



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2018
EMA/HMPC/399627/2018
Committee on Herbal Medicinal Products

Overview of comments received on 'Procedure for the review and revision of European Union herbal monographs and European Union list entries' (EMA/HMPC/124695/2011 Rev. 2)

Table 1: Organisations and/or individuals that commented on the revised ' Procedure for the review and revision of European Union herbal monographs and European Union list entries ' (EMA/HMPC/124695/2011 Rev. 2) as released for public consultation on 31 October 2017 until 31 January 2018

Name of organisation or individual

1 Polish Herbal Committee



1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
1	Polish Herbal Committee appreciates the development of the revision of the above-mentioned Procedure which, by improving the review process, will enable to maintain European Union herbal monographs and European Union list entries in line with recent advances of scientific research.	The HMPC takes notice of this positive appreciation.

2. Specific comments on text

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
193-209	1	Comment: In order to achieve full transparency and enable stakeholders to take their part in the review process, we suggest adding an additional public consultation stage in the procedure for the review of European Union herbal monographs and European Union list entries. According to the proposed wording of the revised procedure, the assessment of most recent scientific data done by the Rapporteur together with the proposal agreed at the MLWP will constitute crucial factors for a decision of HMPC to update or not the monograph. At this stage (step II), if 'No revision' pathway is suggested by the Rapporteur, we propose an opinion of MLWP together with draft list of references supporting the assessment should be published and made open for comments by interested parties before HMPC decision. Even though the call for scientific data is expected to be initiated in the proposed procedure, if 'No revision' pathway is accepted by HMPC, stakeholders would have no possibility to address the scientific assessment of newly-	Not endorsed The HMPC recognizes the concern of the Polish Herbal Committee to maximise the transparency and participation of interested parties in the reviewing of existing monographs and related documents. In this respect, on the one hand the HMPC is of the opinion that when the Committee decides that no revision is needed, transparency is guaranteed by publishing an explanation of the reasons of the decision and a list of key references. Indeed, according to heading 6 of the 'Procedure for the review and revision of European herbal monographs and European Union list entries' <i>"After HMPC decision that no revision is needed, an addendum to the already published assessment report [...] will be published. [...] The addendum containing a summary and conclusion on the review of new data and a list of key references (following the format provided in the template for list of references) will be published within 2 months after the HMPC decision"</i>. With the aim of maximising the level of transparency, the template 'Report on <Periodic> <Unscheduled> review of European Union herbal monograph <(Addendum to Assessment report)> on <plant, plant part>' (Annex 1 to the Procedure) has been amended accordingly and now requires to include an explanation of the decision not to proceed to a revision of an existing herbal monograph.

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		collected data. Firstly, the public consultation could have a remarkably positive effect on understanding of what aspects of collected data have led to its evaluation as irrelevant for the monograph particularly, as the assessment is mostly qualitative. Secondly, the decision not to change the monograph under circumstances of ever-changing medical knowledge should be treated similarly as the decision to adopt a revision of the monograph. Such equivalent approach requires to undertake public consultations as they are foreseen in Step IIIa of the procedure, even if 'No revision' pathway is suggested. Since the participation of interested parties has become a good practice in the process of preparation of European Union herbal monographs, we suggest similar approach in the process of their review. Otherwise there will be no means for stakeholders to comment on the scientific assessment of newly-collected data in case 'No revision' pathway is proposed. Proposed change (if any):	On the other hand the Procedure allows a wide participation of the stakeholders. Firstly, at the start of each review, a Call for data is published for 3 months allowing Interested parties to submit new data they consider relevant for periodic review and potential revision of the existing monograph. Secondly, according to heading 3.2, independent from the periodic review, interested parties can bring new relevant data to the attention of the HMPC (unscheduled review) to potentially start a revision procedure. Furthermore, it should be highlighted that the decision of the HMPC not to start the revision of existing herbal monographs or list entry is not subject to any public consultation because it does not affect the content of the existing monograph and opinion of the HMPC. In particular, it only involves a judgment on the relevance of the information (new scientific data or other findings) publicly available or brought to the attention of the HMPC by other EMA Committees/Working parties, HMPC members, National Competent Authorities or Interested Parties. In this regard, it should be considered that the decision to start the revision procedure is not subject to a public consultation either, as demonstrated by the combined reading of headings 4 and 5.1 of the Procedure In light of the above, the HMPC is not of the opinion that ... <i>there will be no means for stakeholders to comment on the scientific assessment of newly-collected data in case 'No revision' pathway is</i>

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
			<i>proposed</i> ... (citation from the overview of comments). In contrast, the HMPC remains open for new data that could change the content of monographs or list entries at any time. Finally, we like to confirm that according to the procedure once a monograph/list entry is revised, a public consultation of draft revised documents will always give the opportunity to Interested parties for comments and if necessary additional data provision before final adoption by the HMPC.