European Medicines Agency
Evaluation of Medicines for Human Use

London, 4 September 2008
Doc. Ref. EMEA/HMPC/370642/2008

OVERVIEW OF COMMENTS RECEIVED ON 'REFLECTION PAPER ON THE REASONS AND TIMELINES FOR REVISION OF FINAL COMMUNITY HERBAL MONOGRAPHS AND COMMUNITY LIST ENTRIES' (EMEA/HMPC/326440/2008)

Table 1: Organisation(s) that provided comments on the draft 'Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries' as released for consultation on 6 March 2008 until 30 June 2008.

	Organisation
1	The Association of the European Self-Medication Industry (AESGP)

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Table 2: Discussion of comments

GENERAL COMMENTS - OVERVIEW	
We welcome in principle this document which provides clear guidance on the reasons triggering the necessary task of revising a Community herbal monographs and Community list entries. First of all, for transparency reasons, we believe that a **revised version of a monograph or list entry should be published, as draft, for consultation by interested parties**. As any revision of the community monograph or list entry can potentially bear consequences for products which are on the market, any changes in monographs or list entries is particularly important. Therefore interested parties should have the opportunity to review and comment before the revised version is published as final. We believe this point was intended but we would strongly recommend it is clearly reflected in the reflection paper.	The text has been amended in section 3 to reflect that the public consultation will be considered at the time of adoption of the timetable for review.

SPECIFIC COMMENTS ON TEXT

Line no. + para no.	Comment and Rationale	Outcome
Section 3.1, 3.2 and 3.3	Monographs/list entries should be updated in light of new data, on an ad hoc basis. We believe that these **reasons for revision are adequately covered by both section 3.1 "immediate review" and section 3.3 "review for specific reasons**". In light of this, there should be **no need for a review every five years and we recommend that section 3.2 be deleted**. In addition, and in light of its scarce resources, the HMPC should focus on its most important tasks i.e. the development of new monographs/ list entries and the prompt revision of monographs and list taking into account new scientifically relevant data. This would also be fully in line with the abandon of the 5-year renewal of marketing authorisations. We appreciate the option to initiate a review after a period shorter than five years in case of specific reasons. During this process, results from e. g. new clinical studies can be included in order to support the statements on efficacy as well as therapeutic indications. However, in order to take the **quality of scientific publications into account instead of their quantity**, we would like to suggest **replacing "*high volume of scientific publications***" by "***highly relevant scientific publications***". In addition, given that the time of publication of the assessment report is dissociated with the publication of the monograph or list entry itself, the **publication of the assessment report may explain important information** on the content of the monograph/list entry (e.g. comments misinterpreted, etc.) **which may entail asking for a revision of the monograph/list entry** (already published). Therefore, we would recommend **adding a new bullet point under section 3.3**, which should read "***in light of publication of assessment report".***	Not agreed. The experience in Member States has shown that a systematic review is valuable to maintain a high standard of the adopted monographs and list entries. Should this systematic review not be performed, this would result in the co-existence on the website of documents complying with old and new requirements. In addition, the need for such review will be considered every 5 years. Agreed. The text has been amended. Not agreed. The new peer review system aim at avoiding discrepancies in the monographs, list entries and/or assessment reports and at synchronising their publication. The independent assessment in the MLWP and HMPC could be different from the view of the stakeholder who has sent a comment to the EMEA.