/01/26/22/sg/pdf).

Hearing of the Italian Scientific Society of Ayurvedic Medicine – Ayurveda, Traditional Indian Medicine: Hearing before the XII Commission on Hygiene and Health, Italian Senate, 9 April 2009.

European Regulation no. 765/2008. Rome: UNI (https://www.accredia.it/en/documento/regulation-ec-no-765-2008/).

A12.12 Malaysia

Malaysia recognizes and regulates Ayurveda and Unani medicine as medical systems and has laws and frameworks in place to regulate them. In Malaysia, the Programme Standards: Traditional and Complementary Medicine, composed of the recognized standard Ayurveda Curriculum Design and Delivery, was established in 2009 and revised in 2021. In 2016, legislation for traditional and complementary medicine was established to regulate traditional and complementary medicine practitioners and services.

Traditional and complementary medicine regulations 2021. Federal Government Gazette, 23 February (https://tcm.moh.gov.my/ms/upload/smptk/akta/Peraturan-PeraturanPTK2021.pdf).

Programme standards: traditional and complementary medicine, 2nd edition. Cyberjaya: Malaysian Qualifications Agency; 2021 (https://tcm.moh.gov.my/ms/upload/smptk/standard/PSTNCM2NDED.pdf).

Code of professional conduct for T&CM practitioners. Putrajaya: Ministry of Health Malaysia; 2021 (https://tcm.moh.gov.my/en/upload/cpc_firstedition.pdf).

Consumer guideline for proper use of traditional and complementary medicine in Malaysia. Putrajaya: Ministry of Health Malaysia; 2019 (https://tcm.moh.gov.my/ms/upload/garispanduan/consumer/BukuPanduan_BI.pdf).

Practice guideline: shirodhara, 2nd edition. Putrajaya: Ministry of Health Malaysia; 2019 (https://tcm.moh.gov.my/ms/upload/garispanduan/amalan/2019_Shirodhara.pdf).

Practice guideline: herbal therapy as adjunct treatment for cancer, 2nd edition. Putrajaya: Ministry of Health Malaysia; 2018 (https://tcm.moh.gov.my/ms/upload/garispanduan/amalan/2018_HerbalTherapy.pdf).

Traditional and complementary medicine blueprint 2018–2027. Putrajaya: Ministry of Health Malaysia; 2017 (https://tcm.moh.gov.my/ms/upload/Blueprint.pdf).

Practice guideline: varmam. Putrajaya: Ministry of Health Malaysia; 2016 (https://tcm.moh.gov.my/en/upload/garispanduan/amalan/VarmamGuideline.pdf).

Practice guideline: external basti therapy. Putrajaya: Ministry of Health Malaysia; 2015 (https://tcm.moh.gov.my/en/upload/garispanduan/amalan/GarisPanduanBasti-Final.pdf).

Practice guideline: Islamic medicine practice. Putrajaya: Ministry of Health Malaysia; 2011 (https://tcm.moh.gov.my/en/upload/garispanduan/amalan/GPPengubatanIslamSept2011.pdf).

Designation of practitioner body. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/en/index.php/policy/sct-tcm-2016/designationofpractitionerbody).

Malaysian skills certification. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/en/index.php/education/skills).

Recognized practice areas. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/en/index.php/policy/sct-tcm-2016/recognizedpracticeareas).

Registration of traditional and complementary medicine practitioners. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/en/index.php/policy/sct-tcm-2016/pendaftaran-pengamal).

T&CM education system. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/en/index.php/education/education-system).

Traditional and complementary medicine (T&CM) Act 2016 [Act 775]. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/en/index.php/policy/sct-tcm-2016).

Traditional and Complementary Medicine (T&CM) Council. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/en/index.php/policy/sct-tcm-2016/tncmcouncil).

Two-way communication mechanism between T&CM practitioners and registered medical practitioners (RMPs) in Ministry of Health (MoH) hospitals. Putrajaya: Ministry of Health Malaysia (https://tcm.moh.gov.my/en/index.php/guideline/two-way-mechanism).

National policy on traditional and complementary medicine, 2nd edition. Putrajaya: Ministry of Health Malaysia; 2007 (https://tcm.moh.gov.my/en/upload/NationalPolicy.pdf).

Drug registration guidance document, 3rd edition. Putrajaya: Ministry of Health Malaysia; 2021 (https://www.npra.gov.my/index.php/en/component/sppagebuilder/925-drug-registration-guidance-document.html).

