Contribution ID: 5a9c8c33-1f52-40ac-aad4-2523c4c58460
Date: 28/06/2019 09:58:25

Public consultation on EMA Regulatory Science to 2025

Fields marked with * are mandatory.

* Name

* Email

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction

The purpose of this public consultation is to seek views from EMA's stakeholders, partners and the general public on EMA's proposed strategy on Regulatory Science to 2025 and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, you have the opportunity to jointly shape a vision for regulatory science that will in turn feed into the wider EU network strategy in the period 2020-25.

The views being sought on the proposed strategy refer both to the extent and nature of the broader strategic goals and core recommendations. We also seek your views on whether the specific underlying actions proposed are the most appropriate to achieve these goals.

The questionnaire will remain open until June 30, 2019. In case of any queries, please contact: RegulatoryScience2025@ema.europa.eu.

Completing the questionnaire

This questionnaire should be completed once you have read the draft strategy document. The survey is divided into two areas: proposals for human regulatory science and proposals for veterinary regulatory science. You are invited to complete the section which is most relevant to your area of interest or both areas as you prefer.

We thank you for taking the time to provide your input; your responses will help to shape and prioritise our future actions in the field of regulatory science.

Data Protection

By participating in this survey, your submission will be assessed by EMA. EMA collects and stores your personal data for the purpose of this survey and, in the interest of transparency, your submission will be made publicly available.
For more information about the processing of personal data by EMA, please read the privacy statement.

Questionnaire

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

- ○ Individual member of the public
- ○ Patient or Consumer Organisation
- ○ Healthcare professional organisation
- ○ Learned society
- ○ Farming and animal owner organisation
- ○ Academic researcher
- ○ Healthcare professional
- ○ Veterinarian
- ○ European research infrastructure
- ○ Research funder
- ○ Other scientific organisation
- ○ EU Regulatory partner / EU Institution
- ○ Health technology assessment body
- ○ Payer
- ◉ Pharmaceutical industry
- ○ Non-EU regulator / Non-EU regulatory body
- ○ Other

* ***Please specify:***

between 1 and 1 choices

- [ ] Individual company
- [x] Trade association
- [ ] SME

Name of organisation (if applicable):

European Biopharmaceutical Enterprises (EBE)

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.

EMA's Regulatory Science strategy to 2025 is highly welcomed by European Biopharmaceutical Enterprises. We appreciate the opportunity to help EMA in shaping its regulatory science strategy.

Application of novel science and technologies is leading to innovative medicines that are often complex, such as advanced therapy medicinal products and personalised medicines, and to innovation in manufacturing. To foster these innovations, collaboration between EMA, HMA, policy makers, industry and academia is essential to ensure that regulatory policy and guidelines reflect the latest science and are relevant for the assessment of new medicines utilising these new technologies.

EMA Strategic reflection document is important, building on current ways of developing human medicines (e. g. biomarkers and 'OMICs') and looking forwards to nascent technologies (e.g. digital technology and artificial intelligence, nanotechnology). It also refers to novel methods for medicines discovery and development, for manufacturing and evidence generation (e.g. modelling, simulation and extrapolation approaches; use of high-quality real word data (RWD) in decision making).

All five strategic goals mapped out in the EMA's Regulatory Science Strategy to 2025 address important priorities to advance medicines and therapeutic care in Europe. In many cases, the recommendations set out are interrelated and interdependent: in practice, pursuing one recommendation may imply the need to progress others.

Although the top three priorities for EMA's Regulatory Science strategy had to be chosen, EBE would like to stress that these highlighted priorities are equally important for the direction and future skills required by the EU national competent authorities and the Head of Medicines Agency (HMA) through the multi-annual work plan.

In determining the final Regulatory Science Strategy, EMA will need to balance the requirements to deliver near-term progress improvements and the long-term direction. Some recommendations require urgent action (e.g. creation of an integrated evaluation pathway for the assessment of medical devices, in-vitro diagnostics and borderline products), while others are more for long-term (e.g. use of high-quality real word data (RWD) in decision making).

Following EMA's request to select the recommendations considered as the greatest priorities to respond to the needs of the 21st century patient, EBE's three choices are: "Support developments in precision medicines, biomarkers and 'omics'"; "Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products" and "Support translation of Advanced Therapy Medicinal Products cell, gene and tissue-based product into patient treatments".

