Herbal Medicinal Products: Traditional Herbal Registration

In this article, **Dr Rosanna Cooper** explores traditional herbal medicines and traditional herbal registrations.

• Definition of a Herbal Medicinal Product

A product is defined as an **Herbal Medicinal Product** under Regulation 8 of the Human Medicines Regulations 2012 ((SI 2012/1916 as amended); further amended by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020**);** if the active ingredients are **herbal substances** and/or **herbal preparations** only:

"…a product is an herbal medicinal product if the active ingredients are herbal substances and/or herbal preparations only.
An herbal substance is a plant or part of a plant, algae, fungi or lichen, or an unprocessed exudate of a plant, defined by the plant part used and the botanical name of the plant, either fresh or dried, but otherwise unprocessed.
An herbal preparation is when herbal substances are put through specific processes, which include:

- extraction
- distillation
- expression
- fractionation
- purification
- concentration
- fermentation

The herbal substance being processed can be:

- reduced or powdered
- a tincture
- an extract
- an essential oil
- an expressed juice
- a processed exudate (rich protein oozed out of its source).

• Classification

Before a product can be placed on the market in the UK, the product has to be **classified** to ensure that the product obtains the correct licence or authorisation. For a herbal product, the key questions are whether the product is a herbal medicinal product and, if so, whether it falls within the eligibility criteria for obtaining a **Traditional Herbal Registration**, writes **Dr Rosanna Cooper**.

The **Medicines and Healthcare products Regulatory Agency ('MHRA')** provides guidance on the classification of herbal products:

Is my product a herbal medicinal product? There are many herbs with known medicinal uses and at the same time uses as either foods or cosmetics. When considering the status of a herb that does have various uses the Agency will make a judgement as to which is the dominant function and pays particular regard to the purpose of the herb's inclusion in a product. In very general terms the Agency does not usually regard products containing culinary herbs to be medicines unless included for their medicinal properties or claims to treat or prevent disease are made for them. Some herbs, however, have well-known medicinal effects and would usually only be found in products for a medicinal purpose.

A significant number of herbal medicines or remedies sold or supplied in the UK are controlled under Part 7 of the Regulations for which herbal medicinal products can receive a traditional herbal registration instead of a marketing authorisation. A system for registering herbal medicinal products is available.

The scheme is limited to herbal medicinal products for minor health conditions where medical supervision is not required, for example, symptomatic relief of hay fever, rhinitis, muscular pain and stiffness including backache. In order to qualify, applicants will be required to show evidence that the herbal medicinal product has been traditionally used to treat the stated condition for a minimum of 30 years, 15 years of which must have been in the European Union. Registered products have the requirement for efficacy replaced by a requirement for plausible effect on the basis of long-standing use and experience. Guidance on how to apply for a traditional herbal registration (THR) and to market a herbal medicine (remedy) in the UK and permitted indications is available on the website:

- ### Borderline Product – Is the Product a Herbal Medicinal Product, Food Supplement or Cosmetic?

Herbal products can be classified as **herbal medicinal products**, **food supplements** or **cosmetics**. The key is to evaluate the herbal products to ensure that they are correctly classified and therefore compliant under GB law. According to guidance from the MHRA:

There are some products where it is not so easy to distinguish a medicine from, for example, cosmetics or food supplements. These are known as **borderline products**.

A product which is for use only as a toiletry, disinfectant, food or beverage is not normally regarded as a medicinal product, and would not require a marketing authorisation to be sold in the UK.

Dietary supplements containing vitamins, amino acids or minerals, are generally subject to food safety and food labelling legislation rather than medicines control.

In the event that a food and/or cosmetic contain a **pharmacologically active substance or make medicinal claims** (claims to treat or prevent disease, or to interfere with the normal operation of a physiological function of the human body are regarded as medicinal).

- ### Traditional Herbal Medicinal Products

A '**traditional herbal medicinal product**' is an herbal medicinal product registered under the **Traditional Herbal Registration Scheme** that fulfils certain conditions. According to the MHRA guidance:

Products registered under this Scheme must meet established standards of safety and quality for medicines but, instead of the recognised efficacy standards required for a marketing authorisation, the product must have been used for at least 30 years (at least 15 of which must normally have been within the EU or another country approved by MHRA) to demonstrate long-standing traditional use in the specified conditions of use.

…General statement It is a central feature of the traditional herbal medicine registration scheme that the products concerned do not fulfil the requirement to demonstrate efficacy for a marketing authorisation. In particular, such products will not fulfil the efficacy requirements for a marketing authorisation based on well-established medicinal use. If a product fulfils the criteria for a marketing authorisation, then it is not usually appropriate to grant that product a traditional herbal registration. THMs are generally registered for use in minor self-limiting conditions that are suitable for self-management and do not require the intervention of a medical practitioner. All of the general rules about medicines advertising in the Regulations apply to traditional herbal medicinal products. There is one additional requirement for advertising of these products, which is to include a specified form of wording to inform the consumer that the efficacy of the product for the stated indications is not scientifically supported but is based exclusively on evidence of longstanding use...

