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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

Meeting report, 7-8 May 2008

The HMPC held its 23rd meeting at the EMEA on 7-8 May 2008. The HMPC welcomed N. Grigoras, new HMPC member from Romania and M. Hadzihamza and M. Evrosimovska, new observers from the Former Yugoslavian Republic of Macedonia.

During the plenary meeting the HMPC voted to renew, the three-year-term of Prof. O. Pelkonen, co-opted member with expertise in toxicology. The HMPC examined candidatures for the election of a co-opted member with expertise in herbal traditional medicine; votes, however, did not result in the election of such co-opted member. The Committee continued discussing the election of a co-opted member with appropriate expertise in clinical pharmacology and herbal medicinal products following the departure of U. Wissinger-Gräfenhahn who had been previously co-opted to the HMPC to provide such expertise. The HMPC will further discuss the appointment of co-opted members in July 2008.

The composition of the Committee can be found at:

http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_members.html

The HMPC appointed Dr G. Cimino as a member of the Working Party on Community Monographs and Community List (MLWP) in order to utilise his practical experience in the area of paediatric and traditional medicine.

The composition of the MLWP can be found at:

http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_MLWP.html

Upon recommendation from the MLWP, the HMPC adopted the following Community herbal monographs/Community list entries and related documents:

Community list entries:

- 'Community list entry for *Echinacea purpurea* (L.) Moench., herba' (EMEA/HMPC/189629/2007)
- 'Community list entry on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix' (EMEA/HMPC/83756/2007)

Once available in all EU languages, the Community list entry, together with its assessment report and the HMPC opinion, will be transmitted to the European Commission for adoption.

Final Community herbal monographs

- 'Community herbal monograph on *Betula pendula* Roth; *Betula pubescens* Ehrh., folium' (EMEA/HMPC/260019/2006)
- 'Community herbal monograph on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix' (EMEA/HMPC/244569/2006)
- 'Community herbal monograph on *Humulus lupulus* L., flos' (EMEA/HMPC/513617/2006)

The final Community herbal monographs as well as their respective HMPC opinions, assessment reports and overview of comments received during the consultation period, will be published in due course on the EMEA website at:

<http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographsadopt.htm>

The HMPC adopted the following draft Community list entry, released for public consultation until 15 August 2008:

- Draft 'Community list entry on *Mentha x piperita* L., aetheroleum' (EMEA/HMPC/189245/2008)

The document, together with a draft list of references used during the assessment, will be published in due course on the EMEA website at:

<http://www.emea.europa.eu/htms/human/hmpc/hmpclist.htm>

Draft Community herbal monographs, released for public consultation until 15 August 2008:

- Draft 'Community herbal monograph on *Peumus boldus* Molina, folium' (EMEA/HMPC/591648/2007)
- Draft 'Community herbal monograph on *Polypodium vulgare* L., rhizoma' (EMEA/HMPC/600668/2007)
- Draft 'Community herbal monograph on *Urtica dioica* L.; *Urtica urens* L., folium' (EMEA/HMPC/508015/2007)

The draft Community herbal monographs together with a draft list of references used during the assessment will be published in due course on the EMEA website at:

<http://www.emea.europa.eu/htms/human/hmpc/hmpcmonographsdraft.htm>

The HMPC adopted the final 'Reflection paper on the adaptogenic concept' (EMEA/HMPC/99116/2007) together with the overview of comments received on the draft reflection paper during the public consultation. Both documents will be available at:

<http://www.emea.europa.eu/htms/human/hmpc/hmpcguide.htm>

Appointment of Rapporteurs

The HMPC appointed Rapporteurs for the preparation of draft Community herbal monographs/Community list entries for Centellae herba, Tanacetii parthenii herba/folium and Symphyti radix.

Report from the Working Party on Community Monographs and Community List (MLWP)

The MLWP held its 14th meeting at the EMEA on 5-7 May 2008.

In addition to the work that supported the adoption of the above-mentioned documents by the HMPC, the MLWP concluded the scientific work related to Avenae fructus, Avenae herba, Equiseti herba, Meliloti herba, Rusci aculeati rhizoma and Solidaginis virgaureae herba; the adoption of the respective monographs/list entries and related documents will take place at the July 2008 HMPC meeting after their peer-review. The MLWP made significant progress on the scientific work relating to draft monographs and assessment reports on Althaeae radix, Centaurii herba, Hyperici herba and Valerianae radix/Lupuli flores. The MLWP also discussed draft monographs on Absinthii herba, Hamamelis cortex/folium/distillate, Hippocastani semen and Taraxaci radix cum herba.

