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Public consultation on EMA Regulatory Science to 2025

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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

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

Name of organisation (if applicable):

EuropaBio

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.

EuropaBio welcomes the EMA's initiative to lay down its vision of regulatory science over the next 5 to 10 years and give all stakeholders the opportunity to give their views on the Agency's future priorities and allocation of resources as described in the strategic reflection paper. We support the overall direction that the EMA proposes to take to keep pace with science and support delivery of the best treatments for patients. We would recommend that the EMA should remain focused on clear deliverables in dealing with the various challenges that healthcare systems are facing and that it works to avoid both dispersing its limited resources into too many initiatives and reduces any potential duplications of work in similar areas. For example, elements of HTA engagement and the need to generate better quality evidence are repeated in different contexts in Sections 3.2 and 3.3. In addition, we would like to note the importance of the EMA working in close partnership with all the national competent authorities in the EU/EEA Member States of the EU regulatory ecosystem, taking into consideration certain areas which fall within the competence of Member States, such as e.g. the authorisation of clinical trials.

Furthermore, we look to the EMA to continue facilitating development and access to medicines for the benefit of patients and public health in the EU. We would also suggest that the EMA foresees the need for guidance on evidence generation in rare conditions, including the planning of the clinical trial activities in the area of orphan medicinal products. We also recommend that the EMA enhances multi-stakeholder advice in collaboration with patients, healthcare professionals, notified bodies. and HTAs. Finally, we would also like to recommend that the EMA increases the involvement of patients in the complete life-cycle of product development.

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)

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

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.

Rationale for choice
The EU regulatory system should enable the development of emerging technologies including ATMPs for the benefit of patients. Based on ATMPs in development, a significant increase in ATMPs brought forward for approval is expected in the near future. ATMPs have proven their value to patients. Yet, the number of marketing authorisations for ATMPs is small which gives a confusing signal to both patients and medicine developers. Finally, a trend can be noticed that ATMPs are first approved in other regulatory regions, such as e.g. the US, which raises a question about how the EMA is planning to keep pace with other regulatory authorities in the field of ATMPs, such as most notably the FDA. For these reasons, we are convinced that the ambition of the EMA's work in the area of ATMPs should be set very high in order to create a workable ecosystem for ATMPs in the EU.
There are different challenges facing the development of ATMPs in comparison to the types of products /therapies currently available to treat a disease/condition. There is the potential for long-term disease control or cure where previously symptomatic treatment was the only option. In addition, efficacy/effectiveness assessments may need to be made on more limited data than usual as the long-term outcome will often not be known (see comments on 3rd choice recommendation 15). The regulatory system (and downstream payers) must now determine how to balance the unknown with the game changing efficacy of ATMPs to ensure patients can access these treatments. Civil society will increasingly demand this.

Action: Identify therapies that address unmet medical need
Comment: The intent of this action is not clear. How does the Agency plan to identify these therapies? Is this

prospective identification (e.g. horizon scanning SME/academia) or will the Agency identify those presented to the Agency as those addressing unmet need? EMA notes that ATMP applications for approval to date have been very limited. However, this is expected to change significantly in coming years. FDA recently noted more than 800 active cell-based or directly administered gene therapy INDs, with predictions for 10 to 20 cell and gene therapy product approvals per year by 2025 based on an assessment of the current pipeline and the clinical success rates of these products. Rather than looking to identify therapies, the action should be better cooperation with stakeholders (European Commission, national agencies/GMO authorities in the Member States) to ensure that the EU is competitive in the ATMP field so these products can be developed in the EU and there is capacity across the European regulatory network to deal with these products.
If the action is maintained, we suggest greater value will be generated by defining what further actions will be planned once therapies are identified, rather than focusing on the process of simply identifying therapies.

Action: Provide assistance with early planning, method development and clinical evaluation
Comment: It is not clear whether this is planned via PRIME (40% of current PRIME designated therapies being ATMPs) or whether a separate approach is planned. Despite the unique features of ATMPs, any separate approach should be considered holistically, and we support EFPIA's priority topic highlighting the need to "diversify and integrate the provision of regulatory advice along the development continuum". The number of new medicines granted access to the EMA's PRIME scheme was at its lowest level in 2018 in comparison to the number of successful breakthrough therapy applications in the US (40%).

Action: Support evidence generation, pertinent to downstream decision-makers
Comment: Given the challenges in evidence generation for ATMPs, EMA should promote further multi-stakeholder discussions to examine how these products are assessed for efficacy/effectiveness compared to symptomatic treatments (see comments to recommendation 15 actions). As noted under recommendation 15 additional actions below, discussion should cover post-marketing activities as there will be ongoing data generation and the endpoints in a post-approval setting may be different to those in clinical trials supporting a regulatory approval. For example: Luxturna was approved on the basis of a novel endpoint, performance on multi-luminance mobility test, which is not available outside the clinical trial setting .