To address these top priorities, there are also needs to progress other essential inter-related recommendations such as: "Diversify and integrate the provision of regulatory advice along the development continuum (Recommendation 7)", "Foster innovation in clinical trials (Recommendation 9)", "Facilitate the implementation of novel manufacturing technologies (Recommendation 4)", "Promote use of high-quality real-world data in decision making (Recommendation 18)", "Optimising capabilities in modelling, simulation and extrapolation (Recommendation 13)".

To truly reach patients, medicines need to undergo successful Health Technology Assessments and pricing and reimbursement negotiations. To this end, the importance of addressing better coordination in the provision of scientific advice and assessments between regulatory authorities and HTA bodies is recognised.

Finally, it would be useful to identify areas where EMA needs to collaborate with additional stakeholders (National competent authorities, HMA, non-EU regulatory agencies) as some of the items identified are ambitious topics where European and/or internationally harmonised approaches would be important (e.g. use of real-world data).

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)

1. Support developments in precision medicine, biomarkers and 'omics'

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.

EBE has chosen "Support developments in precision medicine, biomarkers and omics" as first choice for the following reasons:

- Due to fast advancements of science in this space, there is an urgent current need for regulatory /procedural support to get products such as "precision medicine, biomarkers and omics" to the patients
- These products guiding treatment selection are already around and this allows very concrete actions to be defined and implemented
- These products are usually intended for serious life-threatening diseases (e.g. oncology)
- These products are likely to become part of routine diagnostic testing in the near future
- Adaptations to the regulatory pathway to fit the challenging areas described below may be a template for future (as yet unknown) developments (see also Recommendation 5).

With respect to the underlying actions, EBE feels that the actions as currently proposed in the EMA consultation document are quite high level. Therefore, to illustrate the gaps and identify additional and more concrete actions needed to fill the current and future gaps in the regulatory system, EBE used the concrete example of comprehensive genomic profiling for diagnostic purposes (further referred to as Next Generation Sequencing products). EBE would like to suggest these practical solutions as additional actions for consideration by EMA.

Due to the size limit for this question, the currently experienced challenges in the EU regulatory system, with EBE's proposed recommendations could not be submitted through the online survey.
Therefore, upon EMA's advices, EBE sent also by email to RegulatoryScience 2025@ema.europa.eu, the EBE's full response to the public consultation on EMA Regulatory Science to 2025.

Second choice (h)

5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products

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.

EBE has selected "Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products" as second priority choice as this recommendation will be a key enabler for the development of both drug-device combination products and personalised medicines with their associated companion diagnostics (CDx).

With respect to drug-device combination products (e.g. pre-filled pens, pre-filled syringes, inhalers), they are growing in importance across the wider pharmaceutical industry. This trend will further increase with the

utilisation of emerging technologies associated with large volume devices for high viscosity biological products and electromechanical devices.
The new Medical Devices regulation (MDR, Regulation (EU) 2017/745, entering into force on 26 May 2020) introduces an important amendment to the medicines legislation, in Article 117. As part of the marketing authorisation application (MAA) for a medicinal product regarded as an integral drug-device combination product, this article requires the Marketing Authorisation Holder to provide a Notified Body's (NB) opinion for the device constituent. However, it is unclear how information for that assessment will be positioned against the medicinal product MAA dossier review by the Medicines Competent Authorities (CA). Moreover, the focus of the NB's opinion compared to the Medicines Competent Authorities' focus in relation to drug-device combination product is not defined. Furthermore, there is currently no understanding of how the process to support this new requirement would work or what is the proposed timing of such assessment relative to the MAA itself.

EBE raised awareness on Industry concerns in this area and published two reflection papers on the identified issues, that were shared with the EMA and other concerned stakeholders:

- EBE Reflection paper: "Medicinal product incorporating a drug delivery device component: An Industry perspective on the EU marketing application technical requirements, regulatory review process and post-approval device related change assessment", 15 January 2018.
- EBE-EFPIA Reflection paper: " An Industry Perspective on Article 117 of the EU Medical Devices Regulation
  and the impact on how Medicines are assessed", 12 July 2018.

At the end of 2018, EBE/EFPIA/Vaccines Europe conducted a survey with their members on the anticipated number of submissions for new MAAs of drug-device combinations, for the period 2020 to 2022. The survey results were shared with EMA in January 2019 and indicated that approximately 15 new MAAs involving drug-device combination products would be submitted under the centralised procedure, on an annual basis. The survey results demonstrated the urgent need for an integrated evaluation pathway for the evaluation of drug-device combination products.

