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Public consultation on EMA Regulatory Science to 2025

Fields marked with * are mandatory.

*Name

Anna Czwarno

*Email

anna.czwarno@vaccineseurope.eu

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):

Vaccines Europe (VE)

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

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

Question 3 (human): What are your overall views about the strategy proposed in EMA's Regulatory Science to 2025?

Please note you will be asked to comment on the core recommendations and underlying actions in the subsequent questions.

EMA's Regulatory science strategy to 2025 is highly welcomed by Vaccines Europe, a trade association representing the major innovative research-based vaccine companies as well as small and medium sized enterprises operating in Europe.
It is generally accepted that vaccines designed to prevent infectious diseases are one of the most cost-effective health care interventions. The World Health Organization estimates that existing vaccines prevent approximately 2–3 million deaths per year. Vaccines have also indirect economic and social benefits such as improved labour productivity and cognitive development, as well as averted treatment costs.
Today, close to 30 diseases are preventable by vaccination but there remain many unmet needs, for example:
• infectious diseases that have an important medical impact and for which safe and effective vaccines remain elusive (e.g. cytomegalovirus, Chlamydia trachomatis, Clostridium difficile, Staphylococcus aureus);
• infectious diseases for which vaccines are already available but for which the efficacy should be further improved (e.g. seasonal influenza, tuberculosis, herpes zoster);
• specific populations that could be better protected (e.g. elderly, immunocompromised patients, travellers).
By preventing infections and so reducing the need to use antibiotics, prophylactic bacterial and viral vaccines are reducing our dependence on antimicrobials. A paper published recently by the independent Review on Antimicrobial Resistance highlights that many vaccines that would play a crucial role in tackling drug resistance are not on the market or even in early stages of development and concludes that there is a need for a much more robust pipeline of new vaccines to help contain rising antimicrobial resistance.
In addition, and in view of the ageing of the population, new vaccines, for instance with adjuvants that specifically target the aged immune system, could help to overcome the limitations of immune senescence and ensure a better protection of the vulnerable elderly population.
The vast majority of the vaccines that are now on the market have been developed through rather straightforward and traditional research models. The complexity of many of the remaining targets necessitates substantial investment of capital and human expertise, making the development of the next generation of innovative vaccines much more complex, challenging, costly and risky for vaccine developers.
Application of novel science and technologies is leading to innovation in manufacturing and to innovative products that are often complex. To foster these innovations, EMA needs to work with other stakeholders including policy makers, academia and industry to facilitate the development of and access to innovative vaccines.
Today there are ongoing EU initiatives related to vaccines and vaccination, such as the EU Joint Action on Vaccination (EU-JAV). In parallel, vaccine manufacturers are operating on a global scale and a large part of vaccines produced in EU are exported to third countries. It would be useful to identify areas where EMA needs to collaborate with additional stakeholders (National competent authorities, HMA, ECDC, WHO, national vaccine policy makers, non-EU regulatory agencies) as some of the items identified are ambitious topics where European and/or internationally harmonized approaches would be important (eg. Real World Data).

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

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

- (●) Yes
- ( ) No

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

- (●) Yes

- ○ No

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

- ◉ Yes
- ○ No

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

- ◉ Yes
- ○ No

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

- ◉ Yes
- ○ No

Question 5 (human): Please identify the top three core recommendations (in order of importance) that you believe will deliver the most significant change in the regulatory system over the next five years and why.

First choice(h)

26. Support innovative approaches to the development and post-authorisation monitoring of vaccines

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.

EMA has a critical role to play in enabling new vaccines to become developed and accessible to the populations in need. VE strongly supports the recommendation to “Support innovative approaches to the development and post-authorisation monitoring of vaccines”.

Comments on underlying actions
Advance methods/tools to characterise immune response and to support definition of vaccine quality attributes: Advance methods/tools to characterise immune response should 1) facilitate the identification of correlates of protection and surrogate markers which will enable the development of innovative vaccines, 2) support the development of new approaches such as in vitro methods to identify measurable characteristics of product safety, quality, and potency.
Examine innovative clinical trial approaches to expedite vaccine development: Classical development of vaccines is long and costly. Promoting innovative clinical trial design allowing to demonstrate positive benefit /risk with a reduced number of subjects in phase 3 is key to deliver new vaccines quicker to the patients. For some vaccines (e.g. improved pertussis, Group B Streptococcus) demonstration of efficacy prior to marketing authorisation will not be feasible. Regulatory acceptance of initial approval based on alternative approaches such as surrogate endpoints or human/animal challenge models combined with post-approval real world data is essential. Acceptability by recommending bodies of such approaches is also key to facilitate access to innovative products. Finally, as manufacturers are conducting global developments, cooperation between major regulatory agencies is needed to guarantee global acceptance of these approaches.
Engage with public health authorities and NITAGs to better inform vaccine decisions: It is important for vaccine developers to be aware of the positions of recommending bodies/payers in the different Member

