Public consultation on European Medicines Agencies Network Strategy to 2028

Fields marked with * are mandatory.

Introduction

The European Medicines Agencies Network is currently working to review and updated its five-year strategy, which originally covered the period 2021 to 2025 (EMANS 2025), to align with the Network's goals and objectives up to 2028.

The updated strategy takes into account the progress made so far (as outlined in the mid-term report) and recognises the need to adapt to emerging initiatives, technological advancements, environmental challenges, and other rapid developments that are reshaping the regulatory landscape.

The updated strategy (**EMANS 2028**) also reflects the ongoing revisions to EU pharmaceutical legislation. While the strategy cannot anticipate the specific outcomes of these legislative changes, it will help the network take preparatory steps to ensure a smooth implementation once they are finalized.

The considerations forming the basis for the draft strategy to 2028 are outlined in **the Reflection Paper on EMANS 2028**. While the Reflection Paper is not open for consultation, it is published alongside the draft strategy document to provide additional context on the proposed goals and objectives.

The updated strategic focus areas for EMANS 2028 will be as follows:
• Accessibility
• Leveraging data, digitisation and artificial intelligence
• Regulatory science, innovation and competitiveness
• Antimicrobial resistance and other health threats
• Availability and supply
• Sustainability of the network

The purpose of this public consultation is to seek views from EMA's and HMA's stakeholders, partners and the general public on the new proposed joint **European Medicines Agencies Network Strategy to 2028** and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, there is an opportunity to help shape the strategy for the coming years, 2025-2028.

The views being sought on the proposed strategy refer both to the extent and nature of the broader strategic theme areas, goals and objectives.
The questionnaire has been launched on **9 October 2024,** to enable stakeholder feedback to be collected on the draft network strategy and will remain open throughout the consultation period until **30 November 2024**. In case of any queries, please contact: EMANS2028@ema.europa.eu.

Additionally, in January 2025, a virtual HMA/EMA multi-stakeholder workshop will be held to present how the feedback received has been incorporated into the draft EMANS and to gather further input before final adoption.

Completing the questionnaire

This questionnaire is designed to simplify the process of providing your input and should be completed once you have read **the draft EMANS to 2028**. The survey is divided into a general section on the whole document and then focuses on each of the goals and objectives per strategic focus areas. You are invited to complete the sections which are most relevant to your areas of interest.

We thank you for taking the time to provide your input. Your responses will help to shape and prioritise the future objectives of the European Medicines Agencies Network.

EMA Data Protection

In this survey EMA does not collect or process personal data. Therefore, please make sure that you do not reveal your identity or include other personal data in the free text answers. The survey is designed to collect the answers only in an aggregate and anonymous format.

The responses will only be evaluated and the results shared in an aggregate way.

For the collection of data in this Survey EMA relies on the EU Survey external system. For more information on how EU Survey processes personal data, please see: https://ec.europa.eu/eusurvey/home/privacystatement

The EU Survey external system uses:

- Session "cookies" in order to ensure communication between the client and the server. Therefore, user's browser must be configured to accept "cookies". The cookies disappear once the session has been terminated.Local storage to save copies of the inputs of a participant to a survey in order to have a backup if the server is not available during submission or the user's computer is switched off accidentally or any other cause.
- The local storage contains the IDs of the questions and the draft answers.
- IP of every connection is saved for security reasons for every server request.
- Once a participant has submitted one's answers successfully to the server or has successfully saved a draft on the server, the data is removed from the local storage

Stakeholder Information

* ***Name of organisation (if applicable):***

If not applicable, please insert "n/a"

EFPIA

* **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 regulatory body
- ○ Other

* ***Please specify:***

Please select one option that best describes your organisation

- ☐ Individual company (non-SME)
- ☑ Trade association
- ☐ SME

* **Question 2: Please indicate which area is relevant to your area of interest?**

Please select one or both options, as applicable

- ☑ Human
- ☐ Veterinary

Strategic Themes - Goals focus

In this section please provide your feedback on goal prioritisation for each strategic theme.

Question 3: 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 further, there is an option to do so in the next section under each of the objectives.

