Contribution ID: f1999105-b008-4b1b-8c41-8d5903ca2427
Date: 28/06/2019 16:09:21

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

* ***Please specify:***

between 1 and 1 choices

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

Name of organisation (if applicable):

Biogen

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.

We welcome the approach taken by the EMA in developing the Regulatory Science Strategy to 2025 (RSS2025). This process of discussion and engagement by the EMA has resulted in a potential strategy for regulatory science that understandably covers a broad remit, with many overlapping topics which may be dependent on one another to advance but which reflect a positive direction for regulatory science in the EU, and progress in any of these areas would benefit the overall regulatory framework and patients. The core recommendations which support the strategic goals through more defined deliverables provide more details about how the work may move forward, but tend to focus more on the nearer term e.g. the next 2-3 years; planning for specific activities beyond this time is challenging and may require reevaluation of the strategy at regular intervals.

Whilst more detailed comments on the core recommendations and underlying actions are included within the body of this response, we would note the following overall views on the proposed strategy for RSS2025.

• There is inherent complexity within the EU medicines regulatory system, which increases further when issues around patient access, reimbursement and evidence generation are also considered. These elements are reflected in RSS2025, particularly under strategic goal 3 'advancing patient-centered access to medicines in partnership with healthcare systems' and progress in this area requires timely co-ordination and engagement of different stakeholders. The EMA has previously taken an active role in this regard through initial efforts to engage other stakeholders (e.g. HTA bodies via parallel scientific/HTA advice; planning for post-license evidence generation) prior to granting a marketing authorisation. Furthermore, activities such as the EMA's registry initiative, which included the disease-area workshops, was another example where the EMA led the way in co-ordinating engagement of registry owners, academics, patients and industry. In order to progress several of the core recommendations in RSS2025 there needs to be strong leadership and co-ordination of input from a wide variety of different stakeholders. As the 'gatekeeper' for assessing new medicines, the EMA plays a key role in connecting many of these different parties and we would like to see the EMA further strengthen its activities in this area.

• Several of the core recommendations could apply broadly across the medicine lifecycle and we welcome this perspective on medicine development as a continuum that extends beyond the initial marketing authorisation. However, in general, the overall strategy appears balanced towards the earlier stages of the medicine development lifecycle, focussing on the review and assessment of new products and initial access

by patients, with less emphasis on advancing the regulatory strategy specifically in the post-licensing setting. The management of products in the post-marketing setting is a significant undertaking for both industry and regulators and ensuring patients and healthcare professionals are informed of fully contextualised, accumulating information about a product can be challenging. Whilst the development of electronic product information could help with this and is supported, a broader consideration of this aspect could be helpful. More generally, the emergence of new technologies and treatment modalities over the next few years (which are readily acknowledged within the RSS2025) may require movement towards a more efficient management of medicinal product lifecycle changes in the future.

• The rapid advancement of technology and innovation and the challenge that regulatory science faces to keep pace is a recurrent theme. The potential for greater flexibility within the system e.g. through the provision of scientific advice along the development continuum and embracing novel manufacturing technologies are fully supported. Additionally, the engagement of the EMA with academia and network scientists to undertake research or address questions about areas of emerging regulatory science will be crucial for the future. Furthermore, the ways in which learnings from these engagements are processed and disseminated to the wider community will also be important. The overall approach to developing and sharing regulatory and scientific guidance in a way that ensures it reflects current expertise and thinking is something that may need to be discussed further in the future. Making use of advances in technology may help facilitate this.

• Finally, whilst the RSS2025 sets out a plan for the next few years, it is clear that it is not possible to plan for every eventuality that may occur. Therefore, the proposal to address emerging health threats is supported. In addition, the potential for regular re-evaluation of the strategy, perhaps in combination with a thorough horizon scanning exercise at regular intervals could be a valuable exercise.

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)

7. Diversify and integrate the provision of regulatory advice along the development continuum

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.

Topic 3.1.7: Diversify and integrate the provision of regulatory advice along the development continuum

The core recommendation for a more frequent, flexible and integrated scientific advice framework to support medicine development across the lifecycle of a product from early/pre-licensing through to marketing authorisation and post-approval has several potential benefits in our view:

- Implementing a flexible advice framework could allow the opportunity for less-formal feedback from regulators on specific questions during the development of a product. Such an approach could help to streamline interactions and potentially alleviate some of the pressure on demand for formal scientific advice procedures. Additionally, integrating advice along the development continuum may provide opportunities for engagement with other scientific committees e.g. the Paediatric Committee at appropriate timepoints in the development pathway, thereby allowing a more holistic view of the entire development plan.

