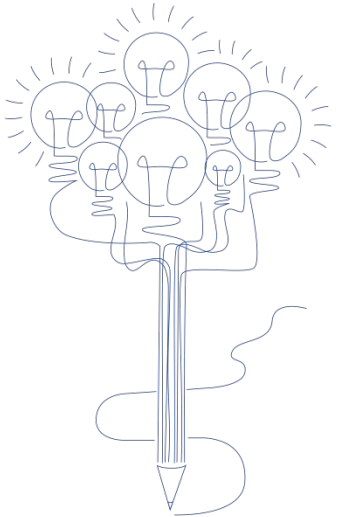
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulation of veterinary medicinal products in the 21st century – Addressing challenges and opportunities across the European Regulatory Framework

EMA's Regulatory Science Response

Veterinary Stakeholders Workshop



Presented by Ivo Claassen on 6 December 2018
Head of Veterinary Medicines Division, EMA

An agency of the European Union

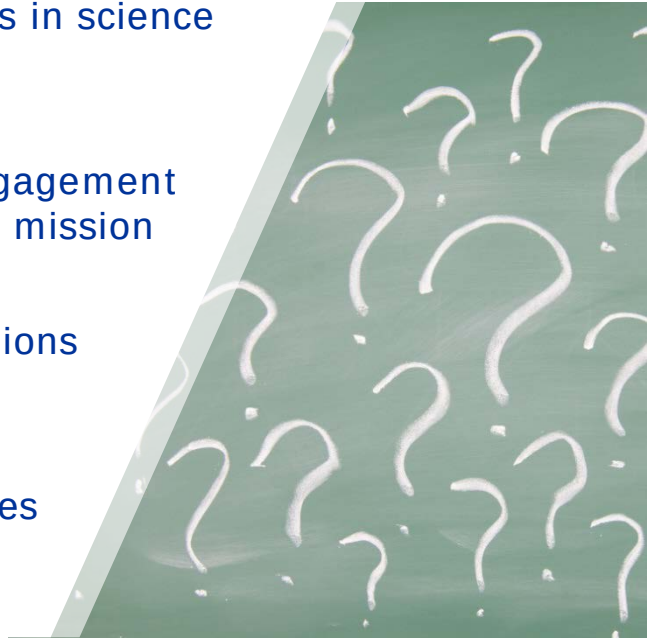
Why now?

To monitor and sign-post emerging and future trends in science and technology

To identify key priorities where new or enhanced engagement is essential to the continued success of the Agency's mission

To prioritise use of resources and external collaborations to strategically advance regulatory science

To shape and influence the vision for the EU Medicines Agencies Network (EMRN) Strategy 2020–25



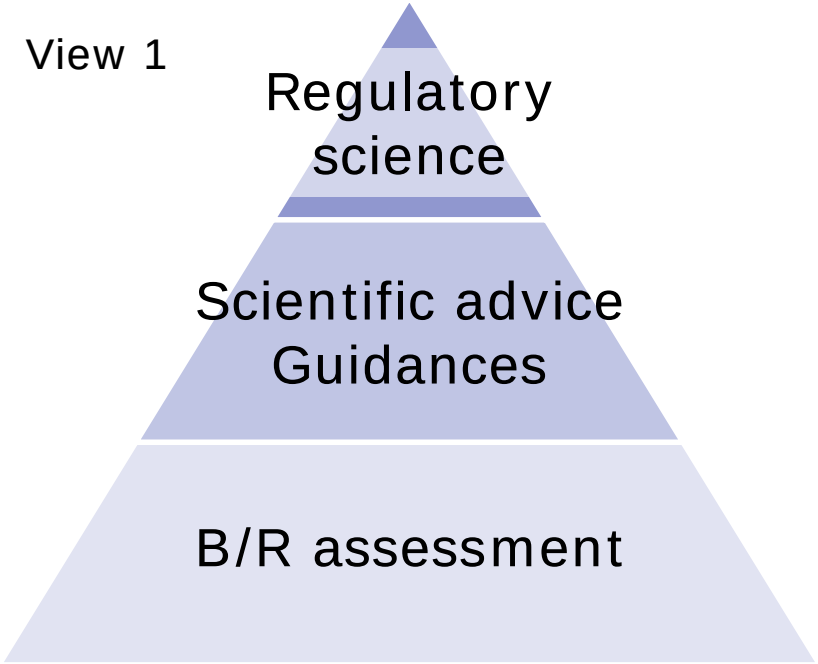
How does EMA define Regulatory Science?

Regulatory science is defined as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of (***veterinary***) medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine.

