Introduction

Ayurveda is a traditional system of medicine using a wide range of modalities to create health and well-being. The primary aim of Ayurvedic health care is to restore the physical, mental and emotional balance in patients, thereby improving health, preventing disease and also treating any current illness.

In pursuit of helping patients to the best of one's ability, it is essential for every Ayurvedic practitioner to treat patients with respect, to cause no harm and to abide by current UK laws regarding the safe use and prescription of Ayurvedic remedies.

The APA Ayurvedic Pharmacopoeia Safety Document has been prepared by the APA Ayurvedic Pharmacopoeia Committee (APC) for the purpose of informing, educating and guiding all APA members on issues related to the safe and legal use of Ayurvedic remedies[1] in the UK. This document will be regularly reviewed and updated by the APC for the continuing guidance of practitioners as well as for the protection of their patients. It also serves to demonstrate to people outside the profession the high safety standards that APA members adhere to in their practice.

In the context of safety and authenticity in Ayurvedic practice the APA particularly:

- encourages adherence to the philosophy and principles of Ayurveda.
- promotes the use of safe, pure and correctly identified remedies.
- promotes the conservation of endangered species and the use of sustainably harvested herbal remedies. The future availability of many herbal remedies is an issue of great international concern, which demands an active involvement of all Ayurvedic practitioners in the protection of our environment. This is an area of ongoing work to be supported by the APA.

1. Ayurvedic Pharmacopoeia Committee (APC)

It is the responsibility of the APC to ensure that APA members are aware of current legislative, safety and conservation issues associated with the use of traditional Ayurvedic remedies in the UK. This awareness is essential for practitioners in order to practise Ayurveda in a way that is safe, sustainable and protective of the health of the public. In particular, members of the APA register are required to:

- take personal responsibility for practising Ayurveda in accordance with UK law in a safe fashion and professional manner.
- be aware of:
    i. known contraindications for using Ayurvedic remedies
    ii. traditional contraindications
    iii. herb-herb and drug-herb interactions
    iv. any toxicity issues concerning remedies from the Ayurvedic pharmacopoeia and understand appropriate dosage, purification and prescription methods.
- report any adverse reactions and inappropriate remedy usage via the Yellow Card Reporting Scheme.

[1] Although Ayurveda considers every substance (*dravya*) to have therapeutic properties and thus to be a potential remedy, in the context of this document the term "remedy" only refers to traditional single and compound substances that are mentioned in the pharmacopoeia of Ayurveda.

- understand that conservation of endangered species, the use of sustainably harvested herbs and the promotion of the health of the environment are of central importance to fulfilling the duties of an Ayurvedic practitioner.

The APC will therefore:

- keep members of the APA informed of all current legislative and conservation issues related to the safe, legal and sustainable use of Ayurvedic remedies.
- aspire to protect the Ayurvedic pharmacopoeia from misrepresentation and unsustainable use.
- promote research into the safe and effective use of Ayurvedic remedies.
- communicate with relevant government bodies regarding any legislation that affects the use of Ayurvedic remedies in the UK.
- collate accurate scientific documentation on the safety of Ayurvedic remedies in order to protect the Ayurvedic pharmacopoeia and to uphold the access to safe and effective remedies for practitioners.
- be responsible for managing a Yellow Card Reporting Scheme for members to report any adverse reactions.

2. Safety

Safety relates to the protection of the public and patients from any potential harm. In this context it is essential that APA members are aware of any potential unwanted reactions that may occur in prescribing Ayurvedic remedies. An 'unwanted reaction' is any undesired effect due to the administration of any remedy.

Reasons and causes for unwanted reactions include:

- contaminated products, which are unfit for use due to either microbiological or heavy metal contamination, pesticide residues, insect contamination or the presence of mycotoxins.
- toxic compounds, which can be found in certain remedies due to incorrect species identification or insufficient purification procedures of ingredients.
- adverse reactions due to incorrect dosage, idiosyncratic reactions, allergies or adverse drug-herb interactions.
- inappropriate prescriptions (e.g. prescribing hot and pungent remedies in a case of acidity or *amlapitta*).

