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Public consultation on EMA Regulatory Science to 2025

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* Name

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction

The purpose of this public consultation is to seek views from EMA's stakeholders, partners and the general public on EMA's proposed strategy on Regulatory Science to 2025 and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, you have the opportunity to jointly shape a vision for regulatory science that will in turn feed into the wider EU network strategy in the period 2020-25.

The views being sought on the proposed strategy refer both to the extent and nature of the broader strategic goals and core recommendations. We also seek your views on whether the specific underlying actions proposed are the most appropriate to achieve these goals.

The questionnaire will remain open until June 30, 2019. In case of any queries, please contact: RegulatoryScience2025@ema.europa.eu.

Completing the questionnaire

This questionnaire should be completed once you have read the draft strategy document. The survey is divided into two areas: proposals for human regulatory science and proposals for veterinary regulatory science. You are invited to complete the section which is most relevant to your area of interest or both areas as you prefer.

We thank you for taking the time to provide your input; your responses will help to shape and prioritise our future actions in the field of regulatory science.

Data Protection

By participating in this survey, your submission will be assessed by EMA. EMA collects and stores your personal data for the purpose of this survey and, in the interest of transparency, your submission will be made publicly available.
For more information about the processing of personal data by EMA, please read the privacy statement.

Questionnaire

Question 1: What stakeholder, partner or group do you represent:

- ○ Individual member of the public
- ○ Patient or Consumer Organisation
- ◉ Healthcare professional organisation
- ○ Learned society
- ○ Farming and animal owner organisation
- ○ Academic researcher
- ○ Healthcare professional
- ○ Veterinarian
- ○ European research infrastructure
- ○ Research funder
- ○ Other scientific organisation
- ○ EU Regulatory partner / EU Institution
- ○ Health technology assessment body
- ○ Payer
- ○ Pharmaceutical industry
- ○ Non-EU regulator / Non-EU regulatory body
- ○ Other

Name of organisation (if applicable):

Federation of Veterinarians of Europe

Question 2: Which part of the proposed strategy document are you commenting upon:

- ○ Human
- ◉ Veterinary
- ○ Both

Question 3 (veterinary): What are your overall views about the strategy proposed in EMA's Regulatory Science to 2025?

Please note you will be asked to comment on the core recommendations and underlying actions in the subsequent questions.

FVE welcomes this EMA regulatory science horizon scanning exercise. Our world is changing at an ever-increasing speed, and it is important for the regulatory framework to keep track. This horizon scanning is crucial to ensure that regulation keeps up with emerging science and technological innovations. We also welcome the broad consultation done by EMA on this topic.

One remark to be made is by splitting up the vision for human medicines and veterinary medicine, we miss a true 'One Health' approach. Many of the goals mentioned in human medicine and not mentioned in veterinary medicine, are also relevant to the veterinary field. The same goals, might be implemented via slightly different actions in the different sectors, but the core principles are often the same. The same type of medicines, same technology, similar distribution networks, similar safety concerns, ePI, shortages, etc are mostly relevant in both fields. This divided approach needs to be changed if we truly want a 'One Health' approach.

Question 4 (veterinary): Do you consider the strategic goals appropriate?

Strategic goal 1: Catalysing the integration of science and technology in medicines development (v)

- ◉ Yes
- ○ No

Strategic goal 2: Driving collaborative evidence generation – improving the scientific quality of evaluations (v)

- ◉ Yes
- ○ No

Strategic goal 3: Addressing emerging health threats and availability/therapeutic challenges (v)

- ◉ Yes
- ○ No

Strategic goal 4: Enabling and leveraging research and innovation in regulatory science (v)

- ○ Yes
- ◉ No

Comments on strategic goal 4 (v):

Please note you will be asked to comment on the core recommendations and underlying actions in the subsequent questions.

Strategic goal 4 is relevant, but some of the goals under SG4 for the human sector as also very relevant for the veterinary sector, especially the following

- Continue to support development of new antibacterial agents and their alternatives
- Promote global cooperation to anticipate and address supply problems
- Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines

Question 5 (veterinary): Please identify the top three core recommendations (in order of importance) that you believe will deliver the most significant change in the regulatory system over the next five years and why.

First choice (v)

Please note that veterinary goals start at no.32

32. Transform the regulatory framework for innovative veterinary medicines

1st choice (v): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

Science and technology are changing quickly, we have to make sure that regulation is prepared for this. Digital health software is coming. On the same time, emerging health treats are arising such as due climate change and global trade/movement of animals, people and goods. Antimicrobial and anti-parasitic resistance shows us we have to reduce our reliance on these products. Companion animals are treated as family members, requiring more ever-more advanced treatments. Big data and other technological advances allow for novel treatment options and optimized, evidence-based treatment. Diagnostics are more and more advanced.
We need regulatory procedures to keep up with this changing environment.

Second choice (v)

Please note that veterinary goals start at no.32

39. Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products

2nd choice (v): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

We need methods to improve the benefit-risk assessment of veterinary medicinal products. Now the Agency and the whole regulatory network is risk-averse (often focusing on 'worst case' scenario), transferring the risk to animal owners and veterinarians who need to treat animals who are sick.

