4 December 2017
EMA/CHMP/CVMP/QWP/504882/2017
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the joint CHMP/ CVMP Quality Working Party (QWP) for 2018

Chairperson: Keith Pugh

Status of the work plan December 2017: Final

The following work plan is a joint human and veterinary plan.

H - indicates a human only topic;

V - indicates a veterinary only topic;

H/V - indicates a joint human/veterinary topic.

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:

- 27 February – 1 March 2018
- 05 – 07 June 2018 (including QWP/ Interested Parties meeting)
- 27 – 29 November 2018

Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products and to progress guidelines, as required.

All QWP plenary meetings have participants with expertise in the quality of human and veterinary medicinal products, observers from the EDQM (European Directorate for Quality of Medicines and HealthCare), EU accession countries and occasionally from regulatory authorities outside the EU. Each

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meeting is scheduled to take 2.5 days involving about 60 experts per meeting. Break-out sessions on specific subjects, involving a subset of the participants are organised during the meetings.

- H/V interested parties meetings (1/year);
- Drafting/expert groups involving, if appropriate, external experts and representatives of other working parties and/or inspectors (virtual meetings - as deemed necessary);
- QWP core team (11 virtual meetings/year) - specific procedures support; and
- H/V joint QWP/BWP/GMDP IWG EMA Process Analytical Technology team (1 x 1 day meetings + 2 virtual meetings).

Additional virtual meetings may be organised ad-hoc to respond to time-sensitive requests on products, as required.

2. Guidelines and Reflection Papers

2.1. New EU Guidelines and Reflection Papers

Action: Lead

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

Target date Final guideline to be published Q2 2018.

Comments Public consultation of the draft guideline ended 13 October 2016. Contribution of BWP.

Guideline on quality and equivalence of topical products (H)

Target date Draft guideline to be released for 6 month public consultation Q2 2018.

Comments Public consultation of the concept paper ended 22 July 2015. Contribution of PKWP.

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

Target date Draft guideline to be released for public consultation Q4 2018.

Comments Public consultation of the concept paper ended 16 May 2017. Contribution of BWP.

Reflection paper on quality aspects of medicines for older people (H)

Target date Final reflection paper to be published Q1 2019.

Comments Public consultation of the reflection paper will end 31 January 2018. Contribution of BWP.

Reflection paper on risk assessment requirements to control elemental impurities in veterinary medicinal products (V)

Target date Final reflection paper to be published Q1 2020.

Comments Reflection paper for public consultation Q1 2019.

Action: Specialised input

Guideline on DNA reactive impurities in veterinary medicinal products, EMA/CVMP/SWP/553001/2016 (V)

Leading group CVMP – SWP

Target date Draft guideline to be released for public consultation Q4 2018.

Comments Contribution on quality aspects. Multidisciplinary project led by SWP-V and involving QWP and EWP-V.

Guideline on equivalence studies for the demonstration of therapeutic equivalence for products that are locally applied locally acting in the gastrointestinal tract as addendum to the guideline on the clinical requirements for locally applied, locally acting products containing known constituents (H)

Leading group PKWP

Target date Final guideline to be published Q4 2018.

Comments Contribution on quality aspects.

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

Leading group BSWP

Target date Comments on the reflection paper received during the public consultation will be discussed in 2018.

Comments Contribution on quality aspects.

Reflection paper providing an overview of the current regulatory testing requirements for Human medicinal products and opportunities for implementation of the 3Rs, EMA/CHMP/CVMP/JEG-3Rs/742466/2015 (H)

Leading group JEG 3Rs

Target date Reflection paper to be finalised following consultation Q3 2018.

Comments Contribution to comments arising from the public consultation on quality aspects.

Reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs, EMA/CHMP/CVMP/JEG-3Rs/164002/2016 (V)

Leading group JEG 3Rs

Target date Reflection paper to be finalised following public consultation Q1 2018.

Comments Contribution to comments arising from the public consultation on quality aspects.

2.2. EU Guidelines under revision

Action: Lead

Guideline on the manufacture of the finished dosage form, EMEA/CVMP/126/95 (V)

Target date Draft guideline to be released for 6 month public consultation Q1 2018.

Comments Public consultation of the concept paper ended 17 October 2015.

