Contribution ID: c7f1f218-884b-483b-9c8d-f656ebb335a0
Date: 28/06/2019 14:39:16

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):

German Environment Agency

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 Global Chemicals Outlook addresses the increasing presence of pharmaceuticals in the environment (UN Environment 2019). The EU Commission has recently published a “Strategic Approach to Pharmaceuticals in the Environment” (COM(2019) 128 final).

We appreciate that the impact of veterinary medicines on the environment is included in the EMA regulatory strategy 2025. We suggest to better reflect the actions of the “Strategic Approach to Pharmaceuticals in the Environment” (COM(2019) 128 final) in the EMA regulatory science strategy.

For human medicines, the EMA regulatory science strategy to 2025 lacks any reference to the environmental impact of the use of existing as well as novel medicines. The actions suggested by the COM in their strategy on pharmaceuticals in the environment should be reflected in the regulatory science strategy.
Among others, a catching-up procedure for human legacy medicines has to be initiated. More than 10 year after adoption of the EMA guideline on environmental risk assessment of human medicines (EMEA/CHMP /SWP/4447/00 corr 2), information on fate and effects is still missing for a large share of existing medicines.
Other relevant aspects from the Strategic Approach to Pharmaceuticals in the Environment may include the support of developing pharmaceuticals that are intrinsically less harmful for the environment and taking into account environmental considerations in the advertising and prescription of medicinal products.
We also suggest to reflect how the environmental risk assessment needs to be adapted for novel therapies. It also has to be discussed how new information from environmental science can be included in the environmental risk assessment. For instance whether more sensitive species could be used and what kind of organisms are appropriate for specific (new) modes of action and the possible inclusion of new endpoints such as behaviour. When developing novel medicines or manufacturing techniques, the environmental impact should be considered at an early stage of development.
We suggest to amend the part for human medicines of the EMA strategic reflection with a chapter “Update Environmental Risk Assessments in link with the latest scientific knowledge” in line with chapter 4.2.1 for veterinary medicines.

According to the Strategic Approach to Pharmaceuticals in the Environment, the emissions of human and veterinary pharmaceuticals from production facilities into the environment need to be better regulated. This is highly relevant to support the One Health Approach to combat AMR. The regulatory system needs to be adapted to address emissions into the environment from existing facilities while also considering potential new environmental impacts from novel manufacturing technologies.
In line with the Strategic Approach to Pharmaceuticals in the Environment we suggest to improve the public access to the main environmental risk assessment results in communication and transparency initiatives for human and veterinary medicines. The ERA results could be published in an EMA data base or in collaboration with ECHA.
Advances in environmental sciences such as non-target analysis will provide better information on occurrence of pharmaceuticals in the environment. Pharmaceutical companies should be encouraged to support the development of appropriate analytical methods and to make them available to the public.

References:
UN Environment (2019): Global Chemical Outlook II. https://wedocs.unep.org/bitstream/handle/20.500.11822/28113/GCOII.pdf?sequence=1&isAllowed=y
EC (2019): Communication From The Commission To The European Parliament, The Council And The European Economic And Social Committee European Union. Strategic Approach to Pharmaceuticals in the Environment. (COM(2019) 128 final) http://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

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

Comments on strategic goal 1 (h & v):

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.

Novel manufacturing methods may reduce the emission of pharmaceuticals into the environment whereas on the other hand new environmental issues may arise. It is suggested to reflect that emissions of pharmaceuticals into the environment from manufacturing need to be regulated.

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

- ○ Yes
- ◉ No

Comments on strategic goal 2 (h & v):

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.

We highly appreciate the suggestion to establish active substance monographs in the chapter for veterinary medicines. The data on fate and effects of active ingredients will provide a good basis for harmonised risk assessments, enhance predictability and reduce regulatory burden.
We also support approaches to better reflect the results of the ERA in the benefit risk assessment, to develop better guidance for aquaculture, to adapt the ERA for novel therapies, and the other aspects mentioned in chapter 4.2.1. For example, if novel effective therapies cause effects on the environment at low concentrations, the action limit for environmental risk assessment may have to be revised.
We do not support the development of a guidance defining when the use of PBT substances is justified, but suggest to support the development of pharmaceuticals intrinsically less harmful for the environment to substitute and finally phase-out PBT substances.

For human medicines, we suggest to add a recommendation on the environmental risk assessment in line with chapter 4.2.1 for veterinary medicines.
Amongst the suggested actions for veterinary medicines, the following bullet points would also be relevant for human medicines:

"- Contribute to the evaluation of novel approaches to ERA and examine the feasibility of establishing active substance monographs

- Cooperate with DG RTD to fund relevant ERA-related research in veterinary medicines, such as antimicrobial resistance in the environment, and endocrine disruptors

- Provide scientific support to the European Commission and the EU network to ensure that a "One Health" approach is applied to ERA, and particularly to antimicrobial resistance

- Increase cooperation in the field of ERA with European agencies, particularly ECHA, and establish cooperation with international institutions, academic organisations and initiatives

- Strengthen capacity and capability to evaluate the environmental fate and effects of novel veterinary therapies, to consider ERA in the risk/ benefit assessment of a product, and to apply ERA to combinations of substances. "

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

Comments on strategic goal 5 (h) / 4 (v):

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.

Research and innovation needs to be complemented by research on potential new risks for the environment from novel medicines, novel manufacturing methods, etc. On the other hand, the development of new medicines or new pharmaceutical forms or routes of administration for existing medicines which are more beneficial for the environment needs to be supported.
In line with the recommendation to “Identify and enable access to the best expertise across Europe and internationally” we suggest to establish a temporary or permanent working party on environmental risk assessment of human medicines and to provide regular training courses. This would implement the action of the Strategic Approach to Pharmaceuticals in the Environment (COM(2019) 128 final) where it says: “in collaboration with the European Medicines Agency and Member States: - Seek to improve the level of environmental expertise in the Committees and networks involved in the environmental risk assessment of medicinal products”.

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
- 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

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
- 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

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.

The strategy lacks any link to the Strategic Approach to Pharmaceuticals in the Environment (COM(2019) 128 final) and any measures to improve the environmental risk assessment of human medicines. For details, see above.
The strategy lacks suggestions to reduce emissions of pharmaceuticals into the environment during manufacturing of medicines.

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'	○	○	○	○	○
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	○	○	○	○	○

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	○	○	○	○	○
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					

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	○	○	○	○	○
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	○	○	○	○	○

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	○	○	○	○	○
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					

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					
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	○	○	○	○	○

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	◉	○	○	○	○
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**:

Comments on recommendation 35 - see comments on goal 2.

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**:

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