17 December 2015
EMA/CHMP/BWP/454652/2015

Work plan for the CHMP Biologics Working Party for 2016

Chairperson: Sol Ruiz
Status: December 2015

1. Meetings scheduled for 2016

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

- 18-20 January
- 15-17 February
- 21-22 March
- 18-20 April
- 17-18 May
- 13-15 June
- 11-13 July
- 5-7 September
- 3-5 October
- 26-28 October (November meeting)
- 5-7 December

Virtual meetings/web sharing will be planned to accommodate scientific input to products, scientific advice and evaluation. Additional teleconferences will be organised ad-hoc to respond to time-sensitive input on products and to progress guidelines, as required.
2. Guidelines

2.1. New EU Guidelines

Joint CVMP/CHMP ad hoc expert group on application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (JEG 3Rs): Guideline on transferring quality control methods validated in collaborative trials to a product/laboratory specific context

**Action:** Guideline to be developed following review of comments received on concept paper (EMA/CHMP/CVMP/JEG-3Rs/94304/2014); draft guideline to be released for public consultation in Q4 2016.

**Comments:** Multidisciplinary project involving JEG 3Rs, IWP and BWP.

Dossier requirements for administration devices supplied as integral part of medicinal product or supplied along with medicinal product

**Action:** Contribution to development of concept paper.

**Comments:** QWP is leading this activity.

Guideline on process validation for manufacture of biotechnology derived active substances

**Action:** Workshop held in April 2013. Draft guideline to be finalised in Q4 2016 following public consultation

**Comments:** Other involved WP(s): QWP

Influenza vaccines: Strain selection

**Action:** To propose the strain composition of the influenza vaccine for the forthcoming annual vaccination campaign

**Comments:** Other involved parties: VWP, CMD(h), WHO

Question and Answer document on excursions from standard conditions for vaccines

**Action:** Development of a Question and Answer document by Q3 2016

**Comments:** Other involved parties: VWP

2.2. Revision of EU Guidelines


**Action:** Updated draft guideline expected to be released for public consultation in Q4 2016

**Comments:** None.
Guideline on the scientific data requirements for a plasma master file (PMF)  
(CPMP/BWP/3794/03)

**Action:** Contribution to revision of the guideline sections on requirements for inspection of blood establishments and centres. Preparation of concept paper for public consultation and revision of guideline

**Comments:** Other involved parties: European Commission, IWP (i.e. blood inspectors)

Revision of the Commission Guideline on Excipients in the Label and Package leaflet for Medicinal Products for Human Use

**Action:** Scientific input on quality aspects as needed.

**Comments:** Lead WP(s): SWP

Similarity of Orphan Medicinal Products

**Action:** Scientific input in relation to biological medicinal products at the request of the European Commission: Review of the BWP Guidance for Biological Medicinal Products (EMEA/CPMP/BWP/6033/03) by Q4 2016.

**Comments:** Other involved WP(s)/parties: COMP, SAWP, QWP, BPWP, SWP, European Commission

Viral safety with respect to hepatitis E

**Action:** Finalisation of Reflection paper on viral safety of plasma-derived medicinal products with respect to hepatitis E virus following public consultation expected Q4 2016

**Comments:** Other involved parties: BPWP

Revision of QWP draft guideline on sterilisation of the drug product active substance

**Action:** Contribution to revision of guideline on aspects related to Biological Medicinal Products.

**Comments:** Lead WP(s): QWP


**Action:** Contribution on quality aspects to finalisation of revised guideline (Q4 2016).

**Comments:** Lead WP(s): BMWP

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### 2.3. **ICH Guidelines**

**ICH Guideline Q12 on Lifecycle Management**

**Action:** Input to development of ICH Guideline Q12 in particular Step 2 document.

**Comments:** Other involved WPs: QWP
3. **Product-related evaluation activities**

3.1. **General support activities**

(Covering the life cycle of product development)

- Recommendation to CHMP and CAT on applications for marketing authorisations and variations
- Recommendation to CHMP, CAT and SAWP on applications for scientific advice and protocol assistance
- 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
- Recommendation to CHMP, as appropriate, 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
- Recommendation to the CAT on the quality aspects of application for certification of the quality data of an Advanced Therapy medicinal product, in accordance with article 18 of Regulation (EC) 1394/2007
- Support, as requested, to Inspections activities, quality defects, sampling and testing
- Liaison with QWP, BPWP, BMWP, VWP and GMDP-IWG on activities of mutual interest
- Liaison with OMCL network and EDQM on activities of mutual interest

3.2. **Specific activities**

**Review of regulatory process, CHMP support and quality of assessment reports**

**Action:** In-line with other Agency initiatives: Review and adaptation of processes associated with the support to relevant Committees (i.e. CHMP), the network and CHMP assessment report preparation.

**Immunoglobulins and potential thromboembolic events**

**Action:** Scientific input, as needed, into the evaluation of compliance with revised monographs

**Comments:** Other involved parties: BPWP, PRAC, CMD(h), EDQM

**Immunoglobulins and haemolysis**

**Action:** Scientific input, as needed, on quality aspects related to haemolysis adverse events

**Comments:** Other involved parties: BPWP, PRAC, CMD(h), EDQM
Quality by Design (QbD) and Process Analytical Technology (PAT)

**Action:** Scientific input, as needed, on biological medicinal products and interaction with EMA QbD/PAT team

**Comments:** Other involved WP(s): EMA QbD/PAT Team QWP, Inspectors Working Party Discussion with interested parties (e.g. EFPIA, Vaccines Manufacturers) to share experience gained with PAT in the production process of biologicals/biotech derived products

4. **International activities engagement (beyond ICH guidelines)**

Scientific input for the elaboration and revision of European Pharmacopoeia monographs, EDQM support and joint activities

**Action:** Scientific input to the preparation of European Pharmacopoeia monographs

**Comments:** Other involved parties: Ph. Eur., e.g. Group 6B, Group 15

International standard on identification of medicinal products (ISO IDMP)

**Action:** Contribution to Agency activities regarding quality aspects of biological substances and medicinal products

**Comments:** Other included WP(s) and Committees: BPWP, BMWP, VWP, PhVWP, CAT

Regulatory Authorities Outside of the EU (excluding ICH activities)

**Action:** International cooperation as appropriate (including WHO, FDA, Health Canada and PMDA)

**Comments:** Contribution on quality aspects for blood, vaccines, ATMP and biosimilars clusters with FDA

5. **Contribution to the dialogue and engagement with stakeholders and external parties**

5.1. **Workshops / Trainings**

Assessor training on virus safety evaluation of biotechnological medicinal products (see also Guideline on virus safety evaluation of biotechnological investigational medicinal products EMEA/CHMP/BWP/398498/2005)

**Action:** BWP contribution to assessor training organised by the EU Network Training Centre

**Comment:** To be organised for Q3/Q4 2016
5.2. Other activities

Adaptive pathways

**Action:** Scientific input with regards to the impact on quality aspects for biologicals  
**Comments:** Support to pilot project on adaptive pathways

Meeting with Interested Parties (e.g. Public Health professionals, Patients’ organisations, Pharmaceutical Industry Representatives)

**Action:** Meeting with pharmaceutical industry representatives on issues of joint interest including EFPIA, Vaccines Europe, PPTA, IPFA, EuropaBio, EBE, EGA, and other interested parties  
**Comments:** To be organised in the margins of the BWP plenary meeting