7 December 2017
EMA/CHMP/CVMP/3Rs/479556/2017
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the joint CVMP/CHMP working group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (J3RsWG)

Chairperson	**Status**
Chair: E.-M. Vestergaard Vice-chair: S. Brendtler-Schwaab	Adopted by CVMP and CHMP in December 2017

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

Plenary meetings:	1 (per meeting: approx. 8 members, 1 day).
Other meetings:	
Drafting/Expert groups	5-10 depending on topics.
Workshop/Focus groups	None.
Training	1 for assessors at a National Competent Authority (3Rs and immunological medicinal products. Their impact on the regulatory field).

Virtual meetings are mainly regarded as complementary to the annual plenary meeting. However, if feasible depending on the workload a plenary meeting could be replaced by virtual meetings.

2. Objectives

The 2018 work plan for J3RsWG continues the works of JEG3RsWG and focuses particularly on:

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(1) Finalisation and adoption of reflection papers and guidelines under development on 3Rs.

(2) 3Rs issues related to batch release testing for immunological veterinary medicinal products (IVMPs) and human vaccines & biologicals.

(3) Supporting implementation of Directive 2010/63/EU.

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. 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)

Action: Guideline to be finalised following consultation (Q1 2018).

Comments: Multidisciplinary project led by J3RsWG and involving QWP, SWP-V, IWP, ERAWP and EWP-V.

3.1.2. 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)

Action: Guideline to be finalised following consultation (Q3 2018).

Comments: Multidisciplinary project led by J3RsWG and involving SWP-H, QWP, BWP, CATS and BMWP.

3.2. Guidance documents to be released for consultation

None.

3.3. Other topics/documents

3.3.1. 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)

Action: Respond to public consultation on Draft 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 (Q1 2018).

Comments: Multidisciplinary project led by J3RsWG and involving QWP, SWP-H, SWP-V, BWP, IWP, VWP and EWP-V.

4. 3Rs issues related to batch release activities

4.1. Review of final product batch testing requirements – case studies

Action: Review animal tests included in product release specifications (e.g., rabbit pyrogen test, abnormal toxicity test) for centrally authorised medicinal products and check compliance with current Ph. Eur monographs. Recommend updates to release specifications where appropriate (Retrospective review Q4 2018).

Comments: Multidisciplinary project involving QWP, VWP, BWP, IWP and led by J3RsWG. While any product specific recommendations will be made directly to marketing authorisation holders, consideration may also be given to publishing a general reflection paper on this topic.

5. Activities with external parties

5.1. Meetings with Interested Parties

None foreseen.

5.2. Communication with stakeholders

Action: Publish recommendations following revisions to Ph. Eur. texts updating requirements for use of animal tests highlighting the need for marketing authorisation holders to update their authorisations accordingly.

Comments: None.

5.3. Supporting implementation of Directive 2010/63/EU

5.3.1. Preliminary analysis of regulatory relevance of new alternative methods (PARERE)

Action: Coordinate development of EMA responses to requests received from the European Union Reference Laboratory for alternatives to animal testing (EURL ECVAM) relating to the potential regulatory relevance of test approaches.

Comments: Multidisciplinary project involving predominantly SWP-H, SWP-V and led by J3RsWG; involvement of QWP, BWP, VWP and IWP may be required on a case by case basis.

5.3.2. Follow developments in relation to creation of an EU database on animal use, specifically with regard to regulatory testing

Actions: Analyse available data to identify areas for follow up following publication of database.

Comments: The Commission is to publish a database providing greater access to statistics on animals used for scientific purposes. The database could be used with a view to identifying areas warranting further work.

6. Organisational matters

6.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the joint CVMP/CHMP working group on the application of the 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (EMA/CHMP/CVMP/3Rs/442724/2012-Rev.2).

6.2. List of organisational documents to be developed/revised in the 2 forthcoming years

None.

6.3. List of proposed scientific guidelines for the next work plan

None.