30 January 2018
EMA/HMPC/547742/2017
Inspections, Human Medicines Pharmacovigilance & Committees Division

Work plan for the Organisational Matters Drafting Group (ORGAM DG) 2018

Chair	**Status**
Gert Laekeman	Final

1. Meetings scheduled for 2018

Scheduled Meeting dates:

20 February 2018 (re-scheduled for 14 March 2018)

23 April 2018

19 June 2018

4 September 2018

9 October 2018

11 December 2018

Six meetings will be held virtually, with consideration of opportunities for at least one meeting in face to face.

2. Update, revision or extension of existing procedural & regulatory guidance

2.1. Finalise and follow-up on the new review and revision procedure of EU herbal monographs/list entries

Action: To finalise the draft procedure after public consultation including comments received during the HMPC Strategic, Review and Learning Meeting in Bucharest and follow up on the implementation of the new review and revision procedure. Upon request by HMPC review and revise documents

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based on the experience of the implementation of the new procedure.
To finalise the draft questionnaire collecting information from EU procedures to monographs and guidelines and link the questionnaire to the review/revision procedure as well as modify the HMPC agenda structure

- Procedure for the review and revision of European Union herbal monographs and European Union list entries (EMA/HMPC/124695/2011 Rev. 2)
- Annex 1 - review template for the draft procedure for the review and revision of European Union herbal monographs and European Union list entries (EMA/HMPC/568792/2017)
- Addendum template (EMA/HMPC/549349/2017)
- Questionnaire (EMA/HMPC/686096/2017)

2.2. Review of guidance documents on prioritisation and data requirements

Action: Based on current experience and future challenges, including the new template adopted for internal use, review and revise if necessary the existing procedures and other guidance documents/ templates including:

- Procedure on management of proposals submitted by interested parties for community list entries or Community Herbal Monographs (EMEA/HMPC/328575/2007 Rev. 1)

2.3. Update of procedural guidance documents

Action: Review and revise if necessary the following procedural guidance documents according to present practice:

- Procedure for the appointment by the HMPC of a rapporteur responsible for a scientific evaluation or the establishment of a community herbal monograph and/or community list entry (EMEA/HMPC/108877/2005 Rev. 1)

Rapporteur: A Le

- Procedure for the preparation of community monographs for traditional herbal medicinal products (EMEA/HMPC/182320/2005 Rev. 2)Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use (EMA/HMPC/182352/2005 Rev. 2)
- Procedure for the preparation of an entry to the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMA/HMPC/57137/2007)

2.4. Review of guidance documents on the requirement to check data protection for studies used in the establishment of monographs and list entries

Action: Review and if necessary revise HMPC procedural guidance documents and templates including:

- Template for information exchange for the preparation of the assessment report supporting the establishment of European Union monographs and list entries (EMA/HMPC/137093/2006 rev.1 corr)

3. Development of new procedural & regulatory guidance

N/A

4. Other

4.1. Procedural consequences for new or revised HMPC documents

Action: Upon request by HMPC perform procedural and regulatory review of new or revised HMPC guidance documents