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Human Medicines Division

3-year work plan for the Biologics Working Party

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1. Strategic goals

1.1. *Short-term strategic goals*

- Provide support to CHMP and other relevant Committees and Working Parties on all Quality matters pertaining to procedures for biologicals for human use, with the aim to prepare BWP positions (peer reviewed/consensus driven) on the quality aspects/Module 3 at key milestones for consideration into the benefit/risk discussion at CHMP.
- Continue to improve efficiency of internal interactions and BWP processes with a risk-based focus.
- Provide support to EU Network, decentralised/national procedures upon CMDh requests. Support to the OMCL network, EDQM and other public health organisations in activities involving quality aspects of biological medicinal products.
- Provide a forum for harmonisation of European approaches to quality matters pertaining to the regulation of human medicines containing biological active substances and to ensure a common interpretation of EU guidelines related to Quality matters.
- Progress development of EU and international guidelines and identify/initiate new guidance topics as relevant. Consolidate learnings from new technologies, e.g. mRNA vaccines, and provide support to training activities on implementation of priority guidelines.
- In collaboration with QIG and other parties in the European Regulatory Network, advance international regulators and stakeholder interactions: academia, trade associations, interested parties, etc. Key areas for technical development / focus in collaboration with QIG: advanced therapies, PRIME early access and risk-based approaches, innovative materials and formulations, novel manufacturing approaches, new analytical technologies, digitalisation in manufacturing and new concepts such as decentralized manufacturing, modelling and platform technologies, and sustainable manufacturing.
- Support the establishment of a European Specialised Expert Community (ESEC) for medicinal products containing biologicals.
- Support establishment of operational expert groups (OEGs) to advise on matters that directly impact the quality, safety and availability of medicines for patients (e.g. nitrosamines, titanium dioxide, infectious diseases, medicines supply issues, etc.). Consolidate learnings from and support knowledge management in relation to such matters.

1.2. *Long-term strategic goals*

The long-term strategic priorities for the BWP, with reference to the European medicines regulatory network (EMRN) and RSS 2025 are as follows:

- Ensure the quality, in relation to the safety and efficacy of marketed medicines.
- Reinforce scientific and regulatory capacity, resilience and capability of the network to improve the scientific quality of evaluations and to manage the increasing volume of procedures for biological products.
- Streamline assessments by application of risk-proportionate approaches.

- Ensure dedicated collaboration with other Committees and Working Parties to advance regulatory science aspects of common interest, e.g. increasing overlap of synthetic processes / biology.
- In collaboration with QIG, facilitate the continued integration of science and technology in medicines development and ensure that the network has sufficient competences to support innovation and associated technology platforms / regulatory science at various stages of medicines development. This includes support to digitalisation and personalised medicines.
- Increase collaboration with Good Manufacturing Practise (GMP)/Good Distribution Practice (GDP) Inspectors Working Group (GMDP IWG) to support synergies between assessment and inspection activities, consistent with simplification of dossiers and enabling risk ownership by Marketing Authorisation Holders.
- Advance collaboration with international partners to support harmonisation and encourage mutual reliance on assessments and inspections.
- Maintain appropriate regulatory science knowledge management as a resource to assist the network. In close collaboration with QIG, ESECs and other WPs of the Quality domain develop training related to new manufacturing technologies and regulatory science developments to equip EU assessors with the skills required to assess these new technologies.
- In collaboration with QIG, enhance collaboration with academic groups.
- Provide support to the European Commission on the development and implementation of new legislation, e.g. Pharma Strategy, Medical Devices, and the variations framework.
- Contribute to crisis and health threat responses and support network capability and agility as part of the response.

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 advance international harmonisation through support to ICH guidelines, to support emerging technologies and to consolidate learnings/support knowledge management for strategic topic areas.

Review of existing BWP guidance and identification of published guidance that may benefit from revision.

Further guidance activities (new guidance/revisions) are expected in relation to the implementation of new/revised pharmaceutical legislation.

(A) Activities ongoing/to be finalised in 2024

EU guidance, New, BWP lead:

- Reflection paper on the structure and properties for the determination of new active substance (NAS) status of biological substances - publication of reflection paper in Q2 2024.
- Questions and answers on BWP learnings - publication of additional Q&A in 2024.

- Guideline on quality aspects of RNA vaccines – publication of draft guideline for public consultation in Q2 2024.
- Guideline on the development and manufacture of human medicinal products specifically designed for phage therapy - publication of draft guideline for public consultation in Q4 2024.
- PMF dossier requirements. Questions and Answers for PMF Holders – publication of additional Q&A in 2024.

EU guidance, New, BWP specialised input:

- Guideline on quality, non-clinical and clinical requirements for applications for clinical trials for ATMPs – led by CAT
- Questions and answers on modelling – led by QIG

EU guidance, Revision, BWP lead:

- CHMP Position Statement on CJD and plasma-derived and urine-derived medicinal products – publication of revised position statement in Q2 2024.
- Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies – publication of draft guideline for public consultation in Q3 2024.