- ## Use for 15 years from a wider range of countries including the EU/EEA countries

Evidence must be produced to the Medicines and Healthcare Products Regulatory Agency (“MHRA”) to show that a **traditional herbal medicinal product**, or a corresponding product, has been in medicinal use throughout a **30 year period preceding the date of application**, including at least **15 years within a wider range of countries in addition to EU/EEA countries**.

From 1 January 2021, the MHRA may be able to accept the 15 years of traditional evidence from a wider range of countries in addition to EU/EEA countries. Suitable countries will be those that have a level of pharmacovigilance equivalent to that of the UK. This is to ensure that any safety issues have been properly identified to support the traditional use of the product. The MHRA will publish a list of suitable countries for this purpose which will be updated as new entries arise.

This provision does not apply to traditional herbal medicines intended to be marketed in Northern Ireland. For these products, traditional use evidence should be provided that the product or a corresponding product has been used for a period of 15 years within the EU/EEA.

• Product Licence - Traditional Herbal Registration

A Traditional Herbal Registration is available, rather than a Marketing Authorisation, for placing **traditional herbal medicinal products on the market** or for their distribution by way of wholesale dealing in the UK.

In the UK, companies can only sell herbal medicines with the appropriate product licence, as follows:

- A full **marketing authorisation** based on the safety, quality and efficacy of the herbal product; or
- A **traditional herbal registration** based on the safety, quality and **evidence of traditional use** of the herbal product.

A THR is only granted if the medicine is used for minor health conditions where medical supervision is not required (e.g. a cold).

If your traditional herbal medicinal product claims to treat major health conditions, you need to apply for a marketing authorisation before you can place it on the market.

Further guidance from the MHRA:

Requirements of the Traditional Herbal Registration Scheme

2.1 Products eligible for the registration scheme: will have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment. The Traditional Herbal Registration Scheme is restricted to products for oral or external use and/or inhalation.

2.2 Products registered must include a statement in their labelling, patient information leaflet and advertising that the product is a traditional herbal medicinal product for use in specified indication(s) exclusively based on long-standing use.

2.3 The majority of successful registration applications will be for products with General Sale List status, although a small number may be restricted to Pharmacy sale.

3. Factors relevant to the need for medical supervision
3.1 Some medicines on account of their ingredient(s) may be inherently unsuitable for use without medical supervision, irrespective of the proposed indications.

3.2 A medicine may present a danger either directly or indirectly, even when taken correctly, if used without medical supervision. This could arise if the product causes adverse reactions that are important because of their seriousness, severity or frequency; or the adverse reaction is one for which there is no suitable preventative action such as the exclusion of a clearly identifiable risk group.

3.3 A requirement for medical supervision may be appropriate if there is evidence that an ingredient or product is widely misused or abused, leading to risk of harm.
3.4 There are other factors that need to be taken into account in determining whether a medicine with its associated indication(s) is suitable for use without medical supervision. Consideration needs to be given to whether:
• symptomatic treatment might mask an underlying condition requiring medical attention;

• incorrect use might lead to a delay in seeking medical treatment with adverse consequences for the patient;

• where particular symptoms are outward manifestations of a diverse range of underlying pathologies and the patient cannot easily self-diagnose the cause of such symptoms, it may be inappropriate to provide symptomatic treatment without management of the underlying disease; • there is a possibility of serious asymptomatic damage in chronic conditions; the conditions or symptoms for which the product is indicated can be correctly diagnosed without medical supervision or easily recognised following initial medical diagnosis. The problem of excluding conditions with similar symptoms but unsuitable for treatment with the product in question may need to be addressed;

• patients understand the natural course of the disease and the possibility and consequences of reoccurrence; and can they recognise contraindications and understand essential precautions and warnings;

• a high incidence of conditions listed as contraindications, extensive precautions and warnings or a high rate of usage of interacting drugs in the population of patients likely to use the drug may increase the incidence and risk of misuse;

• there is significant danger to health if the patient uses the product when it is not indicated, exceeds the recommended dose or recommended length of treatment or fails to heed the contraindications or warnings. Consideration of the consequences of misuse is an important component of the overall safety profile of the product. Concerns over the risk of misuse are lessened where the product causes only few, non-serious side effects. 3.5 Each case, and especially where there is any doubt over the suitability of use without medical supervision, needs to be considered carefully in the round. It is also important to take full account of whether patient information might adequately mitigate any risks associated with use without medical supervision.

○ Conclusion

Companies must ensure compliance with GB law if manufacturing and/or distributing herbal medicinal products in the UK.

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