INTRODUCTION

The following standards are a guide for suppliers of Ayurvedic products and will be used for the assessment of suppliers. Those suppliers who meet or are endeavouring to meet the standards below will be designated by the APA as Approved Suppliers (Full or Provisional). As a voluntary and self-regulating body, the APA establishes this scheme to ensure that APA members, the public and the MHRA can have improved confidence in the Ayurvedic products supply chain.

The APA will work closely with suppliers to assist in achieving the required standards outlined in this document. At the same time it should be noted that:

- matters in addition to those set out below may be raised during an audit of a supplier.
- these standards will require revision in order to reflect any changes in EU or UK law. This is especially relevant, as Section 12.1 of the UK Medicines Act 1968 is to be amended in line with the proposed statutory regulation of practitioners supplying unlicensed herbal remedies.

1. PERSONNEL

Companies are expected to work towards the establishment of a sufficient number of appropriately educated, experienced and trained staff, with well-defined job descriptions, training and objectives, so that they can competently perform the tasks required. Performance and training should be reviewed annually and documented.

An APA-approved supplier is expected to employ a designated person dealing with Quality Assurance issues. This Quality Assurance manager should be suitably trained for the job and demonstrate an ability to produce standards of manufacture on all products sold by the supplier. The supplier is also expected to provide an on-going programme for updating information relating to the latest Quality Assurance requirements.

2. THE PREMISES

- Hygiene of the premises used to store and manufacture Ayurvedic remedies (see Appendix 1).
- Storage of products (temperature/humidity monitoring and recording).

Premises and equipment should be located, designed and constructed to suit their intended purposes. Suppliers should make provisions for storage and Quality Control areas as well as the appropriate location of refreshments, maintenance and office areas, none of which should affect product quality.

Good Manufacturing Practice should be followed in all cleaning procedures and house keeping practices to ensure that materials and products remain free from contamination. Storage and distribution conditions must be such that the growth and multiplication of pathogenic or spoilage micro-organisms is not likely. All companies must have adequate and demonstrable pest control at their facilities. Records of pest control checks must be available for inspection.

Requirements for suppliers undertaking manufacturing will be subject to additional documentation.

3. LABELLING OF PRODUCT

- All products should include batch number and best-before date.
- All products should include the common Ayurvedic and the botanical name.
- All products should contain a full list of excipients where used.
- All material should include the name and contact details of the supplier.
- All organic claims must be verified with appropriate organic certification.
- Warning should be included, if the product is for external use only.
- Breaking bulk: all the above information must be transferred to material that is broken down into smaller batches and/or mixed with other batches.

4. AUTHENTICATION

The APA would expect:

- Suppliers to be able to demonstrate an ability to conform to current Quality Assurance requirements in the UK.
- Approved suppliers to adhere to the APA Pharmacopoeia Safety Document, which details scheduled substances, forbidden substances, herbs under voluntary ban and international CITES regulations.
- Authentication of ingredients as raw ingredients or within finished products. It is acceptable, if this information comes from suppliers and/or third party laboratories. However, the APA prefers and strongly recommends that this information is obtained by the UK supplier from within the EU.
- The utilisation of a pharmacognocist or appropriately qualified person to oversee herbal authentication.

5. RECORD KEEPING

For the operation of the APA Yellow Card scheme it is necessary that the following information is recorded. Documentation of this should be retained.

- Continuity of batch numbers between import, manufacture and sale.
- Prescription records where offering a dispensary service. The APA must be informed, if the supplier provides a dispensary service and the appropriate quality requirements should be demonstrated.

Good documentation practice constitutes an essential part of a Quality Management System. In particular suppliers should have:

- A written procedure for the systematic control of all quality-related documents, such as Quality Manuals and Standard Operating Procedures.
- Documentation for all processes, which have an effect on the quality of their products, including a written procedure for regular review and updating of all GMP documentation, with prompt removal of all obsolete documents and easy access to the current version of a document.
- Approval of all documents by the relevant Technical Management and Quality personnel. Documents should be written in a way that makes them easy to understand. Good documentation design will help to minimise errors. Informal, handwritten instructions should be avoided.

