MEDICINAL PRODUCTS CONTAINING HERBAL INGREDIENTS

Introduction

1 The MHRA is responsible for the administration and enforcement of medicines legislation in the UK. The inclusion of herbal ingredients in a medicinal product does not take that product outside the definition of a medicinal product, but in some circumstances the product may be exempt from the licensing requirements of medicines legislation. The information in this note must be read in conjunction with Guidance Note 8 *A guide to what is a medicinal product*.

2 From the MHRA's viewpoint the first question to be addressed is whether or not the product is a medicinal product. If a product is not a medicinal product then the MHRA will not be involved in its regulation. Some herbs have well-known pharmacological effects and would usually only be found in products for a medicinal purpose. Such products would require marketing authorisations (formerly known as product licences) unless they come within the exemption mentioned below.

The Legislation

3 All herbal medicines or remedies manufactured, sold or supplied in the UK are regulated by the Medicines For Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I.1994/3144) (which in part implements Directive 2001/83/EC) and the Medicines Act 1968 (the Act).

4 The definition of a medicinal product in Article 1.2 of Directive 2001/83/EC reads as follows:

> "Any substance or combination of substances presented for treating or preventing disease in human beings.
>
> Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring correcting or modifying physiological function in human beings is likewise considered a medicinal product".

5 If a product satisfies either or both of the above criteria, it may be classed as a medicinal product. In broad terms, when classifying a product, the Agency looks at the way it is presented and its function, that is, its effects (when administered) on human physiology.

6 Many herbs are used in medicine and a number have active substances that are capable of "restoring, correcting or modifying

physiological function" or are presented as having such properties. Medicinal products with active herbal ingredients, or herbal ingredients that are presented as being active, may only be legally marketed in the UK with a marketing authorisation or, if they qualify, as exempt herbal remedies under section 12 of the Act. A product which comes within the terms of the Section 12 exemption is not regulated as a relevant medicinal product under S.I.1994/3144.

Herbal Remedies

7 Section 132 of the Act defines a herbal remedy as:

> ".... a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or any other process, or of a mixture whose sole ingredients are two or more substances so produced, or of a mixture whose sole ingredients are one or more substances so produced and water or some other inert substance."

8 Section 12(1) allows a person to make, sell and supply a herbal remedy during the course of their business provided the remedy is manufactured or assembled on the premises and that it is sold or supplied as a consequence of a consultation between the person and their patient and in the patient's presence.

9 Section 12 (2) allows the manufacture, sale or supply of herbal remedies (other than by personal consultation) where:-

> the process to which the plant or plants are subjected consists only of drying, crushing or comminuting;
>
> the remedy is sold without any written recommendation as to its use,
> and
>
> the remedy is sold under a designation which only specifies the plant(s) and the process, and does not apply any other name to the remedy.

Controls on the Retail Sale of Herbal Remedies Exempt from Licensing

10 There are further controls on the retail sale of medicinal products including herbal remedies in Sections 52, 53 and 56 of the Act. Sections 52 and 53 set conditions for the retail sale of medicinal products; Section

56 provides exemptions from these conditions for those herbal remedies covered by the section 12 exemptions. Section 56 is however, limited by The Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977 (S.I. 1977/2130). The Order is complex but in essence products containing the substances listed in Part 1 of the Schedule to the Order are excluded from the Section 56 exemption and may not be sold other than through a registered pharmacy and section 12(2) products listed in part II may not be sold other than through a registered pharmacy.

11 To sum up, if a product is a medicinal product it must have a marketing authorisation unless the product is also a herbal remedy within the definition in the Act. Then provided the conditions laid down in Section 12 of the Act are met, the product can be manufactured, sold and supplied without a licence. Sections 52 and 53 of the Act impose further conditions on the retail sale of the product unless the conditions in section 56 are satisfied and the product does not contain a substance listed in SI 1977/2130.