An updated 'Overview of status of HMPC assessment work – priority list – May 2008' (EMEA/HMPC/278067/2006) will be published on the EMEA website at:

<http://www.emea.europa.eu/pdfs/human/hmpc/27806706en.pdf>

On 6 May, the MLWP met representatives from the Association of the European Self-Medication Industry (AESGP) in order to discuss a number of general issues related to Community herbal monographs/Community list entries and related documents adopted by the HMPC. The contribution from companies and European organisations such as AESGP at different stages of the establishment of monographs and list entries was discussed. The AESGP in particular would welcome the opportunity to prompt the possible revision of adopted monographs/list entries upon the submission of a detailed justification based for example on an analysis of the published Assessment Report (AR) or the identification of discrepancies between adopted texts with relevant consequences. The HMPC draft 'Reflection paper on the criteria and timelines for revision of final Community herbal monographs or Community list entries' (EMEA/HMPC/326440/2008) is currently under public consultation and can be found at:

<http://www.emea.europa.eu/pdfs/human/hmpc/32644007en.pdf>

The AESGP took the opportunity to share with the working party feedback from the herbal medicines industry sector on the opportunities offered by the new legislation on traditional use registration,

practical experience with its implementation in the EU Member States and various current challenges such as the lack of binding character of monographs, the low number of list entries adopted so far and the perceived complexity of the mutual recognition procedure (MRP)/ Decentralised Procedure (DP) for many small and medium-sized companies and their associated costs. The AESGP reiterated its support to the work done by the Committee and the HMPC expressed its appreciation of this continued collaboration.

The next meeting of the MLWP is scheduled for 30 June-2 July 2008.

Report from the Quality Drafting Group (Quality DG)

A meeting of the Quality DG was held on 10 April 2008.

The HMPC adopted the QWP 'Concept Paper on the development of a quality guideline on pharmaceutical development of medicines for paediatric use' (EMEA/138931/2008). Upon adoption by the CHMP and PDCO, the concept paper will be published on the EMEA website at:

<http://www.emea.europa.eu/htms/human/humanguidelines/quality.htm>

Report from the Organisational Matters Drafting Group (ORGAM DG)

A teleconference of the ORGAM DG was held on 9 April 2008.

The HMPC adopted the following document:

- 'Procedure on management of proposals submitted by interested parties for Community list entries or Community herbal monographs' (EMEA/HMPC/328575/2007)

The procedure and the overview of comments received during the public consultation will be available on the EMEA website at:

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

Other relevant information

The HMPC progressed its reflection paper on the ethanol content in (traditional) herbal medicinal products used in children. The scope of the document is to reflect the need for safety limits for ethanol exposure by oral herbal medicinal products intended for the paediatric population. The document will now be discussed with the PDCO and CHMP.

The HMPC finalised the 'Guideline on the assessment of genotoxicity of herbal substances/preparations' (EMEA/HMPC/107079/2007) upon review of the comments received during the public consultation. The HMPC maintained the approach proposed in the draft guideline and some minor amendments were brought to the text. The final guideline and the overview of comments will be forwarded to the Safety Working Party of the CHMP, which contributed to the preparation of this guideline. It will then be published on the EMEA website at:

<http://www.emea.europa.eu/htms/human/humanguidelines/nonclinical.htm>

Cooperation with the European Food Safety authority (EFSA) continues with the participation of HMPC representatives in meetings of various groups established at EFSA. HMPC representatives are being associated to the work of EFSA in the area of safety assessment of botanicals and botanic preparations intended for use as food supplements. The HMPC representatives will support the work on case studies by sharing knowledge from animal safety studies and human safety data; expertise in the characterisation of substances or preparations will also be offered.

Furthermore, the HMPC continued its reflection on various aspects of the borderline between therapeutic indications and health claims for herbal ingredients. The HMPC heard a presentation from an EFSA representative on the role of the EFSA panel on dietary products, nutrition and allergies (NDA panel), the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods and the EFSA tasks on claims & advice on the scientific substantiation of health claims. Cooperation with EFSA and its scientific groups is governed by specific guidelines/recommendations on the cooperation between bodies of the European Union as referred to in Article 59 of Regulation (EC) No 726/2004.

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