



14 December 2017
EMA/CHMP/BMWP/420509/2017

Work plan for the Biosimilar Medicinal Products Working Party (BMWP) for 2018

Chairperson: Elena Wolff-Holz

Status of the work plan: Adopted

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

Face-to-face meetings are planned for the following dates:

- 26-27 March 2018
- 24-25 October 2018

The above mentioned dates may be modified as needed. Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products and to progress guidelines, as required.

2. Guidelines

2.1. New EU Guidelines

Action: Lead

None

Action: Specialised input

None



2.2. EU Guidelines under revision

Action: Lead

Revision of Guidelines on similar biological products to reflect the non-clinical stepwise approach and 3Rs principles

Target date Revised guidelines to be released: Q1 2018

Comments Objective: Revision of the non-clinical section of relevant guidelines* on similar biological products to align with the guideline on regulatory acceptance of 3R (replacement, reduction, refinement) testing approaches (EMA/CHMP/CVMP/JEG-3Rs/450091/2012).

* Guideline on similar medicinal products containing somatropin (Annex to guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues) (EMA/CHMP/BMWP/94528/2005) and Guideline on Similar biological medicinal products containing recombinant erythropoietins (EMA/CHMP/BMWP/301636/08)

Reflection paper on similar biological medicinal products containing recombinant interferon alpha
EMA/CHMP/BMWP/102046/2006

Target date Revised reflection paper to be released for public consultation: Q2 2018

Guideline on similar biological medicinal products containing interferon beta
EMA/CHMP/BMWP/652000/2010

Target date Concept paper to be released for public consultation: Q3 2018

Guideline on similar biological medicinal products containing recombinant granulocyte-colony stimulating factor
EMA/CHMP/BMWP/31329/2005

Target date Revised guideline for public consultation: Q1 2018

Action: Specialised input

Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development
EMA/CHMP/138502/2017

Leading group Biostatistics Working Party

Target date Reflection paper

Comments The reflection paper is developed in collaboration with the CHMP Biologics working Party (BWP), the Biosimilar Medicinal Products Working Party (BMWP), the Quality Working Party (QWP) and the Scientific Advice Working Party (SAWP).

2.3. ICH Guidelines

None.

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

- Contribution on relevant methodological and statistical aspects of Scientific Advice and Protocol Assistance relative to biosimilar medicinal products upon request of the SAWP
- Contribution to tailored scientific advice procedure including an in-depth review of quality, analytical and functional data for biosimilar medicinal products upon request of the SAWP.

3.2. Evaluation and supervision activities

Contribution to CHMP marketing authorisation or post-authorisation procedures on Biosimilar medicinal products upon request by the CHMP.

4. Input in European activities

4.1. Training for the network and knowledge building

- Contribution to knowledge sharing on stepwise comparability exercise and on extrapolation in the context of development of biosimilar medicinal products.
- Assessor training on BMWP guidelines
- Maintain awareness of issues arising in order to identify the need for review and update of Guidelines and development of additional guidance documents

4.2. Other input in European activities

- Discussion on pharmacovigilance aspects related to biological medicinal products in collaboration with other Working parties/Committees.
- Discussion on methodological elements related to clinical aspects of biosimilarity in collaboration with other working parties including BSWP.
- Discussion on the need and requirements for functional assays in biosimilarity exercise in collaboration with other relevant working parties.
- Exploration of the need to revise the monoclonal antibody guideline and feasibility for development of specific mAb-product draft guidance documents based on scientific advice and marketing authorisation application experience to date.

5. Input in International activities (beyond ICH guidelines)

- Cooperation on Biosimilar-related matters in conjunction with other appropriate working parties, reinforcing the networking and exchange of experience, e.g. Food and Drug Administration (FDA), Health Canada, Pharmaceuticals and Medical Devices Agency (PMDA), and other Agencies. The Biosimilar cluster with FDA, Health Canada and PMDA will allow the four agencies to increase their degree of interaction. The group will discuss by teleconference around three times a year.
- Exploration to further international exchange (e.g. with World Health Organization (WHO)).

6. Contribution to dialogue and engagement with stakeholders and external parties

6.1. Workshops

None.

6.2. Other activities with stakeholders and external parties

- Organise one meeting with interested parties (e.g., learned societies, patients' organisations, Academia networks, pharmaceutical industry representatives): Q4 2018.
- In collaboration with other working parties, provide support to communication activities on biosimilars e.g. through workshops, medical conferences and publications.

In addition to the actions identified above, the working party can be involved in any other activities foreseen in its mandate:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/08/WC500095453.pdf