Additional actions
There are multiple ATMPs in development. Whilst there may be differences in the products e.g. same or similar transgene/different vector for gene therapy, the overall data to support regulatory approval and reimbursement may be similar across products. Within the proposed recommendation 15 on HTAs some consensus on data requirements would be useful.

Second choice (h)

17. Reinforce patient relevance in evidence 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.

We believe EMA needs to go far beyond and suggest reframing as "ensuring the patient voice is systematically incorporated throughout drug development & associated evidence generation"

S.3.3.3 says "EMA has incorporated methodologies to capture the patient voice all along the regulatory lifecycle of a medicine" and s. 3.2.4 introduces patient preference in benefit risk assessment. We acknowledge EMA's efforts to involve patients, however, the future demands a much more scientific and structured approach. This will ensure the full value of their input can be captured and that this meets the

needs of all stakeholders.
Where relevant, patient preferences should be systematically considered from early in the development lifecycle, informing development programmes on a range of aspects: characterisation of disease, endpoint development and dose selection as well as during benefit-risk assessment (s. 3.2.4)

Action: Enhance patient involvement in EMA scientific committees
The beneficial role of patients in EMA committees is clear and supported by EuropaBio. It is important to ensure contribution from smaller patient organisations and allow them to contribute independently of umbrella organisations. This is particularly relevant for the many rare diseases organisations where resources may be focussed on support for patients and carers. Options to support eligibility of these organisations are welcome
Action: Coordinate the Agency's approach to PROs
Patient reported outcomes are only one component to assess relevance to patients. We stress the need to consider patient centred outcomes. A clinical outcome, reported by a clinician, carer or observer could be equally relevant to a patient. Updating guidelines to include reference to patient centred outcomes would be useful but consideration should also be given to the many conditions where clinical guidelines are not available. Working towards internationally accepted common definitions regarding patient-centred outcomes would be helpful

Action: Co-develop with HTAs a core health-related quality-of-life PRO
Comment: There are already many PRO measures and the real challenge is the sensitivity of the measure. Before developing a new tool, there should be efforts towards consensus building on the appropriate tools across all stakeholders. A pragmatic effort is needed to find ways to identify appropriate tools in the case of rare diseases where validation is not possible due to the rarity of the conditions

Action: Explore additional methodologies to gather and use patient data
We welcome the gathering and use of patient data from the wider patient community but consider this broad patient voice should inform the development phase (natural history, burden of illness, study design, endpoints, patient relevant outcomes) as well as benefit risk evaluation. It is also important that input from patients is representative of the whole patient community with a given disease/condition. Inclusion of input from the wider patient community to inform early dialogues would help ensure that subsequent data generated will meet the needs of all stakeholders, and scientific methodology to gather patient contribution is needed. EMA's strong engagement in initiatives that drive these is essential. Any methodologies considered should put the needs of the patient and their condition first and not be an additional burden
Truly ensuring the patient voice is incorporated throughout the medicine life cycle will require additional actions to those outlined in the consultation and we would appreciate EMA's consideration of the additional actions listed below

Additional actions required
The key questions are how to determine what is relevant to patients, how to measure it and how to ensure a consistent understanding of how various stakeholders will evaluate it. There has been recent guidance from both WHO and FDA on gathering patient input and future guidance is expected from IMI-PREFER and CIOMS. Patients in the EU need EMA to support key EU initiatives like IMI PREFER, IMI PARADIGM & EUPATI whilst at minimum keeping pace with initiatives in other regions
Additional actions proposed
- support existing activity and drive global alignment on the scientific methodology to gather patient contribution to drug development. For example: if a research study follows ISPOR best practice would this be acceptable to all stakeholders from a methodology point of view?
- define expectations for scientific rigour i.e. what constitutes the scientific standard
-drive understanding across stakeholders of what constitutes patient experience data, where the data can take many forms: feedback from focus group, interviews, blogs, etc

- seek agreement on how and where to include patient experience/preference data in regulatory submissions and labelling
- support multi-stakeholder agreement on a framework for evaluation of patient preference data

Third choice (h)

15. Contribute to HTAs' preparedness and downstream decision-making for innovative medicines

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.

