14 December 2017
EMA/CHMP/BWP/400117/2017

Work plan for the Biologics Working Party (BWP) for 2018

Chairperson: Sol Ruiz

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:

- 15-17 January
- 12-14 February
- 12-14 March
- 16-18 April
- 22-23 May
- 18-20 June
- 16-18 July
- 10-12 September
- 8-10 October
- 5-7 November
- 3-5 December

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**

Guidance on the structure and properties for the determination of new active substance (NAS) status of biological substances

**Target date** Development of first draft guidance document for public consultation by Q3 2018

**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 substance

Question and Answer Document on the Haemagglutination Inhibition (HI) test for qualification of seasonal influenza vaccine (inactivated) seed preparations

**Target date** 1st draft to be prepare by Q3 2018

**Comments** New guidance to be developed with support of VWP

**Action: Specialised input**

Guideline on quality requirements of medicinal products containing a device component for delivery or use of the medicinal product (H)

**Leading group** QWP

**Target date** 1st draft to be prepared and released for public consultation by Q4 2018

**Comments** Contribution to development of draft guideline. A concept paper has been published for consultation and information.

Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container, EMA/CHMP/CVMP/QWP/BWP/850374/2015

**Leading group** QWP

**Target date** Final guideline to be published by Q2 2018

**Comments** Contribution to development of guideline on aspects related to Biological Medicinal Products after public consultation

Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development

**Leading group** BSWP

**Target date** Draft reflection paper to be revised following the 12-month public consultation

**Comments** Contribution to revision following public consultation
2.2. **EU Guidelines under revision**

**Action: Lead**


**Target date** Updated draft guideline to be revised following public consultation by Q4 2018  
**Comments** None

Public statement on the evaluation of bovine-spongiform-encephalopathy risk via the use of materials of bovine origin in or during the manufacture of vaccines

**Target date** Finalisation of public statement following public consultation by Q2 2018  
**Comments** Minor update is needed to reflect experience of TSE safety of vaccines since 2001  
Other involved working parties include VWP

Pharmaceutical Aspects of the Product Information for Human Vaccines

**Target date** Finalisation of guidance following public consultation by Q4 2018  
**Comments** Major update required to reflect updated guidance on common names, more recent examples, consistency and complement existing QRD guidance. Other involved working parties are QRD, VWP

Guideline on the scientific data requirements for a plasma master file (PMF) (CPMP/BWP/3794/03)

**Target date** Preparation of concept paper for public consultation and revision of guideline. Updated draft guideline expected to be released for public consultation in Q4 2018  
**Comments** Contribution to revision of the guideline sections on requirements for inspection of blood establishments and centres. Other involved parties: European Commission, IWP (i.e. blood inspectors)

**Action: Specialised input**


**Leading group** CHMP Excipients Drafting Group  
**Target date** Revised Annex to be published Q2 2018  
**Comments** Scientific input on revision in relation to quality aspects as needed
Guideline on quality of water for pharmaceutical use (CPMP/QWP/158/01)

**Leading group**  QWP

**Target date**  Draft Guideline to be released for 6 month public consultation by Q3 2018

**Comments**  Contribution to revision on aspects related to biological medicinal products

Quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells (CHMP/GTWP/671639/2008)

**Leading group**  CAT

**Target date**  Preparation of first draft of revised guideline for public consultation by Q2 2018

**Comments**  Contribution to preparation of first revised draft

### 2.3. ICH Guidelines

ICH Guideline Q12 on Lifecycle Management

**Target date**  N/A. Step 1 completed

**Comments**  Input to the development of ICH Guideline Q12 jointly with QWP

### 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
- Contribution to scientific aspects in relation to quality content in similarity assessments for Orphan designation
- 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, PAT team 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

• Assessor training on overview guidance as part of the CHMP assessment report in relation quality information (Q2 2018)

• 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. Support to and cooperation with EU institutions and Network

• With 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

• With the network and stakeholders: Scientific input to quality aspects for biological medicinal products under accelerated access schemes (Adaptive pathways and PRIME) and support to cross-Agency project in relation to specific activities and knowledge sharing

5. Input in International activities (beyond ICH guidelines)

5.1. Activities with other regulators

Collaboration with international regulatory authorities outside of Europe including 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

Workshop with stakeholders on quality aspects in accelerated access approaches (i.e. PRIME) (timeline Q3/Q4 2018)

6.2. Other activities with stakeholders and external parties

Meeting with Interested Parties (EFPIA, Vaccines Europe, PPTA, IPFA, EuropaBio, EBE, Medicines for Europe, APIC and other interested parties) on issues of joint interest. To be organised in the margins of one of the BWP plenary meetings

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