Contribution ID: 6c5ee511-a388-47ff-bbcb-c3ae0af91451
Date: 23/06/2019 02:00:44

Public consultation on EMA Regulatory Science to 2025

Fields marked with * are mandatory.

* Name

* Email

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):

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.

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

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.

Second choice (v)

Please note that veterinary goals start at no.32

34. Facilitate implementation of novel manufacturing models

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.

Third choice (v)

Please note that veterinary goals start at no.32

47. Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders

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.

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

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**:

33. the 3R principles habe been implemented more than thoroughly and habe reached the stage that they hinder the development of new VMPs. In most countries they habe been implemented strictly and lead to an unbalanced restriction to develop new VMPs for certain indications.
Most studies in animals are and will be even more conducted outside the EEA, even clinical studies. This leads to insufficiently tested products placed on the market, with high risks for the animals, humans and the environment.
Not talking here about the competitiveness of Europe for R&D which is significantly lost compared to many other markets.
This dies not mean, that we should not adapt 3R principles, especially replace certain studies. However, pre-clinical and clinical studies in the target species should stay completely out of these requirements, as Long as they follow the established guidance and thus being compulsory.

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**:

37. Pharmacovigilance is vastly over-regulated for veterinary medicines. The efforts that habe to be taken compared to the value generated dies not justify the current system at all in veterinary medicine. The System requires urgently to be reduced, here to simple in-house Evaluations by Industry and legal Obligation to inform the regulatory authorities in case of repeated issues. Similar System were in place in the 90ies in several countries and fullfilled their Purpose, with only 5 % of the effort required today.
39. not sure, which new approaches to Benefit-Risk are meant here. It appears that the current System is applied efficiently by CVMP; however further harmonisation would be required between member states. A pity, that the 1:1:1 Concept was missed to implement with Regulation 2019/6

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**:

40. efficient tools habe been established, but need Implementation in all member states and worldwide.
42. as long as for the majority of parasites, reliable resistance tests are not available, I wonder how this can progress. There is the need for fundamental research in this area to have the means to measure resistance before we can start thinking about minimising the risk.

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**:

46. this is fundamental to a trustful and efficient System Currently is still leading on the evaluation of VMPs worldwide, but this will have to be maintained.
47. equally important is the sharing of knowledge, Expertise and Innovation to Stakeholders and the Network: a pre-requisite to further development.

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