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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 22-23 November 2005

The Committee on Herbal Medicinal Products met for the eighth time at the EMEA offices on 22-23 November 2005. The Chairman welcomed the new Committee member for Greece, Prof. Ioanna Chinou, and informed the Committee about the nomination of a new alternate member for Greece, Ms Eleni Skaltsa.

The Committee heard presentations from the candidates for co-opted membership 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 shortlisted candidates presented their professional career, involvement in the field of herbal medicines and respective expertise in the above-mentioned areas.

Following the subsequent voting procedure, Dr G. Laekeman was appointed as co-opted member in the field of experimental/non-clinical pharmacology. Presentations and election for the appointment of a co-opted member in the area of paediatric medicine will continue at the HMPC meeting scheduled for 11-12 January 2006. A shortlist of candidates with expertise in the field of traditional herbal medicinal products will be established in the 1st quarter of 2006.

The HMPC adopted the meeting dates for 2007, which can be found in Annex 1 to this report. They are also available together with the previously adopted meeting dates for 2006 at:
<http://www.emea.eu.int/htms/human/hmpc/hmpcmeet.htm>

Reports from the drafting groups' meetings

Organisational matters

The drafting group on organisational matters made progress in the work on a draft assessment report template for the preparation of Community herbal monographs and for the inclusion of herbal substances, preparations and combinations thereof in the Community list, and will have further discussions on this during the drafting group's meeting in January 2006.

The group discussed the possibilities of suggesting a harmonised interpretation of the term 'external use' for use in the framework of traditional use registration. It was decided to continue this work in the group's January 2006 meeting, with a view to presenting a proposal for discussion in the HMPC during the January 2006 plenary meeting.

Comments were received from HMPC members and from the EMEA Quality Review of Documents (QRD) on the procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use. It was decided to discuss these at the group's meeting in January 2006 with an aim to adopt the final document (together with an overview of the comments received) during the January 2006 HMPC meeting.

The drafting group discussed the various options available for literature search and collection of all relevant bibliographic references necessary for the establishment of Community herbal monographs and the preparation of the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. It was agreed to further investigate the possibility of a call for data from third parties, through a procedure subject to certain conditions: a) the procedure will be made public; b) the procedure will take place within a framework of criteria to be predefined by the HMPC (e.g. in relation to literature research strategy); and c) the procedure shall seek to ensure that a complete set of bibliographic references and/or scientific data will be available to the Rapporteur(s).

The scope and practicalities of the procedure will be further discussed in the drafting group's meeting in January 2006.

Quality

The Committee reviewed comments received on the revised CHMP/CVMP 'Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products' and the revised CHMP/CVMP 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products'. It is expected that final discussions will take place during the drafting group's meeting in January 2006 before transmission to the CHMP/CVMP Quality Working Party.

There was an update on 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 January 2006 meeting.

The HMPC was informed about the outcome of the ICH meeting held in Chicago in November 2005, including feedback on the comments the Committee had submitted to the ICH/M5 'Note for guidance on data elements and standards for drug dictionaries' (CPMP/ICH/168535/2005). These have been taken into account in the finalisation of the document, and the Committee was requested to assist the work of preparing a list of herbal substances (genus, species, plants) in line with the agreed mapping and hierarchy structure.

The *ad hoc* GMP Inspection Services Group released an announcement on 11 October 2005 via the EMEA website that the Annex 7 provisions are applicable to traditional herbal medicinal products. The announcement can be found at: <http://www.emea.eu.int/Inspections/WhatsNew.html>. Furthermore, a joint drafting group between the HMPC and *ad hoc* GMP Inspections Services Group has been established for the revision of Annex 7 to the GMP Guide (a meeting of the group is scheduled for 1 December 2005).

Safety and Efficacy

The Committee adopted the following final public statements:

- 'Public statement on the use of herbal medicinal products containing estragole' (EMEA/HMPC/137212/2005)
- 'Public statement on the use of herbal medicinal products containing methyleugenol' (EMEA/HMPC/138363/2005)
- 'Public statement on Capsicum/capsaicin-containing herbal medicinal products' (EMEA/HMPC/138379/2005)
- 'Public statement on the risks associated with the use of herbal products containing Aristolochia species' (EMEA/HMPC/138381/2005)

- ‘Public statement on the use of herbal medicinal products containing pulegone and menthofuran’ (EMEA/HMPC/138386/2005)
- ‘Public statement on the use of herbal medicinal products containing asarone’ (EMEA/HMPC/139215/2005)

They can be found together with overviews of comments received during the consultation period on the EMEA website at:

<http://www.emea.eu.int/hmts/human/hmpc/hmpcguide.htm>

The Committee made progress with the work on draft monographs and assessment reports for Senna leafs and Senna pods. It is expected that the draft monographs will be adopted for release for public consultation at the January 2006 HMPC meeting.

Initial discussions on draft monographs and assessment reports for Barbados aloes and Cape aloes as well as for Frangula cortex are scheduled to take place during the January 2006 HMPC meeting.

