Overview classification in the EU
-
Homeopathic medicinal products without indication

European Coalition on
Homeopathic and Anthroposophic Medicinal Products
European Economic Interest Group

ECHAMP's aim is to achieve full availability of homeopathic and anthroposophic medicinal products in the EU.
ECHAMP represents the industry for homeopathic and anthroposophic medicinal products in Europe. It endorses the important role that homeopathy and anthroposophic medicine play and can play in healthcare and seeks to maximise availability of homeopathic and anthroposophic medicinal products for all citizens of Europe. ECHAMP works to ensure an appropriate regulatory status for these safe, effective and high quality products.

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1. Introduction

There is a long tradition of self-medication with homeopathic single remedies. The broadest and oldest historical roots might exist in Germany, where this tradition goes back to the lifetime of Hahnemann. One of the pre-requisites for a functioning self-medication is the existence of pharmacies providing homeopathic medicinal products. Another is the existence of literature accessible to non-doctors/non-therapists which explains the use of the homeopathic remedies.

Nowadays homeopathic single remedies WITHOUT an indication are marketed in the Member States of the European Union based on several legal backgrounds:

1. Registration according to article 14 of Dir 2001/83/EC
2. Notification under transition law (as transition until a final evaluation according to article 14 or 16 of Dir 2001/83/EC)
3. Grandfather rules according to article 13 of Dir 2001/83/EC
    a. with notification
    b. without notification

The survey for this overview starts from the general impression that in most Member States of the EU homeopathic remedies without indication are not classified as RX. They might be OTC or have a special status as “pharmacy only products”.
Recently, in context with pioneer registration procedures, some Member States announced to classify their first simplified registrations as RX due to the health risk related to the fact that there is no indication on the package. In so doing, they ignore the fact that the products so far have been legally on the market for at least more than 15 years without classification as RX.

2. Objective

- The objective of this table is to gather an overview about the classification of homeopathic single remedies WITHOUT INDICATION in the Member States of the EU.
- The KEY QUESTION is, to which extent these remedies are classified RX for the ONLY REASON OF A POTENTIAL HEALTH RISK LINKED TO THE FACT, THAT THERE IS NO INDICATION ON THE PACKAGE.

This overview shall contribute to a consolidated picture of the practice of classification of homeopathic medicinal products.

3. Achievements

Explanation of questions

(1) Are simplified registered homeopathic medicinal products / homeopathic medicinal products without an indication classified as "prescription only" for the reason that there is no indication? Please indicate yes/no.

The general principle of classification of single remedies without indication is asked without consideration of the legal status. Are they generally classified automatically subject to prescription (RX) or not? Even products with the legal status of an article 16.2 authorisation WITHOUT indication would fit here.

(2) Are there any cases, where these products are treated differently to the general rule? Please describe the particular cases and the reasons for the deviation from the general rule? Please indicate short text.

There might be exceptions. They shall be shortly described here: In which cases is a product without indication classified differently from the general rule and what is the reason for this.

The following table presents answers of the questions which have been collected with the support of the ECHAMP members.

Table 1 – Overview classification in the EU, Homeopathic medicinal products without indication

Member State	Are simplified registered homeopathic medicinal products / homeopathic medicinal products without an indication classified as "prescription only" for the only reasons that there is no indication? YES/NO?	Are there any cases, where these types of products are treated differently as the general rule? Which are the cases and what the reasons are for this? (2)
Austria	No	No
Belgium	No	No
Bulgaria	No	No
Cyprus	No Info	No Info
Czech Republic	No	RX mainly results from the fact, that potencies < D4 were applied for in the 199ieths in Czechoslovakia and nobody complained, today in CZ the release from RX was successful for higher potencies
Denmark	No	No
Estonia	No Info	No Info
Finland	No	Only low potencies are classified as RX
France	No	No
Germany	No	RX if less than 1:100 diluted of a substance RX in Allopathy. Registration not possible if RX.
Greece	No	No Info
Hungary	No	No
Ireland	No	Not clear so far
Italy	No	No
Latvia	No	No
Lithuania	No	No
Luxemburg	No Info	No Info
Malta	No Info	No Info
Netherlands	No	No
Poland	No	It is up to the agency to decide. Conditions for RX: All injectables, products related to a toxicological risk of the substance (certain low potencies)
Portugal	No	No
Romania	No	The competent authorities decide case by case at the moment of registration. An exemplary survey on the homepage of the competent authority showed, that on many approved labels the text “with medical prescription, granted by the homeopathic doctor" could be found. Another investigation showed that clients will receive these products in the pharmacies without prescription by a doctor (ECHAMP publication in preparation).

Table 1 – continuation of Overview classification in the EU, Homeopathic medicinal products without indication

Member State	Are simplified registered homeopathic medicinal products / homeopathic medicinal products without an indication classified as "prescription only" for the only reasons that there is no indication? (yes/no)? (1)	Are there any cases, where these types of products are treated differently as the general rule? Which are the cases and what the reasons are for this? (2)
Slovenia	No	No
Slovakia	No	RX mainly results from the fact, that potencies < D4 were applied for in the 199ieths in Czechoslovakia and nobody complained, today in SK the release from RX is possible
Spain	No	There is not a general rule established for homeopathies. The first registration of an homeopathic according art.14 in Spain (Lycopodium <POT>) is prescription only, but all the rest on the market (status notified) are non-prescription.
Sweden	No	No
United Kingdom	No	Remedies are classified as GSL=General Sales List= OTC, P=Pharmacy only, & POM=Prescription only, depending on the starting material and the dilution level. Although the market place is dominated by General Sales List products, homeopathic pharmacies can dispense prescription homeopathies. It's not a massive market, but it exists.