# 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):*

Medicines Evaluation Board

## 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 Medicines Evaluation Board of the Netherlands (MEB)B considers that the strategic plan foresees in significant contributions to innovating and improving regulatory aspects affecting the entire product life-cycle and its sub domains (quality, non-clinical, clinical and pharmacovigilance), societal and stakeholder interaction, and also provides opportunities for operational optimisation of the European regulatory system by making use of emerging technologies (e.g. big data, artificial intelligence, imaging).

For a successful strategy it is proposed to actively develop systematic ties for regulatory science with a common Network strategy between all NCA's and the EMA. Several of the NCA's, including the MEB, have a long-standing experience in conducting regulatory science, and participating in multistakeholder research projects, such as Innovative Medicines Initiative (IMI) projects and Horizon 2020 funded grants. The expertise of different NCA's in the regulatory science field can be leveraged to come to this common Network strategy on regulatory science. Further synergy can be created by learning from these experiences, and using collaborations these NCA's already have. For example, the MEB regulatory science programme started in 2010. The MEB is currently involved in 20 different PhD projects in regulatory science (https://www.regulatoryscience.nl/editions/2019/08/promovendi), and is part of the Regulatory Science Network Netherlands (http://rsnn.nl).

In addition, a structured method of implementing the innovative solutions and knowledge is needed into day to day practice of the NCA's and EMA. Without a clear framework on how this will be achieved within the EU regulatory space, we will not be able to fully take advantage of the work that will be conducted in light of the Regulatory Science strategy. Implementation of work that is conducted may require changes in IT and information processing, need for novel guidance, training of staff, and additional budgeting.

## 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)

> 28. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science

## 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.

> In the MEB's experience, partnerships with academia and public private partnerships, such as IMI projects and in the Regulatory Science Network Netherlands (RSNN), offer a unique opportunity to investigate regulatory challenges from different viewpoints in order to arrive at regulatory recommendations based on scientific fact. The prerequisite for these interactions is that all regulatory discussions take place in the precompetitive space. An all inclusive approach is crucial not only to integrate all available information , but also to allow broad acceptance and (regulatory) implementation of innovative technologies, proposed strategies, policy changes, and in general, the way forward.
>
> For a successful strategy an active contribution from all NCA's and the EMA is needed in developing a common Network strategy on regulatory science. As indicated in the answer to Question 3, multiple NCA's have a long-standing experience in conducting regulatory science and participating in multistakeholder projects, and this expertise can help to successfully shape the Strategy on Regulatory Science to 2025. Further, it is important that strategic areas of regulatory science are chosen where the entire EU regulatory system will benefit from. Moreover, for a successful implementation in the regulatory system a structured method of implementing the innovative solutions and knowledge is needed.

## Second choice (h)

> 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.

Acceptance and adoption of novel regulatory science and its consequences by all stakeholders requires intensive sharing and dissemination of knowledge. To fully realise the vision of the EMA set out in the strategic plan, a comprehensive and dedicated approach to share data across the network is recommended. It is important to note that while the sharing of knowledge is explicit, it is implicit that this knowledge does not exist for its own sake. Rather, it serves to provide a point of departure for all stakeholders to innovate regulation, remove unnecessary hurdles, make our regulatory system robust and efficient and to ultimately provide safe and effective treatments to patients earlier. These tangible results should be made explicit as well.

### Third choice (h)

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

### 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.

The regulatory network is facing several challenges related to e.g. big data, precision medicine, and medical devices, companion diagnostics and borderline products. These challenges are thoroughly depicted in the summary report of the HMA/EMA Big Data Task Force that was published in February 2019 (https://www. ema.europa.eu/en/news/role-big-data-evaluation-supervision-medicines-eu), which included 47 recommendations related to areas such as data quality, data linkage and provision of guidance as to acceptability of evidence. It is important to come to more specific actions based on these recommendations in the coming years and an implementation of these recommendations in the regulatory system. One challenge will be to keep expertise and guidelines up to date in these innovate areas. It is therefore essential to invest in capacity building across the network to acquire new skills to engage with these emerging areas, as well as to engage proactively with new stakeholders relevant to the big data landscape.

### 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

### 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.

Further support for the ongoing activities concerning innovative veterinary medicines in the new regulation is required in order to achieve the final adoption of the proposals. In addition, the development of accompanying guidelines should commence as soon as possible which requires re-activating the work of the working parties and possibly also alterations to their respective work plans.

40-42 are considered to be very important, but are not directly linked to marketing authorisations, but more to the responsible use of antibiotics ant ati-parasitics. Our choices reflect our focus on the authorisation of veterinary medicinal products.

## Second choice (v)

> 37. Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

## 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.

> Due to the hectic situation on social media regarding Bravecto, we would be able to assure the public about the safety of VMPs. This needs systems and operations in place to minimise the administrative burden.

## Third choice (v)

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

## 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.

> Currently, we use the guidelines and protocols as a means of assessing the VMPs, but we would have more flexibility and increase the availability of VMPs when we actively contribute to the regulatory rules regarding the assessment of these products. The item mentioned under 36 (Apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines) would greatly contribute to the content of the regulatory system in 2025.

## 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.*

1.      For a successful strategy it is proposed to actively develop systematic ties for regulatory science with a common Network strategy between all NCA's and the EMA. Several of the NCA's, including the MEB, have a long-standing experience in conducting regulatory science, and participating in multistakeholder research projects, such as Innovative Medicines Initiative (IMI) projects and Horizon 2020 funded grants. The expertise of different NCA's in the regulatory science field can be leveraged to come to this common Network strategy on regulatory science. Further synergy can be created by learning from these experiences, and using collaborations these NCA's already have.

2.      In addition, a structured method of implementing the innovative solutions and knowledge is needed into day to day practice of the NCA's and EMA. Without a clear framework on how this will be achieved within the EU regulatory space, we will not be able to fully take advantage of the work that will be conducted in light of the Regulatory Science strategy. Implementation of work that is conducted may require changes in IT and information processing, need for novel guidance, training of staff, and additional budgeting.

3.      We would like to stress the importance of implementing a mechanism within the strategic reflection that enables continued interactions between NCA's and the EMA with all stakeholders throughout the entire process. While we underwrite the need for a high level document describing the strategy for the way forward, this can only be reached by a detailed description on how this should be reached. This should start at the onset of further developing the EMA strategic document and include the formulation of research questions, the research, analysis and dissemination of the knowledge.

4.      The EMA definition of regulatory science is focussed on informing regulatory decision making throughout the lifecycle of a medicine and contributes to the development of regulatory standards and tools. This is closely aligned to the definition used by the FDA. However, this definition is limited in scope since it explicitly excludes research of the regulatory system itself. We therefore propose that regulatory science is the science of developing and validating new standards and tools to evaluate and assess the benefit/risk of medicinal products, facilitating sound and transparent regulatory decision making, and also advancing knowledge of regulatory systems in general, via analysis of the frameworks used and of their effectiveness; Does the system deliver what society expects? By including this crucial aspect of regulatory science, deliverables of strategic goals can be further shaped.

No further comments for veterinary.

**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**:

## 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**:

<div style="border:1px solid #888; height:800px"></div>

19

## 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