

## **European Herbal and Traditional Medicine Practitioners Association (EHTPA)**

### **STANDARDS OF DISPENSARY PRACTICE FOR EDUCATIONAL INSTITUTIONS OFFERING PROGRAMMES IN TRADITIONAL AND HERBAL MEDICINE**

#### **OVERVIEW AND INTRODUCTION**

These Standards have been approved by the EHTPA Education Committee following consultation with member Professional Associations for use by all Educational Institutions<sup>1</sup> whose courses have been accredited by the EHTPA.

The Standards are based on current best practice. To maintain currency the Standards will be reviewed regularly, in the first instance during 2011.

The Education Committee requires Institutions to self-assess their Dispensary Practice against these Standards and to complete the Self-assessment Audit Record (SAR) at least annually. As part of the EHTPA Accreditation Board's accreditation, annual review and renewal of accreditation process, Panels will sample the institution's SAR to ensure that its Dispensary Practice satisfies these standards.

The Education Committee expects institutions to have met all of the standards. Should an institution not have met a standard by the time of the self assessment, an action plan must be developed to demonstrate how the standard will be met no later than one month after the self assessment. The action plan will be included in the EHTPA Accreditation Board's sampling process.

It should be noted that:

- (a) Matters in addition to those set out below may be raised during an EHTPA visit to an institution.
- (b) The standards will require annual revision by the Education Committee in order to reflect any changes or developments in professional body requirements and to comply with any changes in EC or UK law or any statutory regulations.
- (c) Advice or guidance on the standards is given in parentheses.

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<sup>1</sup> For convenience, throughout the text the term 'Institutions' refers to '*Educational* Institutions'.

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## 1.0 PERSONNEL

Institutions have a sufficient number of competent dispensary/clinical staff, with job descriptions and training records. Performance and training are reviewed annually and records of these reviews are retained for 7 years.

## 2.0 PREMISES

This includes the:

- Premises and equipment
- Hygiene of premises and Dispensary
- Storage of herb products

Good Manufacturing Practice (GMP)<sup>2</sup> is followed in all matters relating to the premises, cleaning procedures and house keeping practices to ensure that herb materials and products remain free from foreign matter.

The premises and equipment are:

- a) Located, designed and constructed to suit their intended purpose and
- b) Environmental standards and conditions of temperature and humidity are monitored and recorded regularly.

### *Hygiene*

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

*Storage and dispensing conditions* are such that:

- a) the growth and multiplication of pathogenic or spoilage micro-organisms are minimised  
and
- b) There is adequate and demonstrable pest control in all relevant parts of the institution.

## 3.0 LABELLING OF PRODUCT

- All herb products include batch number and best-before date.
- Where appropriate, all herb products include the botanical name and, with the part of the plant used, e.g. *Paeonia lactiflora* (root)
- All herb material includes the name and contact details of the supplier

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<sup>2</sup> GMP guidance can be found in MHRA 'The Orange Guide', Rules and Guidance for Pharmaceutical Manufacturers and Distributors, 2002.

- A warning is included if for External use only.
- Breaking bulk: all the above information is transferred to material removed from the original supply or a record of this information is available, that is, the correct information is on the dispensing container.

#### **4.0 AUTHENTICATION**

The institution:

- Assesses the authentication of the incoming herb material by visual inspection and other appropriate organoleptic tests.
- Has an appropriately trained member of staff to oversee this inspection.
- Adheres to the Codes of Practice on Scheduled Herbs.

#### **5.0 DISPENSARY SERVICE**

Institutions offering a Dispensary Service to patients should fulfil the Dispensary Requirements expected by the appropriate Professional Association(s). In summary this should include but is not restricted to the following:

- Prescription forms. (These should be in a standardised form. They are not only a precise record of the prescription but could be a legal document in the case of an insurance claim.)
- Herb audit information, including changes in batches during prescriptions.
- A Prescription order number for future reference.
- Labelling on herb batches sent to patients that includes Name and Address of institution/Prescription order Number/ Date. The documentation relating to traceability is retained for 7 years. (Traceability is necessary for all herbal prescriptions undertaken by the institution's dispensary.)
- Appropriate Dispensary techniques according to the herbal tradition.
- Appropriate training of Dispensary staff.

