

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 (human and 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.

Please remember to specify if a particular comment relates specifically to the human or veterinary part.

Overall very good, reflect many important points.

I would emphasize the role of imaging in the development of new imaging biomarkers for the assessment of drugs

I think that the drug shortage issue is not sufficiently developed

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

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

- ☒ Yes
- ☐ No

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

- ☒ Yes
- ☐ No

Strategic goal 3: Advancing patient-centred access to medicines in partnership with healthcare systems (h-only)

- ☒ Yes
- ☐ No

Strategic goal 4 (human) / 3 (veterinary): Addressing emerging health threats and availability /therapeutic challenges (h & v)

- ☒ Yes
- ☐ No

Strategic goal 5 (human) / 4 (veterinary): Enabling and leveraging research and innovation in regulatory science (h & v)

- ☒ Yes
☐ No

Question 5 (human): 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(h)

1. Support developments in precision medicine, biomarkers and 'omics'

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

include the imaging part of omics : radiomics
and the imaging part of biomarkers

Both will play a tremendous role in drug efficacy assessment

Second choice (h)

5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products

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

drugs and medical devices are a combination very frequently used by interventional radiologists
and the regulatory aspect of combined therapies should be facilitated

Third choice (h)

2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments

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

close to item number 5, because advanced medicinal products can be delibered through complex medical devices.
and the combination of regulatory pathways should be made easier

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
- ☐ 33. Reinforce and further embed application of the 3Rs principles
- ☐ 34. Facilitate implementation of novel manufacturing models
- ☐ 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
- ☐ 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
- ☐ 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 exchange knowledge, expertise and innovation across the network and to its stakeholders

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 still imaging biomarkers, but not present in the choices

Second choice (v)

Please note that veterinary goals start at no.32

- ☐ 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
- ☐ 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

- ☐ 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
- ☐ 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 exchange knowledge, expertise and innovation across the network and to its stakeholders

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

- ☐ 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
- ☐ 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
- ☐ 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
- ☐ 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 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 (human and veterinary): Are there any significant elements missing in this strategy. Please elaborate which ones (h & v)

Please remember to specify if a particular comment relates specifically to the human or veterinary part.


























not really to my mind.

Question 7 (human): 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 (h)

	Very important	Important	Moderately important	Less important	Not important
1. Support developments in precision medicine, biomarkers and ‘omics’	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. Promote and invest in the Priority Medicines scheme (PRIME)					
4. Facilitate the implementation of novel manufacturing technologies					
5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products					
6. Develop understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals					
7. Diversify and integrate the provision of regulatory advice along the development continuum					

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 (h)

	Very important	Important	Moderately important	Less important	Not important
8. Leverage novel non-clinical models and 3Rs	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Foster innovation in clinical trials	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Develop the regulatory framework for emerging digital clinical data generation	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. Expand benefit-risk assessment and communication	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Invest in special populations initiatives	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Optimise capabilities in modelling and simulation and extrapolation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Exploit digital technology and artificial intelligence in decision-making	<input type="radio"/>	<input checked="" 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: Advancing patient-centred access to medicines in partnership with healthcare systems (h)













	Very important	Important	Moderately important	Less important	Not important
15. Contribute to HTAs' preparedness and downstream decision-making for innovative medicines	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Bridge from evaluation to access through collaboration with Payers	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. Reinforce patient relevance in evidence generation	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Promote use of high-quality real world data (RWD) in decision-making	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Develop network competence and specialist collaborations to engage with big data	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Deliver real-time electronic Product Information (ePI)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. Promote the availability and uptake of biosimilars in healthcare systems	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. Further develop external communications to promote trust and confidence in the EU regulatory system	<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 4: Addressing emerging health threats and availability/therapeutic challenges (h)

	Very important	Important	Moderately important	Less important	Not important
23. Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. Continue to support development of new antimicrobials and their alternatives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

25. Promote global cooperation to anticipate and address supply challenges					
26. Support innovative approaches to the development and post-authorisation monitoring of vaccines					
27. Support the development and implementation of a repurposing framework					

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 5: Enabling and leveraging research and innovation in regulatory science (h)

	Very important	Important	Moderately important	Less important	Not important
28. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. 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"/>
30. 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"/>
31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders	<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:**

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:**
















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 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 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 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 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 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 type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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:**

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 checked="" type="radio"/>	<input 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 checked="" 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:**

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