States on the product profiles they would consider of interest for their country/region. In absence of such systematic early and continuous dialogue, vaccine companies pursue their efforts to develop safe and efficacious vaccines, some of which may ultimately never be included in the national/regional immunisation programmes. For example, a vaccine authorised by regulators based on a demonstrated high level of efficacy may not be considered attractive from a public health perspective if it does not contain some antigens (e.g. does not target some serogroups) and thus may not be recommended in certain countries /regions. Another challenge is that the data generated to support the marketing authorisation of a vaccine are not necessarily the same as the data (usually cost-effectiveness data based on local epidemiology and standards of care) that recommending bodies/payers in the different EU Member States want to have available prior to their decision making. Considerable efforts are being made at the EU level to foster early dialogue with regulators and HTABs through parallel scientific advice procedures. However, for vaccines, NITAGs are responsible for providing independent, evidence-informed advice to health authorities on policy issues related to immunisation and vaccines. The roles of NITAGs and HTABs in the decision-making process vary from country to country. Now that parallel CHMP/HTA scientific advices have shown their added value, the possibility to involve NITAGs in parallel CHMP/HTA/NITAG scientific advices for prophylactic vaccines should be explored. A pilot took place in 2018, VE encourages EMA to continue working with all stakeholders on this topic.
Establish a platform for EU benefit-risk monitoring of vaccines post-approval: The experience with seasonal influenza vaccines illustrates the difficulty to generate post-approval effectiveness data in Europe. The cooperation between regional and national surveillance networks is essential to generate quickly meaningful data on the benefit/risk of prophylactic vaccines. The review of ADVANCE and DRIVE experience may bring important learnings for the creation of a platform to monitor the post-approval benefit/risk of vaccines. Industry should be involved as stakeholder for this topic.
Communicate proactively with key stakeholders on benefit-risk using evidence-based tools to tackle vaccine hesitancy: It is key that accurate and science-based information on the benefit-risk of vaccine is communicated to the public.

Missing elements include (see also Q7):
PRIME: VE wants to insist on the need to have appropriate expertise available in the European regulatory network to guarantee access to PRIME to all categories of products, including prophylactic and therapeutic vaccines.
Novel manufacturing technologies: novel manufacturing technologies are key enablers for effective and sustainable supply of products. It is crucial to understand the regulatory implications of novel approaches. Gaps in regulatory framework should be identified and strategies established to address them.

Second choice (h)

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

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.

The possibility to receive good quality advice from EMA on medicine’s development is very important and several options already exist. However, VE would welcome a more integrated approach to regulatory consultations rather than receiving separate advice from different committees (CHMP, PDCO, etc).
Comments on underlying actions
Promote more integrated medicines development aligning scientific advice, clinical trials approval and GCP oversight: VE welcomes the proposal. The fact that approval of clinical trial applications (CTA) in EU is a national competency has some limitations. Before submitting a CTA, companies may decide to consult a national competent authority to obtain advice on the supportive data package and on the study design. As

