Contribution ID: 7ffd97d2-a3be-448b-9856-0cbbf15fcbc4
Date: 17/06/2019 14:13:43

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

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

Name of organisation (if applicable):

Sanofi

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.

- Overall, this is a well-written and clear document that lays out worthwhile strategic goals and recommendations for EMA.
- The reflection paper addresses the key changes that are happening in the Sector, and especially the speed at which these changes are happening – it is important that projects and initiatives will be properly staffed for the timely execution
- We find strategic goals 1 through 4 on human medicines worthwhile pursuing with the suggestions and modifications provided in the questionnaire below.

- There are specific topics discussed in the reflection paper such as real world evidence, innovative approaches in trial design, emerging technologies, biomarkers, patient-focused drug development etc. It is important that these will be handled in such a way as to create an integrated platform for drug development, rather than as a set of disconnected add-ons to existing processes.

- We are somewhat concerned about strategic goal number 5 for human medicines as detailed below.

- Regarding chapter 5, on which there were no questions in the survey, we suggest that EMA should not only focus on exporting the EU-model (to maturing regions/agencies) but also actively identify and implement best practices from its peers (developed agencies). It is critically important to implement (globally aligned) contemporary processes to fully leverage regulatory science as it evolves – and to keep the EU regulatory system competitive.
- One concern is about the extent to which there will be alignment between the 2025 goals of EMA and the development of the FDA's approaches and capabilities over the same time period. Drug development is global and alignment will serve all stakeholders from patients through society to regulators and industry.

- We do not offer any comments on veterinary medicines

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'
- ( ) 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
- ( ) 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
- ( ) 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
- 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
- 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

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.

Above and beyond items 10, 14, and 18 above we prioritize the following items:

- It is critically important to implement (and align globally) contemporary processes and science (timelier, faster, new designations, digimarkers, innovative statistical methods in CT, QbD) and challenge the legal basis (to allow for full implementation of e.g. ePL, PRIME) to fully leverage regulatory science and technology as it evolves.

- From a CMC perspective the following items would be prioritized:
  - Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products (It is important to have an integrated evaluation of drug device combination products and companion diagnostics)
  - Facilitate the implementation of novel manufacturing technologies (As a manufacturer and MAH of biopharmaceuticals, this priority is of importance to us. We agree with all EMA's underlying actions)
  - Diversify and integrate the provision of regulatory advice along the development continuum

- Deliver real-time electronic Product Information (ePI). There are significant upsides to be gained benefitting the entire sector from patients through society to industry
  - Control of version (Digital Master)
  - Speed of updating (e.g. new warnings)
  - Financial savings
  - No risk of mis-printing leaflets (e.g. only printed one side)
  - Opportunity for patients to increase text size (some current leaflets are almost illegible)
  - Etc. and more

- RWE to support regulatory decision making - the scientific and methodological requirements behind what true Evidence is, need to be extensively discussed

Second choice (h)

- 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
- 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
- 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
- 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
- 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

2nd choice (h): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

Third choice (h)

- 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
- 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
- 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
- 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
- 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

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.

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

• Align requirements: EMA's plan says little about the need to be aware of and align with the developments in regulatory science and regulatory frameworks that are taking place in other jurisdictions. The final part of the document talks briefly about international regulatory science cooperation, but there is very little detail or specific commitment. It would be nice to see some detailed goals and recommendations around this strategic imperative, as we see with the others.

• Leverage contemporary technologies: The dossier in the cloud concept
Technology is bringing a range of opportunities as an enabler of new healthcare paradigms. It allows us not only to optimize the "dossier" assessment process but to redesign it by creating a shared digital space (dynamic and agile cloud-based environment) where real time data is made available for regulatory (and other stakeholders) review. It allows each interested party to have on-line access to all available data /information at the time of review, at the time of decision making, and throughout the lifecycle. It brings a new level of transparency and certainty to the regulatory process as development programs move forward.
More specifically:
• Data is captured and stored directly from the source (investigational trial, stability study etc.) into a cloud environment.
• The cloud environment is an interoperated/interconnected system, accessible and secured through sets of permission rules and allows for auditing, time stamp trails.
• After initial assessment/approval information/data continues to flow into the system and therefore is constantly up-to-date for regulator's use.
• New data/information is screened and evaluated through cognitive computing or machine learning applications. Ideally a "design space" was established and predefined and preagreed algorithms sift through the data. Deviations from the allowed pre-designed outcomes would trigger "human" intervention and reassessment.
• Again, based on preestablished, quality by design criteria, post approval variations are automatically cleared unless otherwise flagged by the system. The Sponsor is pre-certified.
• One common version of the "truth" is stored and accessible to all permitted parties (avoids needless duplication).

