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Regulatory Science Strategy (RSS) and European Medicines Agencies network strategy to 2025

Activities in 2021

Veterinary Medicines Info Day 2021

Presented by Dr Jordi Torren Edo, 25 March 2021
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EMA Regulatory Science to 2025

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The EMA’s Regulatory Science to 2025 is a plan for advancing EMA's engagement with regulatory science over the next five to ten years, covering both human and veterinary medicines. The strategy aims to build a more adaptive regulatory system that will encourage innovation in human and veterinary medicine.

EMA website

The role of regulatory science at EMA

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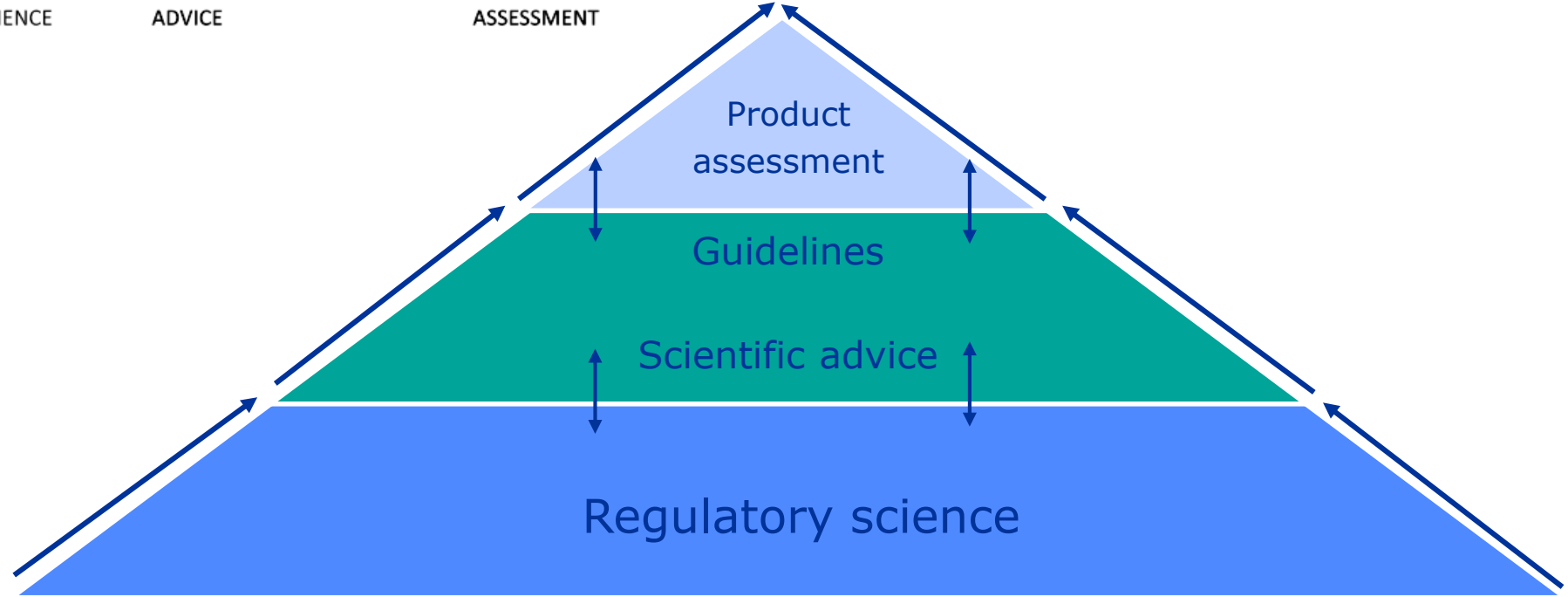
REGULATORY SCIENCE

SCIENTIFIC ADVICE

GUIDELINES

PRODUCT ASSESSMENT



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Veterinary strategic goals

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Veterinary strategic goals

Goal 1

Catalysing the integration of science and technology in medicines development

Transform the regulatory framework for innovative veterinary medicines

Annex II

Replace Reduce Refine

Reinforce and further embed application of the 3Rs principles

Joint 3Rs WP

Facilitate implementation of novel manufacturing models

GMP to be revised

Veterinary strategic goals

Goal 2

Driving collaborative evidence generation - improving the scientific quality of evaluations

- Update Environmental Risk Assessments in line with the latest scientific knowledge — ERAWP Workplan
- Apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines — EFSA collaboration
- Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance — Signal detection
- Develop new and improved communication and engagement channels and methods to reach out to stakeholders — Use of new technologies
- Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products — Art. 40(5) +

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Scope of tender
Lot 1: Pre-clinical research (human and vet)

Studies that may use literature sources or may **generate new *in vitro* or *in vivo* experimental data** (e.g. laboratory trials), apply *in silico* tools or use non-mammalian *in vivo* assays to perform the following evaluations:

- to evaluate formation of **metabolites** and their potential toxicity,
- to predict the potential **mutagenicity** and **carcinogenicity** in humans of impurities or active substances through structure activity relationship analysis,
- to review susceptibility data for **antimicrobial or antiparasitic** substances and assess the effect of microbial interaction on **resistance** development,
- to **evaluate indications, target species or populations**,
- to evaluate **bioequivalence** or effective dose,
- to assess the validity of defined **biomarkers** or models.

