16 January 2023
EMA/CHMP/BWP/860809/2022
Committee for Medicinal Products for Human Use (CHMP)

Work plan for the Biologics Working Party (BWP) for 2023

Chairperson: Sean Barry, **Vice-chair** : tbc

Status of the work plan*

*Disclaimer: Not all activities listed may be pursued. Activities will be reviewed and prioritized on the basis of the regulatory science strategy, and resource considerations for network and EMA secretariat.

1. Meetings scheduled for 2023

Meetings are planned for the following dates:

- 16-18 January 2023 Virtual
- 13-15 February 2023 Face to Face
- 20-22 March 2023 Virtual
- 17-19 April 2023 Face to Face
- 15-17 May 2023 Virtual
- 12-14 June 2023 Face to Face
- 10-12 July 2023 Virtual
- 4-6 September 2023 Virtual + Interested Parties
- 2-4 October 2023 Face to Face
- 30-31 October 2023 (2 day) Virtual
- 4-6 December 2023 Virtual

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.

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2. Guidelines and Reflection Papers

2.1. New EU Guidelines

Action: Lead

2.1.1. Reflection paper on the structure and properties for the determination of new active substance (NAS) status of biological substances

Target date	Updated final reflection paper by Q2 2024
Comments	The document shall discuss BWP's current thinking on scientific aspects in relation to quality matters on the determination of NAS status of biological substances, including ATMPs. Final reflection paper to take account of comments from the 6 months public consultation (Nov 2022 – May 2023) on the draft reflection paper.

2.1.2. Questions and answers on BWP learnings

Target date	4Q 2023
Comments	BWP will review internal experience and learnings and consider a Q&A Potential network training activity under consideration

2.1.3. Questions and answers on modelling

Target date	4Q 2023
Comments	As the topic arises frequently, BWP will consider a Q&A on modelling. Activity with QIG, QWP.

2.1.4. Guideline on quality aspects of RNA vaccines

Target date	Concept paper on development of guideline by Q2 2023
Comments	Development of new guidance in light of experience gained with COVID-19 vaccines

2.1.5. Guideline on phage technology

Target date	Proposal to draft new guideline: Concept paper by Q2 2023
Comments	Note also: drafting of Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy

Action: Specialised input

2.1.6. Guideline on quality, non-clinical and clinical requirements for applications for clinical trials for ATMPs

Leading group	CAT
Target date	Finalise the guideline after external consultation (completion expected by Q4 2023)
Comments	Contribution to quality aspects of draft guideline.

2.2. EU Guidelines under revision

Action: Lead

2.2.1. CHMP Position Statement on CJD and plasma-derived and urine-derived medicinal products (EMA/CHMP/BWP/303353/2010)

Target date	Revised draft guideline following public consultation (4Q 2023)
Comments	UK plasma is now accepted in UK, USA, Ireland, Australia. Stakeholder request for revision.

2.2.2. Note for Guidance on maximum shelf life for sterile products for human use after first opening or following reconstitution.

Target date	Finalisation of Q&A and revision of guideline in 2023
Comments	Stakeholder request for revision.

2.2.3. Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies

Target date	Proposal to revise guideline. Concept paper by Q2 2023.
Comments	Parallel to QWP revision of guideline on radiopharmaceuticals.

Action: Specialised input

2.3. ICH Guidelines

2.3.1. Revision of ICH Q1 Guidelines on Stability Testing and related ICH Q5C Guideline on Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products.

Target date	Q4/2022 - Final Concept Paper, Business Plan Q4/2024 – Complete Step 1 Q4/2025 – Complete Step 4 and initiate training materials
Comments	Input on the revision of ICH Guideline Q1/Q5C jointly with QWP (*with contribution of IWG where relevant*)

2.3.2. ICH Guideline Q3E Extractables and Leachables

Target date	Step 1 sign-off, endorsement Step 2a/b November 2023. Public consultation May 2024. Step 3 sign-off and Step 4 adoption of final GL November 2025.
Comments	Input to the development of ICH Guideline Q3E, led by QWP.

2.3.3. ICH Q5A 'Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin'

Target date	Comments on Step 2b - 10 February 2023
Comments	Step 2b released for consultation Oct 2022

2.3.4. ICH Guideline Q9 Quality Risk Management

Target date	Step 3 on regional regulatory consultation in December 2021 – April 2022, the target completion date for the revision has been delayed by 6 months to March 2023.
Comments	Input to the revision of ICH Q9(R1) and training material, led by IWG, with contributions from BWP and QWP.

2.3.5. ICH Guideline Q12 on Lifecycle Management

Target date	2023
Comments	Input to the guideline implementation in EU, jointly with QWP & GMDP IWG. EU implementation is linked to the EU Pharma Strategy initiative to revise the variation framework for medicines, see 4.2.2.