Regarding personalised medicines and their associated companion diagnostics, the challenges experienced with more conventional diagnostics are also encountered with diagnostics based on genomic profiling and aggravate the challenges severity as highlighted under EBE first priority choice. As there is an overlap between the two topics, positive developments under recommendation 5 are expected to have a favourable impact on recommendation 1. Furthermore, the already implemented EU regulations on medical devices and in vitro diagnostics increase the urgency of further clarification of responsibilities and interactions.

EBE has highlighted challenges that are experienced by the pharmaceutical industry as well as concrete recommendations for consideration by the EMA.

Due to the size limit for this question, the currently experienced challenges in the EU regulatory system, with EBE's proposed recommendations could not be submitted through the online survey.
Therefore, upon EMA's advices, EBE sent also by email to RegulatoryScience 2025@ema.europa.eu, the EBE's full response to the public consultation on EMA Regulatory Science to 2025.

Third choice (h)

2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments

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.

ATMPs are highly innovative and complex products with rapid evolving science and technologies, driven by a strong, complex and fragmented legislative framework. It results in the need for specific expertise and platform to share knowledge, allowing the development of a fruitful ecosystem, with long term actions that facilitate timely patient access to innovation.

ATMPs have great potential to address unmet medical needs and techniques such as genome editing hold the promise to treat and potentially cure a broad range of diseases, that are not adequately addressed by currently available therapies. Despite considerable development activity in this dynamic field, only a limited number of ATMPs (13 MAAs currently) have received Marketing Authorisation in the European Union and a few less has already reached to patients.

Main obstacles are the disconnection from EU (e.g. centralised procedure) to national legislative framework (e.g. GMO assessment). A more integrated system with cross-fertilisation between science/clinical advances to regulatory and access is essential to support an efficient translation of these innovative products into patient treatments.

The rapid pace of the scientific knowledge and process of innovation would merit an efficient continuum of dialogue with stakeholders to allow a more effective way to develop products. This continuous dialogue would allow a more iterative discussion on innovation in clinical trials. This would also better link-up decision-making across the life cycle of a medicine, requiring a more flexible and linked-up approach in the delivery of scientific advice.
ATMPs would also benefit from innovation in clinical trials, RWE integration, new evidence, novel manufacturing technologies, novel non-clinical models …

Therefore, the following proposed interrelated recommendations are key enablers for supporting the translation of ATMPs into patient treatments:

• Promote and invest in PRIME, as an efficient path to ensure early continuous dialogue toward patient access
  PRIME eligibility for non-SMEs is challenging as an exploratory clinical evidence is needed from phase 1. It would be helpful to review the accessibility criteria for non-SMEs.
  PRIME support by the EMA could be critical towards a full understanding when an ATMP under development
  can really translate from an animal model towards real efficacy and safety in Phase I/II studies. The assistance from EMA on early planning, method development and recommendations for clinical development programme appears very important for those translating ATMPs to clinical use. The EMA can help ATMP developers, via PRIME scheme as well as discussing evidence generation through joint EUNet HTA/EMA scientific advice.

• Diversify and integrate the provision of regulatory advice along the development continuum
• Facilitate the implementation of novel manufacturing technologies
  The standardisation of analytical procedures would be helpful in optimising methods used to confirm comparability of ATMP batches.

• Leverage novel non-clinical models
  Non-clinical models are often designed for safety aspects. With regard to ATMPs, there is a need to have more designed animal, in-vitro and, in-vivo models for efficacy, in order to better support the translation

towards “First-in-Human” studies. Non-clinical data might also not predict pre-existing immunogenicity.

- Foster innovation in clinical trials
  For some ATMPs, full demonstration of efficacy prior to marketing authorisation will not be feasible. Therefore, regulatory acceptance of initial approval based on alternative approaches, such as the use of surrogate endpoints combined with post-authorisation real word data generation is essential. Acceptance of such approaches is key to facilitate access to these innovative products. In addition, as ATMPs development is conducted globally, cooperation between major regulatory agencies (e.g. EMA, FDA and PMDA) is also needed to guaranteed global acceptance of these approaches.

- Optimise capabilities in modelling and simulation and extrapolation
- Reinforce patient relevance in evidence generation

- Promote use of high-quality real word data (RWD) in decision making
  Promoting one source of data through well-designed registries and/or follow-up studies to collect high-quality RWD in decision making would be of key added value to generate further evidence for ATMPs.

