

# 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](mailto: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

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### 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.*

The general aims have undoubtedly merit. There is in general little awareness of the the need for immunotherapy in farm animals as a useful alternative to antibiotics. In this respect, a whole array of Biological Response Modifiers (mainly cytokines ) available for use in humans should be made available to veterinarians. In particular, the same rules about immunotherapy applicable to pets should be enforced for farm animals. In pets, precious cytokines registered for humans, like IFNs-alpha, can be compounded at an apothecary laboratory and administered e.g. to FIV-infected cats. This is not possible in farm animals because IFN-Alpha is not included in the annex to COUNCIL REGULATION (EEC) No 2377/90. Yet, paradoxically, IFN-Alpha is endorsed by EFSA and EMA as a useful alternative to antibiotics in pigs (see SCIENTIFIC OPINION of EFSA BIOHAZ Panel and EMA, CVMP, of 8 December 2016). The new European legislation must get over this overt discrepancy.

**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.**

My first choice is accounted for by the reasons put forward in the above section about immunotherapy, meant as a strategic initiative for farm animal health

**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.**

This is a further specification of the above statement. As a general principle, we must consider that immunoregulating active principles, deemed as safe in humans, should be freely available to veterinary practitioners. Thus, if IFN- $\alpha$  is still admitted for parenteral use in humans at 100,000 IU / kg b.w. , it should be freely admitted at say 10 IU / kg b.w. in pigs.

**Third choice (v)**

Please note that veterinary goals start at no.32

40. Continue to promote the responsible use of antimicrobials and their alternatives

**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.**

This is just a further aim, meant as a reasonable conceptual framework for the above proposals

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

On the basis of the previous statements, the strategy toward a substantial reduction of antibiotics should be supported by a wider availability of alternative active principles.

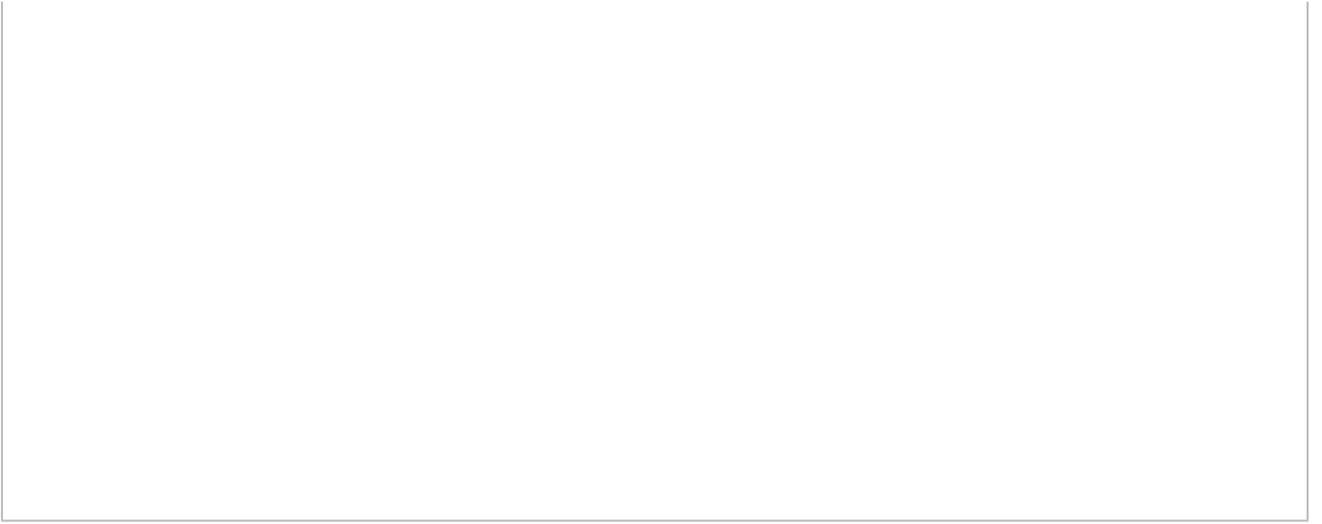
**Question 7 (veterinary): The following is to allow more detailed feedback on prioritisation, which will also help shape the future application of resources. Your further input is therefore highly appreciated. Please choose for each row the option which most closely reflects your opinion. For areas 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 | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> |
| 33. Reinforce and further embed application of the 3Rs principles          | <input type="radio"/>            | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 34. Facilitate implementation of novel manufacturing models                | <input type="radio"/>            | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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:**



**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                         | <input type="radio"/>            | <input type="radio"/>            | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 36. Apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines | <input type="radio"/>            | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> |
| 37. Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance           | <input type="radio"/>            | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> |
| 38. Develop new and improved communication and engagement channels and methods to reach out to stakeholders    | <input type="radio"/>            | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> |
| 39. Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products             | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> |

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:**

**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 | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 41. Coordinate Network activities to improve   | <input type="radio"/>            | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

|  |                                  |                                  |                       |                       |                       |
|--|----------------------------------|----------------------------------|-----------------------|-----------------------|-----------------------|
| data collection on antimicrobial use in animals                                |                                  |                                  |                       |                       |                       |
| 42. Engage with stakeholders to minimise the risks of antiparasitic resistance | <input type="radio"/>            | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 43. Promote and support development of veterinary vaccines                     | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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:**

**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         | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> |
| 45. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> |
| 46. Identify and enable access to the best expertise across Europe and internationally  | <input type="radio"/> | <input checked="" type="radio"/> | <input type="radio"/>            | <input type="radio"/> | <input type="radio"/> |
| 47. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders                   | <input type="radio"/> | <input type="radio"/>            | <input checked="" type="radio"/> | <input type="radio"/> | <input type="radio"/> |

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 \(https://www.ema.europa.eu/en/regulatory-science-strategy-2025\)](https://www.ema.europa.eu/en/regulatory-science-strategy-2025)

### **Background Documents**

[EMA Regulatory Science to 2025.pdf](#)

### **Contact**

RegulatoryScience2025@ema.europa.eu