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Human Medicines Division

3-year work plan for Biosimilar Medicinal Products Working Party (BMWP)

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Work plan period: January 2024 – December 2026 (with a first review point after one year)

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1. Strategic goals

1.1. Short term strategic goals

- Provide support to SAWP and CHMP on aspects pertaining to procedures for biosimilars, with the aim to prepare SAWP/CHMP opinions (peer reviewed/consensus driven opinions) on biosimilarity during SA and MAA procedures upon request by SAWP / CHMP in a feasible scope.
- Continue to improve efficiency of internal process interactions with SAWP with a risk-based focus, e.g. "tailored" regulatory pathway.
- Progress development of EU and international guidelines on Biosimilars and identify/prioritise new guidance topics as relevant, e.g. reduced clinical efficacy studies. Complete agreed Draft Guidelines and provide support to training activities on implementation of priority guidelines.
- Support and enhance the development of Biosimilar products and further clarify the regulatory expectations in manufacturing e.g. if and when statistical assessment of CQAs should be performed as part of the comparability exercise and the evolution of multisource biologicals/biosimilars.
- Provide support to EU Network and public health organisations in activities involving scientific and regulatory aspects of biosimilar medicinal products.
- Collaboration with the European Regulatory Network, advance international regulators and stakeholder interactions: academia, trade associations, interested parties, etc.
- Harmonise communication / procedural outputs for biosimilars, e.g. assessment reports, Product Information and EPARs.
- Consider the potential impact of proposed changes to the EU pharmaceutical legislation for biosimilars, e.g. definitions, bio-hybrid pathway, removal of risk management plan

1.2. Long-term strategic goals

The long-term strategic priorities for the BMWP, with reference to the European Medicines Regulatory Network (EMRN) and Regulatory Science Strategy 2025 are as follows:

- Work to strengthen the availability of medicines to protect the health of European citizens, ensuring that quality, safe and effective biological medicines are available to EU citizens.
- Leverage EMA's extensive experience in approving biosimilars to provide state of the art guidance on developing Biosimilar Medicines in Europe and share experience globally.
- Continue the refinement and efficiency of biosimilars regulatory processes, e.g. adapting the clinical part of the development to the latest scientific knowledge concerning the comparability assessment.
- Prepare and contribute to Questions and Answers documents to facilitate understanding of new and existing guidelines.
- Anticipate evolution in regulatory science and develop guidance for product classes for which Biosimilars may be developed in future. Gain understanding of industry pipeline activities.
- Support and enhance efficient scientific advice procedures by development of Guidance documents for internal or external reference / stakeholders, as required.
- Through HMA interaction, promote the availability and support uptake of biosimilars in healthcare systems with strategic communication campaigns to healthcare providers and patient organisations to reinforce trust and confidence.

2. Tactical goals: activities/projects to deliver the strategic goals

2.1. Guidance activities

The below guideline activities reflect the strategic goals listed above, in particular to refine and improve efficiency of biosimilars regulatory processes and to consolidate learnings/support knowledge management for strategic topic areas.

Activities ongoing/to be finalised in 2024

- Develop a concept paper and (draft) reflection paper to consider the need for comparative efficacy studies and the possibility to reduce the requirement for clinical efficacy studies.
- Develop a revised biosimilar CHMP assessment report template to standardise statements in EPARs, improving consistency / detail of information for Health Care Professionals regarding the comparability exercise .
- Review and enhance the Tailored Scientific Advice process for biosimilars development of biosimilar products and further clarify the concept to reduce the burden on clinical trial data generation, based on experience.
- Determine the need to conclude ongoing / pending Draft Guidelines (filgrastim, interferons, somatropin).

Activities to continue / start in 2025

- Continue activities related to reflection paper on the need for comparative efficacy studies.
- Consider revision of general biosimilar guidelines, in collaboration with BWP. In particular:
  - Guideline on similar biological medicinal products
  - Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues
- Revision of the guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: nonclinical and clinical issues EMA/CHMP/BMWP/403543/2010

Activities to be started in 2026

- Revision of the guideline on similar biological medicinal products containing monoclonal antibodies: non-clinical and clinical issues EMA/CHMP/BMWP/403543/2010
- Evaluate the scientific need for and extent of bridging studies in case a non-EEA sourced reference medicinal product is used in safety and Phase 3 comparability trials and clarify RMP sources.
- Develop regulatory approaches in the analytical comparability, e.g. related to identification and assessment of quality attributes.

Further guideline activities (new guidance/revisions) may arise in relation to the implementation of new/revised pharmaceutical legislation.

2.2. Training activities

- Continue training of EU quality assessors on a regular basis.
  - For each new biosimilar guidance and other revised guidance.
  - maintain awareness of issues arising from product-specific discussions.
- Support the network (e.g. HMA) on communication materials related to interchangeability.
- Enhance training of non-EU regulators in the evaluation of biosimilars.

2.3. Communication and Stakeholder activities

2.3.1. European level

Continue to engage effectively with industry through participation at external meeting platforms on a regular basis to gain external perspective on regulatory science needs. An interested parties meeting can be considered and complemented by ad hoc meetings in smaller groups as needed.

Promote the availability and support uptake of biosimilars in healthcare systems.

- Plan for stakeholder meeting for exchange of information/experiences:
  - Collaborate with HMA Biosimilar Group, to further develop scientific publications +/or strategic communication campaigns to healthcare providers and patient organisations to reinforce trust and confidence.
  - Work with healthcare professionals and patients to facilitate understanding of the science behind the development and regulation of these particular medicines.
  - Improve coordination of information and actions, including implementation of best practices, both for EU regulatory authorities, stakeholders and international partners.

2.3.2. International level

International cluster meetings: advance global information sharing and harmonisation in biosimilar development requirements, identify gaps between different legislators and how this impacts product approvals in EU.

Support IPRP-BWP, e.g. workshop on reduction of clinical data requirements: Comparative Efficacy Studies (CES) and outcomes following workshop (e.g. white paper).

Support international harmonisation initiatives in relevant international fora, including WHO and relevant guideline activities.

2.4. Multidisciplinary collaboration

Maintain or strengthen as relevant, the ongoing collaboration with other working parties and groups, for example on procedural support and guidance, e.g. SAWP, BWP, MWP.

3. Operational goals: medicinal product-specific activities

3.1. Pre-Authorisation activities

- Recommendation to CHMP and SAWP on specific applications for scientific advice and protocol assistance (focus on: new active substances and non-routine procedures/aspects).
- Support BWP on provision of Scientific Advice for the in-depth review of quality data for similar biological medicinal products upon request of the SAWP.

3.2. Evaluation and supervision activities

- Recommendation to CHMP and SAWP on applications for marketing authorisations and other procedures as appropriate (focus: new active substances and non-routine procedures/aspects).
- Support to public health activities related to similar biological medicinal products

4. Priorities 2024

- Development of a concept paper by 1Q 2024 and draft reflection paper by 4Q2024 to consider the need for comparative efficacy studies and the possibility to reduce the requirement for clinical efficacy studies - in light of drawing robust evidence from analytical and functional assays, plus clinical study of PK and/or PD markers in healthy volunteers or patients.
- Review and propose enhanced Tailored Scientific Advice process for biosimilars development by 3Q2024