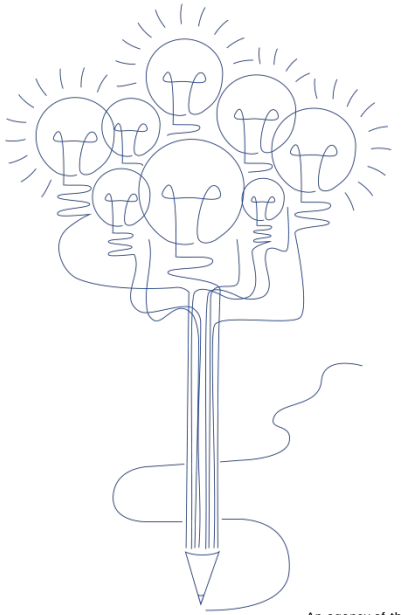
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Catalysing the integration of science and technology in drug development

EMA's core recommendations

Veterinary Stakeholders Workshop



Presented by Rory Breathnach on 6 December 2018
Chair of SAWPv

Core recommendations

Transform the regulatory framework for innovative veterinary medicines

Reinforce and further embed application of 3Rs

Facilitate implementation of novel manufacturing models

Transform the regulatory framework for innovative veterinary medicines

Draft an annex to the new veterinary legislation that defines technical standards for novel veterinary therapies, particularly biologicals

Develop standards for novel therapies and the promotion of new endpoints

Strengthen support to industry throughout the development lifecycle of novel therapies

Transform the regulatory framework for innovative veterinary medicines

Promote the One Health approach, contributing to, and sharing resources with, the human domain in the area of novel therapies

Increase EU network capacity and capability in novel therapies drawing on knowledge and training from human experience

Reinforce and further embed application of 3Rs

- Apply the highest possible 3Rs standards when implementing the new veterinary regulation
- Strengthen cooperation with European and international institutions
- Motivate increased data-sharing by industry to reduce animal use in safety evaluations

Reinforce and further embed application of 3Rs

Encourage medicines' developers to seek qualification of biomarkers that avoid the need for animal studies

Promote in silico methodology (e.g. modelling) and novel in vitro assays to reduce animal use, particularly in toxicology/epidemiology

Explore whether international recognition of qualification of alternative methods strengthens the use of 3Rs principles

Facilitate implementation of novel manufacturing models

- Recruit expertise in novel manufacturing technologies to enhance the assessment process
- Identify bottlenecks and propose modernisation of relevant regulations to facilitate novel manufacturing
- Address regulatory challenges in point-of-care manufacturing such as responsibility for the manufacturing process, the concept of batch control, and the role of the Qualified Person
- Facilitate a flexible approach in application of Good Manufacturing Practice with respect to novel therapies

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