(B) Activities to be started in 2024

EU guidance, Revision, BWP lead:

- Revision of Guideline on epidemiological data on blood transmissible infections

EU guidance, New, BWP specialised input:

- Reflection Paper on tailored clinical approaches for biosimilar developments – led by BMWP

(C) Activities to be started in 2025-2026

BWP will consider the following:

- Contribute to biosimilar guidelines, in collaboration with BMWP. In particular:
    - Revision of Guideline on similar biological medicinal products
    - Revision of Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues
- Revision of Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3)
- Revision of Guideline on the investigation of manufacturing processes for plasma-derived medicinal products with regard to vCJD risk
- Revision of Guideline on the scientific data requirements for a plasma master file (PMF)
- Revision of Influenza vaccines - quality module - Scientific guideline

(D) Ongoing BWP support to ICH guidelines (New/Revision/Training materials/Implementation)

- ICH Q1 Guidelines on Stability Testing and related ICH Q5C Guideline on Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products.
- ICH Guideline Q3E Extractables and Leachables.
- ICH Q5A 'Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin'
- ICH guidelines Q6 Specifications
- ICH Guideline Q9 Quality Risk Management
- ICH Guideline Q12 on Lifecycle Management
- ICH Guideline Q13 on Continuous manufacturing of Drug Substances and Drug Products
- ICH Q14: Analytical Procedure Development and ICH Q2(R2) Analytical Procedure Validation
- ICH Guideline M4Q(R2) on Common technical document for the registration of pharmaceuticals for human use – quality
- Support as needed to ICH discussions on topic selection/prioritisation, and future ICH guideline activities (e.g. Cell and Gene Therapies Discussion Group).

2.2. *Training activities*

Continue training of quality assessors on a regular basis and building on the quality curriculum in the EU network training centre (EU-NTC), together with QIG, QWP, GMDP IWG, CAT, and the HMA IncreaseNET as appropriate. This includes training and knowledge building on the implementation of ICH guidelines, medicinal product/medical device combinations, modelling, and best practise for quality of decision making and reporting. Maintain awareness of issues arising from product-specific discussions, including training on BWP learnings as appropriate.

Training planned for 2024:

- ATMP training (e.g. AAVs)

Training under discussion for 2024-2026:

- Further ATMP training (e.g. CAR-T, CD34 cells, Genome editing)
- Modelling
- ICH Q2/Q14
- Medical devices

Further training to be added as needed.

2.3. *Communication and Stakeholder activities*

2.3.1. European level

Continue to engage effectively with industry through Interested Party meeting platforms on a regular basis (i.e. yearly) to gain external perspective on regulatory science needs. Strategic direction is

aligned with Agency priorities. The interested parties meetings can be complemented by ad hoc meetings in smaller groups as needed.

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.

In close collaboration with ESECs, contribute to horizon scanning with academic partners to determine future regulatory science needs.

To strengthen multistakeholder interactions on priority topics, BWP will continue to support workshops and continue to make the information available by broadcast / recording, and through meeting reports for public / stakeholder information.

Support priority initiatives on regulatory efficiency:

- to support the revision of the pharmaceutical legislation 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 of the variation framework for medicines, through changes in legislation and guidelines, to make the lifecycle management of medicines more efficient and adapted to digitalisation.
- Provide expert support to regulatory partners, such as Notified Bodies, the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), and the European Chemicals Agency (ECHA).

2.3.2. International level

Support harmonisation and encourage mutual reliance on assessments and inspections through collaboration with international regulatory authorities. Support discussions and initiatives of relevant international fora, including WHO, ICMRA. In particular, support to the collaborative ICMRA assessment pilots.

Contribution on quality aspects to clusters on Blood, Vaccines, ATMPs and Biosimilars.

2.4. *Multidisciplinary collaboration*

Maintain, or strengthen as relevant, the ongoing collaboration with other working parties and groups, for example on guidance, e.g. SAWP, QIG, QWP, GMDP IWG, BMWP, 3RsWP, HAEMWP, MWP, PDCO PF-OEG, and VWP.

In particular,

- Increase collaboration with GMDP IWG and establish annual joint BWP/IWG plenary meetings.
- Collaborate with the 3RsWP with regards to the application of the 3Rs in batch release testing of human vaccines and biotechnology derived pharmaceuticals.
- Establish a close working relationship with BMWP on biosimilars, leveraging the synergies and avoiding duplication of work.
- 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 and mRNAVAC group.

3. Operational goals: medicinal product-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 against Orphan medicinal products
- 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, line extensions and variations
- Contribution to the assessment of New Active Substance claims.
- Assessment of similarity of active substances to support the CHMP similarity assessment in the context of marketing authorisation applications and line extensions.
- Recommendation to CHMP on applications for PMF 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 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, BMWP, HAEMWP, MWP, 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. Abbreviations

List of Abbreviations	
3RsWP	3Rs Working Party
AAV	Adeno-associated virus
BMWP	Biosimilar Medicinal Products Working Party
BSP	Biological Standardisation Programme
BWP	Biologics Working Party
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CJD	Creutzfeldt-jakob disease
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EDQM	European Directorate for the Quality of Medicines and HealthCare
EFSA	European Food Safety Authority
EMRN	European medicines regulatory network
EU-NTC	EU network training centre
ESEC	European Specialised Expert Community
GMDP IWG	Good Manufacturing Practise/Good Distribution Practice Inspectors Working Group
GMP	Good Manufacturing Practise
HAEMWP	Haematology Working Party
HMA	Heads of Medicines Agencies
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
mRNA	Messenger ribonucleic acid
mRNAVAC	EDQM mRNA vaccines working party
MWP	Methodology Working Party
NAS	New Active Substance
OEG	Operational expert group

List of Abbreviations	
OMCL	Official medicines control laboratory
PDCO	Paediatric Committee
PF-OEG	Paediatric Formulations Operational Expert Group
PIP	Paediatric investigation plan
PMF	Plasma master file
PRIME	Priority Medicines
QIG	Quality Innovation Group
QWP	Quality Working Party
Q and A	Questions and Answers
RSS 2025	Regulatory Science Strategy 2025
SAWP	Scientific Advice Working Party
SoHO	Substances of Human Origin
VWP	Vaccines Working Party
WHO	World Health Organization