

<b>Q&amp;A</b> <b>TRADITIONAL HERBAL MEDICINAL PRODUCTS</b>
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### **Question 1**

***What is the meaning of a “Community monograph” in the context of MRP/DCP of traditional herbal medicinal products?***

**Answer:** According to Article 16 h (1)(a),(b) and Article 16h (3) of Directive 2001/83/EC the Committee on Herbal Medicinal Products (HMPC) shall establish Community herbal monographs for herbal medicinal products with regard to well-established use as well as traditional use. The monographs contain herbal substances and/or herbal preparations where the HMPC is of the opinion that the legal and scientific requirements for well-established use or traditional use are fulfilled. Whenever possible, scientific opinions of the HMPC are taken by consensus. However, in some cases a consensus cannot be reached; in such situations the opinion is adopted if supported by an absolute majority of the members of the Committee (i.e. favourable votes by at least half of the total number of Committee members eligible to vote plus one). Where members have divergent positions these are included in the opinion of the Committee and are publicly available. Monographs are drafted in the style of a SmPC and reflect the scientific opinion of the HMPC concerning efficacy (well-established use), plausibility of efficacy (traditional use) and safety.

Community herbal monographs, the assessment report as well as the list of references and the HMPC opinion with any divergent positions are published on the website of the European Medicines Agency (EMA) and can be found via the “document library” search using the document type “Community herbal monograph”:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/document\\_library/landing/document\\_library\\_search.jsp&mid](http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid)

Final monographs shall be taken into account by the member states when examining an application. Even though the member states are not obliged to follow the monographs, any decision not to accept the content of the monograph as it is adopted by the HMPC should

be duly justified taking into account their important role to bring harmonisation to this field and to facilitate the use of the simplified registration procedure

According to Article 16d of Directive 2001/83/EC MRP/DCP shall apply by analogy to THMP registrations provided that a respective Community herbal monograph exists.

## Question 2

***What is the meaning of a “Community list entry” in the context of MRP/DCP of traditional herbal medicinal products?***

**Answer:** According to Article 16f(1) of Directive 2001/83/EC, a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (THMP) is gradually developed by list entries. List entries are drafted by the Committee on Herbal Medicinal Products (HMPC) on the basis of a monograph on traditional use provided that the data publicly available is sufficient to document the safe use of the included herbal substances / herbal preparations. The draft list entries are approved and published by the European Commission:

[http://ec.europa.eu/health/human-use/herbal-medicines/index\\_en.htm](http://ec.europa.eu/health/human-use/herbal-medicines/index_en.htm)

After approval by the European Commission the Community list entries are legally binding in so far as

- An applicant will not be required to provide evidence on the safe and traditional use of a medicinal product [i.e. Article 16c(1)(b)(c) and (d)] for which he seeks a traditional use registration, if he demonstrates that the proposed product and related claims in the application comply with the information contained in the Community list;
- Competent authorities will not have the opportunity to require additional data to assess the safety and the traditional use of the product [i.e. Article 16e(1)(c) and (d)].

However, data demonstrating the quality of the THMP submitted for registration has to be provided in the dossier.

According to Article 16d of Directive 2001/83/EC MRP/DCP shall apply by analogy to THMP registrations provided that the THMP submitted for registration consists of herbal substances, preparations or combinations thereof contained in the Community list.

## Question 3

***What type of registration procedure is applicable for a THMP that consists of an herbal substance, herbal preparation or combination thereof which is contained in a Community monograph or Community list entry?***

**Answer:** If the registration of a THMP as described above is intended in a single Member State the respective national procedure is applicable. According to Article 16d of Directive 2001/83/EC, if the registration of a THMP as described above is intended in more than one Member State, DCP should apply and, if a THMP as described above is already registered in a Member State and the applicant intends registration in further

Member States, MRP should apply. The applicant should be aware of any divergent positions on the Community monograph.

#### **Question 4**

***Is the use of MRP/DCP possible even if neither a Community list entry nor a Community monograph exists for the active substance(s) (herbal substance, herbal preparation, combination)?***

**Answer:** The CMDh agreed that MRP/DCP is possible for registration of THMPs on a voluntary basis even if neither a Community list entry nor a Community monograph exists provided that adequate and sufficient documentation for traditional use and safety is enclosed in the dossier submitted. However, it should be clarified that the use of MRP/DCP is the decision of the Member State. Discussion with Member States intended to be included in any procedure, is recommended before submission of an application.

#### **Question 5**

***Registrations are not within the scope of the EC Regulation 1234/2008 (“Variation Regulation”) and have to follow national procedures. How can the dossier and the SmPC be kept harmonized?***

**Answer:** In order to keep the documents (dossier and SmPC post approval ) harmonized between member states, the CMDh agreed to apply the Variation Regulation by analogy, in case MRP/DCP had been used for registration of a THMP.