- Contribute to HTA’s preparedness and downstream decision-making for innovative medicines

EBE suggested concrete additional proposed actions for consideration by the EMA.
Due to the size limit for this question, EBE's proposed recommendations could not be submitted through the online survey.
Therefore, upon EMA's advices, EBE sent also by email to RegulatoryScience 2025@ema.europa.eu, the EBE's full response to the public consultation on EMA Regulatory Science to 2025.

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

As previously highlighted, in many cases, the recommendations set out are interrelated and interdependent: in practice, pursuing one recommendation may imply the need to progress others.
Therefore, EBE think that the strategy would benefit from a more integrated, holistic approach.
For instance, this was illustrated by the example of comprehensive genomic profiling used for diagnostic purposes. As can be seen from EBE's recommendations, some crucial actions to facilitate the development of personalised medicines are in the category of medical devices and diagnostics. These interactions can only be optimised when looking at the processes, in a holistic way.
The same general comment applies for the translation of ATMPs into patient treatments (EBE third priority choice).

Additional missing elements in this strategy have been highlighted throughout question 5.
Please refer to EBE's response sent by e-mail to RegulatoryScience2025@ema.europa.eu, for proposed suggestions for additional actions proposed for consideration by EMA.

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:

Overall the recommendations in this strategic goal are regarded as very important by EBE members to support advances in science and technology for medicines development. EBE's top priorities are all under strategic goal 1.

Indeed, new technologies play a critical role in the development and manufacturing of innovative medicines. Therefore EBE welcomes this strategic goal which aims at translating advances in science and technology in new prevention and treatments for human diseases.

The following comments are provided on recommendations not selected as top priorities and regarded as enablers to support the top priorities.

• Recommendation 3 "PRIME" - EBE would like to encourage EMA to further invest in the PRIME scheme that has proved to be of real benefit for companies involved in early drug development, to optimise developed plans and expedited evaluation. As discussed during the "Prime" workshop organised by EMA in 2017, further improvement would be welcome.

• Recommendation 4 "Novel manufacturing technologies"
Introduction of novel manufacturing technologies is a key enabler for effective and sustainable supply of pharmaceutical products, requiring relentless consideration to ensure up-to-date approaches for development and lifecycle management. In particular, novel manufacturing technologies can contribute to reduce development costs and timing, upon increased efficiency, and innovative control strategies, ensuring fast access to patients without compromising product quality, safety and efficacy. Moreover, improved process understanding and simplification granted by innovative and reliable manufacturing/ control strategies can provide rationales for definition of new, phase-appropriate expectations on GMP and process performance qualification, for instance when working with technologies such as continuous manufacturing. In this context, it is crucial to understand the regulatory implications of such novel approaches. To this aim, structured communication with Health Authorities is an indispensable step, in order to clarify gaps in regulatory framework (including GMP expectations) and define strategies and actions to address them.

• Recommendation 7 "Diversify and integrate the provision of regulatory advice along the development continuum" is regarded as very important.
Indeed, the fast pace of development and science impacts innovative medicines, increasing the need for more interactive scientific discussions with regulators and other stakeholders, early on through the drug development. The procedures currently in place (National Innovation Task Force, National Scientific Advice meetings, EMA Scientific Advices…) are long and with disparate assessments. A holistic approach of innovative and flexible dialogue would facilitate development of new medicines. Learning from PRIME may help the vision of an integrated system of advice, along the development continuum. It would also be beneficial to further engage with other stakeholders (HTA bodies, patients, HCPs) in the provision of regulatory advice. Finally, it is proposed to redesign a more flexible and integrated R&D product support mechanism, providing rolling advice across the life cycle of the medicines, including an opportunity for iterative CMC data submission during review of dossiers by relevant bodies.

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**:

This strategic goal is appropriate in order to address an area of fast change and importance for medicines development (new evidence sources and standards, new clinical trial approaches).

Recommendations 8, 11 and 12 are ongoing priorities for the EMA and EBE expects that progress on these topics will be maintained.

Additional comments are provided for:

• Recommendation 9 " Foster innovation in clinical trials" is regarded as very important.
Clinical trials constitute the foundation of drug development. Innovative products, in particular those with long term effects need new type of clinical trial design (e.g. adaptive design) and possibly new end-points to
demonstrate effects. Those new designs should be accepted by all stakeholders including HTA bodies, medical community, patients and regulators. Related recommendations for fostering innovation in clinical trials are: "Develop the regulatory framework for emerging clinical data generation (recommendation 10)" and "Reinforce patient relevance in evidence generation (recommendation 17).