In order to avoid the above, it is essential for Ayurvedic practitioners to:

- use remedies that come from a known source and a reliable supplier with an external audit system that guarantees correct species identification and implementation of appropriate purification procedures.
- use remedies that are produced with the help of an effective quality control management system that ensures batch traceability, species identification, testing, hygienic storage and safe distribution.
- understand the process of metabolism of Ayurvedic remedies in the body.
- be familiar with the current data and evidence regarding contraindications and drug-herb interactions.
- prescribe in accordance with the Ayurvedic principles of *dravyaguna vigyana.*

APA members are advised to buy Ayurvedic remedies only from suppliers that have auditable quality control management systems in place. The APA has introduced an audited Approved Supplier Scheme, so that members are informed about reliable suppliers that provide remedies according to high quality and safety standards.

In the interest of patient safety, the APA highly recommends that practitioners ask, and record in writing, at every initial consultation whether a patient has ever had hepatitis, liver problems or kidney infections. Clear information about the medical history of these organs is essential, since medicinal metabolites pass through these detoxifying organs and can affect their physiology. These organs are most frequently implicated in adverse reactions.

The use of liver function tests may be advisable in patients with psoriasis, a history of hepatitis, raised liver enzymes or alcohol/drug problems. These patients should be referred to their GP for a liver function test.

The APA further recommends that practitioners give written advice to their patients that any signs of nausea, diarrhoea, distaste for food or alcohol, severe tiredness, upper abdominal or hypochondriac pain, jaundice or a general feeling of being unwell should be reported in person to the practitioner. These symptoms may indicate toxic reactions that require immediate attention, such as suspending the use of remedies or appropriate medical intervention.

3. Restrictions for Ayurvedic Remedies in the UK

Although Ayurvedic remedies have generally a very low incidence rate of toxicity, some of them are powerful medicines and can, if used inappropriately, be potentially harmful. Certain remedies are restricted for use under UK medicines laws: they are either banned, restricted for use by a pharmacist only, under voluntary suspension, or permitted only when strict dosage guidelines are adhered to. The website of the Medicines and Healthcare products Regulatory Agency (MHRA) contains further information as well as regular updates on these issues (see below 6.2. Contacts).

3.1. The Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 SI 2130 – Part I

The sale and supply (including general retail or following a one-to-one consultation with a practitioner) of any Ayurvedic remedy is prohibited by The Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 SI 2130 Part I, if it contains one or more of the following herbal ingredients, which may only be sold in premises that are a registered pharmacy and by, or under the supervision of, a pharmacist.

Common Name	**Latin Name**	**Ayurvedic Name**
Areca	*Areca catechu*	Betel nut, *Supari*, *Pooga*
Embelia	*Embelia ribes, E. robusta*	*Vidanga*
Holarrhena	*Holarrhena antidysenterica*	*Kutaj*
Pomegranate (bark)	*Punica granatum*	*Anar twak*

For a complete list of ingredients restricted by this order, please refer to the annex sections in *Traditional Ethnic Medicines: Public Health and Compliance with Medicines Law*. This is a guidance document published by the MCA (now MHRA) in November 2001 and available from the downloadable area of the APA website www.apa.uk.com.

3.2. The Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 SI 2130 – Part II & III

Ayurvedic remedies containing herbal ingredients listed in Part II of SI 2130 can only be sold following a one-to-one consultation with a practitioner, and only at the dosages and by the route of administration specified in Part III. If the dosage specified is exceeded, or if the route of administration differs from that specified, the

remedies containing these plants can only be supplied in premises that are registered pharmacies and by, or under the supervision of, a pharmacist.

Note: % applies where the ingredient is for external use only
MD = maximum dose
MDD = maximum daily dose

Aconite (*Visha* in Ayurveda) – 1.3% of formula (for external use only)

- *Aconitum napellus*
- *Aconitum stoerkianum*
- *Aconitum uncinatum var japonicum*
- *Aconitum deinorrhizum*
- *Aconitum balfourii*
- *Aconitum chasmanthum*
- *Aconitum spicatum*
- *Aconitum lycoctonum*

Belladonna (*Angurshapha* in Ayurveda) – Herb: 50 mg (MD), 150 mg (MDD)
Root: 30 mg (MD), 90 mg (MDD)

- *Atropa belladonna*
- *Atropa acuminata*

Cinchona bark (*Sinkona* in Ayurveda) – 250 mg (MD), 750 mg (MDD)