most clinical trials are multi-country, sponsors must consult several national regulatory agencies and may have to reconcile divergent opinions. The possibility of multi-country pre-CTA advice should be promoted.
Create complementary and flexible advice mechanisms to support innovative product development expanding multistakeholder consultation platforms: The value of parallel CHMP/HTABs scientific advice is recognized for drugs. For prophylactic vaccines, involvement of recommending bodies (NITAGs) is key and not yet routinely possible (only one pilot so far). VE wants to insist on the need to consider vaccine specificities when creating multistakeholder consultation platforms. See comment on 1st choice.
Facilitate translation of innovation via a re-engineered ITF and synergy with an evolving EU-Innovation Network platform: With the emergence of new technologies, it will be key that appropriate expertise is available in the European regulatory network to provide relevant advice to vaccine developers.
Additional comments
Advice on target product profile (TPP): FDA offers the possibility of early consultation on TPPs. TPP discussion early in development is very useful as it allows the company to understand what data package would be needed to support specific label claims. EMA should consider offering a similar option.
Pre-competitive discussions on regulatory requirements: Discussion at the Vaccine Working Party in 2017 on regulatory requirements for the development of Group B Streptococcus vaccines and FDA workshop on the development of respiratory syncytial virus vaccines in 2015 are examples of multi-stakeholder pre-competitive discussions. Such early engagement on specific class of vaccines or specific diseases are very important for vaccine manufacturers. Such initiatives should be more systematically organised and be further improved by involving regulators from the major regulatory agencies, involving NITAGs and ensuring that follow-up discussions occur when new data become available.
FDA/EMA parallel Scientific Advice (SA): VE acknowledges that EMA/FDA parallel SA is possible but not frequently used by industry. One reason is that the same questions must be asked to both agencies. Therefore, companies using the parallel SA may need additional consultations with one or both agencies separately to address agency-specific questions (e.g. questions on EOP2 relevant only for FDA). To improve the procedure, companies could be allowed to identify questions addressed to both agencies or relevant for EMA or FDA only as is the case for parallel EMA/HTA SA. VE recommends that potential improvements of the FDA/EMA parallel SA are discussed in the context of EMA Focus Group on opportunities leading to a more integrated R&D product support.
Development of vaccines for use outside EU/EEA: EMA plays a critical role in advising companies on the development of vaccines for use outside EU/EEA. VE encourages EMA to strengthen the collaboration with WHO and national regulatory authorities.
Earlier appointment of the rapporteur: Early appointment of rapporteurs is only possible for products granted PRIME designation. Extending this concept to any product would allow EMA to provide comprehensive feedback along the development continuum and streamline the assessment of the marketing authorisation application.
Clinical trials with GMO: In EU, the genetically modified organism (GMO) notification is study specific, a new submission must be done for each clinical study even if conducted with the same GMO. Although there is a central EU legislation governing clinical studies with GMOs, interpretation and application at national level vary from country to country, resulting in different procedural requirements, different review timelines, and can result in different opinions, with the same GMO considered as deliberate release or contained use depending on the country. The introduction of a supra-national review process (e.g. by the creation of an expert committee at EMA level) leading to an assessment valid across EU and alleviating the need for submission of dossier for subsequent studies in other countries unless new data emerge, would reduce the overall complexity of the process.

Third choice (h)

25. Promote global cooperation to anticipate and address supply challenges

3rd choice (h): please comment on your choice, the underlying actions proposed and identify any additional actions you think might be needed to effect these changes.

The vaccine market is characterised by a very limited number of suppliers. This is mainly due to the complexity and risks associated with vaccine manufacture which is “one of the most challenging industries” (Plotkin, 2017). The vaccine sector faces unique challenges raising fundamental sustainability questions. Improving availability of high quality, safe and effective vaccines in times of increased but insufficiently predictable global demand within the constraints of complex manufacturing processes, long production lead times and increasing complexity of regulatory requirements, whilst ensuring investment in future vaccines, can only be achieved by a strong industry willing and able to invest. It requires an environment that recognizes, rewards and invests in the added value of existing and new vaccines and promotes mutual efforts to increase efficiency in forecasting, procurement and supply of vaccines.

Shortages of medicines, including vaccines are of increasing concern. The causes of vaccine shortages are multiple and include: 1)increased global demand, 2)lack of mechanism to anticipate the demand sufficiently in advance, 3)long manufacturing and control processes due to the characteristics of vaccines which are complex biological products, 4)need to comply with ever increasing and diverse regulatory requirements worldwide and 5)impact of pricing, reimbursement and procurement policies.

Vaccine industry does its best to avoid shortages. Manufacturers: 1)increase industrial capacity by continuously optimising existing manufacturing process and analytical methods robustness as well investing in new facilities; 2)do their best logistically to manage the lack of harmonization and insufficient reliance /mutual recognition in terms of i)country specific product and packaging requirements, ii)management of non-standardised quality requirements, non-harmonised pharmacopoeias, product specifications and quality control methods, iii)management of an increasing number of national control laboratories testing successively the same batch (same batch tested up to 6 times), iv)CMC post-approval complexity; 3) communicate with authorities on potential supply disruptions to facilitate appropriate response and mitigation; 4)engage in dialogue with Health Authorities to improve supply continuity. VE continues to reflect on the causes of vaccine shortages and to propose solutions that could allow to reduce vaccine shortages. However, finding solutions will require concerted efforts and dialogue with the involvement of all key stakeholders.

