14 December 2017
EMA/CHMP/SWP/420217/2017

# Work plan for the Safety Working Party (SWP) for 2018

**Chairperson:** Jan Willem van der Laan

**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 and virtual meetings (VM) are planned for the following dates:

- 16 January 2018 (VM)
- 13-14 February 2018 (F2F)
- 13 March 2018 (VM
- 17 April 2018 (VM)
- 23 May 2018 (VM)
- 19 June 2018 (VM)
- 17 July 2018 (VM)
- 21 August 2018 (VM)
- 11 September 2018 (VM)
- 9-10 October 2018 (F2F)
- 6 November 2018 (VM)
- 4 December 2018 (VM)

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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

# 2. Guidelines

## 2.1. New EU Guidelines

### Action: Lead

Guideline on the non-clinical evaluation of radiopharmaceuticals

**Target date** Draft to be published for consultation Q3 2018

**Comments** None

Reflection paper on the qualification of non-genotoxic impurities

**Target date** Draft to be published for consultation Q2 2018

**Comments** None

Reflection paper on non-clinical requirements for plasma-derived replacement therapies

**Target date** Draft to be published for consultation Q3 2018

**Comments** None

### Action: Specialised input

Implementation of risk based prevention of cross contamination in production, and Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/SWP/169430/2012) – Question and answer document

**Leading group** GMP Inspectors WG

**Target date** Final Q&A document to be published Q2 2018

**Comments** None

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

**Leading group** J3RsWG

**Target date** Final reflection paper to be adopted in Q3 2018

**Comments** Published for 6-month consultation in November 2016

Review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products – Report on actions taken (EMA/CHMP/CVMP/JEG-3Rs/677407/2015)

**Leading group** J3RsWG

**Target date** Final report to be adopted in Q1 2018

**Comments** Public consultation until 31 October 2016

## 2.2. EU Guidelines under revision

### *Action: Lead*

Environmental risk assessment of medicinal products for human use (EMEA/CHMP/SWP/4447/00)

**Target date** Draft guideline to be released for public consultation in Q2 2018

**Comments** Concept paper published Q2 2016. Drafting group involving SWP members and specialised ERA assessors

### *Action: Specialised input*

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

**Leading group** CHMP Excipients Drafting Group

**Target date** Revised Annex to be published Q2 2018

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

## 2.3. ICH Guidelines

ICH S1: Rodent Carcinogenicity Studies for Human Pharmaceuticals - Regulatory Notice Document

**Target date** Step 2a/b planned for Q4 2019

**Comments** Regulatory review of Carcinogenicity Assessment Documents (CAD) and Carcinogenicity Study Summaries ongoing

ICH S5 (R3): Detection of Toxicity to Reproduction for Medicinal Products and male fertility- Revision

**Target date** Step 4 planned for Q3 2019

**Comments** Step 3 documents under public consultation until 28th February 2018

ICH S9 Q&A: Nonclinical Evaluation for Anticancer Pharmaceuticals— Questions and Answers

**Target date** Step 4 planned for Q1 2018

**Comments** Ongoing drafting work to address public comments received

ICH S11: Nonclinical Safety Testing in Support of Development of Paediatric Medicines

**Target date** Step 2b to be released for consultation Q2 2018

**Comments** None

ICH M7 (R2) Addendum: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

**Target date** Step 2a/b document to be released for consultation Q4 2018

**Comments** None

ICH Q3C (R6) Impurities: Guideline for Residual Solvents

**Target date** Step 2a/b document to be released for public consultation Q2 2018

**Comments** Work ongoing on 2-methyltetrahydrofuran, cyclopentylmethylether and tert-butanol

ICH Q3D Impurities: Guideline for Elemental Impurities

**Target date** Step 2a/b document planned by June 2018

**Comments** Definition of PDEs for dermal route of administration for 26 elemental impurities

# 3. Medicinal Products-specific activities

## *3.1. Pre-Authorisation activities*

- Contribution to Scientific Advice and Protocol Assistance activities, discussed at monthly SWP virtual meetings (15/year)
- Expert contribution to Innovation Task Force (ITF) (5/year)

## *3.2. Evaluation and supervision activities*

- Requests from CHMP for input on evaluation activities (5/year)
- Expert contribution to the Non-clinical Working Group of the PDCO (monthly teleconferences with individual SWP members)
- Contribution to product-related assessment post-authorisation following specific CHMP request (4/year)
- Other requests from other Scientific committees (e.g. PRAC, CAT, CVMP, HMPC) and working parties (e.g. QWP, BWP, etc.) on product-related issues (6/year)

# 4. Input in European activities

## *4.1. Training for the network and knowledge building*

- Contribution to annual pre-clinical assessor meeting. Date and location to be defined
- Contribution to GMP Inspectors training on Implementation of risk based prevention of cross contamination in production, and Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/SWP/169430/2012), date to be defined
- Contribution to EU NTC training activities in non-clinical area upon request
- Activities to promote network awareness of novel reproductive toxicity evaluation framework (see ICH S5(R3)

## *4.2. Other input in European activities*

- Contribution and involvement in non-clinical safety projects of the Innovative Medicines Initiative (IMI), such as: TRANSQST, SafeSciMET
- Contribution to Horizon 2020 research projects: EU-ToxRisk
- Contribution to other EU Institutions (EC, EU Agencies) and Initiatives as required: EMCDDA risk assessment activities; EPAA (European Partnership for Alternative Approaches to Animal Testing); etc.

# 5. Input in International activities (beyond ICH guidelines)

- Quarterly virtual meetings with FDA on non-clinical development of oncology products
- Health and Environmental Sciences Institute part of International Life Sciences Institute (ILSI-HESI):
    - Translational Biomarkers of Neurotoxicity (NeuTox)
    - Framework for intelligent non-animal alternative methods project
    - Technical Commission on emerging issues
    - Developmental and Reproductive Toxicology Working Group
    - CT-TRACS (Cell-therapy TRAcking, Circulation, & Safety)

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

- Annual SWP – Interested parties meeting (12 February 2018)
- Brainstorming sessions on emerging non-clinical safety topics with EFPIA in the margins of the annual pre-clinical assessors meeting

- Meeting with interested parties as needed e.g. learned societies, public health stakeholders (public health professionals, patients' organisations), and pharmaceutical industry representatives upon request

***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/2010/02/WC500073581.pdf*