#### **6.0 RECORD KEEPING**

##### **6.1 Control of quality records**

- Records can be paper or electronic or both.
- Quality records include, but are not limited to:
  - Audit reports
  - Calibration certificates (eg for balances)
  - Change control documentation
  - Complaints records
  - Investigation reports
  - Training records
  - Self -assessment Audit Records (SARs)
- Quality records are correctly identified, suitably stored and readily available.

##### **6.2 Information and Documentation**

Institutions follow good documentation practice:

- Documentation exists for all processes which have an effect on the quality of herbs and herb products, including a written procedure for regular review and updating of all documentation.
- All procedures are approved by the relevant member of staff.
- All information and documentation is up to date and current.
- The institution has a procedure for maintaining the currency of its documentation.
- At least one member of staff is responsible for document control.
- All hand-written corrections are signed and dated.
- Adequate protection of all records from water, microbial and fire damage
- A Herb Audit trail is in place that
  - a) records continuity of batch numbers between receipt and dispensing,
  - b) has prescription records.
  - c) retains this documentation for 7 years.
- A Yellow Card warning system is in operation.

## **7.0 COMPLAINTS AND RECALL PROCEDURES**

Institutions have documented complaints and product recall procedures.

## **8.0 TRAINING**

There is an effective mechanism for identifying training needs and taking appropriate action to ensure that all staff are appropriately qualified and adequately trained.

- Qualification and training needs are identified, documented and regularly reviewed.
- Dispensary training is repeated at prescribed intervals for all relevant personnel.
- Training records are maintained in accordance with GMP documentation requirements and must be retained for 7 years.

## **9.0 CORRECTIVE AND PREVENTATIVE ACTION**

The causes of actual and potential non-conformance in the quality system are identified and eliminated. Action is appropriate to the severity of the non-conformance. Changes resulting from corrective and/ or preventative action are documented and the records are retained for 7 years.

## **10.0 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY.**

Loss or damage or deterioration are prevented during the handling, storage, packaging and preservation of material from receipt through to dispensing.

In particular:

- Incoming herbs are not mixed with existing stocks until they have been inspected.
- Herbs and herb products are handled in an environment giving adequate protection against contamination.
- Secure storage facilities are designated for use to prevent damage or deterioration of materials. These are kept clean and tidy and subject to appropriate pest control measures.

- Receipts into and despatches from storage are authorised and recorded, using either the “First in First out” (FIFO) or “First Expired, First Out” (FEFO) method.
- The condition of stored material is assessed for any degradation at appropriate intervals.
- Storage procedures ensure segregation of materials.
- Materials which have been rejected, recalled or returned are physically segregated from other stock until their final disposition has been determined.
- Herbs used solely for the purpose of teaching are identified and segregated from the stock used for dispensing.
- Marking and labelling are legible and durable, provide sufficient information for accurate identification and indicate, if appropriate, required storage conditions and expiry date.
- Tracking records of dispensed items are maintained for 7 years so that, if necessary, users can be contacted.

### **11.0 CHANGE CONTROL**

The institution has established a system for controlling change. (This may include change of suppliers, change of working practices and procedures, change of premises. Often a change is made for reasons of improving quality but can have the opposite effect. Therefore, there is a need a procedure for managing change within the institution, including a record of the reasons for the change.)

### **12.0 COMMUNICATIONS**

The institution has a means of communicating effectively with:

- Its supply companies. (For continuing quality assurance and quality enhancement purposes.)
- The professional associations and regulatory bodies (To ensure that it is informed of current directives and developments.)

### **13.0 REFERENCE MATERIAL**

Copies of the following are available either in hard copy or electronically.

1. MHRA, Medicines Act, section 12, (1),(2) 1968.
2. MHRA, Safety of herbal medicinal products, 2002.
3. MHRA, ‘The Orange Guide’, Rules and Guidance for Pharmaceutical Manufacturers and Distributors, 2002.
4. MHRA, The reforms of section 12.1 of the medicines act 1968. 2007.
5. Professional body guidelines on adverse reactions/ yellow card reporting, no date.
6. Professional body guidelines on drug-herb interactions 2006.
7. NIMH, National Professional Standards in Herbal Medicine: Unit HM3 - Dispense herbal medicines and products, 2003 or RCHM, Dispensary guidelines, 2002.