

## UNLICENSED HERBAL REMEDIES

### Definitions

Words and phrases appearing in italics shall be defined according to the meaning ascribed to them by the Medicines Act 1968, and, in the case of the term 'Herbal Practitioner', shall be defined as any person who sells, supplies, manufactures or assembles an unlicensed *Herbal Remedy* in the course of a business in compliance with the conditions prescribed by section 12 (1) (a) and (b) of that act.

### Member's Declaration

The member agrees to uphold the objects, standards and requirements prescribed by this Code of Good Practice and to cooperate with the British Herbal Medicine Association (B.H.M.A.) and the United Kingdom Medicines Control Agency (M.C.A.) in regulating and promoting compliance with the Code and relevant United Kingdom and European legislation and regulations governing unlicensed *Herbal Remedies*.

### Object

To promote the safety and efficacy of unlicensed *Herbal Remedies* by prescribing a clear framework of Good Practice within the United Kingdom and applicable European legislation with the object of protecting the health and well being of the patient/customer when choosing an unlicensed *Herbal Remedy*.

### Raw Materials

- 1 The use of all ingredients excluding excipients used in the manufacture of an unlicensed *Herbal Remedy* shall, in so far as such ingredients appear, comply with the status and category prescribed by the provisions of the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order 1984, as amended and the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 and all other regulations, restrictions or requirements as may from time to time be applicable to the use of such ingredients.
- 2 All ingredients excluding excipients used in the manufacture of an unlicensed *Herbal Remedy* shall conform to the standards prescribed in the relevant sections of the publications referred to in Schedule I.

### Manufacture

- 3 All procedures followed and processes used in the manufacture of an unlicensed *Herbal Remedy* shall, save in the case of those prepared by herbal practitioner, conform to the standards recommended by Her Majesty's Government (HMG) publication 'A Guide to Good Manufacturing Practice' or such other HMG publication as may from time to time replace or amend the same.
- 4 The substances referred to in Schedule II shall not be included as ingredients in the manufacture of any unlicensed *Herbal Remedy*.

### Labelling

- 5 The *labelling* of all *containers* and *packages* used in the storage of unlicensed *Herbal Remedies* for the purpose of marketing, sale or other provision to the public shall comply with all relevant regulations made pursuant to section 85(1) Medicines Act and, where appropriate with other provisions of that act and pursuant regulations regarding the inclusion of *appropriate quantitative particulars* and, in any event, with EC Directive (92/27 EC).

### Quality Defects & Adverse Reactions

- 6 Any member who suspects an unlicensed *Herbal Remedy* of being defective, either as a result of its qualitative standards or as a result of an adverse reaction suffered by a patient/customer, shall report full details of the defect to the B.H.M.A. who may, at their discretion pass the report to the Defect Medicines Reporting Centre or the Adverse Reaction/Pharmacovigilance Group in the M.C.A.
- 7 Members shall respond promptly and responsibly to any warnings issued by either the B.H.M.A. or the M.C.A. concerning the quality or safety of any unlicensed Herbal remedy products.

### Enforcement

- 8 The regulation of this Code of Good Practice shall be the responsibility of the B.H.M.A. who will work with the support and cooperation of the M.C.A.

## CODE OF GOOD PRACTICE

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### Schedule I

#### Publications

*The European Pharmacopoeia*

*The British Pharmacopoeia/Compendia*

*The British Herbal Pharmacopoeia*

*The Chinese Pharmacopoeia*

### Schedule II

#### Prohibited Substances

*Heavy metals or their chemical derivatives*

*Synthetic medicinal substances*

*Substances derived from endangered animal species*