15 December 2016
EMA/CHMP/643117/2016
Committee for Medicinal Products for Human Use (CHMP)

Work plan for the Pharmacokinetics Working Party (PKWP) for 2017

Chairperson: Jan Welink

Status of the work plan: December 2016

1. Meetings scheduled for 2017

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

- 25-26 April 2017
- 25-26 October 2017

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

Note for guidance on qualification and reporting of physiologically-based pharmacokinetics modelling and analyses, EMA/CHMP/211243/2014.

Target date	Final guideline to be released 2017.
Comments	Public consultation ended 31st January 2017. Comments received will be incorporated into the final guideline.

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Guidance on pharmacokinetics and dosing for obese patients.

Target date	Draft reflection paper to be released for 6 month public consultation 2017
Comments	New guideline to reflect on current scientific developments rather than having a specific sub-section in individual e.g. therapeutic guidelines

Product-Specific guidance for demonstration of Bioequivalence (PSBEG).

Target date	Final and draft PSBEGs on a bi-annual basis (in batches of 5 guidelines) for publication.
Comments	CMDh to nominate 5 further products entering the PSBEG cycle in January 2017 and 5 in July 2017.

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, EMA/649730/2016.

Target date	Draft to be released for public consultation Q1 2017.
Comments	Q1 2017. Input has been received from the Gastroenterology Drafting Group and the Quality Working Party.

Action: Specialised input

Guideline on quality and equivalence of topical products.

Leading group	Quality Working Party
Target date	Draft expected to be released for public consultation 2017.
Comments	The public consultation on the associated concept paper (EMA/CHMP/QWP/558185/2014) ended July 2015. PKWP input is focussed on bioequivalence requirements.

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

Leading group	Biostatistics Working Party
Target date	Draft reflection paper expected to be released for a 6-month public consultation Q1 2017.
Comments	The reflection paper is developed in collaboration with the CHMP Biologics working Party (BWP), the Biosimilar Medicinal Products Working Party (BMWP), the Quality Working Party (QWP) and the Scientific Advice Working Party (SAWP).

2.2. EU Guidelines under revision

Action: Lead

Guideline on the investigation of bioequivalence, CPMP/EWP/QWP/1401/98 Rev.1

Target date	Concept paper to be released for public consultation Q4 2017.

Comments A revision will be progressed in light of experience since the previous revision and taking account of a series of Questions & Answers and ongoing related work (see below).

Guideline on the investigation of bioequivalence (Appendix 1)

Target date Finalise the discussion with BSWP and QWP on the acceptability of the Mahalanobis distance for the similarity of dissolution profiles.

Comments This is a joint request from the CHMP Pharmacokinetics WP and the Quality WP.

Type I error control in two-stage designs in bioequivalence studies

Target date BSWP to provide responses to PKWP by Q2 2017

Comments Finalise work related to type I error control in two-stage designs in bioequivalence studies. Collaboration with the Biostatistics Working Party.

Note for guidance on the role of pharmacokinetics in the development of medicinal products in the paediatric population, EMEA/CHMP/EWP/147013/2004

Target date Draft guideline to be released for public consultation Q1 2017

Comments Concept paper public consultation ended

Guideline on the investigation of drug interactions, EMEA/CHMP/EWP/147013/2004

Target date Concept paper to be released for public consultation Q1 2017

Comments Work ongoing including FDA liaison.

2.3. ICH Guidelines

ICH M9 Guideline on Biopharmaceutics Classification System-based Biowaivers

Target date Step 2b document to be agreed at ICH level Q2 2018

Comments PKWP as a whole will input on the draft currently being developed.

ICH M10 Guideline on Bioanalytical Method Validation

Target date Step 2b document to be agreed at ICH level Q2 2018

Comments PKWP as a whole will input on the draft currently being developed.

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

Contribution on relevant pharmacokinetic aspects to Scientific Advice protocol assistance upon request from the Scientific Advice Working Party.

Comments: Expected to input into 8 procedures

Contribution to product-related assessment pre-authorisation following specific CHMP request.

Comments: Expected to input into 4 procedures

3.2. Evaluation and supervision activities

Questions and Answers document on pharmacokinetic aspects for biosimilars in response to a request from CHMP Q4 2017

Comments: PKWP to lead in developing a Q & A in collaboration with Biosimilars Working Party (BMWP), Biologics Working Party (BWP) and the Modelling and Simulation Working Group (MSWG).

Bioequivalence issues upon request from CMD(h)

Comments: Expected to input into 8 requests/procedures

Paediatric medicines issues upon request from (PDCO)

Comments: Expected to input into 2 requests/procedures

Pharmacovigilance issues upon request from the CHMP and PRAC

Comments: Expected to input into 2 requests/procedures

Contribution to product-related assessment post-authorisation following specific CHMP request.

Comments: Expected to input into 4 procedures

Other requests received from EMA Committees and Working Parties, e.g. Quality Working Party, Modelling and Simulation Drafting Group, Biologics Working Party, Biostatistics Working Party.

Comments: Expected to input into 4 procedures

Publication on EMA website of Questions & Answers related to positions on specific questions addressed to the PKWP that impact on current guidance.

Comments: Expected to publish 6 Questions & Answers

Update of CHMP Day 80 Assessment Report to reflect drug interactions in line with the guideline, EMEA/CHMP/EWP/147013/2004

Comments: this started in 2013 following the publication of the Guideline on drug interactions EMEA/CHMP/EWP/147013/2004 and the proposal now is to progress with this in light of current experience.

4. Input in European activities

4.1. Training for the network and knowledge building

Assessor Training on the new PBPK guideline

Format to be defined. Earliest Q4 2017.

5. Input in International activities (beyond ICH guidelines)

Ad-hoc discussion with the FDA and other Regions, as appropriate, will be organised around specific topics. Particular activity is envisaged with the FDA in terms of the revision of the bioequivalence guideline.

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

6.1. Workshops

None

6.2. Other activities with stakeholders and external parties

Jan Welink to represent CHMP at the WRIB annual meeting