- The potential for early engagement of multiple different stakeholders within the regulatory advice procedure, with further touchpoints during the development pathway is supported.

- Integrating advice across the EU network would help drive consistency across the EMA and National Competent Authorities (NCAs). This is particularly important in the context of new therapeutic modalities or when medicinal products are following innovative or complex development plans. Without more integration across the EU network, the disconnected nature of scientific advice between the NCAs and the EMA increases the likelihood of differences in views and interpretation which may in turn lead reduced efficiency e. g. a company may be following EMA scientific advice but then face different questions from an NCA when submitting clinical trial applications (CTA).

- A more flexible, product-centric perspective will be beneficial to all medicines but especially for those undergoing accelerated assessment. The need for such an approach is well illustrated in the example of the lifecycle management of a product approved via an accelerated pathway. In this case, if modifications to a post-approval change management protocol (PACMP) were being considered then the opportunity for scientific advice to be provided by parties familiar with the product and aware of the original risk/benefit considerations is of particular importance, especially in time-sensitive areas where change may be driven by events rather than by careful planning.

- Finally, it is assumed that advances in this area have the potential to support innovative products irrespective of modality or therapeutic area and will not be restricted to a specific regulatory pathway (e.g. for products already eligible for PRIME). Whilst some of the changes needed to drive product-specific integrated advice could be generally applied, it is also expected that some aspects, such as early engagement, may be resource-intensive and the availability of other stakeholders to participate may be limited. It will therefore be important to understand if there will be any restriction on which products are considered eligible for integrated scientific advice or if it will be available broadly. We would support a broad applicability for innovative products for integrated advice as far as possible.

Actions:

- Investigate possible IT solutions to facilitate the sharing of scientific advice documentation (briefing materials, meeting outcomes, minutes) easily across the EU regulatory network and with individual companies e.g. via a dedicated, confidential portal. This could be product-specific and would be added to during the lifecycle of the product.

- Consider how to rapidly share key learnings from this type of scientific advice with industry and other stakeholders in order to refine and improve the process as it moves forwards.

Second choice (h)

10. Develop the regulatory framework for emerging digital clinical data generation

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.

Topic 3.2.3: Develop the regulatory framework for emerging digital clinical data generation

The core recommendation to develop the regulatory framework to accommodate emerging clinical data is fully supported.

- With the rapid advances in technology it is inevitable that there will be increasing use of digital tools and data generated by wearable devices incorporated into clinical studies. The introduction of these tools could lead to many benefits to patients through increasingly sensitive endpoints and convenience of monitoring. However, a clear framework on how to handle and incorporate these types of data into regulatory decision making is needed.

- Action on this in the shorter term could also potentially help with alignment across major regulators on key issues e.g. the proposals in the 2018 FDA draft regulatory framework for drug-related software. Furthermore, with the announcement earlier in 2019 by the Danish Medicines Agency regarding their plans to develop their own data analysis centre of expertise, it will be important to ensure that there is a co-ordinated and consistent approach to the handling of these types of data across the EU regulatory network.

- In developing the regulatory framework for emerging clinical data generation, it will be important to also incorporate the views and perspectives of other stakeholders on the value assigned to digital data generation. In this case, the opportunities for multi-stakeholder engagement during early development (as outlined in topic 3.1.7) would also be very helpful.

- The potential use of digital clinical data in regulatory decision making extends beyond the initial marketing authorisation into post-marketing and is also reflected in core recommendation 3.3.4. Examples of learning healthcare systems that are able to create standardised, high quality data repositories should also be considered in the context of the developing regulatory framework.

Third choice (h)

11. Expand benefit-risk assessment and communication

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.

Topic 3.2.4 Expand benefit-risk assessment and communication

The core recommendation to expand the benefit-risk assessment and communication is fully supported.

- Timely patient access to new medicines is a very important area and we welcome the proposals made in several areas within the RSS2025 (including core recommendations 3.3.1 and 3.3.2) to address this. However, the potential to revise the benefit risk assessment to incorporate patient preferences and promote the systematic application of structured benefit-risk methodology across the network seems to be a realistic priority that, along with improved communication with HTAs and payers, may have the potential to help reduce the time between regulatory approval and patient access decisions.

- The various models that have been used to-date for quantitative benefit risk analysis include the Markov model, the BRAT framework and a modified version of the BRAT framework. It is possible that these currently available models may not apply universally across all disease areas. In particular, the applicability to quantitative benefit risk for products in rare disease areas, emerging indications or advanced therapy medicinal products (ATMPs) may require further consideration. Furthermore, consideration of these tools in chronic versus acute conditions may also require further detailed work.