National occupational skills standards: Ayurvedic panchakarma therapy. Putrajaya: Department of Skills Development; 2016 (https://www.myspike.my/index.php?NossinfoSearch%5Bnosscode%5D=&NossinfoSearch%5Bnossname%5D=PANCHA&NossinfoSearch%5Bjoblevelid%5D=&NossinfoSearch%5Bsectorid%5D=&NossinfoSearch%5Bdivisionid%5D=&NossinfoSearch%5Bsubsectorid%5D=&NossinfoSearch%5Bir4%5D=&NossinfoSearch%5Bformat%5D=&r=umum-noss%2Findex-noss&sort=-nossname&page=2).

A12.13 Mauritius

The Ayurveda and other Traditional Medicine Act came into effect in 1989. In 1992, Ayurvedic clinics were started in the Government hospitals and clinics in Mauritius. Ayurveda is now integrated within the Mauritian health system.

Ayurvedic and Other Traditional Medicines Act. Act no. 37 of 1989. Port Louis: Attorney General's Office, Mauritius (https://attorneygeneral.govmu.org/Documents/Laws%20of%20Mauritius/A-Z%20Acts/A/AYURVEDICANDOTHERTRADITIONALMEDICINESACTNo37of1989.pdf).

A12.14 Nepal

Nepal recognizes and regulates Ayurveda and Unani medicine as medical systems.

Codes on sales and distribution of drugs, 2071. Kathmandu: Department of Drug Administration, Ministry of Health and Population (https://www.dda.gov.np/content/codes-on-sales-and-distribution-of-drugs-2071).

Nepal Health Service Act 2053. Kathmandu: Department of Drug Administration, Ministry of Health and Population (https://www.dda.gov.np/content/nepal-health-service-act-2053).

National drug policy 1995. Kathmandu: Department of Drug Administration, Ministry of Health and Population (https://www.dda.gov.np/content/national-drug-policy-1995).

National health policy 2071. Kathmandu: Department of Drug Administration, Ministry of Health and Population (https://www.dda.gov.np/content/national-health-policy-2071).

Formation rules, 2037(1970). Kathmandu: Drugs Advisory Council and Drugs Advisory Committee (https://www.lawcommission.gov.np/en/wp-content/uploads/2018/09/drugs-advisory-council-and-drugs-advisory-committee-formation-rules-2037-1970.pdf).

Ayurveda Medical Council Act, 2045 (1988). Kathmandu: Ministry of Health and Population (http://nepalpolicynet.com/images/documents/publichealth/acts/1988_Ayurveda%20Medical%20Council%20Act.pdf).

A12.15 Netherlands

Ayurveda and Unani medicine are classified as complementary and alternative medicine. There is no Government regulation for complementary and alternative medicine, and provision of alternative care is legal. Both medically and non-medically qualified professionals are allowed to practise complementary and alternative medicine.

By passing amendments to the Individual Health Care Professions Act on 1 December 1997 (Beroepen in de Individuele Gezondheidszorg), practice of medicine is open to all, with some limitations; some procedures may be carried out only by categories of professional practitioners authorized to do so by law.

According to the Individual Health Care Professions Act, the performance of certain medical procedures is limited to categories of professional practitioners authorized to do so by law. The eight health professions regulated by Section 3 of the Individual Health Care Professions Act are dentist, doctor, health-care psychologist, midwife, nurse, pharmacist, physiotherapist and psychotherapist. The new registration and title protection of these professions started on 1 December 1997. Performance of such a procedure by an unauthorized practitioner is a criminal offence. The procedures specified are artificial insemination (including vasti), cardioversion, catheterizations and endoscopies, defibrillation, electroconvulsive therapy, general anaesthetics, lithotripsy, obstetric procedures, procedures involving the use of radioactive substances and ionising radiation, punctures and injections, and surgical procedures.

A new health insurance system was introduced in 2006. Complementary and alternative medicine treatments are not covered by basic health insurance, but health insurers cover alternative treatment as either additional "free" benefits or covered by complementary voluntary health insurance. Ayurveda treatments and fees for consultation are partially covered by private insurance companies. The prerequisite for such reimbursement is that the Ayurveda practitioner needs to be a registered member of a professional body. If Ayurveda treatment is offered by a Bachelor of Ayurvedic Medicine and Surgery or an Ayurveda practitioner educated on accredited institutes in the Netherlands and in accordance with WHO guidelines for Ayurveda education, most health insurers will reimburse all or part of the treatment or consultation under the supplementary package. Most insurers do not require referral from a doctor for Ayurvedic treatment.