Fundamental to achieving patient access is ensuring evidence generation pertinent to regulator, HTA, payer needs, and patients will be defined early in drug development.
There are multiple ongoing initiatives beyond the scope of this consultation looking at this, e.g. the Commission proposal for a Regulation on health technology assessment, Commission Expert Group on Safe and Timely Access to Medicines for Patients initiative, etc. We are primarily selecting this as a priority to ensure this aspect is integrated into EMA's work as regards our 1st choice on ATMPs, as well as other areas where innovation puts pressure on the EU system e.g. personalised medicines and medicines for rare diseases. Success in supporting translation of innovative medicines, incl. ATMPs, into patient treatments will not come unless all stakeholders work together end to end.

Action: Ensure the evidence needed by HTAs
We support input from all stakeholders, including HTA/payer and patients (see our comments to 2nd choice), early in drug development. For innovative products it's important for all stakeholders to consider the data that will be required to support a timely approval, to ensure early patient access to potentially transformative therapies. Key to achieving this is awareness early in development of any limitations in data at launch and, importantly, proposals to mitigate any limitations to enable access. A sustained therapeutic effect is anticipated with many future ATMPs and determination of the extent of durability will only be possible with long-term post-marketing follow-up. Early multi-stakeholder discussions on potential mitigating proposals e. g. pay for performance whilst long-term data are generated, would help enable access. In relation to rare diseases, the clinical trial population is often small and heterogeneous, and input from all stakeholders is needed to determine how limited data in some patient populations can be managed to improve patient access. For some stakeholders, including many payers, there may be limited ability to be involved in all early advice processes. Availability of documentation to support why decisions were made would assist HTAs /payers reviewing submissions at a later date.

Action: Enable information exchange with HTAs
Information exchange between EMA and HTAs is important and EuropaBio fully supports more dialogue. Within this information exchange it is important for the EMA to communicate to HTAs how it arrived at the decisions taken during the approval process, e.g. why the agency accepted the trial design, the endpoints for approval, why a given duration of trial was acceptable.
The proposed related EMA recommendation to communicate considerations on positioning of a product given the therapeutic context during benefit risk evaluation is welcomed. This is particularly relevant for ATMPs where a once only administered product may be considered in the context of a chronically administered treatment. Better clarity is required in the content of EPAR to help stakeholders to understand the regulatory decision making. It is important for EMA to indicate why, in their view, the data supports benefit risk in the indications approved, especially where the indication approved is broader or more restricted than the trial population, or where data in some patients may be limited. This would help provide context for the HTA in their assessment.

Action: Discuss with HTAs guidance and methodologies
EuropaBio agrees EMA and HTA should discuss guidance and methodologies for evidence generation and review. Lack of guidance can mean EMA and HTA may come up with different conclusions based on review of the same data. Regulators can accept a threshold for uncertainty in regulatory decision making but the consideration is a lifetime approach for subsequent payers.

Action: Contribute to the identification of priorities for HTAs
We are unsure what EMA mean by identifying priorities in this action, is this horizon scanning?

Additional actions required:
EMA support for aligning priorities for post-marketing activities would be welcome.
Post-marketing activities are mostly PASS and sometimes long-term efficacy. HTA requirements include long-term efficacy, quality of life (QoL), activities of daily living (ADL), data in specific age groups, subgroups and biomarkers. Data quality e.g. if gathered using wearables is an additional important consideration. There needs to be a continued dialogue on what evidence is necessary in the post-marketing setting. In situations where the EMA and HTA are not fully aligned on post approval data requirements, dialogue to agree on the appropriateness of measures to follow-up is useful for HTA. This would be particularly useful where evolving knowledge during development suggests a different endpoint or way of monitoring would be more appropriate in the post-marketing setting than utilised in clinical trials. See our comments to 1st choice.

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

What we identify as missing and still significant in this strategy document is:

a. a reflection on the EMA resources, human and financial, as well as capabilities to deliver on the ambition set out in this document, and specifically when it comes to assessing innovative treatments,

b. a reflection on the concept of modernisation of PIP/paediatric elements, collaboration/integration with different authorities in this aspect, as well as how PIPs for ATMPs/novel products are best approached where the scientific knowledge base is still evolving.

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:

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

EuropaBio ranked recommendation 7 ‘Diversify and integrate the provision of regulatory advice along the development continuum’ as very important. The Agency recommendation to invest the necessary resources to strengthen and improve scientific advisory platforms is welcomed. Given the rate of innovation the advice opportunities need to be both flexible and faster. The US Biotech industry perception is that the EU advice pathways are too slow and cumbersome and create gaps with how quickly development can progress compared to the US. Development is global and EU advice needs to be commensurate with global advice timelines to ensure timely start to global clinical studies including EU patients, otherwise EU patients may lose the opportunity to enrol. With increasingly complex innovative products there need to be opportunities for CMC quality advice that are agile and able to respond to rapidly evolving data. The increased use of connected devices with medicines and biomarkers will require joint advice from notified bodies, national competent authorities and/or EMA to address questions with overlapping remit.
Furthermore, a platform to get multi-stakeholder feedback on the digital endpoint should be developed. Current options are the qualification opinion or scientific advice. However, both are lengthy processes that are not adapted to the agility sponsor’s need.