• Recommendation 13 "Optimise capabilities in modelling and simulation and extrapolation"
Increasing acceptance of predictive approaches, based on modelling, simulation and extrapolation will bring
advances in the quality, non-clinical and clinical fields. For example, in the CMC area, process modelling of the manufacturing process could be used to support development and scale-up, and to set up the control strategy.

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**:

This strategic goal aims to advance patient-centred access to medicines which is something that EBE strongly supports.

To truly reach the patients, medicines need to undergo successful Health Technology Assessments and pricing and reimbursement negotiations. To this end, EBE recognises the clear value of stakeholder engagement and better coordination and alignment between regulatory authorities and HTA bodies.

Please find below additional comments:

• Recommendation 15 " Contribute to HTAs' preparedness and downstream decision-making for innovative medicines"
New evidence types, new endpoints and specifically innovative and complex products (such as ATMPs) highlight the need of readiness of the downstream decision-making stakeholders to reduce gaps between evaluation of medicines by regulatory authorities and other stakeholders. EMA has undertaken significant efforts to bridge these gaps between decision makers, and there have been some gains achieved. To really deliver a step-change in consistent, aligned decision-making for the benefit of patients will require significant
collaborative work, recognising that regulatory, HTA and reimbursement processes are different stages of assessment.

• Recommendation 16 " Bridge from evaluation to access through collaboration with payers"
Payers are a fundamental decision-maker with regard to access to medicines. There are benefits to engage with payers earlier to gain insight into their perspectives on unmet needs and priorities. Early engagement also helps to prepare payers for potential major impacts from breakthrough innovation. However, it is thought that regulatory processes and pricing determinations should maintain their distinctiveness and that regulators should keep their scientific focus. It is considered that initiatives to address procurement decision-
making should be undertaken by other agencies at the European Commission and national levels.

• Recommendation 18 "Promote use of high-quality real-world data (RWD) in decision-making"
High-quality of RWD is key for innovative clinical development, and specifically for ATMPs to complete the evidence. In order to be efficiently used, there is a need of appropriate biostatistical methodologies and generation of high quality RWD. Reaching a global harmonised system as well as a common core data model would leverage full capacity of RWD, avoiding limitations due to national fragmentations in the pre- and post-marketing setting.
Promoting the use of high-quality RWD suggests a key role for EMA to experiment in Europe. Experiments and piloted approaches are ongoing in other regions and EMAs should remain engaged with the frontier of this research and practice internationally.

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**:

EBE thinks that addressing emerging health threats and the availability/therapeutic challenges is a core responsibility of a regulatory authority. As such, this must remain a key component of Agency strategy.
The recommendations capture a number of areas that are recognised as societal priorities for current health needs: antimicrobial resistance, supply challenges, development of vaccines.

The relatively lower priority given to recommendations in this section reflects the view that these are not strategic goals to establish but ongoing priorities that the Agency must maintain.

Greater priority is given to:

- Recommendation 24 "Continue to support development of new antibacterial agents and their alternatives"
  To address Antimicrobial Resistance (AMR), Industry has advocated for collective actions.
  The underlying actions proposed by EMA in the strategy document are welcome. Although not within the remit of EMA, the critical importance of new business models is recognised. The proposal to work with HTAs and payers to define and explain the relevance of evidence requirements for new antibacterial medicines is much needed.

- Recommendation 25 "Promote global cooperation to anticipate and address supply challenges"
  The issues related to supply challenges are getting more and more attention. It is important to address the reasons for unavailability at global level, as they are related to supply chain complexities.

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**:

Overall, this goal is considered to be one enabler of numerous recommendations under the previous strategic goals. Therefore, although the goal and the recommendations as described in the consultation document seem to focus narrowly on the engagement between regulatory authorities and academics, industry also recognises the value of this goal.

Recommendations 28 and 29: Industry welcomes to be associated with academic network and collaboration. With respect to ATMPs, most of the initial research occurred within academia. It appears important to develop networks and leverage collaborations. A lot of non-clinical disease models have also been developed within academia. Although the role of academics is recognised, both academic and industrial researchers should be reflected in the strategy, to truly enabling and leveraging research and innovation in regulatory science.

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