Registering as a healthcare professional. Den Haag: BIG-register (https://business.gov.nl/regulation/registering-as-healthcare-professional/).

A12.16 Oman

Ayurveda practice is regulated by the National Office for Traditional and Complementary Medicine, under the Ministry of Health.

Guidelines for licensing manufacturing plant for human medicines herbal medicines and medical devices. Muscat: Ministry of Health (https://www.moh.gov.om/documents/16539/1767901/Guidelines+for+Licensing+Manufacturing+Plant+for+Human+Medicines+Herbal+Medicines+and+Medical+Devices+-English.pdf/1fdc9c38-a680-4c2c-8971-f3a372dbc1b5).

Cir. 28 of 2008. Registration of herbal companies and products. Muscat: Ministry of Health; 2008.

Cir. 56 of 2021. Registration/re-registration of health products. Muscat: Ministry of Health; 2021 (https://moh.gov.om/documents/16539/1722100/Cir++56+of+2021+-+Registration+and+re-registration+of+health+products.pdf/2b4b047e-c41d-f873-b152-9fe193c83b5f).

A12.17 Pakistan

Pakistan recognizes and regulates Ayurveda and Unani medicine as medical systems and has specific laws and frameworks in place to regulate these systems.

Unani, Ayurvedic and Homeopathic practitioners Act 1965 (https://pakistanlaw.pk/statutes/9307/unani-ayurvedic-and-homeopathic-practitioners-act-1965).

Drug Regulatory Authority of Pakistan Act, 2012 (Act No. XXI or 2012) (https://www.fao.org/faolex/results/details/en/c/LEX-FAOC188913/).

A12.18 Qatar

The Qatar Council for Healthcare Practitioners has approved the practice of Ayurveda since 2016.

A12.19 Serbia

The Ministry of Health of published and adopted the *Rule book on detailed conditions and ways of implementation of complementary medicine* in 2007, which allows doctors of medicine or dentistry, with appropriate training, to use Ayurvedic knowledge within the practice of illness prevention, diagnosis, treatment and rehabilitation. The updated version was adopted in December 2019.

The Rule book on detailed conditions and ways of implementation of complementary medicine: methods and procedures. Belgrade: Ministry of Health of Serbia; 2019 (https://www.paragraf.rs/propisi/pravilnik-o-blizim-uslovima-i-nacinu-obavljanja-metoda-i-postupaka-komplementarne-medicine.html).

Legal status and regulation of CAM in Europe: part I – CAM regulations in the European countries. Munich: CAMbrella; 2010.

Luketina-Šunjka M, Rančić N, Subotić S, Jakovljević M. Komplementarna i alternativna medicina u srbiji: pregled literature. Acta Med Med. 2020;59(3).

A12.20 Singapore

Ayurveda practice runs within a self-regulatory framework supported by an operation manual, practice guidelines and code of ethics. All products, including Ayurvedic medicines, are used in clinical practice with a consent by the Health Sciences Authority issued for each batch of manufactured medicines. Therapy practices are not currently regulated by the Ministry of Health.

Operations handbook. Singapore: Singapore Ayurveda Practitioners' Association (http://www.ayurvedicpractitioners.org/download/APAS-operations-handbook.pdf).

Self-regulation framework. Singapore: Singapore Ayurveda Practitioners' Association (http://www.ayurvedicpractitioners.org/download/APAS-self-regulation-framework.pdf).

Code of ethics and practice standards of Ayurveda practitioners. Singapore: Singapore Ayurveda Practitioners' Association (http://www.ayurvedicpractitioners.org/download/code-of-ethics.pdf).

A12.21 South Africa

South Africa recognizes and regulates Ayurveda and Unani medicine as allied health professions.

Allied Health Professions Act 63 of 1982 (https://ahpcsa.co.za/wp-content/uploads/2019/02/The-AHP-Act_63-of-1982_as-amended.pdf).

Regulations in terms of the Associated Health Service Professions Act, 1982. Pretoria: Allied Health Professions Council of South Africa; 1982 (https://ahpcsa.co.za/wp-content/uploads/2015/10/Regulations-1982_as-amended_2.pdf).

Rules specifying the acts or omissions in respect of which disciplinary action may be taken by the board. Pretoria: Allied Health Professions Council of South Africa; 1983 (https://ahpcsa.co.za/wp-content/uploads/2015/10/Regulations-1983.pdf).

