

NOTICE TO APPLICANTS

Creation of generic groups for herbal medicinal products in the list of generic groups

Objectives

The creation of generic groups without reference products for herbal medicinal products primarily addresses the desire to promote herbal medicinal products that benefit from the marketing authorisation (MA) framework, as opposed to food supplements that contain an identical plant but are not covered by this authorisation.

It should also be noted that the intention is for these medicinal products to be included in groups without reference products, thereby allowing the prescriber and the provider to obtain a clearer understanding of herbal medicinal products referring to the same monograph. The purpose of this initiative is not substitution as such, but rather to highlight these medicinal products by offering a clear and legible framework for patients, pharmacists and prescribers.

Scope of application

Herbal medicinal products as defined in article L.5121-1 5° b) of the French Public Health Code and covered by an MA may be included in the list of generic groups.

Traditional herbal medicinal products as defined in article L.5121-14-1 of the French Public Health Code that are subject to registration are excluded.

According to article 61 of Law no. 2014-1554, included in the list of generic groups are herbal medicinal products covered by an MA, with the same qualitative and quantitative composition in terms of herbal active substance, the same pharmaceutical form and equivalent therapeutic activity and the active substance of which is described in accordance with a herbal monograph published by the European Medicines Agency (EMA) for well-established medical use (see the following link):

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/herbal_search.jsp&mid=WC0b01ac058001fa1d

These monographs are prepared at the EMA by the Committee on Herbal Medicinal Products (HMPC) within the context of well-established medical use on the bibliographic database.

Types of active substances concerned

The active substances are present either directly in the form of the herbal drug, or in the form of preparations (powder, essential oils, extracts, tinctures, etc.)

Extracts are defined by their state (dry, soft, or liquid), the extraction solvent and the drug/extract ratio (ratio between the quantity of herbal drug used in the manufacture of the preparation and the quantity of preparation obtained). Each extract corresponds to one active substance.

In the specific case of standardised extract, the active substance is not defined in relation to the extract itself, but in relation to the component(s) positively identified as responsible for the activity (for laxative herbs containing anthraquinone glycosides).

Procedures for creating generic groups for herbal medicinal products

A new appendix II has been created in the List of generic groups; the list of excipients with known effects has now become appendix III. The purpose of appendix II is to list the generic groups of herbal medicinal products without reference products.

In this appendix, a group will be created when at least two herbal medicinal products covered by an MA have the same qualitative and quantitative composition in terms of herbal active substance, the same pharmaceutical form and equivalent therapeutic activity, and the active substance of which is described in accordance with a herbal monograph published by the European Medicines Agency (EMA) for well-established medical use.

The group will be identified by the active substance.

For the same monograph, the same number of groups as active substances described will be created, once the previously defined criteria have been met.

The creation of such a group is based on the similarity of the pharmaceutical forms (solid form, liquid form, etc.) and on the consistency of the indications of the herbal medicinal products considered with those described in the corresponding European monograph.

Additionally, insofar as the primary factor enabling the creation of a group is that the active substance is described in accordance with a monograph published by the EMA, if two medicinal products satisfy all of the criteria linked to this active substance described in the monograph, they will appear in the same group even if their expressed dosage is different, providing that the posology for the same indication is ultimately identical.

ANSM is responsible for making decisions regarding inclusion in a generic group without reference products and shall first notify the relevant marketing authorisation holders who will be able to submit their observations.

In all instances, MA holders for herbal medicinal products may submit an application for the creation of a group to the Director General of ANSM.