- In the event of correction to formal documentation, all hand-written corrections should be signed and dated. The use of correction fluids is unacceptable. Changes to documents should follow written procedures.
- Adequate protection of all records from damage (water, microbial and fire).
- Retention of master, original documentation and batch documents by the supplier for a minimum of seven (7) years.

6. COMPLAINTS AND RECALL PROCEDURES

Approved suppliers are expected to have:

- A formal, documented complaints system, with a person designated to operate it. Product complaints must be handled swiftly and brought to the attention of the Quality Manager / Responsible Person.
- The ability to resolve a complaint by ensuring that the root cause(s) are identified and that measures are taken to prevent a recurrence of the defect.
- A documented procedure to allow the recall of batches that are discovered after distribution to be faulty, with retention of full distribution lists for any materials and products.

7. CONTRACT MANUFACTURE AND ANALYSIS

The APA recognises that contract manufacture plays a large role in the production and distribution of Ayurvedic remedies. It is especially important that a UK supplier can provide detailed information from suppliers abroad regarding their Quality Assurance and Quality System.

Some suppliers contract out the manufacture and analysis of products they supply. However, responsibility for the product may not be contracted out and suppliers should satisfy themselves that third party contractors also fulfil the requirements of EU Quality Assurance as outlined in this document.

Suppliers must establish that contractors have the necessary premises, equipment and staff. An appropriate and up-to-date supplier questionnaire should be available for inspection.

Suppliers should establish written permission to perform their own customer audit.

Supplier audits should be carried out on an annual basis.

8. SELF INSPECTION & AUDITS

A formal self inspection system should be established and followed to verify that the company's Quality System is effective. This should be based on weekly, monthly and annual checks.

Independent external audits should be expected in order to demonstrate adherence to internal procedures and GMP.

HACCP is a legal requirement in the UK for all food distribution companies. A Manufacturing Licence will be required by manufacturers by around 2011 and a Warehouse and Distribution (and/or Importers) Licence will be required by around 2011. For the immediate future it is satisfactory for compliance with the APA Approved Supplier Scheme that companies are working towards these requirements.

9. CONTAMINATION CONTROL

Premises where products are exposed to the environment shall be sited, constructed, maintained and operated in such a way as to minimise contamination and permit effective cleaning.

Effective measures shall be taken to prevent the entry of rodents, insects and other undesirable animal life into the product and areas where the product is exposed to the environment.

Environmental standards and conditions should be established in-house and recorded in log books. Where the product is exposed to the environment, any ventilation or air extraction systems used shall not introduce contamination.

10. INSPECTION AND TEST STATUS

Certificates of analysis in accordance with the Guide to GMP 2002 should be available where required.

The APA requires that all raw materials and finished goods tests should be carried out in the EU.

11. TRAINING

There should be an effective mechanism for identifying training needs and taking appropriate action to ensure all personnel (including temporary staff and Managers) are appropriately qualified and adequately trained:

- Qualification and training needs should be identified and documented and regularly reviewed.
- GMP awareness training should be repeated at prescribed intervals for all relevant personnel.
- Training records are GMP documentation and should be retained.
- Tasks should be assigned on the basis of qualification, training and experience.

12. CORRECTIVE AND PREVENTATIVE ACTION

Cause(s) of actual or potential non-conformance in products, processes or the quality system itself should be identified and eliminated. Action should be appropriate to the severity of the non-conformance. Changes resulting from corrective and preventative action should be documented and adequately controlled.

Corrective action is intended to both rectify an existing non-conformance and avoid a recurrence. Corrective action may arise from customer complaints, audit findings, management reviews and other situations where non-conformance is likely to be identified. All customer complaints should be recorded, promptly investigated and reported in accordance with a written approved procedure. In the event of a serious and potentially life threatening situation, (local and national) authorities should be informed and their advice sought.

Preventative action is intended to avoid the initial occurrence of a non-conformance.

13. HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

Loss or damage or deterioration should be prevented during the handling, storage, packaging and preservation of material from receipt through to despatch and, if appropriate, delivery to the customer. The application of relevant procedures should be adequately controlled and monitored.

Incoming materials should not be mixed with existing stocks and have to be stored in a designated quarantine area until they have been inspected and tested.

Weighing or subdivision of material prior to use should be performed in a designated appropriate area to minimise the risk of cross contamination.

