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Inspections, Human Medicines Pharmacovigilance & Committees Division

Work plan for the HMPC Quality Drafting Group (Q DG) 2018

Chair

L. Anderson

Status

Final

1. Meetings scheduled for 2018

Meeting dates: 22 February, 19 April, 21 June, 06 September, 11 October and 13 December

One face-to-face meeting will be organised in February 2018, other meetings will be held virtually.

2. New guidance documents

- Reflection paper on the use of new analytical methods for the quality control of herbal medicinal products.

  Action: Publication of reflection paper taking into account comments on the concept paper published in 2017

- Guidance on the control of pyrrolizidine alkaloids (PAs) and polycyclic aromatic hydrocarbons (PAHs) in herbal medicinal products.

  Action: Check existing quality guidance documents (including GACP and specification guidelines) for necessary updates and initiate subsequent revisions and/or draft Q&A.

- Consideration of the implications of ICH Q3D for herbal medicinal products

  Action: Development of Q&A, as appropriate; consider implications for existing gulidelines

3. Update, extension or revision of existing guidance documents

- Revision of the Guideline on quality on herbal medicinal products

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Action: Publication of the draft revised guideline for consultation after coordination with QWP/CHMP and CVMP.

- Revision of the Guideline on specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and HMP/THMPs.

  Action: Publication of the draft revised guideline for consultation after coordination with QWP/CHMP and CVMP.

- Update/revision of questions & answers on quality of herbal medicinal products (EMA/HMPC/41500/2010).

  Action: (1) review and add new Q&A following revision of the quality and specifications guideline, quality assessors training 2015 (skip testing, stability, GACP/GMP, assay and markers; microbiological issues), and reflection paper on microbiological aspects; (2) remove redundant Q&A taken into account for revised guidelines.

- Review of the Reflection paper on markers used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products.

  Action: Review for suitability vis-a-vis Ph. Eur. definitions and HMPC monographs/assessment reports with focus on definitions.

4. Coordination with EDQM

- Development and review of pharmacopoeial monographs and general chapters, methods and notices (including PAs, essential oils, assay methods).

  Action: On-going activity, selection and discussion of relevant topics for the HMPC via participation of an EDQM representative in Q DG meetings and Q DG members in Ph. Eur. expert groups 13A (K. Reh), 13B (K. Reh) and TCM (R. Laenger). If necessary additional participation on specific items.

5. General

- Provide input to general quality guidelines and other guidance documents applicable to herbal substances/preparations/medicinal products.

  Action: On-going activity, monitor QWP activities and draft/propose to HMPC input as necessary.

- Provide input on quality questions for herbal medicinal products in the framework of HMPC coordination with other EMA committees/working parties (e.g. SA procedures with SAWP) if required.