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Public consultation on EMA Regulatory Science to 2025

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* Name

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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):

Parenteral Drug Association

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

- (•) Human
- ( ) Veterinary
- ( ) Both

Question 3 (human): 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.

In general, the Parenteral Drug Association (PDA) supports the strategy. The strategy's focus on updating and modernizing regulatory approaches to support innovative products and manufacturing techniques, and technology is particularly important.

Question 4 (human): Do you consider the strategic goals appropriate?

Strategic goal 1: Catalysing the integration of science and technology in medicines development (h)

- (•) Yes
- ( ) No

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

- (•) Yes
- ( ) No

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

- (•) Yes
- ( ) No

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

- (•) Yes
- ( ) No

Strategic goal 5: Enabling and leveraging research and innovation in regulatory science (h)

- (●) 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)

4. Facilitate the implementation of novel manufacturing technologies

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.

Novel manufacturing technologies can improve the production of many different products and may help address the lack of supply of certain drugs. EMA's support for these new technologies is very important.

PDA suggests that EMA consider including the following as additional Underlying Actions, all of which would assist in effecting these changes:

- Strengthen the transparency and communication of EMA's criteria for acceptance of innovative manufacturing process technologies.
- Incorporate the benefits of innovative manufacturing process technologies in the assessment and consideration of related risk-based alternative approaches.
- Encourage and embrace alternative/non-traditional risk-based approaches to manufacturing process control.
- Partner with industry to consider ways to remove or reduce barriers to manufacturing innovation, in both the pre-approval and post-approval environment, without negatively impacting quality.

In particular, the use of continuous manufacturing could accelerate the time-to-market of new products and reduce costs and waste. A small but important step would be to have a strong stance regarding the regulatory models for this type of manufacturing, especially regarding Qualification and OPV, and the use of online monitoring technology. In addition, EMA should consider incentives for companies to modernize their processes through a well-defined but simple regulatory vision.

Second choice (h)

14. Exploit digital technology and artificial intelligence in decision-making

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)

25. Promote global cooperation to anticipate and address supply challenges

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.

Just as the supply chain is global, supply challenges are global. The quality and safety of the supply chain affects patients globally. Global cooperation, particularly in regulatory approaches, as well as collaboration between regulators, industry, and non-governmental organizations, can help us find workable, mutually acceptable solutions in the most efficient manner possible.

PDA encourages EMA to continue to consider important issues relating to harmonization and the consistency of language and interpretation. Implementation of regulatory science initiatives depends on clear understanding by both the health authority and industry, as well as the ability to implement consistently in a global marketplace. To that end, we suggest the following additional priorities that will aid in ensuring a consistent global supply of high-quality products:

- Partner with industry on effective training to ensure consistent interpretation and enforcement of regulatory expectations among inspectors.
- Harmonize language and approach with other major health authorities and within the EMA.

PDA further encourages EMA to explore opportunities for harmonizing global standards relating to the traceability of medicines, in order to to avoid unintended consequences on the supply chain of legitimate medicines while also preventing falsified, substandard, and adulterated products from entering the supply chain.

Question 6 (human): Are there any significant elements missing in this strategy. Please elaborate which ones (h)

PDA suggests that EMA also consider prioritizing the following under Goal 1, “Catalysing the integration of science and technology in medicines development”:

- Plan for the impact of innovation and technologies (including those associated with manufacturing processes) not currently known, including the agency’s approach to and assistance with such new developments. While the Strategic Reflection discusses the developing technologies that are known, unanticipated new technologies and innovations also are likely to arise. EMA’s regulatory strategy should consider its response to these developments.
- Promote partnership with medical product manufacturers and technology suppliers to develop and use innovative technology.
- Focus on process sustainability and product availability, as well as product safety and efficacy. In light of the public health, the impact of regulatory factors (including harmonization, time of review, and support for new technologies) on product availability should be considered alongside other factors when incorporating new scientific and technical knowledge and considering changes to GMP requirements and standards.

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:

3. When considering accelerated pathways, including PRIME, PDA suggests that EMA prioritize defining the chemistry, manufacturing, and controls (CMC) requirements for products going through these pathways, and align these definitions with other global regulators. Often, CMC requirements can be the “bottleneck” to approving the products in an accelerated manner. With other global regulators also applying accelerated pathways to pharmaceuticals that serve unmet medical needs, manufacturers and patients alike would benefit if key regulatory agencies were to clearly define the requirements and understand any non-alignment between the approaches in different jurisdictions.

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**:

PDA is not providing input regarding recommendations 8, 9, 10, and 12, because these are outside of our organization's scope.

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**:

PDA is not providing input regarding recommendations 16 and 20 because these are outside of our organization's scope. (Please disregard the answer we have inadvertently provided to #20, as we cannot seem to delete it.)

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**:

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