All materials should be handled in an environment giving adequate protection against contamination. Adequate protection for employees should be given.

Secure storage facilities should be designated for use to prevent deterioration or damage of materials. These facilities should be kept clean and tidy and subject to appropriate pest control measures.

Receipt into, and despatch from, storage should be authorised and recorded. The principles of "First in, first out" (FIFO) or "First expired, first out" (FEFO) are recommended.

The condition of stored material should be assessed at appropriate intervals. Storage conditions for herbs and herb products, if possible, should be based upon stability studies taking into account time, temperature and humidity.

Storage procedures should ensure segregation of materials to avoid occurrence of mix-ups. Materials that have been rejected, recalled or returned, should be physically segregated from other stock until their final disposition has been determined.

Labelling and packaging processes should be defined and controlled to ensure that correct packaging materials are used correctly. Printed labels should be securely stored to avoid mix-ups. Marking and labelling should be legible and durable, provide sufficient information for accurate identification and indicate, if appropriate, required storage conditions and expiry date.

Precautions should be taken to ensure that herbs and herb products are adequately preserved and that materials used for preservation are in line with current EU guidelines.

Records of distribution should be maintained so that, if necessary, users can be readily contacted.

14. CONTROL OF QUALITY RECORDS

Quality records are documents, which provide objective evidence for the effective operation of the Quality system. It is important that records are correctly identified, suitably stored and available when required.

Quality records may include, but are not limited to, the following:

- Audit reports
- Cleaning records
- Calibration certificates

- Training records
- Batch and analytical records
- Complaints records
- Change control documentation
- Test records

15. INFORMATION AND DOCUMENTATION

All information and documentation should be kept up-to-date. Suppliers should have a procedure relating to the up-keep of documentation, and a member of staff should be trained in good documentation practice and be made responsible for this. Apart from keeping quality-related documentation current, all information in catalogues and on the company web-site should be regularly updated and maintained accurate.

16. CHANGE CONTROL

It is essential that a company establishes a system for controlling change. This may include a change of suppliers, of premises or of working practices and procedures. Usually, a change is made within a company for reasons of improving quality, but it can have opposite effects. For this reason a procedure for managing change within a company should be introduced and the reasoning for significant change documented. Changes can then be reviewed and their impact on quality assessed objectively.

17. CONTROL OF RAW MATERIALS

Companies should establish an auditable supply trail for their raw material supply. Documentation of Good Agricultural and Collection Practices (GACP) should also be maintained.

18. REFERENCES

All suppliers are expected to have knowledge of the contents and stipulations of the following documents from the Medicines and Healthcare products Regulatory Agency (MHRA) and The European Medicines Agency (EMEA).

1. *Traditional Ethnic Medicines: Public Health and Compliance with Medicines Law*. MHRA 2001.
2. *Review of Herbal Ingredients for Use in Unlicensed Herbal Medicinal Products*. MHRA 2001.
3. *Guideline on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Products*. EMEA 2006.
4. *Notes for Guidance on Specifications: Test procedures and Acceptance Criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/ Traditional Medicinal Products*. EMEA 2005.
5. *Rules and Guidance for Pharmaceutical Manufacturers and Distributors*. MHRA 2002.
6. *Consultation Papers on the Reforms of S12(1)*. MHRA 2007.

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APPENDIX 1

HYGIENE of the premises used to store and manufacture Ayurvedic remedies:

- Direct contact with raw herbs and herbal products should be avoided.
- Clothing should be designed to protect both product and personnel. Clothing should be clean and changed when necessary.
- Personnel suffering from an infectious disease or having open lesions on the exposed surface of the body should avoid activities, which could compromise the quality of the product.
- Smoking, drinking, eating, chewing and storage of food should be restricted to designated areas separate from the Storage, Handling and Dispensing areas.
- Changing, washing, toilet and refreshment rooms should be separate from Storage, Handling and Dispensing areas.
- Areas used to store, or control raw herbs, herb products and packaging materials should be kept clean and tidy.
- Sanitation or disinfection agents and their usage should be specified.
- Product contact surfaces should be easily cleanable.
- Surfaces and equipment should be protected from recontamination and checked for cleanliness before use.