Actions:
- In terms of actions, engagement across multiple stakeholders will be important to drive this forward. An initial workshop to develop a pilot program in this area might also be helpful.

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

The strategy is broad and comprehensive and covers the majority of topics. However, the following elements are missing:

- The strategic reflection highlights the development and use of some new modalities e.g. ATMPs but very little in regard to oligonucleotide investigational products, their manufacture or quality attributes. Although not classed as an ATMP, the oligonucleotide modality is likely to be increasingly popular as a means to modify expression of human genes in the future and there may need further consideration of this, and other future emerging therapeutic modalities, that might fall outside of the current regulatory framework.

- Whilst further development of the PRIME scheme is highlighted as a core recommendation and a way to achieve earlier access to patients, there is no mention in the strategic reflection of adaptive licensing. The outcome of the adaptive licensing pilot concluded that the EMA remains open to the concept but that industry should proactively consider pursuing a conditional marketing authorization as a way to fulfill this. However, the same challenges to adaptive licensing remain with a conditional marketing authorization i.e. patient access and reimbursement. There are several core recommendations made in RSS2025 that seek to address patient access, but not specifically in relation to the conditional marketing authorization route.

- Some of the initiatives highlighted in the document would benefit from parallel advances in information technology (IT). Further information on progress with IT systems or the EU telematics strategy and how this may facilitate some of the core recommendations would be helpful.

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:

All the core recommendations made in support of this strategic goal 1 would have a positive impact on the future EU regulatory framework. Additional comments are included on the following core recommendations:

(2) Support translation of advanced therapy medicinal products (ATMPs) into patient treatments
The EMA already provides enhanced regulatory support for the development of ATMPs i.e. through assistance with early planning, method development and clinical evaluation for Small Medium Enterprises (SMEs). Patient access is a key issue for ATMPs and progress is needed to ensure that these modalities that have successfully obtained an EU marketing authorization can be delivered to patients over the long term. The enhanced regulatory support that the EMA provides for ATMP development is welcomed and can be further strengthened through other routes e.g. the PRIME scheme (see below). However, there needs to be greater co-ordination of the views of other stakeholders, particularly HTA-Bs, patients and payers during the development of these new treatments to enable sustained patient access and plan appropriately for realistic and proportionate post-licensing follow-up of treated patients. The acknowledgement in RSS2025 of the need for a more coordinated approach to evidence generation across the EU network and with international partners is welcomed. It is anticipated that the EMA will play a key role in this coordination and will further build on their previous work with other stakeholders in order to meet the needs of patients.

(3) Promote and Invest in the Priority Medicine PRIME Scheme
The PRIME scheme offers many potential benefits to the development of new medicines e.g. the early appointment of the Rapporteur, shortened timelines for scientific advice, and the potential for accelerated assessment. These aspects have been widely discussed since the scheme was introduced in 2016 and during this time the EMA has proactively sought out views on how the scheme is working and whether improvements or refinements need to be made. This engagement with stakeholders has been productive and should be continued. We believe that PRIME would still benefit from allowing more flexibility in the opportunities for scientific advice and less-formal discussions – something also reflected in the core recommendation 3.1.7 (provision of regulatory advice along the continuum). We welcome further investment in the PRIME scheme as highlighted in the RSS2025 since this has the potential to result in more efficient development of innovative therapies for significant unmet medical need. However, the overall benefit of the PRIME scheme has not yet been proven so further refinements may still be needed.

(4) Facilitate the implementation of novel manufacturing technologies
Novel approaches and the implementation of new technologies are used to support continuous improvement in manufacturing and meet the demands of capacity expansion and globalisation of supply chains, whilst ensuring a reliable supply of products. Inclusion of this core recommendation in RSS2025, and particularly the proposal to modernise relevant regulations to facilitate novel manufacturing is fully supported and welcomed. The potential to introduce sufficient flexibility to accommodate these advances and reduce the post-approval change burden associated with continual improvement of manufacturing and supply would greatly benefit the EU regulatory framework.

