

Please note that the Word forms are an aid for respondents who wish to collaborate and agree on the responses before filling out the online questionnaire. They are not to be submitted to EMA as a response to the questionnaire.

All submissions must be made via the online questionnaire.

Fields marked with * are mandatory.

* Name

* Email



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](#).

Question 1: What stakeholder, partner or group do you represent?

- ☐ Individual member of the public*
- ☐ Patient or Consumer Organisation
- ☐ Healthcare professional organization
- ☐ 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

*** Please indicate the capacity in which you are responding:**

between 1 and 3 choices

- ☐ Citizen
- ☐ Patient
- ☒ Carer
- ☐ Animal owner
- ☐ Farmer

**** Please specify:**

between 1 and 1 choices

- ☒ Individual company
- ☐ Trade association
- ☐ SME

Please specify: Press/media/NGO/Not-for profit organisation/other scientific organisations/policy maker, etc.

Not-for profit organisation

Name of organisation (if applicable):

European Society of Clinical Microbiology and Infectious Diseases (ESCMID)

Question 2: Which part of the proposed strategy document are you commenting upon?

- ☒ 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.

Our overall views are positive about the strategy proposed by EMA.

However the document is very general and we would like to see in the future more detailed objectives, recommendations and actions

We still think that innovation should not hamper the use and the education with validated methods. Consequently we recommend moving the axis 1 to the fifth position.

VETERINARY: The strategic goals seem appropriate and are all important. Especially, more (fundamental) research in partnership with academia and a transformation of the regulatory framework are important

recommendations. Innovative medicines or strategies that can replace or reduce the use of (traditional) antimicrobials (including antiparasitics) might need more emphasis.

HUMAN AND VETERINARY: This is good initiative to address the two strategies, human and veterinary, together.

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.

HUMAN: Who could be against this? this is not new, but has been done in the past under different headlines. This should be done seriously, without being impressed by novelties. We need to be aware that the new technologies will increase the cost of Health for most of them. This should not hamper the dissemination of Medicine, Sciences and Health in all the EU countries and inside them.

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.

HUMAN: We may wonder about collaborative evidence vs evidence: what is the difference except for the political aspect of involvement, sharing and translation? Will this render critical peer review and challenge obsolete or impossible?

We will support this strategic goal especially for non clinical models, benefice-risk assessment and innovation in clinical trials.

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

☒ Yes

☐ No

Comments on strategic goal 3 (h):

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.

HUMAN: Positive - isn't this how is being/ should be done in Europe?

Develop network competence and specialist collaborations is a challenge in which ESCMID will definitely help. This is one of the major point and goal we should achieve. If EMA can do this, we will support 100% by improving the knowledge and education in the field.

We need to be careful of not favoring available therapies based on absence of evidence but which could be supported by patients. They should not compete with evidence-based medicine.

In some countries in Europe, more work is going into the administration/documentation of health care than into delivering this. In these countries, counter-intuitive, private medicine/doctor offices are thriving.

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

☒ Yes

☐ No

Comments on strategic goal 4 (h) / 3 (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.

HUMAN: Big issue is not only "emerging" health threats, but consistently repeated health threats in high risk patients with significant individual and overall health care costs (e.g. Epstein Barr lymphoma in paediatric transplant recipients, BK polyomavirus in kidney and allogeneic haematopoietic stem cell transplant recipients). Patients are treated increasingly with monoclonal biologicals and new small molecule therapies in some countries in Europe with increase risks for infectious diseases, even tuberculosis.

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.

HUMAN: Primum nihil nocere. medicine is for good reasons conservative

We encourage the networking with academia for not only fundamental research but also clinical.

Need to be aware of not increasing gap between patient alternative health approaches and evidence-based/regulatory progress

Enabling access of expertise across Europe and even international should be conducted carefully since this can lead to a money driven medicine

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.

There is an urgent need for (fundamental) research on new medicines and to fill knowledge gaps. Partnership with academia is a sensible approach to ensure that regulatory science remains at the cutting edge. Collaboration is necessary to be able to answer complex questions.

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.

The current regulatory framework hampers the development and market authorization of innovative veterinary medicines and alternatives for antimicrobials.

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.

Infection prevention is a key for reducing antimicrobial use. However this recommendation should not be limited to vaccines, but should also include other preventive interventions strategies (e.g. immunomodulation, feed additives, probiotics)

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.

VETERINARY: Regulatory science to support optimization of antimicrobial dosage regimens (evidence based pk/pd) and clinical breakpoints for susceptibility testing appears to be missing and could be integrated to strategic goal 4

among the research topics in strategic areas of regulatory science.

As mentioned above, the development of prevention intervention strategies, other than vaccines, should be promoted and supported as well. There is a need for supporting and preventive innovative therapies that address unmet clinical needs in veterinary medicine. This could be addressed in strategic goal 3.

A better understanding of the contribution of the different ecosystems to another should be promoted. This should be based on scientific evidence and assessment, rather than on emotions or politics. This is most probable integrated in strategic goal 2.

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

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="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Foster innovation in clinical trials	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Develop the regulatory framework for emerging digital clinical data generation	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Expand benefit- risk assessment and communication	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Invest in special populations initiatives	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Optimise capabilities in modelling and simulation and extrapolation	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Exploit digital technology and artificial intelligence in decision-making	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

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:

There si an error on the questionnaire above (one tick box line should not be present). Here our correct evaluations:

- 15: important
- 16: important
- 17: very important
- 18: important
- 19: important
- 20: very important
- 21: important
- 22: important

Strategic goal 4: Addressing emerging health threats and availability/therapeutic challenges (h)

Very important	Important	Moderately important	Less important	Not important
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23. Implement EMA's health threats plan, ring- fence resources and refine preparedness approaches	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Continue to support development of new antimicrobials and their alternatives	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Promote global cooperation to anticipate and address supply challenges	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Support innovative approaches to the development and post- authorisation monitoring of vaccines	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Support the development and implementation of a repurposing framework	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Identify and enable access to the best expertise across	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Reinforce and further embed application of the 3Rs principles	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Facilitate implementation of novel manufacturing models	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

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="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
41. Coordinate Network activities to improve data collection on antimicrobial use in animals	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
42. Engage with stakeholders to minimise the risks of antiparasitic resistance	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
43. Promote and support development of veterinary vaccines	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

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.