International Conference, 19-21 September 2022

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

Open Debate: 3Rs

Moderator: Lukas Bruckner,
Swiss Delegation of the Ph. Eur. Commission

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

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COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Open debate on the 3Rs

11th edition conference

20 September 2022

Lukas BRUCKNER

Chair of BSP SC, member of the European Pharmacopoeia Commission

Laurent MALLET, Emmanuelle CHARTON, EDQM

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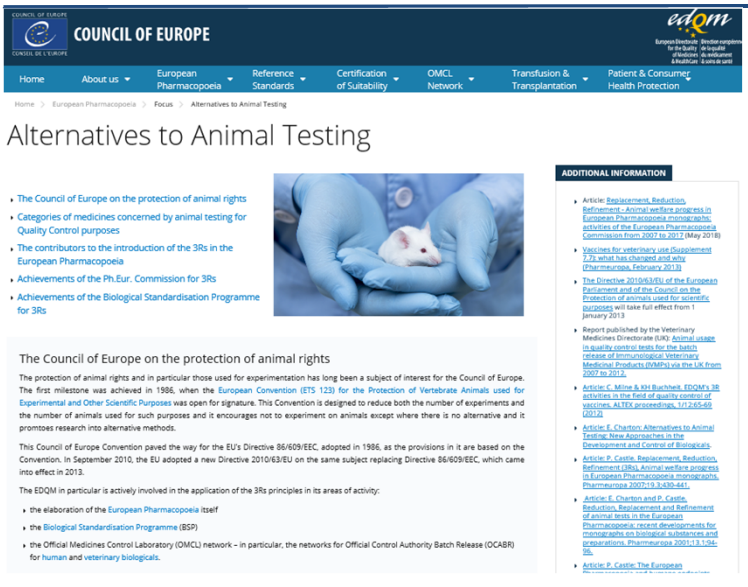
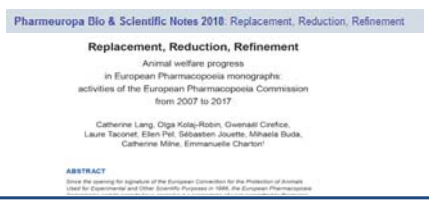
Alternatives to Animal Testing at EDQM



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



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EDQM collaborations

Experts of the Ph. Eur.

European Commission

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EURL ECVAM

The European Partnership for Alternative Approaches to Animal Testing

The European Network of Official Medicines Control Laboratories (OMCLs)

World Health Organization

vac2vac

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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"**
- **Acceptance of humane endpoints, review and reduction #of animals used in animal tests**
- **Extraneous agents strategy (human and veterinary vaccines): risk assessment; removal of animal tests; introduction of broad molecular methods**

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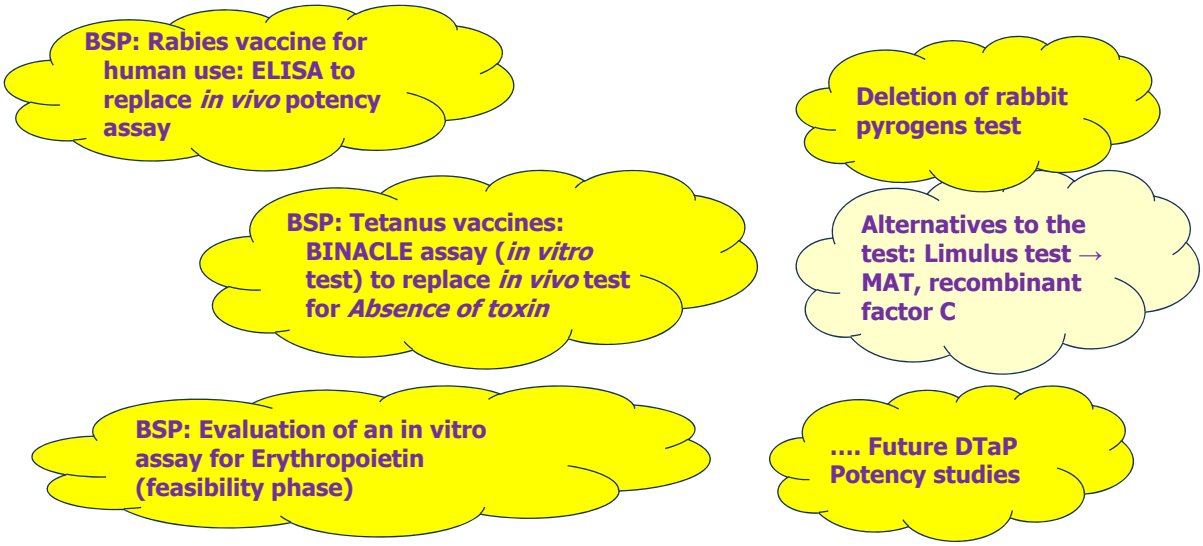
Perspectives: Ongoing and future targets



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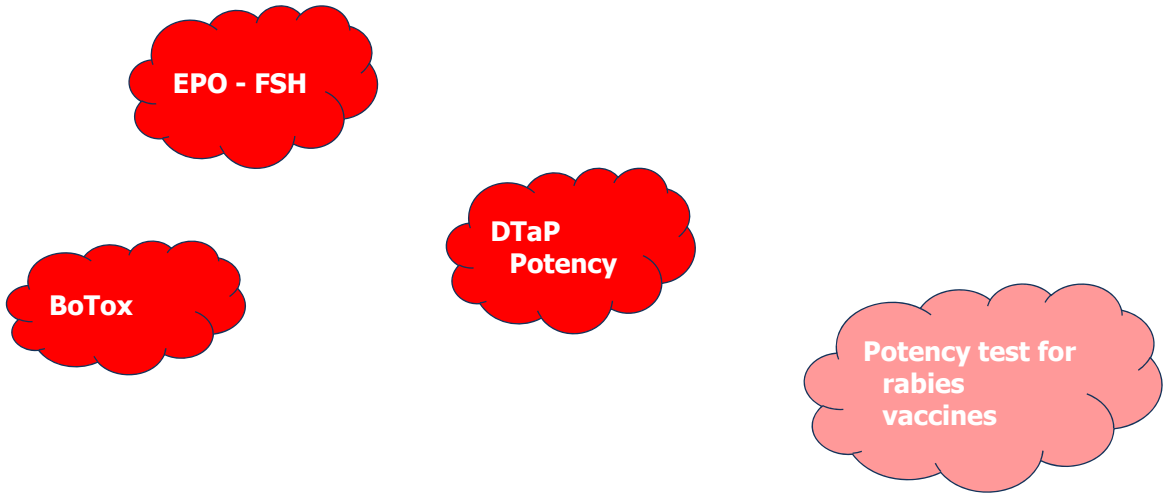
What are the gaps?



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Open debate:

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

The floor is yours!

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Thank you for your attention

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