Assessment work for a number of plants is scheduled to commence in the remainder of 2005 and throughout 2006. An overview covering the period October 2005 – December 2006 can be found in Annex 2 to this report.

Pharmacovigilance of herbal medicinal products

The Committee reviewed the comments received during the consultation period on ‘Public statement on CPMP List of herbal drugs with serious risks dated 1992’ (EMEA/HMPC/246736/2005). In general, the Committee finds the list to contain relevant information that needs to be addressed and considered. In light of the comments received, the Committee decided to amend the public statement by making reference to the new legislative framework under which the safety of herbal preparations must be documented with an assessment on a case-by-case basis. New safety aspects concerning the plants on the CPMP List of herbal drugs with serious risks, dated 1992, may be identified during the establishment of Community herbal monographs or entries to the List of herbal substances, preparations or combinations thereof for use in traditional herbal medicinal products. The revised public statement can be found at:

<http://www.emea.eu.int/pdfs/human/hmpc/24673605.pdf>

Discussion on regulatory & legal topics

The Committee discussed a number of legal and regulatory topics, including further discussion on 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. In light of this response, the drafted guideline on the assessment of clinical safety and efficacy in applications for marketing authorisation for well-established herbal medicinal products or for registration of traditional herbal medicinal products will be further developed and discussed at the January 2006 HMPC meeting.

Coordination matters

The HMPC was pleased to accept an invitation to attend the meetings of the EMEA/CHMP Working Group with Patients’ Organisations as observer on a regular basis and appointed the Icelandic HMPC member, Thorbjörg Kjartandsdóttir, as representative. The Committee welcomes this opportunity to follow closely the various initiatives undertaken by the working group as well as to actively contribute to the work of the group.

Hearing with interested parties to the Committee held on 22 November 2005

A hearing with interested parties to the HMPC was conducted on 22 November 2005 with representation from scientific associations, healthcare professionals' organisations & patients' organisations and from industry associations.

The purpose of the hearing was for the HMPC to present the key achievements since its establishment in September 2004 and for the interested parties to express their views on the Committee's work and their expectations for the Committee's deliveries in 2006.

A number of interested parties provided the HMPC with their view on the prioritisation of the ongoing work on draft Community herbal monographs and draft entries to the Community list. A few associations indicated their intent to send their views after the hearing.

The HMPC indicated that opportunities for dialogue with interested parties in other fora than annual hearings will be investigated.

Both the Committee and the participants expressed their appreciation for this opportunity to exchange information and viewpoints.

For further information, please contact:

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**Committee on Herbal Medicinal Products
Meeting dates in 2007**

MONTH	DATE	ROOM
January	Wed 10 – Thu 11	3A
March	Wed 7 – Thu 8	3A
May	Tues 8	3A
July	Wed 4 – Thu 5	3A
September	Wed 5 – Thu 6	3A
October	Tues 30 – Wed 31	3A

**Working Party on Community monographs and Community list
Meeting dates in 2007**

MONTH	DATE	ROOM
January	Tues 9 – Wed 10	3A
March	Tues 6 – Wed 7	3A
May	Mon 7	3A
July	Tues 3 – Wed 4	3A
September	Tues 4 – Wed 5	3A
October	Mon 29 – Tues 30	3A



**Overview of plants for which assessment work
is scheduled to commence October 2005 – December 2006**

*The names are listed in alphabetical order
and the list is subject to changes following HMPC decisions*

Absinthii herba	Meliloti herba
Allii sativi bulbus	Melissae folium
Aloe capensis	Menthae piperitae aetheroleum
Anisi fructus	Menthae piperitae folium
Betulae folium	Passiflorae herba
Boldo folium	Polygalae radix
Calendulae flos	Primulae radix
Carvi fructus	Rhamni purshianae cortex
Centaurii herba	Rhei radix
Curcumae longae rhizoma	Ribis nigri folium
Echinaceae purpureae herba	Salicis cortex
Eleutherococci radix	Sennae folium
Foeniculi fructus	Sennae fructus
Frangulae cortex	Solidaginis virgaureae herba
Hamamelidis cortex	Thymi herba
Hamamelidis folium	Urticae folium
Hamamelidis folium et cortex	Urticae herba
Harpagophyti radix	Urticae radix
Lichen islandicus	Uvae ursi folium
Lupuli flos	Zingiberis Rhizoma

Community herbal monographs for ispaghula husk (*plantago ovata*, tegumentum), ispaghula seed (*plantago ovata*, semen), psyllium seed (*plantago afra* et *plantago indica*, semen), linseed (*linum*, semen) and valerian root (*valeriana*, radix) have been released for public consultation until 31 January 2006 and can be found at: <http://www.emea.eu.int/hmts/human/hmpc/hmpcmonographs.htm>

Draft entries to the Community list for linseed (*linum*, semen) and valerian root (*valeriana*, radix) have been released for public consultation until 31 January 2006 and can be found at: <http://www.emea.eu.int/hmts/human/hmpc/hmpclist.htm>