- *Cinchona calisaya*
- *Cinchona ledgerana*
- *Cinchona officinalis*
- *Cinchona succirubra*
- *Cinchona micrantha*

Ephedra (*Somalata* in Ayurveda) - 600 mg (MD), 1800mg (MDD)

- *Ephedra sinica*
- *Ephedra equisetina*
- *Ephedra distachya*
- *Ephedra intermedia*
- *Ephedra gerardiana*

Hyoscyamus (*Parasikava* in Ayurveda) - 100 mg (MD), 300 mg (MDD)

- *Hyoscyamus niger*
- *Hyoscyamus albus*
- *Hyoscyamus muticus*

Stramonium (*Dhattura* in Ayurveda) - 50mg (MD), 150 mg (MDD)

- *Datura stramonium*
- *Datura innoxia*

For a complete list of ingredients restricted by this order, please refer to the annex sections in *Traditional Ethnic Medicines: Public Health and Compliance with Medicines Law*. This is a guidance document published by the MCA (now MHRA) in November 2001 and available from the downloadable area of the APA website www.apa.uk.com.

3.3. The Prescription Only Medicines (Human Use) Order 1997 SI 1830

Ayurvedic remedies containing ingredients listed under SI 1830 are prescription only medicines (POMs), and can only be made available via a prescription from a registered doctor or dentist.

Common Name	Latin Name	Ayurvedic Name
Rauwolfia	*Rauwolfia serpentina*	*Sarpagandha*
Poppy (capsule)	*Papaver somnifera*	*Ahiphena*
Nux vomica (seeds)	*Strychnos nux-vomica*	*Karaskara* or *Kupilu*

For a complete list of ingredients restricted by this order, please refer to the annex sections in *Traditional Ethnic Medicines: Public Health and Compliance with Medicines Law*. This is a guidance document published by the MCA (now MHRA) in November 2001 and available from the downloadable area of the APA website www.apa.uk.com.

3.4. The Medicines (Prohibition) Order 2001 SI 1841

Aristolochia species and all herbs that may be confused with *Aristolochia* species are banned under The Medicines (Prohibition) Order 2001 SI 1841. This ban also applies to *Aristolochia indica* (*Ishwari*), which is used in Ayurveda.

For a complete list of ingredients restricted by this order, please refer to the annex sections in *Traditional Ethnic Medicines: Public Health and Compliance with Medicines Law*. This is a guidance document published by the MCA (now MHRA) in November 2001 and available from the downloadable area of the APA website www.apa.uk.com.

3.5. Voluntary Restriction

Due to the presence of photosensitivity-inducing furanocoumarins in *Bakuchi* (*Psoralea corylifolia*), which may cause skin sensitivities in those undergoing light therapy (e.g. PUVA), the use of *Psoralea corylifolia* has been voluntarily restricted by the EHPA to internal use only; i.e. it is not to be applied externally.

3.6. Non-Herbal Ingredients

Traditional Ayurvedic medicine has a long and safe history of using non-herbal ingredients (animal products, minerals and metals). However, at present, the exemption from licensing accorded to herbal products under Section 12 of the Medicines Act 1968 **does not** encompass non-herbal active ingredients. Only inert substances such as water are allowed**.**

The APA **strongly advises** all Ayurvedic practitioners to abide by the current UK medicine legislation and to practice within this law.

4. Conservation

4.1. Sustainability

The APA strongly encourages its members to ensure that the remedies they use are from sustainable sources. In accordance with Ayurvedic teachings, it is incumbent on members to respect and protect the natural environment. The present burden that human populations put on natural resources threatens the future existence of many herb species and also of remedies from animal and mineral sources. As Ayurveda grows in popularity, so too does the number of companies that try to cater to the increasing demands for Ayurvedic products. Unfortunately, many companies have little respect for the protection of our environment. For example, 90% of all herbal remedies in India are at present unsustainably collected from the wild. Ayurvedic practitioners therefore have a duty to source their remedies from companies that supply sustainably grown and harvested ingredients, and should always demand proof of sustainability from manufacturers. It is essential for practitioners to dispense remedies with an awareness of their traceability and source.

It is also important to remember that certain remedies traditionally used in Ayurveda take a long time to grow and should therefore be used with great caution. *Chandan* or Sandalwood (*Santalum album*) is a good example: it should only be obtained from a Government of India approved source and practitioners should restrict its use to exceptional cases.

