EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reinforce and further embed application of the 3Rs principles

Underlying actions

EMA's Regulatory Science Strategy to 2025 – Veterinary Stakeholder Workshop

Chaired by Raffaella Corvi, EC - Ellen-Margrethe Vestergaard, 3Rs WG
Presented by Nicholas Jarrett, EMA on 6 December 2019

Combined actions and feedback

- Networking/global dimension: international forum to encourage uptake and training on 3Rs — All stakeholders
- Networking: regulator/industry partnership to explore/prioritise/develop 3Rs methods — All stakeholders
- Networking: learn from other sectors successfully using 3Rs (e.g. pharmaceuticals vs vaccines/HMPs vs VMPs) — EMA/industry
- Networking: lobby for implementation of validated/accepted 3Rs methods internationally (e.g. push for acceptance of VICH GL in as many countries as possible) — All stakeholders
- Develop dialogue with NCAs responsible for implementation of Directive 2010/63 — EMA

Combined actions and feedback - continued

- Training for assessors to enhance regulatory acceptance — EMA/other relevant experts
- Enable *early dialogue* between industry and regulatory authorities specifically on 3Rs — more than current SA — EMA
- Incentive to explore 3Rs: provide above-mentioned procedure for free — EMA
- Encourage data/method sharing (e.g. biologicals potency testing; 'marketplace') — Industry/(EMA)

Combined actions and feedback - continued

- Retrospective analysis to review robustness/validity of standard tests (non-validated) and to support validation/confidence in in silico/in vitro methods (systematic review) — EMA/academia
- Systematically include 3Rs methods/concepts in all relevant CVMP GLs — EMA
- Review GL on requirements for combined vaccines to counter competitive disadvantages — EMA
- Identify/facilitate access to 3Rs methods relevant for regulatory testing (mapping of methods available) — ?

Any questions?

Further information

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