15 December 2016
EMA/CHMP/BWP/612761/2016

Work plan for the Biologics Working Party (BWP) for 2017

Chairperson: Sol Ruiz

Status of the work plan: December 2016 - adopted

1. Meetings scheduled for 2017

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

- 16-18 January
- 13-15 February
- 13-15 March
- 10-11 April
- 10-11 May
- 12-14 June
- 10-12 July
- 4-6 September
- 2-4 October
- 30-31 October (November meeting)
- 4-6 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*

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

**Leading group** BWP  
**Target date** Development of a draft points to consider document is to be initiated in Q2 2017  
**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

*Action: Specialised input*

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

**Leading group** JEG 3RsWG  
**Target date** Q3 2017  
**Comments** Guideline to be reviewed in 2017 following a public consultation. Multidisciplinary project involving JEG 3Rs, IWP and BWP

Joint CVMP/CHMP guideline on regulatory acceptance of 3R (replacement, reduction, refinement) testing approaches

**Leading group** JEG 3RsWG  
**Target date** Q1 2017  
**Comments** Guideline to be revised in 2017 following a public consultation. Multidisciplinary project involving JEG 3Rs, IWP, SWP, EWP-V, SWP-V and BWP

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** Concept paper to be released for public consultation Q1 2017  
**Comments** Contribution to development of draft guideline. A concept paper is in preparation
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 Q4 2017

**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 expected to be released for a 6-month public consultation in Q1 2017.

**Comments** Contribution to revision following public consultation

Guideline on comparability of cell-based medicinal products

**Leading group** CAT

**Target date** Finalise a concept paper on the above mentioned guideline, to be published by 3Q 2017

**Comments** Contribution to preparation of concept paper

### 2.2. **EU Guidelines under revision**

**Action: Lead**


**Target date** Updated draft guideline expected to be released for public consultation in Q1 2017

**Comments** none

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 Q1 2017.

**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)
Guideline on the requirements for quality documentation concerning biological investigational medicinal products in clinical trials (EMA/CHMP/BWP/534898/2008)

**Target date**  
Finalisation of revision following public consultation, by Q2 2017

**Comments**  
Other involved parties: European Commission

Influenza vaccines - Quality module

**Target date**  
Q1 2017

**Comments**  
Minor update to reflect new vaccine terminology and legislative references

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**  
Q3 2017

**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**  
Q4 2017

**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

**Action: Specialised input**

European Commission Notice to Applicants Volume 3B Guideline ‘Excipients in the Label and Package leaflet for Medicinal Products for Human Use’ and its Annex

**Leading group**  
CHMP ExcpDG

**Target date**  
Q4 2017 (to be integrated to the Annex of the Core Guideline ‘Excipients in the Label and Package leaflet for Medicinal Products for Human Use’)

**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**  
Concept paper to be released for public consultation by Q1 2017

**Comments**  
Contribution to revision on aspects related to biological medicinal products
Draft Guideline on manufacture of the finished dosage form (EMA/CHMP/QWP/245074/2015)

**Leading group** QWP

**Target date** Final guideline to be released by Q1 2017

**Comments** Contribution to revision following public consultation

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

**Leading group** CAT

**Target date** Finalise a concept paper on the revision of the above mentioned guideline, to be published by 2Q 2017

**Comments** Contribution to preparation of concept paper

### 2.3. ICH Guidelines

ICH Guideline Q12 on Lifecycle Management

**Target date** Step 2 to be completed in 2017

**Comments** Input to development of ICH Guideline Q12 in particular Step 2 document 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 for the EU network on the Guideline Process validation for the manufacture of
biotechnology-derived active substances and data to be provided in the regulatory submission
(by Q4 2017)
• Support the network and the relevant Committees (i.e. CHMP) through adaptation of review
processes on the quality information in particular in relation to the CHMP assessment report
preparation.
• 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 15/6B contribution and participation to the BSP Steering Committee
meetings
• Organise an annual meeting with relevant experts on Influenza vaccines: 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 in relation to prior knowledge and use of in accelerated access schemes (timeline Q3/Q4 2017)

6.2. Other activities with stakeholders and external parties

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

Action: Meeting with stakeholder representatives on issues of joint interest including EFPIA, Vaccines Europe, PPTA, IPFA, EuropaBio, EBE, Medicines for Europe, and other interested parties

Comments: To be organised in the margins of the BWP plenary meeting

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