Public consultation on EMA Regulatory Science to 2025

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.

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):

> Danish Medicines 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 strategic reflection document sets out very well key areas for EMA to engage in in the future.
>
> In particular, we have noted the coverage of AMR for both the human and veterinary domains. AMR is the single, largest threat to public health and needs diligent and immediate attention from both the human and veterinary perspectives. It is of utmost importance to strengthen the work in this area, including in the regulatory context.
>
> However, in terms of EMA's proposed work on clinical trials (on humans) - both in terms of innovation of clinical trials and of facilitation of clinical trial authorisation - it is important to bear in mind that the authorisation of clinical trials is a national competence. Therefore, any such actions need to be aligned with the NCAs and should not be implemented without involvement of the NCAs.
>
> Furthermore, we have noted that pharmacovigilance is barely mentioned in the human part. Developments with precision medicines, biomarkers and more specialised indications should lead to a greater focus on pharmacovigilance in the future to ensure continuous positive B/R of authorised medicines.
>
> In general, to implement many of the proposed recommendation would be a Network effort where capacity and expertise would reside with the NCAs for EMA to rely upon in the scientific assessment.
>
> While we acknowledge that this proposal for strategy in regulatory science has innovation and new technological developments to underpin innovation as its main focus, EMA's and the Network's strategy should have a broader scope to address jointly also other challenges for the Network.

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)

24. Continue to support development of new antimicrobials and their alternatives

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.

As already mentioned in the overall comments, AMR is the single largest threath to public and therefore it should have the highest priority in both the human and the veterinary area since the two domains are interlinked when it comes to AMR.

Second choice (h)

19. Develop network competence and specialist collaborations to engage with big data

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.

The Network has to be prepared to deal with big data in the regulatory setting and in our regulatory decision-making in the very near future. The preparation has to be a Network effort with collaboration between EMA and the NCAs.

Third choice (h)

13. Optimise capabilities in modelling and simulation and extrapolation

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.

Also here a Network effort is required to implement necessary actions to fulfil this recommendation.

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

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

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.

As already mentioned in the overall comments, AMR is the single largest threath to public and therefore it should have the highest priority in both the human and the veterinary area since the two domains are interlinked when it comes to AMR.

This is in our view the recommendation that targets the AMR and related issues the best for the veterinary area.

Second choice (v)

Please note that veterinary goals start at no.32

39. Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products

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

This is continues to be relevant.

Third choice (v)

Please note that veterinary goals start at no.32

41. Coordinate Network activities to improve data collection on antimicrobial use in animals

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.

> Data on the use of antimicrobials underpins other work to combat AMR and this recommendation is therefore important.
>
> We support that EMA contributes to the implementation of this recommendation though the ultimate responsibility for a number of the underlying actions would seem to be with the European Commission.

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.

> For the human domain, the view of patients and their needs as well as their involvement and empowerment seem not reflected in the outline of the strategy and should be included explicitly.

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:

Recommendation 5: While we are uncerrtain what is envisaged by the recommendation to create an integrated evaluation pathway, we find that the Network assessors should be equipped to deal with the convergence of technologies of medicines and medical devices.

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**:

Recommendation 11: A process for continuous monitoring of benefit-risk after initial approval incorporating RWE should be established, i.e. move away from single time point approval in highly selected population demonstrating efficacy, not effectiveness in target population.

Recommendation 14: The Network should have capacity to review AI based technology and AI generated results from applicants/MAHs. Furthermore, the Network should also apply AI in our own work, i.e. apply AI in our analysis of data to support our decision-making. This links to recommendation 19.

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**:

15

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**:

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