Code of ethics in terms of Section 54(9) of Regulations No. R.127 of 12 February 2001 to the Allied Health Professions Act, Act 63 of 1982, as amended including guidelines for good practice and guidelines for making professional services known. Government Gazette, 18 December 2015 (https://ahpcsa.co.za/wp-content/uploads/2015/10/39531_18-12_NationalGovernment-1.pdf).

Safety guidelines: Ayurveda – Ayurvedic therapies. Pretoria: Allied Health Professions Council of South Africa; 2020 (https://www.gov.za/sites/default/files/gcis_document/202010/43810bn126.pdf).

Safety guidelines: Unani-Tibb – cupping therapy. Pretoria: Allied Health Professions Council of South Africa; 2020 (https://www.gov.za/documents/allied-health-professions-act-safety-guidelines-unani-tibb-cupping-therapy-16-oct-2020).

A7.22 Sri Lanka

Ayurveda and Unani medicine are recognized and regulated as medical systems and has specific laws and frameworks in place to regulate training and practice of these systems. Both Ayurveda and Unani medicine are part of health system establishments. The services are delivered through government and private establishments.

Acts Nos. 31 of 1961 and 5 of 1962. Ayurveda (https://www.lawnet.gov.lk/ayurveda/).

Ayurveda Act No. 31 of 1961 (http://www.commonlii.org/lk/legis/num_act/aa31o1961156/).

Ayurveda (Amendment) Law (No. 7 of 1977) (http://www.commonlii.org/lk/legis/num_act/al7o1977248/).

Ayurveda (http://www.commonlii.org/lk/legis/consol_act/a116153.pdf).

Ayurveda rules (https://www.srilankalaw.lk/Volume-I/ayurveda-act.html).

A12.23 Switzerland

In 2009, further to the federal popular initiative Yes for Complementary Medicine, accepted by more than 67% of Swiss voters, the Swiss constitution was amended to better recognize and support complementary medicine. This opened new avenues for complementary and alternative medicine, including for Ayurveda.

Since 2012, introductory courses on complementary and alternative medicine have been given to undergraduate medical students at Swiss medical faculties. In that at the medical faculty of Lausanne, a course on Ayurveda is included.

In 2015, two federal Ayurvedic diplomas were created under the authority of the State Secretariat for Education, Research and Innovation: Naturopath in Ayurvedic Medicine, and Complementary Therapist in Ayurveda. These diplomas should favour recognition and integration of Ayurveda. Furthermore, more supplementary health insurers will reimburse Ayurvedic care in 2022.

Certification, titre. Solothurn: Organisation du monde du travail de la médecine alternative Suisse (https://www.oda-am.ch/fr/profession/certification-titre/).

Descriptifs des modules M1–M7 de l'examen professionnel supérieur de naturopathe. Solothurn: Organisation du monde du travail de la médecine alternative Suisse; 2014 (https://www.odaam.ch/fileadmin/sites/oda/files/hoehere_fachpruefung/hfp/QSK_NO_Modulbeschreibungen_M1-M7_190506_A_FR.pdf).

Méthodes de la thérapie complémentaire reconnues par l'OrTra TC. Solothurn: Organisation der Arbeitswelt KomplementärTherapie OdA KT (https://www.oda-kt.ch/fr/methodes/).

Professional profile AM (alternative medicine). Solothurn: Organisation du monde du travail de la médecine alternative OrTra MA (https://www.oda-am.ch/fr/profession/profil-professionel/).

Government regulations for the profession of (naturopathic) practitioner in alternative medicine (OdA AM) (extracts): fundamentals AM (alternative medicine). Solothurn: Organisation du monde du travail de la médecine alternative OrTra MA (https://www.oda-am.ch/fr/profession/fondamentauxma).

Extract of the official guidelines for the principles and training content of the modules (M1–M7) required for the federal diploma AM. Solothurn: Organisation du monde du travail de la médecine alternative OrTra MA (https://www.odaam.ch/fileadmin/sites/oda/files/hoehere_fachpruefung/hfp/QSK_NO_Modulbeschreibungen_M1-M7_190506_A_FR.pdf).

A12.24 United Arab Emirates

The Traditional Complementary and Alternative Medicine Unit was established in 2002 under the Ministry of Health, and the Department of Traditional Complementary and Alternative Medicine started licensing Ayurveda and Unani medicine practice.

