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Post-authorisation Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 11-12 January 2006

The Committee on Herbal Medicinal Products met for the ninth time at the EMEA offices on 11-12 January 2006. The Chairman welcomed the new Committee member for Slovakia, Ms Dáša Salugová.

The Committee held an election for co-opted membership in the field of paediatric medicines and Prof. Kurt M. Widhalm, University of Vienna, was appointed as co-opted member in this area.

Reports from the drafting groups' meetings

Organisational matters

The HMPC Drafting Group on Organisational Matters discussed the possibilities of suggesting a harmonised interpretation of the term 'external use' for use in the framework of traditional-use registration. A final proposal for the interpretation was subsequently agreed by the HMPC and will be published on the EMEA website after adoption by HMPC via written procedure in February 2006.

The drafting group had further discussions on revisions of the draft documents 'Procedure for the preparation of Community monographs for traditional herbal medicinal products' (EMEA/HMPC/182320/2005) and 'Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use' (EMEA/HMPC/182352/2005) in light of the comments received, in particular those received from the EMEA Quality Review of Documents (QRD-group). Finalisation of the documents is expected during the drafting group's next meeting, in February 2006, for adoption by the HMPC in March 2006.

In addition, the group had in-depth discussions on a number of issues remaining from 2005, which will need further attention at the group's next meeting.

Quality

The HMPC adopted revisions to the 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 CHMP/CVMP 'Guideline on quality of herbal medicinal products/traditional herbal medicinal products', as revised by the HMPC Drafting Group on Quality following public consultation. Both guidelines will be transmitted to the CHMP/CVMP Quality Working Party with a view to subsequent adoption by CHMP and CVMP.

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A joint drafting group between the HMPC and the *ad hoc* GMP Inspection Services Group held a meeting on 1 December 2005, during which a proposal for a revised Annex 7 to the GMP Guide was discussed. The document was endorsed by the HMPC and will be transmitted to the *ad hoc* GMP Inspection Services Group.

The Committee wishes to remind marketing authorisation holders and applicants that herbal medicinal products are subject to Volume IV of the rules governing medicinal products in the European Union i.e. the GMP requirements laid down in Directive 2003/94/EC and interpreted in the GMP Guide. The requirement of GMP compliance includes the finished product as well as the active substance.

In addition, the drafting group discussed the final version of the 'Public statement on good agricultural and collection practice for starting materials of herbal origin (GACP)' (EMEA/HMPC/246816/05) in light of the comments received and taking into account discussions with stakeholders at a meeting organised by EUROPAM in December 2005. In light of the new procedure on EU Guidelines, the document was adopted by the HMPC as a guideline, which will also be transmitted to the *ad hoc* GMP Inspection Services Group for their information. When released, the document will be available on the EMEA website at: http://www.emea.eu.int/htms/human/hmpc/hmpcguide.htm

Safety and efficacy

The HMPC adopted the following draft Community herbal monographs, which will soon be released for public consultation:

- Senna leafs (Sennae folium)
  Draft Community herbal monograph (EMEA/HMPC/)

- Senna pods, Alexandrian (Sennae fructus acutifoliae) and Senna pods, Tinnevelly (Sennae fructus angustifoliae)
  Draft Community herbal monograph (EMEA/HMPC/)

It is expected that the draft monographs will be for consultation until the end of April 2006. When released, they will be available at: http://www.emea.eu.int/htms/human/hmpc/hmpcmonographs.htm

The Committee made progress with the work on draft monographs and assessment reports for Barbados aloes and Cape aloes as well as for Frangula cortex. Further discussions are scheduled to take place during the March 2006 HMPC meeting.

The HMPC adopted the following final guideline:

- Guideline on the clinical assessment of fixed combinations of herbal substances/herbal preparations (EMEA/HMPC/166326/05);

as well as the following draft guideline, which is released for public consultation until 15 April 2006:

- Guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation (bibliographical and mixed applications) and in applications for simplified registration (EMEA/HMPC/32116/05)

The documents (and an overview of comments received during the consultation period for the final guideline) can be found on the EMEA website at:
http://www.emea.eu.int/htms/human/hmpc/hmpcguide.htm

The HMPC adopted the following final public statement:

- Public statement on the allergenic potency of herbal medicinal products containing soya/peanut protein (EMEA/HMPC/138139/05)

When released, the document, together with an overview of comments received during the consultation period, will be available at on the EMEA website at:
http://www.emea.eu.int/htms/human/hmpc/hmpcguide.htm

In addition, the Committee had further discussions on the 'Public statement on chamomilla containing herbal medicinal products' (EMEA/HMPC/138309/05), which is expected to be published after the HMPC meeting in March 2006.

Pharmacovigilance of herbal medicinal products

The Committee discussed the publication of the final version of the HMPC assessment report on hepatotoxicity cases associated with Cimicifuga racemosa (black cohosh), which have been reviewed by the Pharmacovigilance Working Party. When released, the document will be available at:
http://www.emea.eu.int/htms/human/hmpc/hmpcguide.htm

Working methodology

The HMPC established a permanent Working Party on Community monographs & Community list, which replaces the temporary Safety & Efficacy Drafting Group. Dr Heribert Pittner was elected by the HMPC as Chairman of the new working party for the remaining period of the HMPC's current mandate (until September 2007). The first meeting of the working party is scheduled to take place on 7-8 March 2006.

The Drafting Group on Quality and the Drafting Group on Organisational Matters will continue their work in 2006. Dr Dairine Dempsey and Dr Emiel van Galen were re-confirmed as Chairpersons for the respective drafting groups.

The composition of the HMPC working party and the two drafting groups is provided in annex I.

Interaction with interested parties

The Committee reflected on the outcome of the hearing with interested parties to the HMPC held at the EMEA on 22 November 2005. In line with the Committee's approach to transparency, the following document was adopted for publication on the EMEA website:

- Minutes from hearing with interested parties to the HMPC, 22 November 2005 (EMEA/HMPC/405043/2005)

The document has been reviewed and accepted for publication by all participating organisations, and can be found on the EMEA website at: http://www.emea.eu.int/htms/human/hmpc/hmpcmeetings.htm

For further information, please contact:

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ANNEX I

COMPOSITION OF HMPC WORKING PARTY AND DRAFTING GROUPS

HMPC Working Party on Community monographs and Community list:

Anderson Linda
Biró-Sándor Zsuzsanna
Chinou Ioanna
Claeson Per
Demspey Dairine
Delbò Marisa
Fossum Gro
García Lorente Gloria
Heroutová Marie
Keller Konstantin
Kreft Samo
Kroes Burt
Laekeman Gert
Pakalns Dailonis
Pelkonen Olavi
Pinto Ferreira Maria Helena
Pittner Heribert
Raal Ain
Törrönen Anneli
Viguet-Poupelloz Jacqueline
Vlietinck Arnold
Werner Christine
Widy-Tyszkiewicz Ewa
Wissinger-Gräfenhahn Ulrike

HMPC Drafting Group on Organisational Matters:

Bager Steffen
Claeson Ubonwan
Cuschieri Christian
Dymowski Wojciech
García Lorente Gloria
Martins Ana Paula
Razinger Barbara
Reh Klaus
van Galen Emiel
Viguet-Poupelloz Jacqueline

HMPC Drafting Group on Quality:

Anderson Linda
Delbò Marisa
Demspey Dairine
Fouraste Isabelle
Hvolby Kristine
Koski Sari
Kroes Burt
Kubelka Wolfgang
Neef Heidi
Reh Klaus