4.2. Convention on International Trade in Endangered Species (CITES)

The Convention on International Trade in Endangered Species (CITES) lists the flora and fauna that are regulated for trade. This convention stipulates that all member countries (UK, India and Sri Lanka are signatories) must only trade internationally in the listed species with official documentation.

CITES divides species into three categories:

- **CITES Appendix I** includes species that are threatened with extinction. Trade in specimens of these species is permitted only in exceptional circumstances. Examples for Ayurvedic remedies included here are *Secreto moschus* (*Kasturi*) and *Sausserea lappa* (*Kushtha*).
- **CITES Appendix II** includes species that are not necessarily threatened with extinction, but in which trade must be controlled in order to avoid utilization incompatible with their survival. Trade is often accepted if specimens are from verifiable cultivated sources. Examples for Ayurvedic remedies included in this category are *Podophyllum emodii* (*Laghu patra*), *Pterocarpus santalinus* (Red Sandalwood or *Rakta chandana*) and *Rauwolfia serpentina* (*Sarpagandha*).
- **CITES Appendix III** contains species protected in at least one country, which has asked other CITES parties for assistance in controlling the trade. Examples for Ayurvedic remedies included in this category are: *Nardostachys jatamansi* or *grandiflora* (*Jatamansi*) and *Picrorhiza kurroa* (*Katuka*).

5. Adverse Reactions

It is the responsibility of every Ayurvedic practitioner to use the national Yellow Card Scheme in order to ensure that clusters of unwanted patient responses are correctly monitored and reported. Any adverse reaction must be reported to the APC by using an APA Yellow Card Adverse Event Reporting Form (available from the APA website). Please note that using this form for reports is an essential part of pharmacovigilance and in no way represents a judgment of practitioners or their prescriptions. It is a method used to assess product quality and to identify adulterated or contaminated batches of remedies.

6. Appendix

6.1. Quality Control

Quality control is important in all aspects of herbal medicine harvesting, processing and manufacturing. The prime points of consideration are sustainability, efficacy and safety. These were abundantly clear to early Ayurvedic practitioners and various Ayurvedic texts make references to the nature of ideal medicinal collection:

“The herbs should be gathered on a good day by someone in a good state of mind who is clean, facing the sun, silent and who has paid homage in his heart to the god Shiva. When collecting from normal land, one should choose one’s ingredients from

the higher ground. Medicinal herbs which grow on termite hills, in dirty places, in bogs, in cemeteries, salty ground, or on the streets, are not effective. Nor are those which have been affected by parasites, fire or frost." *Sharngadhara Samhita* 1.56-58

Herbal medicine is currently being legislated by governments all over the world in an attempt to raise the quality of production standards. The World Health Organisation (WHO) has set standards on quality control methods for medicinal plants, and also individual nations have set legal standards for herbal medicine production, like Good Manufacturing Practice (GMP) with standards similar to those in the pharmaceutical industry. GMP is a system that includes assurances, procedures and checks to assess the quality and purity of products in order to ensure that only appropriately safe and effective remedies are released for therapeutic purposes.

The important points are:

- Appropriate botanical identification in the field to ensure correct species.
- Sustainability of harvesting practices.
- Correct harvesting times to maximise active ingredients.
- Correct drying to optimise vitality and maximise marker compound ingredients.
- Validiation of storage facilities, equipment and processes.
- An effective quality control management system.
- Standard operating procedures (SOP) in place for every process of storage, quarantine, manufacture, batch identification, batch traceability, stability testing, releasing products, recording complaints and recall procedures.
- Correct species identification and quality determination using pharmacopoeial recommendations including macroscopic analysis, microscopic analysis, tests for foreign matter and moisture content, ash tests, thin layer chromatography (TLC), gas chromatography (GC) or high performance liquid chromatography (HPLC).
- Organoleptic tests to ensure the 'feel' is correct; visual identity, colour, smell, friability.
- Microbiological analysis.
- Heavy metal and pesticide analysis.
- Marker compound testing.
- Appropriate analysis of the above information to ensure that the intended product is released in a consistent and repeatable form.

6.2. Contacts for Further Information

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Medicines and Healthcare products Regulatory Agency (MHRA)
Web: www.mhra.gov.uk

Conservation Info
Web: www.cites.org
www.traffic.org