Unified healthcare professional qualification requirements. Abu Dhabi: Dubai Health Authority; 2017 (https://www.dha.gov.ae/Documents/HRD/Healthcare%20Professionals%20Qualification%20Requirements%20(PQR)%202014-1.pdf).

Introduction to professional qualification requirement (PQR). Abu Dhabi: Department of Health (https://www.doh.gov.ae/en/pqr).

Traditional, complementary and alternative medicine (TCAM). Abu Dhabi: United Arab Emirates Government (https://u.ae/en/information-and-services/health-and-fitness/alternative-medicine).

TCAM (traditional complementary and alternative medicine) examination. Abu Dhabi: Ministry of Health (https://www.homeoweb.com/moh_cam_exam.htm).

Requirements and considerations for TCAM. Abu Dhabi: Department of Health (https://www.doh.gov.ae/en/pqr/tcam).

Traditional, complementary and alternative medicine scope of practice. Health Regulation Department: Dubai Health Authority; 2011 (https://www.dha.gov.ae/Documents/HRD/Healthcare%20professionals/Scope%20Of%20Practice/SCOPE%20OF%20PRACTICE%20FOR%20TCAM%20PRACTITONERS_v_01.pdf).

Registration of a pharmaceutical product derived from natural sources. Abu Dhabi: Ministry of Health and Prevention (https://www.mohap.gov.ae/en/services/registration-of-a-pharmaceutical-product-derived-from-natural-sources).

Assessment of an alternative medicine technician. Abu Dhabi: Ministry of Health and Prevention.

A12.25 United Kingdom of Great Britain and Northern Ireland

There is no statutory recognition for Ayurveda or Unani, but there are increasing numbers of practitioners and their associations. Several courses have been conducted by private institutions, often under the aegis of medical associations, providing different levels of Ayurveda and Unani training.

Code of ethics including code of conduct and disciplinary procedures of British Ayurvedic Medical Council incorporating the British Association of Accredited Ayurvedic Practitioners. Harrow: British Association of Accredited Ayurvedic Practitioners (http://www.britayurpractitioners.com/download/d774c6dc-6856-11e6-a3a0-153011a6e257/).

A12.26 United States of America

Standalone Ayurveda or Unani practice is permissible in the Health Freedom States, where Ayurvedic clinical services are provided by Ayurvedic health counsellors, Ayurvedic practitioners and Ayurveda doctor graduates. Ayurvedic panchakarma services are provided by trained massage therapists or other licensed health-care practitioners if the services are allowed within their licence's scope of practice. For example, doctors of medicine and licensed acupuncturists and naturopathic doctors are allowed to practise Ayurveda under their licences in some states.

University-based Ayurveda practitioner training programmes started in 2008. These are designed to impart training to all, including people with no previous medical education. There are currently courses for training Ayurvedic health counsellors, Ayurvedic practitioners and Ayurvedic doctors, among others. There are also other types of Ayurveda training, including a programme that trains conventional practitioners as part of their integrative medicine training module, and a programme that trains conventional medicine students in relevant aspects of Ayurveda as part of their university-based undergraduate medical training.

NAMA program hours requirement for programs beginning on or after January 1, 2021. Los Angeles, CA: National Ayurveda Medical Association; 2022 (https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/60ffc92ffc4e9c661ef983cf/1627375921127/Educational+Requirements+Updated_+07–26–21.pdf).

Ayurvedic doctor. Los Angeles, CA: National Ayurveda Medical Association; 2020 (https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5f4687a521edba068cf785e4/1598457776508/AD_Educational+Outline+for+Competency+-08–04–20+.pdf).

Ayurvedic health counselor. Los Angeles, CA: National Ayurveda Medical Association; 2020 (https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5f4687072bb98c2aba27dab5/1598457615679/AHC_Competency+Guidelines-05–13–20.pdf).

Ayurvedic practitioner. Los Angeles, CA: National Ayurveda Medical Association; 2020 (https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5f46874203b6c37608a9b82c/1598457689673/AP_Educational+Outline+for+Competncy_08–04–20.pdf).

Code of ethics and professional conduct. Los Angeles, CA: National Ayurveda Medical Association; 2020 (https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5ed5450fe2056a2c1c3169f2/1591035151731/NAMA+ethics+-Updated+05–28–20.pdf).

Client/patient encounter guidelines. Los Angeles, CA: National Ayurveda Medical Association; 2019 (https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/60a44460d5bb325fd22d99a5/1621378144229/_Client+Encounter+Requirement+up+to+6–30–22.pdf).