Taking the learnings from PRIME, national agency experts could provide advice and lead on to be Rapporteurs allowing integration of the advice from clinical trial through approval and throughout the lifecycle. To enable agility, EU experts would need to be in a position to provide EU scientific advice rather than requiring a formal EU CHMP/SAWP advice procedure. Expanding PRIME eligibility based on non-clinical and tolerability data to non-SME/academia would also be helpful.

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**:

Comment on recommendation 9. Foster innovation in clinical trials

Rapid progress in science and technology, with an evident example being ATMP, requires a fast adaptation of the regulatory, hence clinical, landscape.

“Traditional” clinical development path and regulatory path are not always possible for novel therapies, yet when possible, they are subject to the intrinsic variability of such novel therapies.

- Foster innovation in clinical trials by tailoring clinical development to the specificity of a treatment, rather than tailoring a specific treatment to the traditional development.
- Work closely with developers in understanding the nuances of unmet medical needs, rapid progresses and changes in the medical field and build together a dynamic development plan which would adapt easily to moving targets (adapting the scope of use of a certain therapy is not necessarily a change in therapy which requires a brand new development).
- Implement clear and defined rules for the use of registries and data extrapolation, to reduce the time between FIH and market availability of novel therapies.
- Increase collaboration between Member States’ competent authorities and EMA in key scientific and regulatory aspects, in particular clinical trials. For example, GMO requirements remain an obstacle to the conduct of clinical trials in different countries . This forces developers to focus on few countries extending the time for completion of the development program.

Comment on recommendation 11. Expand benefit-risk assessment and communication

EuropaBio members ranked this recommendation as ‘very important’ and related to our 2nd and 3rd recommendation to ensure the patient voice is systematically incorporated throughout drug development and associated evidence generation and contributing to HTA preparedness. EuropaBio consider the underlying action of incorporating patient preferences into the benefit risk should start, where relevant, early in the product development lifecycle to inform the clinical development and later during benefit-risk assessment. Improving communication with HTA and payers relating to benefit risk, therapeutic context, patient perspective and, where relevant, patient preference should start early in the development process.

Comment on recommendation 13. Optimise capabilities in modelling and simulation and extrapolation

We support EFPIA’s comment on this, which is as follows: Currently European regulators appear to be reluctant to accept alternative approaches to the provision of evidence during development, pre and post initial authorisation. Increasing acceptance of predictive approaches, based on modelling, simulation and extrapolation will advance the clinical development of medicines. In addition, acceptance of models for non-clinical, CMC and Quality factors will also add value.

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**:

Comment on recommendation 18: Promote use of high-quality real-world data (RWD) in decision-making Despite not choosing this among our top three core recommendations, EuropaBio members ranked this recommendation as 'very important'. EFPIA has selected this as one of their top three priorities and we support EFPIA's position on this topic.

We must harness the opportunities provided both by novel sources of data and by emerging approaches (e. g. modelling and artificial intelligence/ machine learning). EMA's openness to engage with initiatives on this topic would improve understanding and support acceptability of this data and we would encourage further EMA engagement. In parallel, patients, HTA bodies and HCPs must also be included as this work progresses.

This point also links to the need for EMA to play a leading global role in ensuring the patient voice is incorporated throughout the medicine life cycle. Please see our comments on our second core recommendation 'Reinforce patient relevance in evidence generation' for our thoughts on this matter.

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**:

EuropaBio ranked recommendation 25. 'Promote global cooperation to anticipate and address supply challenges' as very important.

The EU is in stark competition with emerging markets in terms of manufacturing investments in the area of biologicals. To reach the goal of promoting global cooperation to anticipate and address supply challenges, the EMA has a very important role to play in increasing the attractiveness of the EU to bio-pharmaceutical companies as an investment location for manufacturing activities.
Likewise, the benefits of global regulatory cooperation should be reinforced and broadened by working towards extension of mutual recognition agreements to cover all inspections where possible, including good manufacturing practice, batch testing and good clinical practice.

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**:

EuropaBio appreciates and values strengthening the collaborations between stakeholders involved in improving the health of EU citizens, which include very prominently the research community. To foster biotech healthcare innovation in the EU we would recommend:

- development of innovative funding models for translating bioscience research into new therapies, including advanced therapies

- explaining incentive models to all stakeholders, including from public research and public services (EU and national).

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