(not the complete list)

Tender available from here,
open until 30th April 2021

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Lot 2: Veterinary studies

Development and use of veterinary medicinal products (VMP) in companion and farm animals and the associated hazards for public health, animal health or the environment:

- Data sources, to establish an **inventory of real world data** and metadata pertaining to various veterinary areas
- Prospective and retrospective **observational studies on risks and efficacy** or effectiveness, regulatory outcomes, and measures taken to identify, characterise and anticipate future trends
- Analysis of **regulatory** and non-regulatory information on **efficacy and safety**
- Analysis of **regulatory** outcomes from other **international** regulatory authorities
- Feasibility to establish the required infrastructures and implement pilots for cost- and resource- effective, prospective, controlled studies in **farm animals** using commercial farm management systems
- Rapid descriptive studies to facilitate key decision-making process in the context of **crisis situation**
- **Questions** that may need to be **answered** very **rapidly** (i.e. within a few weeks), e.g. in relation to the extent of VMP usage or numbers of cases of a suspected adverse reactions.

Veterinary strategic goals

Goal 3

Addressing emerging health threats and availability/ therapeutic challenges

- Continue to promote the responsible use of antimicrobials and their alternatives — Rev. RP alternatives to AM
- Coordinate Network activities to improve data collection on antimicrobial use in animals — Delegated act
- Engage with stakeholders to minimise the risks of antiparasitic resistance — Collaborating expert + OIE
- Promote and support development of veterinary vaccines — Concept papers

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#RegScience2025

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20 January 2021
EMA/CVMP/IWP/671155/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper on the provision of field efficacy studies in support of marketing authorisation applications for immunological veterinary medicinal products and on indications for veterinary vaccines

Agreed by Immunologicals Working Party	17 December 2020
Adopted by CVMP for release for consultation	20 January 2021
Start of public consultation	29 January 2021
End of consultation (deadline for comments)	31 March 2021

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20 January2021
EMA/CVMP/IWP/674640/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the development of a guideline on data requirements for vaccine antigen master files (VAMF)

Agreed by Immunologicals Working Party	17 December 2020
Adopted by CVMP for release for consultation	20 January 2021
Start of public consultation	29 January 2021
End of consultation (deadline for comments)	31 March 2021

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20 January 2021
EMA/CVMP/IWP/600275/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza (AI), Blue Tongue (BT) and Foot and Mouth Disease (FMD)

Agreed by Immunologicals Working Party	17 December 2020
Adopted by CVMP for release for consultation	20 January 2021
Start of public consultation	29 January 2021
End of consultation (deadline for comments)	31 March 2021

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20 January 2021
EMA/CVMP/IWP/630533/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the development of a guideline on data requirements for authorisation of immunological veterinary medicinal products under exceptional circumstances

Agreed by Immunologicals Working Party	17 December 2020
Adopted by CVMP for release for consultation	20 January 2021
Start of public consultation	29 January 2021
End of consultation (deadline for comments)	31 March 2021

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20 January 2021
EMA/CVMP/IWP/582191/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper for the development of a guideline on data requirements for vaccine platform technology master files (PTMF)

Agreed by Immunologicals Working Party (IWP)	17 December 2020
Adopted by CVMP for release for consultation	20 January 2021
Start of public consultation	29 January 2021
End of consultation (deadline for comments)	31 March 2021

All documents under consultation available from here: [Open consultations | European Medicines Agency (europa.eu)]

Veterinary strategic goals

Goal 4

Enabling and leveraging research and innovation in regulatory science

- Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science
- Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions
- Identify and enable access to the best expertise across Europe and internationally
- Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders

Academia matrix + experts collaboration

Work on WPs

EU NTC

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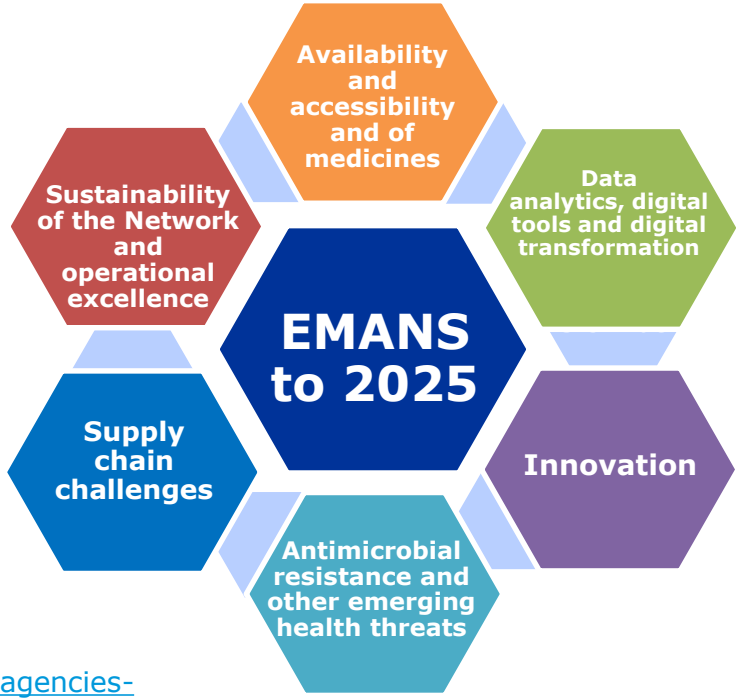
Strategic focus areas:

- Availability and accessibility of medicines
- Data analytics, digital tools and digital transformation
- Innovation
- Antimicrobial resistance and other emerging health threats
- Supply chain challenges
- Sustainability of the Network and operational excellence

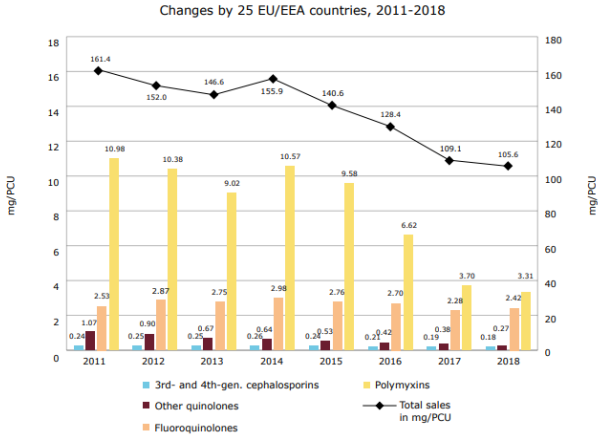


https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

Reduction in sales of antimicrobials

In the veterinary medicine area, the Network is fully committed to the practical implementation of the Veterinary Regulation (Regulation (EU) 2019/6), which will provide the means to address many of the issues raised in the strategy below. However, the future will also be shaped, inter alia, by the EU environmental strategy (European Green Deal) which is currently under discussion and which aims to improve public and animal health and the environment by a range of proposed measures, including significant reduction in use of chemicals in agriculture and of sales of antimicrobials for farmed animals and in aquaculture by 2030, and by the EU Farm-to-Fork Strategy as well as following up on the European Union Strategic Approach to Pharmaceuticals in the Environment.

Figure 23. Changes in aggregated overall sales in mg/PCU, as well as sales of fluoroquinolones, other quinolones, 3rd- and 4th-generation cephalosporins and polymyxins, for 25 EU/EEA countries[1], from 2011 to 2018 (note the difference in the scales of the y-axes)



[1] Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

Limited markets

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medicines regulation (Regulation (EU) 2019/6) will provide new measures to increase the availability of veterinary medicines such as stimulation of the development of innovative veterinary medicines, including products for limited markets, and to improve the functioning of the internal market for veterinary medicines, not least by publishing information on the availability of veterinary medicines, not least by publishing information on the availability of veterinary medicines in the Union database on veterinary medicinal products (Union Product Database or UPD). Although not outlined in this

17 February 2021
EMA/CVMP/235292/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on classification of a product as intended for a limited market and eligibility for authorisation according to Article 23 (Applications for limited markets)
Draft

Draft agreed by DG on limited market eligibility criteria	February 2021
Adopted by CVMP for release for consultation	17 February 2021
Start of public consultation	25 February 2021
End of consultation (deadline for comments)	15 May 2021

Conclusion and progress update

- The strategies (RSS and network) are very ambitious - many objectives.
- In the middle of a pandemic and implementation of Regulation (EU) 2019/6
  - it will be difficult to succeed in all the objectives.
- In most of the areas, progress has been made.

The Network Strategy will be reviewed after 18 months

Any questions?

Further information

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