Scope of practice of an Ayurvedic practitioner. Los Angeles, CA: National Ayurveda Medical Association; 2018 (https://cdn.ymaws.com/ayurvedanama.site-ym.com/resource/resmgr/3_official_documents/nama_sop_doc_updated_08-08-1.pdf).

Ayurvedic yoga therapist. Los Angeles, CA: National Ayurveda Medical Association; 2017 (https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/5c77fa11c83025c5ed620d79/1551366673736/NAMA_AYTCompetencies_4.2017.pdf).

NAMA client encounter requirements effective July 1, 2022. Los Angeles, CA: National Ayurveda Medical Association (https://static1.squarespace.com/static/5a2aa80890bade905ec03b63/t/60a44597775afc3733a9a997/1621378455973/Client+Encounters+Requirement+from+7–1-22+Onward.pdf).

Annex 13. WHO working group meeting

The following were participants at the WHO working group meeting for developing the documents *Benchmarks for the practice of Ayurveda*, *Benchmarks for the practice of Unani medicine*, and *Benchmarks for the practice of Panchakarma* held in Jaipur, India, 17–19 September 2018:

S Ajit, Chief Executive Officer, Planet Ayurveda, New Zealand

Alireza Abbassian, Assistant Professor, Department of Traditional Medicine, Tehran University of Medical Sciences, Islamic Republic of Iran

Madhaw Singh Baghel, former Director, Institute for Post Graduate Teaching and Research in Ayurveda, India

Jorge Luis Berra, Director, Fundacion de Salud Ayurveda Prema, Argentina (Rapporteur: Ayurveda subgroup)

Santosh Kumar Bhatted, Associate Professor, Department of Panchakarma, All India Institute of Ayurveda, India

Swapan Kumar Datta, Ayurvedic Expert, Directorate General of Drug Administration, Bangladesh

Sohrab Dehghan, Shahid Beheshti University of Medical Sciences, Islamic Republic of Iran

Kartar Singh Dhiman, Director General, Central Council for Research in Ayurvedic Sciences, India

Stephen Yao Gbedema, Associate Professor and Head, Department of Pharmaceutics, Kwame Nkrumah University of Science and Technology, Ghana (Rapporteur: Unani subgroup)

Mujeeb Hoosen, Coordinator – Unani Tibb, School of Natural Medicine, Faculty of Community and Health Sciences, University of the Western Cape, South Africa (Rapporteur: Unani subgroup)

Simone Hunziker, Swiss Ayurvedic Medical Academy, Switzerland (Rapporteur: Ayurveda subgroup)

Mohammad Idris, Principal and Medical Superintendent, Ayurvedic and Unani Tibbia College and Hospital, India

Raveendra Nathan Pillai Indusekhar, President, Ayurveda Practitioners Association of Singapore, Singapore

Syed Shakir Jamil, Department of Moalajat, School of Unani Medical Education and Research, India (Co-Chair: Unani subgroup)

Ghazala Javed, Research Officer, Central Council for Research in Unani Medicine, India

Dinesh Katoch, Advisor, Ministry of AYUSH, India (Co-Chair: Ayurveda subgroup)

Asim Ali Khan, Director General, Central Council for Research in Unani Medicine, India

AK Azad Khan, Dean, Faculty of Unani Medicine, Hamdard University; and President, Diabetic Association of Bangladesh, Bangladesh

Manoj Kumar, Professor and Head, Department of Panchakarma, Ayurveda College, India

Prakash Mangalasseri, Associate Professor, Department of Kaya*cikitsā*, Ayurveda College, India

Abdul Mannan, Vice Chancellor, Hamdard University Bangladesh, Bangladesh (Co-Chair: Unani subgroup)

Antonio Morandi, Ayurvedic Point, Italy (Co-Chair: Ayurveda subgroup)

Paulo Peter Mhame, Assistant Director Responsible for Traditional Medicine, Ministry of Health, Community Development, Gender, Elderly and Children, United Republic of Tanzania

Kalanther Lebbe Mohamed Nakfer, Director, Ayurvedic Research Hospital, Sri Lanka

Manoj Nesari, Adviser (Ayurveda), Ministry of AYUSH, India (Co-Chair: Panchakarma subgroup)

Valdis Pirags, Director, International Institute for Indic Studies and Professor of Medicine, University of Latvia, Latvia

Buduru Sreenivasa Prasad, Principal, KLE University's Shri BM Kankanawadi Ayurveda Mahavidyalaya, India