The Traditional Herbal Medicines Directive

12 The Traditional Herbal Medicines Directive (Directive 2004/24/EC) was published on 30 April 2004 ("A" day). It introduces a registration scheme for traditional herbal medicines. The exemption from the requirement for a licence under Section 12(2) of the Act will be amended and, most, if not all, herbal remedies sold over the counter in the UK will have to be registered. The UK's associated legislation will come into force on 30 October 2005 ("B" day). There will be a transitional period of seven years for products which were legally on the market at "A" day. Products coming on to the market between "A" and "B" day must be registered by "B" day. All herbal remedies on the market must be registered by 30 April 2011 ("C" day). Further details may be obtained from the Agency's website

13 A product may be classified as medicinal because of the claims being made for it (as is currently the case). Products which include herbal ingredients for which a ‘no’ is noted in the medicinal uses column in the list of herbal ingredients (see paras 18-21) may therefore be classified as medicinal products because of the way they are presented and as such would need to be registered.

THE CLASSIFICATION OF HERBAL PRODUCTS

14 There are many herbs that are known to have medicinal uses and, at the same time, have known uses as either foods or cosmetics. The MHRA obtains its information from various sources, but mostly from

respected textbooks and published data. Occasionally the MHRA has to consider the status of a herb that does have uses other than medicinal ones and in such cases, will make a judgement as to which is the dominant function and pay particular regard to the purpose of the herb's inclusion in a particular product.

15 Where the available data suggests that a herb has food uses which are limited to the local indigenous population of its country of origin, then it is unlikely to be regarded as the dominant function - especially if its origins lie in a different continent, particularly where its consumption is for a purpose other than nutrition.

16 When the MHRA considers the uses and property of a particular herb, we consider the known/reported uses of the herb, whether those uses apply to the whole plant or a particular part of the plant (leaves, fruit, root etc.) and how this information relates to the product in question. The MHRA also considers the amount of each ingredient when coming to a view on the status of a product. Nothing in this guidance affects a company's right to a review by the Independent Review Panel where a provisional determination is issued. Please see Guidance Note 8 *A guide to what is a medicinal product* for information on how the MHRA assesses the claims made for a product.

17 UK medicines legislation does not provide a definitive list of substances whose inclusion automatically makes a product a medicinal product. The decision as to whether or not a product *is* a medicinal product is made on a case by case basis taking into account the factors set out in paragraphs 11- 23 of Guidance Note 8.

Herbal Aide-Memoire

18 To assist companies in determining the likely status of their product the MHRA has compiled a list of herbal ingredients. The list gives the botanical and other names of various plants together with the known uses of those plants.

19 The list is not exhaustive **and the following points should always be considered** -

- The list is for information only, the status of a product under medicines legislation is determined on a individual basis taking into account all the factors detailed in Guidance Note 8.
- Products which contain an ingredient for which a 'no' is noted in the medicinal uses column may nonetheless be classified as medicinal depending on the product's presentation

- The list has no legal status
- If a product is not a medicinal product advice should be sought from the relevant regulatory body on the legality of that product. The fact that a product is not a medicinal product does **not** necessarily mean that it is safe, acceptable or legal under other legislation. For example a herbal product may be a food, cosmetic or a consumer product and specific legislation will apply. Manufacturers should therefore consult the appropriate regulatory bodies, including the Food Standards Agency (FSA) (for foods and food supplements), the Department of Trade and Industry (for cosmetics or consumer products). Additional information may be obtained from the Trading Standards Service of the relevant Local Authority.
- Although food use may be recorded or reported for a herbal ingredient it is for an individual to check with the FSA that a herb or product is safe for human consumption. The Food Safety Act (1990) states that all food sold in the UK should not be injurious to health. The MHRA accepts no responsibility on this point.
- In addition, we have been advised by the FSA that herbal ingredients which do not have a history of significant consumption within the EU prior to May 1997 may be subject to the controls of Novel Food Regulation (EC) 258/97. Advice on this point should be sought from the Food Standards Agency either in writing or by e-mailing herbals@foodstandards.gsi.gov.uk.

20 The list gives the following information:

- Botanical name
- Common name
- Any recorded medicinal uses
- Any recorded food uses.
- Recorded use in aromatherapy
- Recorded use in cosmetic products
- General comments
- The part(s) of the plant used medicinally