CMDh Questions & Answers on Homeopathic Medicinal Products

Homeopathic medicinal products - Disagreement in procedures - Referral to CMDh

1. What will be the situation for homeopathic medicinal product (as defined in Article 14 of Directive 2001/83/EC) if no agreement could be reached at the end of a MRP or DCP?

According to Article 13 (1) of Directive 2001/83/EC, for the registration of homeopathic medicinal products only Article 29 (1) to (3) shall apply. Therefore if a Member State cannot approve within the timeframe given in Article 28 (4), the assessment report and the labelling on the grounds of potential serious risk to public health, the RMS will refer the points of disagreement to the CMDh.

2. What will be the situation for homeopathic medicinal product (as defined in Article 14 of Directive 2001/83/EC) if no agreement could be reached at the end of the CMDh-Referral?

If no agreement could be reached at the end of the CMDh-Referral between the Member States concerned by the procedure, the issue will not be forwarded to the European Medicines Agency for arbitration. As no further information is given in the legislation how to conclude the national phase of the registration, MS and the EU-Commission have agreed in the spirit of the legislation on the following interpretation: It is a national decision - taking into account the assessment report of the RMS and the discussion at the CMDh - of each MS concerned by the procedure to issue a registration for this homeopathic medicinal product or not.
Number of application forms for registration of homeopathic medicinal products

3. We plan to submit an application for a MRP or DCP for a registered homeopathic medicinal product. The application will involve several potencies (dilutions and/or triturations) of a homeopathic stock. Please can you advise how many application forms are necessary?

In the case of several dilutions of a homeopathic stock a separate application form per each pharmaceutical form of medicinal products derived from this homeopathic stock is needed.

The individual potencies (dilutions and/or triturations) have to be listed in the application form. The application for a registered homeopathic medicinal product in MRP or DCP is characterised by the normal MRP/DCP-numbering system (CC/D/nnnn/sss/X/vvv; The Notice to Applicants Volume 2A Procedures for marketing authorisation, Chapter 2 Mutual Recognition, Section 7. Numbering System for the Procedures for Mutual Recognition and Decentralised Procedure; Revision 5, February 2007) in which 'n' is the specific number (4 digits) for the actual medicinal product which equals to the homeopathic stock and is further characterised by 's' (sequential speciality number) for the individual potencies (dilutions and/or triturations). No sub-numbering system is in place if the same final dilution is the result of a series of potencies (dilutions and/or triturations): C' or 'CH' (centesimal), D', 'DH' or 'X' (decimal), 'LM'.

Further characterisation of the potencies (dilutions and/or triturations) of a homeopathic stock by a different numbering system may exist in Member States.