



London, 24 October 2005  
Doc. Ref. EMEA/HMPC/322553/2005

## COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

### **Meeting report, 19-20 September 2005**

The Committee on Herbal Medicinal Products met for the seventh time at the EMEA offices on 19-20 September 2005. The Chairman welcomed the participation of representatives from the Bulgarian and Romanian Medicines Agencies as observers in the Committee following an EU grant under the PHARE<sup>1</sup> programme.

The Committee reviewed experts' nominations from HMPC members with a view to appointing three co-opted members in the areas of paediatric medicine, experimental/non-clinical pharmacology and traditional herbal medicinal products (such as Traditional Chinese, Ayurvedic and Anthroposophic herbal medicinal products). The experts will be invited to present their professional career, involvement in the field of herbal medicines and respective expertise in the above-mentioned areas at the HMPC meeting scheduled for 22-23 November 2005. Following the presentations, elections will be held.

#### **Reports from drafting groups meetings**

##### *Organisational matters*

The drafting group on organisational matters made progress in the establishment of a framework for the performance of tasks arising from Article 16c(1) and (4). These are respectively:

- the duty to provide Member States upon request with opinions on the adequacy of the evidence of the long-standing use of a traditional herbal medicinal product and
- the preparation of an opinion on a product, which has been used in the Community for less than 15 years but is otherwise eligible for traditional use registration and is referred to the Committee by a Member State.

Clarification is being sought from the European Commission on the procedure to follow when referring to these provisions and a proposal is being submitted to the Notice to Applicants group for modification of Chapter 3 of Volume 2A of the Notice to Applicants.

The Committee adopted a concept paper for the preparation of a guideline on how to present the application for a traditional herbal medicinal product in Common Technical Document (CTD) format; it is expected that the guideline will provide valuable information to help future applicants in their submission.

The concept paper (EMEA/HMPC/261344/2005) is released for consultation until 31 December 2005 and can be found at the following location:

<http://www.emea.eu.int/pdfs/human/hmpc/261344en.pdf>

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<sup>1</sup> PHARE: Poland-Hungary Aid for the Restructuring of the Economy: Originally created in 1989 to assist Poland and Hungary, the PHARE programme currently covers 10 countries: the 8 new Member States (the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia and Slovenia) as well as Bulgaria and Romania, assisting them in a period of economic restructuring and political change.

The Committee finalised the following documents after reviewing comments received during the consultation period.

- 'Structure of the List of herbal substances, preparations and combinations thereof' (EMEA/HMPC/100824/2005)
- 'Guideline on the documentation to be submitted for inclusion in the List of herbal substances, preparations and combinations thereof' (EMEA/HMPC/107399/2005)
- 'Procedure for the appointment by the HMPC of a Rapporteur responsible in the simplified procedure for the evaluation of a proposal for inclusion in the List of herbal substances, preparations and combinations thereof / for the development of a Community herbal monograph' (EMEA/HMPC/108877/2005)
- 'Template for a Community herbal monograph' (EMEA/HMPC/107436/2005)
- 'Timetable for the establishment of a Community herbal monograph [not resulting from any referral procedure]' (EMEA/HMPC/126542/2005)
- 'Template for submission of a request for expert advice on herbal medicinal products' (EMEA/HMPC/119889/2005)

Final versions of the documents and overviews of comments received can be found at the following location:

<http://www.emea.eu.int/htms/general/direct/legislation/legislationherbal.htm>

### *Quality*

The drafting group made some progress with the preparation of a guideline on the declaration of herbal substances/herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC. It is expected that the draft guideline will be adopted by the Committee for release for consultation at the November 2005 meeting.

Further coordination with the *ad hoc* GMP Inspection Services Group will continue on a revised proposal for amendment of Annex 7 to the guide to good manufacturing practice (GMP) on the manufacture of herbal medicinal products. It is expected that the above-mentioned group will release before 31 October 2005 an announcement on the EMEA website that the Annex 7 provisions are applicable to traditional herbal medicinal products.

The drafting group considered and suggested amendments for a proposal for a 'Controlled Vocabulary on Plants and Herbal Preparations' discussed in the context of the development of the ICH/M5 'Note for guidance on data elements and standards for drug dictionaries' (CPMP/ICH/168535/2005).

The Committee adopted a proposal prepared by the drafting group to include an annex on herbal substances/preparations in the CHMP/CVMP 'Guideline on active substance master file procedure' (CPMP/QWP/227/02 Rev.1, EMEA/CVMP/134/02 Rev.1). This annex takes into account the particularities of herbal substances/preparations while also highlighting that this procedure can be applied to active substances of herbal origin. The proposal was transmitted to the CHMP/CVMP Quality Working Party.

