



European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 11 July 2006

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HMPC WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY
LIST (MLWP)

HEARING WITH INTERESTED PARTIES

11 July 2006 – 17.00 to 19.00

*7 Westferry Circus, Canary Wharf, London E14 4HB
EMEA, conference room 3A, 3rd floor*

Chairman: Prof H. Pittner

1. Welcome of all participants
2. Presentation by Chairpersons of achievements by the HMPC (Dr K. Keller) / MLWP (Prof. H. Pittner)
3. Presentations by interested parties
4. Discussion on the progress made with preparation of Community herbal monographs/Community list entries by MLWP and the support of assessment work by interested parties
 - Background document: E-mail dated 8 July 2006 from S. Mills, ESCOP re. delays in submission of literature to Rapporteurs
5. Discussion on HMPC assessment priorities in relation to establishment of Community herbal monographs/Community list entries
 - Background document: List of plants for which HMPC assessment work is ongoing or scheduled (including progress status July 2006)
6. Conclusions

List of interested parties

The Association of the European Self-Medication Industry (AESGP)
The European Scientific Cooperative on Phytotherapy (ESCOP)

The meeting had been arranged on the initiative of the MLWP Chairman with the purpose of strengthening contacts to those interested parties that have provided the most substantial support to the assessment work in terms of submission of bibliographic data to Rapporteurs. These organisations being AESGP and ESCOP, representatives had been invited to such a meeting in the margins of the July 2006 MLWP meeting (cf. attached list of representatives). A draft 'agenda for the hearing with interested parties 11 July 2006' (EMEA/HMPC/222795/2006 Rev.2) was distributed as basis for discussions.

The MLWP Chairman introduced the participants of the meeting and provided an update on the establishment of MLWP (March 2006) and the working party's progress since then. In addition, the HMPC Chairman summarised the overall achievements of the HMPC, focusing mainly on problems regarding resource constraints in relation to assessment work for Community herbal monographs/Community list entries, and a status on the current support from the interested parties.

Following introductions by the AESGP and ESCOP representatives there was a discussion on the future support by interested parties to the MLWP/HMPC assessment work. The ESCOP representative gave reference to an e-mail dated 8 July 2006 from S. Mills, ESCOP regarding 'delays in submission of literature to Rapporteurs' (distributed at the meeting). He elaborated on the message given in the e-mail, explaining that ESCOP has found it necessary to suspend submissions to the MLWP of bibliographic material held by ESCOP. This situation is caused by concerns relating to the copyright status of material held by ESCOP. Due to the vast amount of literature used by ESCOP and the spread of time and range of sources from which they have come, it has not been possible to yet establish an overview of which material can be submitted to the MLWP without violating copyright rules.

The ESCOP representative stressed that ESCOP regrets the situation, but does indeed maintain the intention of providing as much support as possible to the MLWP/HMPC in terms of understanding how ESCOP reaches its own assessment conclusions.

The AESGP representatives indicated that AESGP regards ESCOP as the appropriate organisation for providing the core support to the MLWP/HMPC. However, AESGP will continue its efforts to submit literature in relation to ongoing MLWP assessment work. AESGP furthermore acknowledged the importance of maintaining a high quality of the Community herbal monographs, also if that would entail delays of the underlying assessments.

AESGP took the opportunity to inquire specifically about the status of the draft 'guideline on non-clinical documentation for herbal medicinal products in applications for marketing authorisation' – in particular with regard to genotoxicity. The HMPC Chairman clarified that the guideline had been adopted for transmission to the HMPC during the morning session and thus still was to be discussed in the HMPC. However, he explained that the guideline describes reduced requirements for testing of genotoxicity and introduces a stepwise approach to these.

In this context, the HMPC Chairman informed the participants that the MLWP and HMPC had identified a problem concerning lack of available safety data relating to genotoxicity. In the current situation, two entries to the Community 'list of herbal substances, preparations and combinations thereof' have been almost finalised. However, as the MLWP had decided during the morning session to recommend that a positive opinion should *not* be adopted by the HMPC until such safety data become available, the draft list entries would likely not be submitted to the Eur.Com. as expected. The HMPC Chairman therefore took the opportunity to encourage the industry to look further into these issues.

AESGP in addition raised minor questions regarding combination herbal products and scientific advice on HMPs. For both issues reference was given to information available on the EMEA website. Furthermore, there was some interest in the Eur.Com. report on application of the provisions of Chapter 2a of Directive 2001/83/EC as amended. The HMPC Chairman clarified that this is a Commission document, but that the HMPC does not foresee any major extension of the scope of TU-registration at this point in time.

As the last point on the agenda, there was a discussion on the HMPC assessment priorities in relation to establishment of Community herbal monographs/Community list entries. The AESGP representative inquired about the prioritisation criteria of the HMPC as the organisation receives many questions as to why some plants are included on the current priority list and others not.

The HMPC Chairman clarified that the MLWP is currently working from a pragmatic approach, where herbal substances for which 'core data' documents exist are assessed first. As a background document, the 'List of plants for which HMPC assessment work is ongoing or scheduled (including progress status July 2006)' had been distributed and the HMPC Chairman pointed out that many of these plants are also found among the priorities previously provided by interested parties to the HMPC. He furthermore stressed that assessments are carried out as non-reimbursed work by Rapporteurs in NCAs and that resources therefore are limited. He encouraged the interested parties to submit well-structured documentation in order to facilitate these assessments as much as possible.

The ESCOP representative informed that 21 new ESCOP monographs and 5 revised ESCOP monographs are expected for publication in early 2007.

The MLWP Chairman briefly summarised the main discussion points of the meeting, which he characterised as interesting and fruitful. He stressed that the MLWP finds it important to maintain close contacts with interested parties and would expect future meetings with a similar scope to be arranged.

List of Participants

Representatives from AESGP:

Dr Christelle Anquez-Traxler
Dr Werner Busse
Dr Hubertus Cranz
Dr Bernd Eberwein
Dr Willmar Schwabe

Representatives from ESCOP:

Mr Victor Perfitt

Chairman of the MLWP:

Dr Heribert Pittner

MLWP members:

Prof. Arnold Vlietinck
Dr Marie Heroutová
Pharm. Ain Raal
Dr Anneli Törrönen
Dr Jacqueline Viguet Poupelloz
Prof. Ioanna Chinou
Pharm. Zsuzsanna Biró-Sándor
Pharm. Marisa Delbó
Dr Dailonis Pakalns
Dr Burt Kroes
Pharm. Gro Fossum
Dr Ewa Widy-Tyszkiewicz
Dr Helena Pinto Ferreira
Prof. Samo Kreft
Dr Gloria Garcia Lorente
Dr Per Claeson
Dr Linda Anderson
Prof. Olavi Pelkonen
Dr Ulrike Wissinger-Gräfenhahn
Prof. Gert Laekeman
Dr Konstantin Keller

Experts:

Dr Cora Nestor (IE)
Gioacchino Calapai (IT)
Dr Ubonwan Claeson (SE)
Pharm. Ms Stephanie Bodamann
Dr Sinead Harrington
Dr Heidi Neef

Representatives from EMEA:

Mr Anders Blaedel-Lassen
Ms Lucia D'Apote
Mr Anthony Humphreys