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**:

We view all the core recommendations made in support of this strategic goal 2 as having a positive impact on the future EU regulatory framework. Core recommendations 10 and 11 have already been highlighted in our top 3 priorities. We are providing additional comments on core recommendation 9 below:

(9) Foster innovation in clinical trials:
The use of innovative, complex clinical trial designs (e.g. various types of adaptive, seamless, umbrella and basket approaches) can increase efficiency in the development of new medicines and minimise the exposure of patients to sub-optimal treatment arms. However, whilst the EMA has recognised the value of innovation in this area and acknowledges that some innovations e.g. adaptive clinical trial designs are now well established, the proposals made in RSS2025 to strengthen acceptance and understanding across the EU regulatory network and other stakeholders is supported. Such action is needed to help to align the perspectives of the regulatory authorities (EMA and NCAs), Ethics Committees and HTA-Bs. This will be particularly important once the Clinical Trial Information System (CTIS) is operational and the Clinical Trial Regulation is implemented. Use of opportunities for stakeholder interaction to share information on innovative trial designs, including aligned understanding of best practises, concerns and limitations will be valuable to ensure that this area continues to progress in the future.

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**:

(15) Contribute to HTA's preparedness and downstream decision making for innovative medicines.
This core recommendation builds on work already initiated by the EMA and the proposed actions outline some ways in which closer alignment on clinical efficacy and clinical effectiveness may be achieved. However, it is anticipated that this approach would still be limited to certain medicines, given the resource challenges, particularly on the HTA-B side and that the potential new HTA regulation may also necessitate changes in approach. Further development of the current system for joint scientific and HTA parallel advice is supported with the understanding that such an approach remains optional.

(16) Bridge from evaluation to access through collaboration with payers.
The initial effort made by the EMA to start engaging with payers through a workshop in 2017 are welcomed. The actions recommended, in particular creating opportunities for horizon scanning, would be a positive move forward, particularly if this was an ongoing activity and provided an opportunity to begin evaluating unmet need vs value in particular disease areas before new products are licensed in the EU. However, this will require investment of time and resources from both the EMA and the payer community and we acknowledge that some of these actions are therefore not directly within the control of the EMA but we believe there is a real need for coordination and leadership and welcome the positive steps outlined in RSS2025. Furthermore, discussion around information in the labelling and its role for prescribers versus payers is an important topic that is reflected in the RSS2025 and further work in this area on expectations for labelling could potentially help to address several of the issues raised.

(17) Reinforce patient relevance in evidence generation
Incorporating patient views into medicine development is critically important and the potential to capture patient experience via new technology and tools is only likely to increase. Therefore, the actions listed under this core recommendation are fully supported.

(18) Promote use of high-quality real world data (RWD) in decision making.
The possibility to collect and analyse large volumes of healthcare data to support regulatory decision making over the lifecycle of a product will be an important advance and the specific actions listed under this core recommendation are supported. Given that some National Competent Authorities are also beginning to think about developing their own expertise in data collation and analysis it will be important to ensure that any initiatives undertaken by the EMA are coordinated across the EU network. Additionally, continued work to optimise the role of disease registries as sources of real-world data for decision making and their use is important. Whilst disease registries offer a route for data collection and assimilation they require support and co-ordination. The work of the EMA in this area is acknowledged but we would like to see further actions reflected in RSS2025. For example, there have been instances of resistance to using registries at a physician level driven by a lack of awareness of their significance to medical research – public and private. Given the 'evidentiary standards' required of industry through the registry environment, some form of platform or EMA outreach programme would do much to encourage the formation of unified disease registries.

(20) Deliver real-time electronic Product Information (ePI)
This core recommendation is already being progressed and is fully supported. The provision of real-time electronic Product Information would be a significant step forward and would minimize the time that it takes for a change in labelling to reach the patient. Developing electronic formats for the delivery of product information should also consider ways in which new information could be highlighted in the electronic patient leaflet (in the current paper format it is not possible to highlight recent updates within the patient leaflet, other than referring to the date the leaflet was updated). Other approaches such as the use of QR codes to link to videos showing e.g. self-administration of a medicine etc could become much more widely used.

(22) Further develop external communications to promote trust and confidence in the EU regulatory system.
Any actions that build awareness, trust and confidence in the EU regulatory system are important and will help with initiatives that require input and participation by other stakeholders. In addition to HTA-Bs, patients, payers and Healthcare Professionals, it is also important to build on communication to other regulators (NCAs and in other jurisdictions) – a topic reflected in core recommendation 3.5.4. Also, whilst patients are listed in the specific actions, raising awareness of the activities and role of the EMA amongst the general public would also be helpful.

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**:

The core recommendations under strategic goal 4 are positive steps in the overall regulatory framework. However, we do not have specific comments on any of the core recommendations.

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**:

(31) Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders
Dissemination and sharing expertise and knowledge across the regulatory network are important to drive a consistent approach and ensure that regulatory science keeps pace with innovations in science and technology. The proposal to conduct horizon scanning for innovation with the EU innovation network, academia and ICMRA is fully supported – the potential value of also including industry in these activities could also be considered.

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