Comments on underlying actions

Build on deliverables from the work plan of the HMA/EMA TFAAM: Industry is committed to work with authorities to find solutions to have medicinal products accessible to people globally, and make healthcare more sustainable whilst securing future medical innovation. VE welcomes the setting up of a pilot when the HMA/EMA guidance on shortage notification will become effective. A pilot phase is essential for industry to adapt internal processes to ensure compliance, and for both industry and regulators to test the concepts and requirements described in the guidance in view of proposing improvements if necessary.

Explore mechanisms to increase manufacturing capacity in Europe and internationally: Reasons for vaccine shortages are multiple and finding solutions will require concerted efforts and dialogue with all key stakeholders. It is important to underline that vaccine manufacturers are producing vaccines for EU and beyond, and that the multiplicity of languages and individual market requirements make vaccine supply particularly complex in EU. VE has identified a series of recommendations to improve vaccine supply and is willing to cooperate with different stakeholders on this topic. Amongst these recommendations, global regulatory convergence, mutual recognition agreements between EU and non-EU countries, and replacement of paper by e-leaflet are topics falling under the remit of EU institutions and that could increase supply in the EU and beyond. Promoting and facilitating implementation of novel manufacturing technologies is also important to increase capacity.

Enhance collaboration with WHO in the area of supply disruptions due to manufacturing quality issues & Promote greater knowledge exchange with international stakeholders on shortages due to quality /manufacturing issues: VE is ready to collaborate with relevant stakeholders, including EC, EMA, HMA and WHO on these topics.

Continue to engage with HCPs, patients and consumers organisations and the industry to address the

causes and consequences of lack of medicines availability: VE welcomes the fact that EMA considers industry as a key stakeholder for any further discussion on this topic.
Support international harmonisation of regulatory science standards for complex generic medicines addressing bioequivalence, waivers and modelling: Not applicable for vaccines.

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

Missing elements have been highlighted in responses to questions 5 and 7.

Question 7 (human): The following is to allow more detailed feedback on prioritisation, which will also help shape the future application of resources. Your further input is therefore highly appreciated. Please choose for each row the option which most closely reflects your opinion. For areas outside your interest or experience, please leave blank.

Should you wish to comment on any of the core recommendations (and their underlying actions) there is an option to do so.

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

	Very important	Important	Moderately important	Less important	Not important
1. Support developments in precision medicine, biomarkers and 'omics'	○	◉	○	○	○
2. Support translation of Advanced Therapy Medicinal Products cell, genes and tissue-based products into patient treatments	○	○	○	○	◉

3. Promote and invest in the Priority Medicines scheme (PRIME)	◉	○	○	○	○
4. Facilitate the implementation of novel manufacturing technologies	◉	○	○	○	○
5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products	○	○	○	◉	○
6. Develop understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals	○	○	○	◉	○
7. Diversify and integrate the provision of regulatory advice along the development continuum	◉	○	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation** you are commenting on:

Overall comment on strategic goal 1
New technologies will play a critical role in the development of innovative prophylactic and therapeutic vaccines as well as in vaccine manufacturing. VE therefore welcomes this strategic goal which aims at translating advances in science and technology into patient access to innovative medicines.
Science-based assessment of the benefit/risk balance of innovative vaccines using or produced by new technologies will be particularly important in the context of vaccine hesitancy.
The creation of complementary and flexible advice mechanisms to support innovative product development expanding multi-stakeholder consultation platforms as suggested by EMA is of importance but also access to already existing schemes, like PRIME for candidate vaccines that address unmet medical need would be beneficial.
Appropriate vaccine expertise in the European regulatory network to assess new technologies will be essential to facilitate the development of new vaccines and ensure public confidence.