Mukhtar Ahmad Qasmi, Joint Advisor, Unani Ministry of AYUSH, AYUSH Bhawan, India

Revana Siddappa Sarashetti, Professor and AYUSH Chair, Peoples' Friendship University of Russia, Russian Federation

Anusha Sehgal, Chair, National Ayurveda Medical Association Certification Board, United States of America

Sanjeev Kumar Sharma, Director, National Institute of Ayurveda, India

Mansoor Ahmed Siddiqui, National Institute of Unani Medicine Bengaluru, India

Goh Cheng Soon, Director, Traditional and Complementary Medicine, Malaysia (Co-Chair: Ayurveda subgroup)

Anup Kumar Thakar, Director, Institute for Post Graduate Teaching and Research in Ayurveda, India

Siddhartha Kumar Thakur, Executive Director, National Ayurveda Research and Training Center, Nepal (Rapporteur: Panchakarma subgroup)

Sivarama Prasad Vinjamury, Professor, Research, Southern California University of Health Sciences, United States of America

Ugyen Wangchuk, Medical Specialist, National Traditional Medicine Hospital, Department of Traditional Medicine Services, Ministry of Health, Bhutan

Tilakasiri Weerarathna, Deputy Director (Technical-Medical), Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka (Co-Chair: Panchakarma subgroup)

Asmita Ashish Wele, Ayurveda Chair, University of Debrecen, Hungary (Rapporteur: Panchakarma subgroup)

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Aditi Bana, Technical Officer, Traditional, Complementary and Integrative Medicine Unit, WHO, Switzerland

Sungchol Kim, Regional Adviser, Traditional Medicine, WHO South-East Asia Regional Office, India

Geetha Krishnan Gopalakrishna Pillai, Technical Officer, Traditional, Complementary and Integrative Medicine Unit, WHO Switzerland

Local secretariat

Staff of the National Institute of Ayurveda, India, under guidance of its Director Sanjeev Kumar Sharma

Staff of the International Cooperation Section of the Ministry of AYUSH, India

Annex 14. WHO expert consultation meeting

The following were participants at the WHO expert consultation meeting for developing the documents *Benchmarks for the practice of Ayurveda*, *Benchmarks for the practice of Unani medicine*, and *Benchmarks for the practice of Panchakarma* and updating the documents *Benchmarks for the training of Ayurveda* and *Benchmarks for the training of Unani medicine* held in Jamnagar, India, 26–29 November 2019:

Alireza Abbassian, Assistant Professor, Department of Traditional Medicine, Tehran University of Medical Sciences; and Deputy Manager of Persian and Complementary Medicine, Ministry of Health and Medical Education, Islamic Republic of Iran

Saifulla Khalid Adamji, Coordinator in Charge, Traditional, Complementary and Alternative Medicine Unit, Department of Private Medical Licensing, Ministry of Health and Prevention, United Arab Emirates (Co-Chair: Unani subgroup)

Kalpanaben Ajoodhea, Senior Ayurvedic Medical Officer, Ministry of Health and Wellness, Mauritius

Sartaj Nafees Bano Ansari, Principal, Hakeem Syed Ziaul Hasan Government Unani Medical College, India

Sitesh C Bachar, Professor and Chair, Department of Pharmacy, University of Dhaka, Bangladesh

Jorge Luis Berra, Director, Fundacion de Salud Ayurveda Prema, Argentina (Rapporteur: Ayurveda subgroup)

Parthiv Bhatt, Professor and Head, Department of Swasthavritta, Government Ayurveda College, India

Santosh Bhatted, Associate Professor, Department of Panchakarma, All India Institute of Ayurveda, India

Buhari Mohammed Rishad, Senior Ayurveda Medical Officer, National Institute of Traditional Medicine (Siddha and Unani Division), Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka

Vijay Carolin, President, International Ayurveda Medical Association; and Chief Consultant, Kerala Ayurveda Institute Barcelona, Spain

Radhakrishnan Chandrasekharan, Director and Senior Ayurveda Physician, Kerala Ayur Wellness Centre, Malaysia

Chitane Mushtaq Ahamed, Professor and Head of the Department, Moalijat (Unani General Medicine), Government Unani Medical college, Chennai; and Chair, Board of Studies (Unani), Tamilnadu Dr MGR Medical University Chennai, India