Such a process removes the traditional concept of dossier as a static entity and adapts to the dynamic (rolling review) reality of today's science, technology, and patient expectations. It brings overall efficiency by removing non-value-added steps, unnecessary duplications of efforts and by simplifying administration. This is a paradigm shift where linked, ready to use up-to-date information is constantly available and managed for both initial decision making and beyond.
• Leverage data sources: Technology is bringing a range of opportunities as an enabler of new healthcare paradigms. Amongst such opportunities is the use of data and information previously not available or not easily integrated into existing processes. Sources and origins of such data include but are not limited to Digimarkers, i.e. biomarkers and other clinical endpoints captured with wearables and similar smart devices, Real world data (RWD) and evidence (RWE), and Patient related outcomes and Quality of life

measures. A progressive and forward looking discussion on how these new types of data sources could be utilized to support regulatory decision making, beyond signal detection and PhV-purposes, is desirable.

• Offer new pathways: What measures could be taken to foster and speed up the approval/registration processes of novel and innovative treatments in the EU. European regulatory procedures are sturdy and robust but lack some of the speed and flexibility expected by patients, society and, other stakeholders in the sector. Current regulatory procedures in the European Union are not necessarily optimized for where science has taken us today and their effectiveness is trailing behind international benchmark.

• There is no reference to the Post Approval Change Management process simplification, e.g. ICH Q12 - while this discussion is already ongoing a reflection on next steps is lacking and constitutes a missed opportunity

• We believe it would be of benefit to the sector if a clear distinction between “Relative efficacy” (defined as the extent to which an intervention does more good than harm, compared with one or more alternative interventions under ideal circumstances, that is clinical trials) and “Relative effectiveness assessment or comparative effectiveness assessment” (which is the same but for data collected under the usual circumstances of health care practice) was to be made

• A discussion on COS (core outcome set) which are the minimum set of outcomes that should be measured and reported in all clinical trials for a specific condition is lacking – the concept has been successfully applied to gain multi-stakeholder alignment on, e.g. NASH and hemophilia, and could be expanded to other areas

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:

1. We welcome the action that would require EMA to enhance early engagement with novel biomarker developers to facilitate regulatory qualification. We note your comment about digital biomarkers and agree that this is something that deserves attention; indeed EMA should move beyond classical biomarkers and promote the uptake and development of novel "digimarkers" captured with wearables and other technologies – such digimarkers can be translated into clinical utility and they do provide value.
2. This is an important topic and the underlying actions that EMA is proposing are valuable
3. The PRIME initiative is good as such but limited in scope by current legislation. EMA should seek solutions above and beyond current legislation such that it can offer contemporary and competitive regulatory pathways to meet today's science.
4. ICH Q12 is still not fully implemented so this would be a first helpful step forward.
CQAs (Critical Quality Attributes) and CPPs (Critical Process Parameters) are key elements of QbD and not easy to change over the product life cycle. It is critically important that innovation over a product's life-cycle is accepted such that new technologies can be readily implemented. Focus should be risk-based and center on changes with significant impact. International alignment should – as always – be at the forefront.
Continuous manufacturing in addition to traditional batch manufacturing should be better recognized as 'flexible approaches' in the application of GMPs for some novel manufacturing models.

5a. The recently issued MDR & IVDR are sources of additional regulatory burden for innovative products such as Drug-Device Combinations and CdX. An integrated evaluation process is needed to achieve timely access to these innovative medicines for patients
5b. There is a growing number of digital therapeutics on the market today that are being developed in accordance with internationally recognized design, quality, and manufacturing standards. Digital therapeutics are distinguished from other digital health categories through their primary function of delivering software-generated therapeutic interventions directly to patients to prevent, manage, or treat a medical disorder or disease. EMA should explore and identify best practices and correlating standards in
the areas of product quality and design, clinical validation, patient utilization, and regulatory approval oversight of these novel therapeutics.
7. Today PIPs have to be agreed very early on in the development process. This makes the PIP to a great extent rely on assumptions which later, often enough, turn out to have not been very accurate. This creates extra work for both sponsors and regulators alike. As an alternative, to overcome current shortcomings, the timing of PIPs could be more flexible and agreed on during early scientific advice such that they become based more on evidence than as currently on speculative assumptions.

