15 December 2016
EMA/799154/2016

Work plan for the Modelling and Simulation Working Group (MSWG) for 2017

Chairperson: Ine Skottheim Rusten

1. Meetings scheduled for 2017

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

- 30 November – 1 December

10 monthly virtual meetings/web sharing will be planned to accommodate scientific input to products scientific advice and evaluation.

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	In collaboration with PKWP. Public consultation ended 31st January 2017. Comments received will be incorporated into the final guideline.

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Action: Specialised input

Reflection paper on extrapolation of efficacy and safety in paediatric medicine development

Target date	Final guideline to be released 2017.
Comments	In collaboration with BSWP, EWG and PKWP. Comments received will be incorporated into the final guideline.

Guidance on pharmacokinetics and dosing for obese patients

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

Paediatric Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections

Target date	Draft to be released for public consultation Q2 2017.
Comments	In collaboration with IDWP.

Guideline on good pharmacogenomic practice, EMA/CHMP/268544/2016

Target date	Final guideline to be released Q3 2017.
Comments	MSWG input is focussed on in silico methods to support optimisation and analysis of PG data into drug development.

2.2. EU Guidelines under revision

Action: Specialised input

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). This has to be agreed by CHMP.

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 Q2 2017.
Comments	Concept paper public consultation ended.

Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products (EMEA/CHMP/SWP/28367/07)

Leading group	Ad-hoc multidisciplinary Expert Group.
Target date	Final guideline to be adopted in Q2 2017.

Comments	Multidisciplinary group involving non-clinical and clinical experts from EMA Committees/Working parties and the Head of Medicines Agencies' Clinical Trial Facilitation Group.

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

E11(R1) Clinical investigation of medicinal products in the paediatric population

Target date	Step 4 is planned in 2017.
Comments	Draft addendum was published in September 2016. Support E11 (R1) EU members from CHMP and the Paediatric Committee (PDCO) in the development of the addendum.

ICH E14 working group on collaborative data gathering and analyses

Target date	The white paper on technical aspects of C-QT planned to be published in 2017.
Comments	

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

Contribution on relevant M&S aspects to Scientific Advice and protocol assistance upon request from the Scientific Advice Working Party.

Comments: Expected to contribute into 60 procedures.

Contribution on relevant M&S aspects to Scientific Advice and protocol assistance upon request from the PDCO.

Comments: Expected to contribute into 50 procedures.

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

Comments: Expected to contribute into 4 procedures.

3.2. Evaluation and supervision activities

M&S issues upon request from CMD(h).

Comments: Expected to input into 1 requests/procedures.

Pharmacovigilance issues upon request from the CHMP and PRAC.
Comments: Expected to contribute into 1 requests/procedures.

Contribution to product-related assessment post-authorisation following specific CHMP request.
Comments: Expected to contribute into 1 procedures.

Other requests received from EMA Committees and Working Parties, e.g. Quality Working Party, PWKP, Biologics Working Party, Biostatistics Working Party.
Comments: Expected to contribute into 1 procedures.

4. Input in European activities

4.1. Training for the network and knowledge building

Assessor Training on the Extrapolation

Format to be defined

Assessor Training on the new PBPK guideline

Format to be defined

Assessor Training on the Exposure Response Analysis

Format to be defined

Software Specific Trainings

Format to be defined

4.2. Other

Questions and Answers document on pharmacokinetic aspects for biosimilars in response to a request from CHMP Q4 2017
Comments: MSWG to contribute in developing a Q&A in collaboration with Biosimilars Working Party (BMWP), Biologics Working Party (BWP) and the Pharmacokinetics Working Party (PKWP - Lead).

Update the required information on M&S in PIP Summary Reports and in the key binding elements in the PIP opinions

Comments:

5. Input in International activities (beyond ICH guidelines)

International regulatory cluster on M&S with participation of EMA, US-FDA, MHLW/PMDA and Health Canada.

Comments: 4 Cluster TCs are planned.

Gaucher disease: A strategic collaborative approach from EMA and FDA

Comments: Format to be defined.

Paediatric Pulmonary Arterial Hypertension (PAH) - Global regulatory and scientific challenges

Comments: Workshop in Q2 2017. Ad-hoc TCs planned.

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

6.1. Workshops

Expert meeting on Uncertainty quantification for pop-PK/PD, PBPK, QSP and VPH models

Format to be defined. Q3 2017.

6.2. Other activities with stakeholders and external parties

Regulatory Presentation at PAGE meeting 2017 and ACOP meeting 2017 and other fora.

The MSWG will continue to encourage industry and academia led activities towards better standardisation and utilisation of M&S.