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Collaboration, Innovation and Scientific Excellence: the European Pharmacopoeia 11th Edition

Open Debate: 3Rs

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THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

Open debate on the 3Rs

11th edition conference

20 September 2022

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Alternatives to Animal Testing at EDQM



Alternatives to Animal Testing

- The Council of Europe on the protection of animal rights
- Categories of medicines concerned by animal testing for Quality Control purposes
- The contributors to the introduction of the 3Rs in the European Pharmacopoeia
- Achievements of the Ph.Eur. Commission for 3Rs
- Achievements of the Biological Standardisation Programme for 3Rs



The Council of Europe on the protection of animal rights

The protection of animal rights and in particular those used for experimentation has long been a subject of interest for the Council of Europe. The first milestone was achieved in 1986, when the European Convention (ETS 123) for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes was open for signature. This Convention is designed to reduce both the number of experiments and the number of animals used for such purposes and it encourages not to experiment on animals except where there is no alternative and it promotes research into alternative methods.

This Council of Europe Convention paved the way for the EU's Directive 86/609/EEC, adopted in 1986, as the provisions in it are based on the Convention. In September 2010, the EU adopted a new Directive 2010/63/EU on the same subject replacing Directive 86/609/EEC, which came into effect in 2013.

The EDQM in particular is actively involved in the application of the 3Rs principles in its areas of activity:

- the elaboration of the European Pharmacopoeia itself
- the Biological Standardisation Programme (BSP)
- the Official Medicines Control Laboratory (OMCL) network – in particular, the networks for Official Control Authority Batch Release (OCABR) for human and veterinary biologicals.

ADDITIONAL INFORMATION

- [Article: Replacement, Reduction, Refinement - Animal welfare progress in European Pharmacopoeia monographs: activities of the European Pharmacopoeia Commission from 2007 to 2017 \(May 2018\)](#)
- [Report for veterinary use \(Replacement 7.7\): what has changed and why \(Pharmacopoeia, January 2013\)](#)
- [The Directive 2010/63/EU of the European Parliament and of the Council on the Protection of Animals Used for Scientific Purposes will take full effect from 1 January 2013](#)
- [Report published by the Veterinary Medicines Directorate \(UK\): *Animal welfare in quality control tests for the batch release of immunological Veterinary Medicinal Products \(VMPs\) via the UK from 2007 to 2016*](#)
- [Article: C. Mirra & J.H. Burnham, EDQM's 18 activities in the field of quality control of medicinal ALTDs \(premedicals\) \(J. Pharm. Med. 2007; 11: 245-65\)](#)
- [Article: F. Charton, Alternatives to Animal Testing: New Approaches in the Development and Control of Biologics](#)
- [Article: P. Castle, Replacement, Reduction, Refinement \(RRR\), Animal welfare progress in European Pharmacopoeia monographs \(Pharmazie 2007; 62: 343-6\)](#)
- [Article: F. Charton and P. Castle, Reduction, Replacement and Refinement of animal tests in the European Pharmacopoeia: recent developments for monographs on biological substances and preparations \(Pharmazie 2011; 66: 1241-56\)](#)
- [Article: P. Castle, The European](#)

Biological Standardisation Programme (BSP)

- Started in 1991
- 170 Projects initiated/concluded
- As part of the mission, elaborate alternative methods for the quality control of biologicals in order to apply the 3Rs concept (refine, reduce, replace) to use of animals in laboratory experiments
- 29 3Rs projects

Ph. Eur. Commission

Pharmeuropa Bio & Scientific Notes 2016: Replacement, Reduction, Refinement

Animal welfare progress in European Pharmacopoeia monographs: activities of the European Pharmacopoeia Commission from 2007 to 2017

Catherine Lang, Olga Kotly-Rubin, Ovenshii Cinefco, Laure Taconet, Ellen Piel, Sébastien Jouette, Mhaëlle Burke, Catherine Mirra, Emmanuelle Charton

ABSTRACT

Since the signing of signature of the European Convention for the Protection of Animals Used for Experimental and Other Scientific Purposes in 1986, the European Pharmacopoeia

EDQM collaborations

Experts of the Ph. Eur.



The European Network of Official Medicines Control Laboratories (OMCLs)



Recent achievements in the Ph. Eur. – selected examples

Suppression of abnormal toxicity test

Replacement of HIST for aP vaccines

Toxicity testing requirements for tetanus vaccines

General chapter 5.2.14 "substitution"

Extraneous agents strategy (human and veterinary vaccines): risk assessment; removal of animal tests; introduction of broad molecular methods

Acceptance of humane endpoints, review and reduction # of animals used in animal tests

Perspectives: Ongoing and future targets

BSP: Rabies vaccine for human use: ELISA to replace *in vivo* potency assay

BSP: Tetanus vaccines: BINACLE assay (*in vitro* test) to replace *in vivo* test for *Absence of toxin*

BSP: Evaluation of an *in vitro* assay for Erythropoietin (feasibility phase)

Deletion of rabbit pyrogens test

Alternatives to the test: Limulus test → MAT, recombinant factor C

.... Future DTaP Potency studies

What are the gaps?

EPO - FSH

BoTox

**DTaP
Potency**

Potency test for rabies vaccines

Open debate:

What should we do
to further accelerate
the implementation of the 3Rs?

The floor is yours!



Thank you for your attention



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