

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.

The strategy is well written and comprehensive.

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'
- 2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments
- 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
- 8. Leverage novel non-clinical models and 3Rs
- 9. Foster innovation in clinical trials
- 10. Develop the regulatory framework for emerging digital clinical data generation
- 11. Expand benefit-risk assessment and communication
- 12. Invest in special populations initiatives
- 13. Optimise capabilities in modelling and simulation and extrapolation
- 14. Exploit digital technology and artificial intelligence in decision-making
- 15. Contribute to HTAs' preparedness and downstream decision-making for innovative medicines
- 16. Bridge from evaluation to access through collaboration with Payers
- 17. Reinforce patient relevance in evidence generation
- 18. Promote use of high-quality real world data (RWD) in decision-making
- 19. Develop network competence and specialist collaborations to engage with big data
- 20. Deliver real-time electronic Product Information (ePI)
- 21. Promote the availability and uptake of biosimilars in healthcare systems
- 22. Further develop external communications to promote trust and confidence in the EU regulatory system
- 23. Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches
- 24. Continue to support development of new antimicrobials and their alternatives
- 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
- 28. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science
- 29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions
- 30. Identify and enable access to the best expertise across Europe and internationally
- 31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders

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.

Second choice (h)

- 1. Support developments in precision medicine, biomarkers and 'omics'
- 2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments
- 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
- 8. Leverage novel non-clinical models and 3Rs
- 9. Foster innovation in clinical trials
- 10. Develop the regulatory framework for emerging digital clinical data generation
- 11. Expand benefit-risk assessment and communication
- 12. Invest in special populations initiatives
- 13. Optimise capabilities in modelling and simulation and extrapolation
- 14. Exploit digital technology and artificial intelligence in decision-making
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- 28. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science
- 29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions
- 30. Identify and enable access to the best expertise across Europe and internationally

- 31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders

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.

Third choice (h)

- 1. Support developments in precision medicine, biomarkers and 'omics'
- 2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments
- 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
- 8. Leverage novel non-clinical models and 3Rs
- 9. Foster innovation in clinical trials
- 10. Develop the regulatory framework for emerging digital clinical data generation
- 11. Expand benefit-risk assessment and communication
- 12. Invest in special populations initiatives
- 13. Optimise capabilities in modelling and simulation and extrapolation
- 14. Exploit digital technology and artificial intelligence in decision-making
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- 27. Support the development and implementation of a repurposing framework
- 28. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science
- 29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions

- 30. Identify and enable access to the best expertise across Europe and internationally
- 31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders

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.

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.

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.

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 type="radio"/>				
2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments	<input type="radio"/>				
3. Promote and invest in the Priority Medicines scheme (PRIME)	<input type="radio"/>				
4. Facilitate the implementation of novel manufacturing technologies	<input type="radio"/>				
5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products	<input type="radio"/>				
6. Develop understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals	<input type="radio"/>				
7. Diversify and integrate the provision of regulatory advice along the development continuum	<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 (h)

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

11. Expand benefit-risk assessment and communication	<input type="radio"/>				
12. Invest in special populations initiatives	<input type="radio"/>				
13. Optimise capabilities in modelling and simulation and extrapolation	<input type="radio"/>				
14. Exploit digital technology and artificial intelligence in decision-making	<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:**

ad 8)

a) We highly appreciate that the strategy highlights the importance of the 3Rs.

b) Is there any reason why 3Rs are mentioned under strategic goal 2 for human medicines whereas under strategic goal 1 for veterinary medicines? Please harmonise and place 3Rs under strategic goal 1.

c) In the strict sense of the definition of the 3Rs (replacement, reduction, refinement of ANIMAL tests), the use of animals seems to be the basis for science and innovation. The strategy should promote the use of non-animal based methods wherever possible e.g. by reinforcing the text under 3.2.1, page 16; if animals need to be used the 3Rs principles / approaches should be preferred wherever possible.

d) Please consider harmonising the text on the 3Rs and non-animal based methods in the chapters on human (3.2.1) and veterinary medicines (4.1.2). Already in the heading of the related chapters the use on non-animal methods should appear, e.g. "Reinforce and further embed application of non-animal methods and 3Rs approaches"

e) The use of non-animal methods should be captured in core recommendations

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"/>				
16. Bridge from evaluation to access through collaboration with Payers	<input type="radio"/>				
17. Reinforce patient relevance in evidence generation	<input type="radio"/>				
18. Promote use of high-quality real world data (RWD) in decision-making	<input type="radio"/>				
19. Develop network competence and specialist collaborations to engage with big data	<input type="radio"/>				
20. Deliver real-time electronic Product Information (ePI)	<input type="radio"/>				
21. Promote the availability and uptake of biosimilars in healthcare systems	<input type="radio"/>				
22. Further develop external communications to promote trust and confidence in the EU regulatory system	<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"/>				
24. Continue to support development of new antimicrobials and their alternatives	<input type="radio"/>				

25. Promote global cooperation to anticipate and address supply challenges	<input type="radio"/>				
26. Support innovative approaches to the development and post-authorisation monitoring of vaccines	<input type="radio"/>				
27. Support the development and implementation of a repurposing framework	<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:**

Apart from 24), we recommend adding "Continue to promote the responsible use of antimicrobials and their alternatives" as mentioned for veterinary medicines

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 type="radio"/>				
29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	<input type="radio"/>				
30. Identify and enable access to the best expertise across Europe and internationally	<input type="radio"/>				
31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders	<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
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32. Transform the regulatory framework for innovative veterinary medicines	<input type="radio"/>				
33. Reinforce and further embed application of the 3Rs principles	<input type="radio"/>				
34. Facilitate implementation of novel manufacturing models	<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:**

33) see our comment on 8).

Please add non-animal methods or approaches and change "3Rs principles" to "3Rs approaches".

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

41. Coordinate Network activities to improve data collection on antimicrobial use in animals	<input type="radio"/>				
42. Engage with stakeholders to minimise the risks of antiparasitic resistance	<input type="radio"/>				
43. Promote and support development of veterinary vaccines	<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"/>				
45. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	<input type="radio"/>				
46. Identify and enable access to the best expertise across Europe and internationally	<input type="radio"/>				
47. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders	<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

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