Guideline on quality of water for pharmaceutical use, CPMP/QWP/158/01 (H+V)

Target date Draft guideline to be released for 6 month public consultation Q3 2018.

Comments Public consultation of the concept paper ended 6 June 2017. Contribution of GMP/GDP IWG, CAT, BWP, IWP.

Guideline on the pharmaceutical quality of inhalation and nasal products, EMEA/CHMP/QWP/49313/2005 (H)

Target date Draft guideline to be released for 6 month public consultation Q3 2018.

Comments Public consultation of the concept paper ended 30 June 2017. Contribution of Respiratory DG.

Action: Specialised input

Guideline on the conduct of bioequivalence studies for veterinary medicinal products, EMEA/CVMP/016/00-Rev.3 (V)

Leading group CVMP - EWP

Target date Draft revised guideline to be finalised following public consultation Q2 2018.

Comments Contribution on quality aspects to revision of existing guideline. Multidisciplinary topic led by EWP-V and involving QWP. Revision proposed as consequence of finalisation of corresponding VICH GL52.

Guideline on the requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD) in adults and for use in the treatment of asthma in children and adolescents, EMEA/CPMP/EWP/4151/00 Rev.1 (H)

Leading group CHMP – Respiratory Drafting Group

Target date Draft guideline to be released for 6 month public consultation in 2018.

Comments Contribution on quality aspects.

Annex to the European Commission Guideline (EMA/CHMP/302620/2017) 'Excipients in the Label and Package leaflet for Medicinal Products for Human Use' (SANTE 2017-11668) (H)

Leading group CHMP ExcpDG

Target date Revised Annex to be published Q2 2018.

Comments Contribution on quality aspects. Multidisciplinary group. Revised Annex (containing updated ethanol) and public consultation of PL information for other individual excipients.

GMP Guide: Annex 1 (Manufacture of Sterile Medicinal Products)

Target date	To provide the European Commission with a final text for publication Q4 2018.
Comments	Contribution on quality aspects, as needed.

2.3. (V)ICH Guidelines

ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

Target date N/A

Comments Step 1 completed. Input to the development of ICH Guideline Q12 jointly with BWP.

Discussion on the Common Technical Document (ICH topic M4).

VICH GL3 – Annex - Stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV

Target date Contribute to EU position.

Comments Step 2 ongoing.

VICH GL18 – Impurities: Residual solvents in new veterinary medicinal products, active substances and excipients

Target date N/A

Comments Step 9 - develop revised guideline, bringing it in line with revisions made in ICH Q3C (R5) and ICH Q3C (R6).

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

Contribution to the scientific advice and protocol assistance provided by the SAWPs (H or V) upon their request

Contribution to Innovation Task Force

3.2. Evaluation and Supervision activities

Contribution/recommendation to CHMP/CVMP marketing authorisation or post-authorisation evaluation procedures upon request of CHMP/CVMP

Input on non-centrally authorised product evaluation/referral procedures upon request of CMDh/ CMDv

Contribution to referral discussions upon request from CHMP/CVMP

4. Input in European activities

4.1. Training for the network and knowledge building

Organise specific virtual trainings

5. Input in International activities (beyond ICH guidelines)

5.1. Activities with other regulators

H/V collaboration with drug regulatory authorities outside the EU/EEA in addition to (V)ICH activities:

- Liaison with FDA (e.g. through the EMA PAT team), Health Canada and the Japanese Ministry of Health, Labour and Welfare, on matters of common interest.

5.2. Activities with international bodies

H/V collaboration with EDQM on:

- Project for impurities: review of qualification and limits of impurities of existing medicinal products authorised on the market in the EU/EEA with regards to new or revisions of specific monographs;
- Review of pharmacopoeial monographs and general chapters and notices;
- Sampling and testing of centrally authorised products;
- Pharmacopoeial discussion group (PDG), through matters referred to the QWP by EDQM;
- Involvement in and contribution to CEP procedures; and
- Involvement in and contribution to quality related seminars organised by EDQM.

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

- Organisation of the annual meeting with pharmaceutical industry representatives on issues of joint interest: June 2018.
- Continue dialogue on new technologies and approaches (e.g. consultation on QWP concept papers and guidelines, through workshops with interested parties on topics of common interest).

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/2009/11/WC500014313.pdf