Recommendation 3: Promote and invest in the Priority Medicines scheme (PRIME):
EMA is providing guidance along the development of medicines via the publication of regulatory guidelines and through direct interactions with medicines' developers during Scientific Advice consultations which is appreciated.
The PRIME scheme is also considered by industry to be a very useful tool to obtain enhanced and continuous support from the Agency during the development of innovative products. However, so far only four vaccines were granted PRIME designation, all of them targeting emerging threats. It is the view of vaccine manufacturers that some vaccines currently in development and intended for routine vaccination (e. g. RSV vaccines) should also benefit from PRIME. The proposal to promote and invest in PRIME is supported. However, vaccine manufacturers would like to insist on the need to have appropriate expertise available in the European regulatory network to guarantee access to PRIME to all categories of products, and in particular for prophylactic and therapeutic vaccines.

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

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**:

Overall comment on strategic goal 2
VE welcomes this strategy goal aiming at facilitating the development of and access to new medicines by implementing new tools, new clinical trial approaches and improved communication with other stakeholders. Vaccines specificities, for instance in terms of clinical trial design and stakeholders (National Immunisation Technical Advisory Groups, NITAGs), should be specifically covered in the ongoing reflection.

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**:

Overall comment on strategic goal 3
This strategic goal aims to advance patient-centred access to medicines which is something that VE strongly supports. This is particularly relevant for prophylactic vaccines administered to patients with chronic illnesses and for therapeutic vaccines.
VE recognizes the clear value of stakeholder engagement and alignment foreseen, and the new means to evaluate medicines (RWD, Big Data) and communicate these assessments in a more dynamic fashion (ePI).

Recommendation 18: RWD is important to vaccines because it is essential data that simply cannot generally be replicated in a clinical trial environment without excessive burden, limiting the ability to compete for resources with non-vaccine products, and without delaying access to potential public health benefits.

Recommendation 20: Delivering improved product information in electronic format (ePI) is important but VE considers that acceptability of a common label on the primary container, a common/single pack across EU /EEA MSs is also needed.
The labelling and packaging requirements applicable across EU/EEA countries are described in Directive 2001/83/EC on the Community code relating to medicinal products for human use. Despite this common basis, complexity arises from the local implementation of the directive requirements by the different MSs and from the need to translate the outer/immediate packaging and the package leaflet into the 24 official EU languages to comply with legal requirements. For vaccines, the use of multilingual packs/package leaflets is strongly limited by logistical constraints. Indeed, since the vast majority of vaccines have to be stored in refrigerated conditions, it is critical to reduce as much as possible the size of the packs to facilitate storage. For vaccines, multilingual packs are therefore limited to a maximum of three different languages. Acceptability of a common label on the primary container, a common/single pack across EU/EEA MSs and the replacement of the paper package leaflet by an electronic package leaflet available in all 24 EU languages would be key measures to facilitate the transfer of doses within EU/EEA and ultimately vaccine supply.

Recommendation 22: This is considered more important for vaccines than for other pharmaceutical products as vaccines are usually given to healthy people, including young infants. Transparency and trust in the European regulatory system are key to address vaccine hesitancy.

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**:

Overall comment on strategic goal 4
VE welcomes strategic goal 4 which is to ensure that the regulatory system can respond effectively to address the need for, and availability of medicinal products to tackle existing and emerging health threats such as antimicrobial resistance and emergence of new pathogens.
VE has selected the following recommendations from strategic goal 4 “Support innovative approaches to the development and post-authorisation monitoring of vaccines” and “Promote global cooperation to anticipate and address supply problems” as top priorities (see answer to Question 5).

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

	Very important	Important	Moderately important	Less important	Not important
28. Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science	○	◉	○	○	○
29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	○	○	◉	○	○
30. Identify and enable access to the best expertise across Europe and internationally	○	◉	○	○	○
31. Disseminate and share knowledge, expertise and innovation across the regulatory network and to its stakeholders	○	◉	○	○	○

Please feel free to comment on any of the above core recommendations or their underlying actions. **Kindly indicate the number of the recommendation you are commenting on**:

Overall comment on strategic goal 5
Overall, VE considers this goal to be one enabler of numerous recommendations under the previous goals. Consequently, although the strategic goal 5 and the recommendations as described in the consultation document seem to focus narrowly on the engagement between regulatory authorities and academics, the industry also recognizes the value of this goal.
Moreover, VE would like to emphasize that to truly achieve the goal of enabling and leveraging research and innovation in regulatory science, both academic and industrial researchers should be involved in this strategy.

Recommendations 28 and 29: Industry welcomes to be associated with academic network and collaboration.
Recommendation 31: Appropriate vaccine expertise in the European regulatory network is essential. Therefore, dissemination and sharing knowledge across the network is considered important by VE.

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