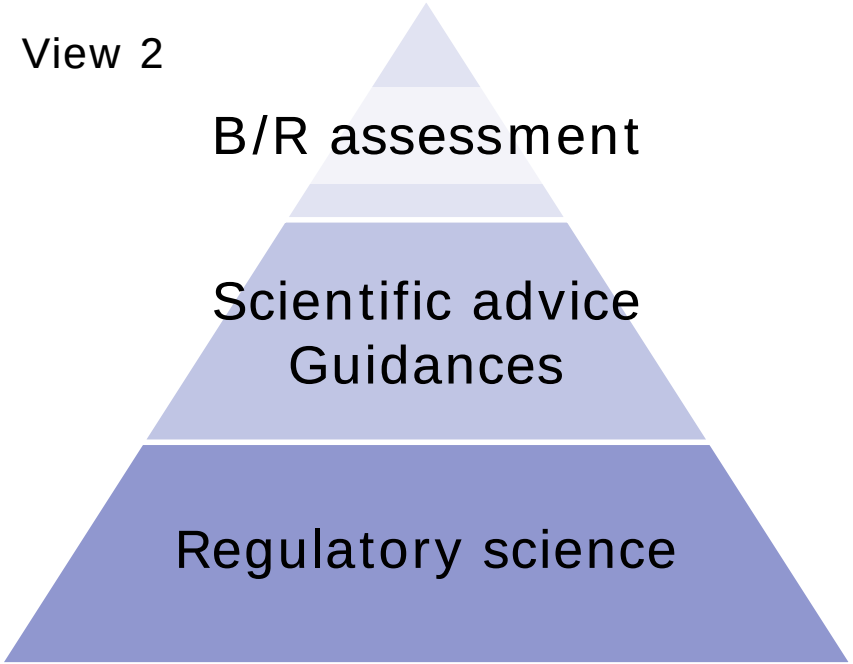
It encompasses basic and applied (***veterinary***) medicinal science and social sciences, and contributes to the development of regulatory standards and tools.

The role of regulatory science at EMA?

View 1

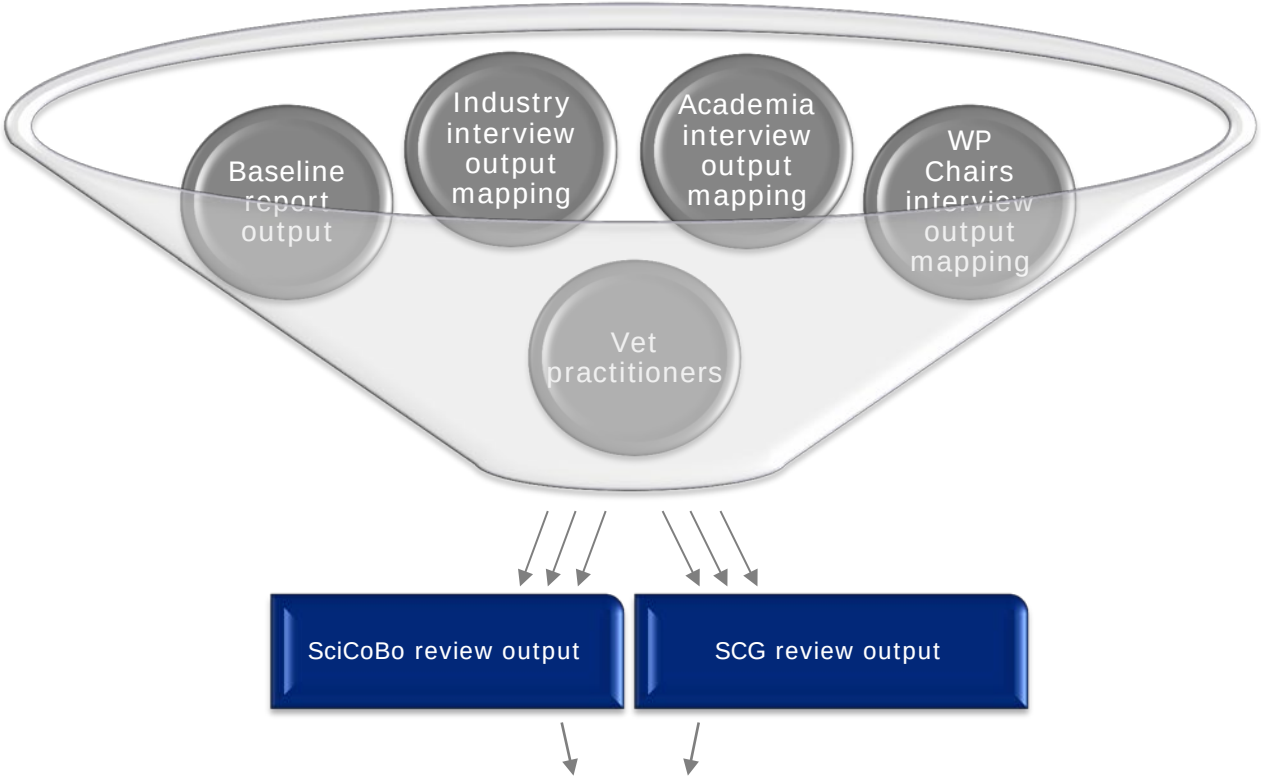


View 2



Vision—EMA Regulatory Science to 2025

"To foster scientific excellence in the regulation of veterinary medicines for the benefit of animal and public health while facilitating and promoting innovation and access to novel medicinal products."



Regulatory Science to 2025

Strategic goal 1

To catalyse the integration of science and technology in drug development.

Strategic goal 2

To drive collaborative evidence generation to improve the scientific quality of evaluations.

Strategic goal 3

To address emerging health threats and availability/therapeutic challenges.

Strategic goal 4

To enable and leverage research and innovation in regulatory science.

EMA Regulatory Science to 2025 - Timeline

Legislation follows science, not the other way round:
embracing innovation ambition beyond implementation of NVR?

David Murphy,
Chair of CVMP

Nancy de Briyne,
FVE

Christian Siebert,
DG Santé

Jean-Pierre Orand,
HMA Management Group

Alexander Böttner,
AnimalhealthEurope