VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

REGULATION
concerning Marketing Authorisations for Natural Medicinal Products and Registration of Traditional Herbal Medicinal Products, No. 142/2011.

CHAPTER I
Scope and definitions.

Article 1
Scope.

This Regulation shall apply to marketing authorisations for natural medicinal products for human and veterinary use and to registration of traditional herbal medicinal products for human use.

This Regulation shall not apply to homoeopathic medicinal products.

Article 2
Natural medicinal products.

A "natural medicinal product" shall mean a medicinal product which:

1) contains one or more active substances which occur naturally, in a concentration which is not considerably greater than occurs in nature;
2) is intended for oral use or local use on skin or mucous membrane;
3) is indicated exclusively for mild illnesses, i.e. when it is normally unnecessary to seek the assistance of a medical practitioner;
4) is available without prescription.

Article 3
Traditional herbal medicinal products.

A "traditional herbal medicinal product" shall mean a medicinal product which:

1) is intended for human use;
2) has indications which apply exclusively 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 purpose, prescription or treatment;
3) is intended exclusively for administration in accordance with a specified strength and posology;
4) is intended for oral or external use and/or inhalation;
5) fulfils the period of traditional use as laid down in Article 4; and
6) for which the data on traditional use of the herbal medicinal product is deemed sufficient, i.e. when the product has been proven not to be harmful in the specified conditions of use and the pharmacological effects and efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

Article 4

Period of traditional use.

The “period of traditional use” shall mean that the medicinal product in question or a corresponding product must have been in medicinal use for a period of at least 30 years preceding the date of the application, including at least 15 years in the European Economic Area (EEA).

The requirement for documenting the period of traditional use of the medicinal product in question is satisfied even if the marketing of the product has not been based on a specific authorisation. The requirement is also satisfied if the quantity of the active ingredient in the medicinal product has been reduced during the said period.

A “corresponding product during the period of traditional use” shall mean a product which:

1) is characterised by having the same active ingredients, irrespective of the excipients used,
2) serves the same or similar purpose,
3) has the same strength and posology,
4) has the same or similar route of administration as the medicinal product applied for.

Article 5

Herbal medicinal products and herbal substances.

An “herbal medicinal product” shall mean any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more complete herbal medicinal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.

An “herbal substance” is a whole, fragmented or cut plant, plant parts, algae, fungi or lichens in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

A “ready-to-use herbal preparation” means a ready-to-use preparation obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

CHAPTER II

Marketing authorisations for natural medicinal products.

Article 6

Application for a marketing authorisation.

Application must be made for a marketing authorisation for natural medicinal products in accordance with the Regulation on Marketing Authorisations for Proprietary Medicinal Products, their Labelling and Package Leaflets. Toxicological, pharmacological and clinical data will not be required, according to item j of paragraph 1 of Article 12 of the Regulation on Marketing Authorisations for Proprietary Medicinal Products, their Labelling and Package Leaflets, *cf.* Article 15 of that Regulation, if an applicant can demonstrate that there is at least a ten-year tradition for the medical use of the active substances in the natural medicinal product within the EEA, that their effect is recognised and their safety is satisfactory, having regard to the requirements laid down in Annex 1 to Directive 2001/83/EC, as amended by Directive 2003/63/EC, Directive 2004/24/EC and Directive 2004/27/EC.

The same shall apply to natural medicinal products for veterinary use, but having regard to the requirements laid down in Annex 1 to Directive 2001/82/EC, as amended by Directive 2004/28/EC and Directive 2009/9/EC. In the case of veterinary medicinal products, no demands will be made for the data listed in items a and b of paragraph 1 of Article 13 of the Regulation on Marketing Authorisations for Proprietary Medicinal Products, their Labelling and Package Leaflets.

An applicant as referred to in this provision shall instead of the data referred to in paragraphs 1 and 2 provide relevant scientific publications instead of conclusions from research and trials.

Article 7

Issuance of a marketing authorisation.

The Icelandic Medicines Agency shall issue marketing authorisations for natural medicinal products.

CHAPTER III

Simple registration of traditional herbal medicinal products.

Article 8

General provisions.

Traditional herbal medicinal products may be placed on the market without a marketing authorisation according to Article 7 of the Medicinal Products Act, with a simple registration.

A simple registration can be used for herbal medicinal products containing vitamins or minerals, provided that their safety is well known and that the vitamins and minerals support the effects of the active ingredients in the herbal medicinal product with reference to its registered indication.

If, in the assessment of the Icelandic Medicines Agency, an application for simple registration fulfils the requirements of the Regulation for Application for a Marketing Authorisation for a Medicinal Product, or the requirements for registration as a homoeopathic medicinal product, the herbal medicinal product may not be registered according to the provisions of this Chapter.

Article 9

Application for registration of traditional herbal medicinal products.

An application for registration of a traditional herbal medicinal product shall be submitted to the Icelandic Medicines Agency. The application must be accompanied by the following information:

1) The name and address of the applicant and/or producer.
2) The name of the medicinal product. Care shall be taken to ensure that a proprietary name does not cause a misunderstanding due to a generic name.
3) Qualitative and quantitative information on all the contents of the medicinal product, including a reference to its international generic name recommended by the World Health Organisation (WHO), if available, or a reference to the relevant chemical name.
4) An assessment of possible environmental risk resulting from the product and proposals to limit the risk. The impact shall be assessed and specific measures taken in each case to reduce it.
5) A description of the method of production.
6) Indications, contraindications and adverse reactions.
7) Posology, pharmaceutical form, method and route of administration and estimated shelf life.
8) Reasons for caution and security measures, which need to be taken when a medicinal product is stored, administered to patients or waste is disposed of, together with suggestions of possible risk to the environment which could result from the medicinal product.
9) A description of the research methods used by the producer, to analyse the qualitative and quantitative contents and finished product, special testing concerning heavy metal contents, studies of shelf life, biological and toxicological tests and tests to control manufacturing production.
10) The results of pharmacological (physical, chemical, biological and microbiological) tests.
11) A draft Summary of Product Characteristics (SPC), cf. here the provisions of the Regulation on Marketing Authorisations for Proprietary Medicinal Products, Labelling and Package Leaflets, but without pharmacodynamic information.
12) A sample or draft of labels and package leaflets.
13) A certificate that the producer is approved by authorities in its home state to manufacture the medicinal product in question.
14) Exhaustive information on herbal mixtures and/or their manufacture, if they contain vitamins or minerals and on traditional use of the mixture. If the individual active ingredients are not sufficiently known, the data shall also relate to them.
15) A copy of the marketing authorisation for the medicinal product or its registration in another EU/EEA state or third country, in addition to detailed information on applications for marketing authorisation or registration elsewhere which has been refused and the reasons for such.
16) Bibliographical or expert evidence confirming the period of traditional use, cf. Article 4 of the Regulation.