## *Safety and Efficacy*

The Committee adopted the following Community herbal monographs and entries in the List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. They are released for consultation until the end of January 2006. They can be found at the following location:

- Valerian root (Valerianae radix)  
Draft Community herbal monograph (EMEA/HMPC/340719/2005)  
<http://www.emea.eu.int/pdfs/human/hmpc/34071905en.pdf>  
Draft Entry to List of herbal substances, preparations and combinations thereof  
(EMEA/HMPC/340779/2005)  
<http://www.emea.eu.int/pdfs/human/hmpc/34077905en.pdf>
- Linseed (Lini semen)  
Draft Community herbal monograph (EMEA/HMPC/340849/2005)  
<http://www.emea.eu.int/pdfs/human/hmpc/34084905en.pdf>  
Draft Entry to List of herbal substances, preparations and combinations thereof  
(EMEA/HMPC/340854/2005)  
<http://www.emea.eu.int/pdfs/human/hmpc/34085405en.pdf>
- Ispaghula husk (Plantaginis ovatae seminis tegumentum)  
Draft Community herbal monograph (EMEA/HMPC/340857/2005)  
<http://www.emea.eu.int/pdfs/human/hmpc/34085705en.pdf>
- Ispaghula seed (Plantaginis ovatae semen)  
Draft Community herbal monograph (EMEA/HMPC/340861/2005)  
<http://www.emea.eu.int/pdfs/human/hmpc/34086105en.pdf>
- Psyllium seed (Psyllii semen)  
Draft Community herbal monograph (EMEA/HMPC/340865/2005)  
<http://www.emea.eu.int/pdfs/human/hmpc/34086505en.pdf>

Further Rapporteur appointments were made for the preparation of draft monographs/List entries as shown in the Rapporteurship overview given in the Annex. Starting dates were agreed with respective Rapporteurs for a number of plants in accordance with the above-mentioned 'Timetable for the establishment of a Community herbal monograph [not resulting from any referral procedure]' (EMEA/HMPC/126542/2005).

The Committee discussed the various options available for the literature search and collection of all relevant bibliographic references necessary for the establishment of Community herbal monographs and the preparation of the List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. The Committee faces challenges with available resources to carry out these tasks, which are expected to enhance European harmonisation for well-established and traditional herbal medicinal products and to facilitate access to the market. The Committee discussed with AESGP<sup>2</sup> and ESCOP<sup>3</sup> how they may support these tasks. A possible co-operation with interested parties will be further explored at the hearing scheduled for 22 November 2005, given that the Committee anticipates the support of some interested parties for compiling the latest published and unpublished scientific data.

The HMPC continued to reflect on the criteria such as public health considerations when selecting the priority order for the establishment of monographs/preparation of List entries in the medium/long term.

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<sup>2</sup> The Association of the European Self-Medication Industry

<sup>3</sup> The European Scientific Cooperative on Phytotherapy

## **Discussion on Regulatory & Legal Topics**

The Committee discussed a number of legal and regulatory topics, in particular the response received from the European Commission providing clarification on the provisions for the marketing authorisation of herbal medicinal products based on the “well-established use” provisions. Further discussion will take place at the November 2005 meeting. These clarifications will be taken into account in further developing the draft guideline on the assessment of clinical safety and efficacy in applications for marketing authorisations for well-established herbal medicinal products or for registration of traditional herbal medicinal products.

## **Coordination matters**

The Committee was informed about the ‘Guideline on reporting of suspected transmission of any infectious agent via a medicinal product’ (EMEA/CHMP/296412), which introduces the need to report any suspected transmission via a medicinal product of any infectious agent through pharmacovigilance procedures, as required by Regulation (EC) No 726/2004. The Committee made some comments on the document. The guideline was adopted by the CHMP in September 2005 and will be transmitted to the European Commission.

The Committee considered a report from the HMPC representative who attended the meeting of the EMEA/CHMP “Working Group with Patients’ Organisations” held on 7 September 2005. The Committee will closely follow the various initiatives undertaken by the group, with a view to contributing to any action relevant to the Committee’s mandate.

For further information, please contact:

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**HMPC: RAPPORTEURSHIP DISTRIBUTION FOR PREPARATION OF COMMUNITY HERBAL MONOGRAPHS/LIST ENTRIES  
STATUS September 2005**

HMPC Delegates <sup>4</sup>	HMPC March 05		HMPC May 05		HMPC July 05		HMPC September 05		HMPC November 05		HMPC January 06		HMPC March 06		Total R
	R	[Co-R]	R	[Co-R]	R	[Co-R]	R	[Co-R]	R	[Co-R]	R	[Co-R]	R	[Co-R]	
Austria (AT)					3										3
Belgium (BE)					3										3
Cyprus (CY)															
Czech Republic (CZ)															
Denmark (DK)					1										1
Estonia (EE)							1								1
Finland (FI)															
France (FR)					1										1
Germany (DE)	5		2		5										12
Greece (EL)															
Hungary (HU)					3										3
Ireland (IE)					2										2
Italy (IT)					2										2
Latvia (LV)					1										1
Lithuania (LT)															
Luxembourg (LU)															
Malta (MT)															
The Netherlands (NL)					1		1								2
Poland (PL)							1								1
Portugal (PT)					3										3
Slovakia (SK)															
Slovenia (SI)					1										1
Spain (ES)					3										3
Sweden (SE)					2										2
United-Kingdom (UK)					2										2
Iceland (IS)					1										1
Norway (NO)															
U. Wissinger-Gräfenhahn							1								
O. Pelkonen								1							
<b>TOTAL R</b>	<b>5</b>		<b>2</b>		<b>34</b>		<b>4</b>		<b>1</b>						<b>45</b>

R = Rapporteur

Co-R = Co-Rapporteur

<sup>4</sup> The list includes HMPC member and alternate for each Member State.