In respect to vaccines, we need to be prepared BEFORE a European disease outbreak. Good disease forecasting exist, regulators should follow this to be sure we are prepared. The benefit-risk assessment should take into account different epidemiological scenarios. We should in the future try to prevent situations were a European outbreak occurs e.g. LSD, for which we do not have a European vaccine authorized and where the only possibility is to import vaccines from third countries.
A different benefit- risk approach is needed for the assessment of specific vaccine types, minor-use-minor-species products including vaccines and vaccines for exceptional circumstances

Technology also advances rapidly; we can detect the smallest residue. We need to ensure how to deal with this and we need a framework for dealing with uncertainties.

Risk-mitigation measures should be more considered and worked on.

Third choice (v)

Please note that veterinary goals start at no.32

45. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions

3rd choice (v): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

SMEs and academia are the source of most innovation. However, when products receive approval, almost all are owned by pharmaceutical companies. Pharmaceutical companies only license products which will in the end give a return on investment. This leads to unmet needs existing for all species, and especially for minor species or minor use products.
This problem of unmet needs and availability can best be remedied by a close collaboration with all parties involved, namely the industry, the veterinary profession, regulators and academia.
Academia can help with defining the needs, disease forecast and research. To allow academia to better play this role, a greater collaboration is need between academia and regulators.

Question 6 (veterinary): Are there any significant elements missing in this strategy. Please elaborate which ones (v)

As explained before, a true 'One Health' approach is missing. We need to consider a model where information and expertise gained in one field, should be available, transferable and applicable easily in both sectors. That will minimize the need for resources, avoid redundancy, while multiply the positive results.

Another issue missing, in both human and veterinary field, is how the Agency and Network can deal with the increasing technological innovations, IT projects and needs.

Question 7 (veterinary): The following is to allow more detailed feedback on prioritisation, which will also help shape the future application of resources.Your further input is therefore highly appreciated. Please choose for each row the option which most closely reflects your opinion. For areas outside your interest or experience, please leave blank.

Should you wish to comment on any of the core recommendations (and their underlying actions) there is an option to do so.

Strategic goal 1: Catalysing the integration of science and technology in medicines development (v)

	Very important	Important	Moderately important	Less important	Not important
32. Transform the regulatory framework for innovative veterinary medicines	○	◉	○	○	○
33. Reinforce and further embed application of the 3Rs principles	○	◉	○	○	○
34. Facilitate implementation of novel manufacturing models	○	◉	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

All are important

Strategic goal 2: Driving collaborative evidence generation – improving the scientific quality of evaluations (v)

	Very important	Important	Moderately important	Less important	Not important
35. Update Environmental Risk Assessments in line with the latest scientific knowledge	○	◉	○	○	○
36. Apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines	○	○	◉	○	○
37. Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance	◉	○	○	○	○
38. Develop new and improved communication and engagement channels and methods to reach out to stakeholders	○	◉	○	○	○
39. Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products	◉	○	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

In respect to collaboration with stakeholders, regulators should enlarge their stakeholder network. The focus until now has to be to liaise with industry stakeholders. Much more effort should be done to reach out to other important stakeholder groups such as farmers organisations, companion animal organisations, veterinary organisations, consumer organisations and academia.

Strategic goal 3: Addressing emerging health threats and availability/therapeutic challenges (v)

	Very important	Important	Moderately important	Less important	Not important
40. Continue to promote the responsible use of antimicrobials and their alternatives	○	◉	○	○	○

41. Coordinate Network activities to improve data collection on antimicrobial use in animals	○	◉	○	○	○
42. Engage with stakeholders to minimise the risks of antiparasitic resistance	○	◉	○	○	○
43. Promote and support development of veterinary vaccines	○	◉	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

- We suggest to split up goal 40 into two goals, namely 1/ continue to promote responsible use of antimicrobials and 2/ continue to research alternatives to antimicrobials.

Alternatives to antimicrobials are essential in the fight against AMR. Not only development of vaccines but also the potential use of phages, biocides, immunomodulators, essential oils, etc. Most of these are currently in a grey regulatory area. It is essential to find a place for them in the regulatory framework.

- A goal is missing on ensuring availability and meeting therapeutic challenges. This in veterinary medicines, is one of the biggest problems we have. While hopefully the new Veterinary Medicines Regulation will increase availability to some extent, this will always stay an important goal. Ways need to be found to monitor availability gaps and to try to address the worst of them.

Strategic goal 4: Enabling and leveraging research and innovation in regulatory science (v)

	Very important	Important	Moderately important	Less important	Not important
44. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science	◉	○	○	○	○
45. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	◉	○	○	○	○
46. Identify and enable access to the best expertise across Europe and internationally	○	◉	○	○	○
47. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders	○	◉	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

Thank you very much for completing the survey. We value your opinion and encourage you to inform others who you know would be interested.

Useful links

EMA website: Public consultation page (https://www.ema.europa.eu/en/regulatory-science-strategy-2025)

Background Documents

EMA Regulatory Science to 2025.pdf

Contact

RegulatoryScience2025@ema.europa.eu