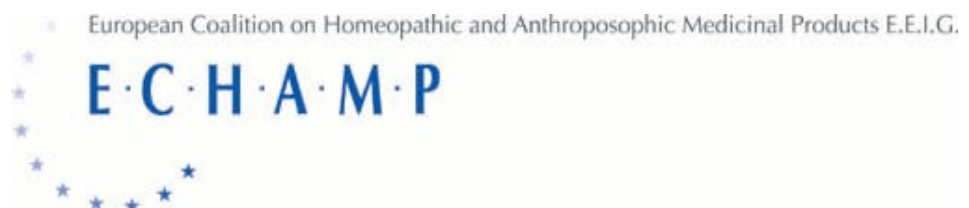


**The status of Homeopathic Starting Materials
(Homeopathic Stocks) purchased
in order to make magistral preparations
in a pharmacy or on request of a pharmacy**

Position Paper 2003/01



The status of Homeopathic Starting Materials (Homeopathic Stocks) purchased in order to make magistral preparations in a pharmacy or on request of a pharmacy.

Two definitions of Directive 2001/83/EC are the basis for this position paper:

***Medicinal Products: 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 functions in human beings is likewise considered a medicinal products (Art. 1.2).**

*** Homeopathic Medicinal Products : any medicinal products prepared from products, substances or compositions called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in absence thereof, by the pharmacopoeias currently used officially in the Member States.**

I. Background

Inspectors from the Netherlands representing the competent health authority have adopted a particular view, on the status of homeopathic stocks and homeopathic intermediate products. They consider that these products as for instance mother tinctures or any further homeopathic dilution, which have been imported from another member state by a pharmacy or which have been purchased as starting materials by a pharmacy from a Dutch manufacturer of homeopathic medicinal products, in order to prepare magistral medicinal products (and officinal medicinal products) are to be considered intermediate products according to 75/319/EC. The authority is of the opinion that intermediate products would not need to be registered or authorised when they are traded between manufacturing licence-holders, but would need a registration or a marketing authorisation when they are delivered to a pharmacy.

In this case even the homeopathic stocks are considered intermediate products of homeopathic medicinal products which must be covered by a registration or a marketing authorisation. This is because homeopathic stocks 'as such' exist on the Dutch market as finished homeopathic medicinal products and have a marketing authorisation (Art. 16.1 of Dir. 2001/83).

The Inspector said he could not find any legal base to consider homeopathic stocks and further dilutions (low potencies and higher potencies) as not being intermediate products.

He also said that the designation on the label: "not for delivery", does not change the status, because the manufacturer and the pharmacist still can make the choice to use the product as an intermediate product or to deliver it as a finished product.

II. ECHAMP Opinion

a) According to the Directive 2001/83/EC, title II, art. 3, 1 and 2, the Directive does not apply to any medicinal product prepared in a pharmacy as magistral or officinal formula.

b) Homeopathic stocks (or substances) are not to be considered “a medicinal product” if they are “not presented” (form and labelling) for treating or preventing disease in human beings [or animals].
(Dir. 2001/83/EC, title I, definitions, art. 1, 2)

It is not correct to assume that any *starting material* for the production of a homeopathic magistral or officinal product is to be considered a medicinal product, just because the Directive defines a homeopathic medicinal product as a product prepared from homeopathic stocks in accordance with a ... pharmacopoeia.
(Directive 2001/83 title 1, definitions, art. 1, 5)

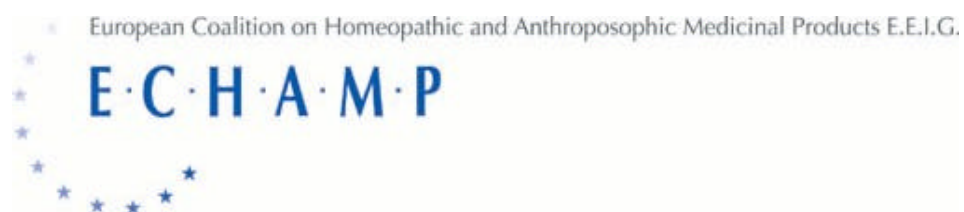
Homeopathic stocks (mother tinctures or further dilutions) may be identical in their quality to a homeopathic medicinal product but the distinction between homeopathic stocks (or starting materials) and homeopathic medicinal products is possible by the way these products are being presented, or in other words, how they are being labelled. The same article under No 2 defines a medicinal product as “*any substance or combination of substances presented for treating or preventing disease in human beings*”. Therefore, in homeopathic products, the way the product is presented or labelled according to its designation defines clearly a homeopathic stock or substance, or alternatively, its character as a homeopathic medicinal product.

As European coalition of manufacturers of homeopathic and anthroposophic medicinal products we would very much appreciate to have the possibility to explain our concern and proposals to any competent health authority currently dealing with the problem of the starting materials, homeopathic stocks and first potencies being supplied to make homeopathic magistral and officinal preparations.

III. Conclusion

According to the above-cited definitions of the Directive, it is clearly erroneous to consider homeopathic stocks as medicinal products (or intermediate products) if their presentation allows for a clear identification and designation of the product as stock for the manufacturing of a homeopathic medicinal product. This is also the way competent authorities in other Member States are currently dealing with identical situations which means that homeopathic starting materials do not need a registration or a marketing authorisation under the above mentioned circumstances. Therefore ECHAMP asks the competent authorities in the Netherlands, i.e. the Inspection Authority, to revise their point of view and to bring it in line with the status in the other member states and with the provisions of the EU-Directive 2001/83 as mentioned before.

We agree that supplying homeopathic dilutions potentised up to D4 and higher as intermediate products gives reason for concern regarding the analytical control on identity and quality. We would support any initiative to lay down rules about this item, in particular rules on the control of the quality of starting materials and intermediate products (stocks and low potencies) used in the manufacturing of finished homeopathic medicinal products. A first suggestion could be for instance that pharmacists purchase their homeopathic stocks and further low dilutions for homeopathic magistral and officinal preparations only from GMP-licensed manufacturers, and with analytical certificate.



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