Swapan Kumar Datta, Principal-cum-Superintendent (Incharge) and Head of Department, Ayurvedic Medicine, Government Unani and Ayurvedic Medical College and Hospital, Bangladesh

Jayant Deopujari, President, Central Council of Indian Medicine, India

Kartar Singh Dhiman, Director General, Central Council for Research in Ayurvedic Sciences, India

Stephen Yao Gbedema, Associate Professor and Head, Department of Pharmaceutics, Kwame Nkrumah University of Science and Technology, Ghana (Rapporteur: Unani subgroup)

Pradip Kumar Goswami, Director, North East Institute of Ayurveda and Homeopathy, India

Mujeeb Hoosen, Coordinator – Unani Tibb, School of Natural Medicine, Faculty of Community and Health Sciences, University of the Western Cape, South Africa (Rapporteur: Unani subgroup)

Simone Hunziker, Swiss Ayurvedic Medical Academy, Switzerland (Rapporteur: Ayurveda subgroup)

Raveendra Nathan Pillai Indusekhar, President, Ayurveda Practitioners Association of Singapore, Singapore

Syed Shakir Jamil, Department of Moalajat, School of Unani Medical Education and Research, India (Co-Chair: Unani subgroup)

Dinesh Katoch, Advisor, Ministry of AYUSH, India (Co-Chair: Ayurveda subgroup)

Asim Ali Khan, Director General, Central Council for Research in Unani Medicine, India

Shariq H Khan, Head of Department and Associate Professor of Unani Medicine, Department of Unani Medicine, Government Unani-Ayurvedic Medical College and Hospital, Bangladesh

Anupama Kizhakkeveettil, Southern California University of Health Sciences, United States of America

Mita Kotecha, Professor and Head, Department of Dravyaguna Vigyan, National Institute of Ayurveda, India

Paulo Peter Mhame, Assistant Director Responsible for Traditional Medicine, Ministry of Health, Community Development, Gender, Elderly and Children, United Republic of Tanzania

Antonio Morandi, Ayurvedic Point, Italy (Co-Chair: Ayurveda subgroup)

Manoj Nesari, Advisor, Ministry of AYUSH, India (Co-Chair: Panchakarma subgroup)

Tanuja Nesari, Director, All India Institute of Ayurveda, India

Valdis Pirags, Director, International Institute for Indic Studies and Professor of Medicine, University of Latvia, Latvia

Mukhtar Ahmad Qasmi, Joint Advisor, Unani Ministry of AYUSH, AYUSH Bhawan, India

Prasanna Narasimha Rao, Principal and Professor, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, India

Franz Rutz, Board Member, Swiss Regulatory Body of Alternative Medicine, Veda Center, Switzerland

Iftikhar Ahmed Saifi, Ibn Al Nafees Medical Clinic, United Arab Emirates

Revana Siddappa Sarashetti, Professor and AYUSH Chair, Peoples' Friendship University of Russia, Russian Federation

Sanjeev Sharma, Director, National Institute of Ayurveda, India

Viswanathan Pillai Shyam, Dr. Shyam's Ayurveda Centre, United Arab Emirates

Narayanam Srikanth, Deputy Director General, Central Council for Research in Ayurvedic Sciences, India

Elmar Stapelfeldt, Charité Outpatient Department and Research Center, Immanuel Clinic, Germany

Noushad Ali Thachaparamban, Chief Physician, Atreya Ayurveda, Russian Federation

Anup Kumar Thakar, Director, Institute for Post Graduate Teaching and Research in Ayurveda, India

Siddhartha Thakur, Senior Consultant (Ayurveda) Physician, Central Ayurveda Hospital, Nepal

Sunil Kumar Vijayagopal, Senior Researcher, Evangelisches Krankenhaus, Germany

Sivarama Prasad Vinjamury, Professor, Research, Southern California University of Health Sciences, United States of America (Rapporteur: Panchakarma subgroup)

Padmashree Dr Mohammed Abdul Waheed, former Officiating Director, Central Research Institute of Unani Medicine Hyderabad, Ministry of AYUSH, India

Tilakasiri Weerarathna, Deputy Director (Technical-Medical), Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka (Co-Chair: Panchakarma subgroup)

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Sungchol Kim, Regional Adviser, Traditional Medicine, WHO South-East Asia Regional Office, India

Geetha Krishnan Gopalakrishna Pillai, Technical Officer, Traditional, Complementary and Integrative Medicine Unit, WHO, Switzerland

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Staff of the International Cooperation Section of the Ministry of AYUSH, India