2.3.6. ICH Guideline Q13 on Continuous manufacturing of Drug Substances and Drug Products

Target date	2023
Comments	Input to the development of training materials.

2.3.7. ICH Q2/Q14: Analytical Procedure Development and Revision of Q2(R1) Analytical Validation

Target date	Step 2a/Step 2b: March 2022. Step 4 November 2023. Expected formation of an IWG to develop and publish training material.
Comments	Input to the development of ICH Guideline Q14 and revision of Q2(R1), led by QWP, with IWG, where relevant.

2.3.8. ICH Guideline M4Q(R2) on Common technical document for the registration of pharmaceuticals for human use - quality

Target date	Step 1/2: Q3 2023
Comments	Input to the revision of ICH Guideline M4Q, jointly with QWP and GMDP IWG.

General ICH activities affecting Biologicals and Biotechnological products

Comments	Contribution to other ICH initiatives with a scope of Biological and Biotechnological products, e.g. ICH Q6B

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

- Recommendation to CHMP, CAT and SAWP on applications for scientific advice and protocol assistance
- Provision of Scientific Advice for the in-depth review of quality data for similar biological medicinal products upon request of the SAWP
- Recommendation to the CAT on data submitted to the Agency for scientific evaluation and certification of the quality/non-clinical quality data of an ATMP (Art. 18 of Regulation (EC) 1394/2007)
- Contribution to Innovation Task Force and Quality Innovation Group
- Contribution to scientific aspects in relation to quality content in similarity assessments for Orphan designation
- Contribution to scientific aspects in relation to procedures of PRIME designated product developments
- Contribution to paediatric investigation plans (PIP) upon request of PDCO

3.2. Evaluation and supervision activities

- Recommendation to CHMP and CAT on applications for marketing authorisations and variations
- Recommendation to CHMP on applications for PMF certificates and VAMF certificates
- Recommendation to CHMP on quality in relation to quality and safety aspects of human blood derivatives used as ancillary substances in medical devices and on other ancillary biological substances in medical devices
- Recommendation to CMDh on requests, as adopted by CHMP, affecting scientific aspects in relation to nationally approved medicinal products
- Recommendation to CHMP, as appropriate, on scientific opinion in cooperation with WHO for evaluation of medicinal products intended exclusively for markets outside the community
- Support, as requested, to Inspections activities, quality defects, sampling and testing and liaison with OMCL network and EDQM on activities of mutual interest
- Liaison with and specialised input to CAT, CHMP, QWP, BPWP, BMWP, VWP and GMDP-IWG, QIG and other groups, working parties and committees, where required, on activities of mutual interest
- Quality support to public health activities related to biological medicinal products

4. Input in European activities

4.1. Training for the network and knowledge building

- Training to network on implementation of ICH guidelines. Jointly with QWP & GMDP IWG, as appropriate. Maintain awareness of issues arising from product-specific discussions. Possible training on BWP learnings, following review.
- 'Quality of decision making and reporting'. e.g. on the length and content of D80 reports/D80 templates, analytical methods in CTDs, etc. 'what is a good LOQ' etc. Network Training.

4.2. Other input in European activities

- BWP expert support to EDQM: Scientific input for the elaboration and revision of European Pharmacopoeia monographs and scientific input and collaboration with EDQM including bilateral meetings, ad hoc discussion at BWP, Group 6/6B/15 contribution and participation to the BSP Steering Committee meetings
- Organise an annual meeting with relevant experts on Influenza vaccines: for strain selection and to elaborate a proposal for the strain composition of the influenza vaccine for the forthcoming annual vaccination campaign. Other involved parties: VWP, CMDh, WHO

Contribute to development of Pharma Strategy. European Commission activities.

Contribute to priority initiatives on regulatory efficiency:

- to support the revision of the pharmaceutical legislation and to provide for simplification, the streamlining of approval procedures and flexibility for the timely adaptation of technical requirements to scientific and technological developments.

- To support the revision the variation framework for medicines, through changes in legislation and guidelines, to make the lifecycle management of medicines more efficient and adapted to digitalisation (2021-2023)

5. Input in International activities (beyond ICH guidelines)

Collaboration with international regulatory authorities outside of Europe including ICMRA, WHO, FDA, Health Canada and PMDA and contribution on quality aspects to EMA-FDA clusters on Blood, Vaccines, ATMPs and Biosimilars.

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

6.1. Workshops

None

6.2. Other activities with stakeholders and external parties

Interested Parties meeting with Industry stakeholders, scheduled for September 2023.

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/2009/10/WC500004663.pdf