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**:

8. For 3R and regulatory science, alternatives, especially when it comes to in vivo testing to release vaccine batches, analytical methods (i.e. compendial analytical methods) need to be considered. A far too high number of animals are still used for Quality Control purposes.
9. It would be important for EMA to consider seamless clinical trials (where there is no step transition from Phase I to II to III). It is important to avoid a situation where seamless trials were possible in one regulatory jurisdiction but not in the other
10. Go beyond classical biomarkers and include novel “digimarkers” captured with wearables and other technologies – when such digimarkers can be translated into clinical utility they provide value
13. The proper application of modeling and simulation can replace long expensive clinical trials and yield similar degrees of confidence for decision making – this is an area that deserves additional attention
14. Artificial intelligence brings new methods and thinking to the table, but in depth work on understanding the methods and their properties is needed from both ends, industry and regulators alike. Many critical decisions along the drug discovery and development value chain could be made through AI and machine learning.

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. As an example, the involvement of HTAs could be sought at the time of PRIME designation to, for instance, cross check the unmet medical need. The ultimate goal is access to patients: it does not help to have PRIME if HTAs are not in the loop
17. Patient-focused drug development is a significant topic of discussion. EMA's recommendations here are centered around PROs and seem quite conservative – e.g. 'coordinate Agency's approach to PROs'. EMA should be encouraged to take a more vigorous approach to the whole issue of patient-focused drug development. Patient perception of value should rightfully be reflected in the SmPC.
18. The scope of this could be expanded beyond RWD to include any new data source to support regulatory decision making. This would include but is not limited to Digimarkers, i.e. biomarkers and other clinical end-points captured with wearables and other smart devices, Real world data (RWD) and evidence (RWE), and Patient related outcomes and quality of life measures.
19. The publication of the HMA-EMA Joint Big Data Taskforce summary report in February 2019 shows the willingness to promote a data sharing culture, and to establish a Regulatory Network across various stakeholders. It is important that the mandate of the task-force is extended
20. It is important to take advantage of contemporary technologies and make available product and labeling information through digital means and push the envelope beyond current thinking. It should be possible to facilitate patient engagement by giving them an interactive and customizable product information experience. Having said that, while digital media-based product information should be the default, paper based rendering should still be offered when appropriate.
Shortage of medicines, and especially shortage of vaccines, is of great concern in many regulatory jurisdictions and a problem recognized by the entire health care sector. The requirement for country specific packs, labels, leaflets etc. does reduce packaging line capacity and jeopardizes cold chain integrity. This is a is self-inflicted situation originating from the mosaic of country and region specific regulatory requirements

and could easily be remedied and overcome by retiring dated paper based product information requirements in favor of digital media versions. For vaccines, such a transition should be particularly straight forward considering that they are administered under the oversight of, and by, well-educated and highly trained HCPs.

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**:

25. Shortage of medicines, and especially shortage of vaccines, is of great concern in many regulatory jurisdictions and a problem recognized by the entire health care sector. The requirement for country specific packs, labels, leaflets etc. does reduce vaccines packaging line capacity and jeopardizes cold chain integrity. This is a is self-inflicted situation originating from the mosaic of country and region specific regulatory requirements and could easily be remedied and overcome by retiring dated paper based product information requirements in favor of digital media versions. For vaccines, such a transition should be particularly straight forward considering that they are administered under the oversight of, and by, well-educated and highly trained HCPs.
Morover, OMCLs perform double-testing which delay the release of vaccine batches and jeopardizes the

availability of vaccine doses.
EMA could further the discussion in this area with the ultimate goal to arrive at more practical requirements that still uphold adequate Q, S, and E standards.
26. The current EU Variations Regulation has been in place since 2008 and could be revised taking into account the scientific, technical, and regulatory experience gained over the years. In particular a revision should center on the introduction of risk-based principles and tools (cfr. ICH Q12 Life Cycle Management and Q10 Pharmaceutical Quality System), allow for future developments and innovation, focus on changes with significant impact, and promote international alignment.

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**:

28. It is important to include industry in this endeavor to maximize transparency and cooperation on regulatory science. The regulatory science discussion should be defined, fueled, and driven by industry's pipeline – not as a siloed academic exercise.
29. This is a variation of 28 but exacerbated by the mentioning of ring fenced resources so the same comment as under 28 applies: It is important to include industry in this endeavor to maximize transparency and cooperation on regulatory science. The regulatory science discussion should be defined, fueled, and driven by industry's pipeline – not as a siloed academic exercise.

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