Strategic Theme area 1: Accessibility

	Very important	Important	Moderately important	Less important	Not important
1) Optimise the path to accessibility by working with other decision makers (HTA bodies and payers).	○	◉	○	○	○
2) Deepen engagement with healthcare policy makers on initiatives and research relevant to sustain health technology accessibility.	○	○	◉	○	○

Strategic Theme area 2: Leveraging data, digitalisation, and artificial intelligence

	Very important	Important	Moderately important	Less important	Not important

1) Maximise the generation, interoperability, use and exchange of data to support EU decision-making.	○	◉	○	○	○
2) Leverage digitalisation, experimentation and innovation to deliver optimised regulatory processes.	◉	○	○	○	○
3) Realise the network vision on AI across all EMANS focus areas.	◉	○	○	○	○

Strategic Theme area 3: Regulatory science, innovation, and competitiveness

	Very important	Important	Moderately important	Less important	Not important
1) Promote the integration of advancing science and technology in medicines development and manufacturing.	◉	○	○	○	○
2) Foster generation of high quality and impactful evidence with particular focus on clinical trials.	◉	○	○	○	○
3) Promote stakeholder cooperation to accelerate the translation of innovation into therapies, facilitate the repurposing of existing therapies and increase EU competitiveness.	○	◉	○	○	○

Strategic Theme area 4: Antimicrobial resistance and other health threats

	Very important	Important	Moderately important	Less important	Not important

1) Contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach.	○	◉	○	○	○
2) Support development of new antimicrobial agents and alternatives to the use of antimicrobials in collaboration with international partners.	◉	○	○	○	○
3) Strengthen regulatory preparedness for health threats.	○	○	◉	○	○

Strategic Theme area 5: Availability and supply of medicines

	Very important	Important	Moderately important	Less important	Not important
1) Strengthen the availability of medicines to protect public and animal health.	○	◉	○	○	○
2) Reinforce the oversight and protection of the supply chain and increase inspector capacity.	○	○	◉	○	○

Strategic Theme area 6: Sustainability of the network

	Very important	Important	Moderately important	Less important	Not important
1) Reinforce the scientific and regulatory capacity and capability of the network.	◉	○	○	○	○
2) Establish a shared operating model to support network activities and collaboration.	◉	○	○	○	○

3) Strengthen public and stakeholder engagement and global convergence with international partners.	◉	○	○	○	○

Strategic Themes - Objectives focus

In this section please provide your feedback on the identified objectives for each Strategic Themes.

* Please indicate which Strategic Theme area(s) you would like to provide input on:

Please select as many choices as applicable.

- ☑ 1. Accessibility
- ☑ 2. Leveraging data, digitalisation, and artificial intelligence
- ☑ 3. Regulatory science, innovation, and competitiveness
- ☑ 4. Antimicrobial resistance and other health threats
- ☑ 5. Availability and supply of medicines chain challenges
- ☑ 6. Sustainability of the network

Strategic Theme area 1: Accessibility

Question 4: How would you rate each objective in terms of priority?

Contribute to the successful implementation of the HTA Regulation.	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA shares the goal of timely access to medicines for patients. Collaboration with HTA bodies is crucial to improve accessibility and sustain HTA, although their distinct roles must be maintained. EFPIA values scientific advice from regulators and HTA bodies but stresses the need to uphold the remits of regulators, HTA bodies, and payers, as they provide critical checks-and-balances. EFPIA supports the network's aim to create a predictable path to accessibility, but emphasises the need for caution so that added requests for evidence, duplication, and over-administration do not create a deadlock to advance development - reducing the EU's innovation competitiveness

Foster the generation of robust scientific evidence to serve different decision makers (regulators, HTA bodies and payers).	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports collaboration between HTA bodies and EMA to ensure access to products, particularly through expedited regulatory pathways, and to manage uncertainty. However, EFPIA warns against raising evidence requirements unnecessarily, as this could add complexity to development programmes, reduce efficiency, and delay access to new medicines. Evidence generation should be appropriate, balanced, and context-specific. Developers should retain full control on how they address evidence expectations of both regulatory and HTA bodies. Given their role in evidence generation plans and investments it remains important for industry to participate in methodological discussions with decision-makers
Enhance communication with other decision makers about the scientific considerations leading to regulatory outcomes.	Answer: ( ) High priority (●) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports transparency of how MA decisions are taken but cautions that not all information should be exchanged between regulators and HTA bodies; each has distinct remits and may draw different conclusions from the same data. Confidential information that is shared should be safeguarded. EMA should continue its practice of explaining to HTA bodies how they reached their decisions. This helps contextualize the acceptance of higher uncertainty and informs HTA bodies about the clinical and disease context. This is particularly the case where science has evolved, has been qualified and validated by regulators, and should be acknowledged and recognised by HTA bodies in their decision-making

Contribute to initiatives exploring the perspective different stakeholders have about unmet medical needs and how they inform considerations about clinical significance, significant benefit and major contributions to patient care.	Answer: ○ High priority ○ Medium priority ◉ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports calls for a common understanding of UMN but recognises that common considerations won't always lead to the same decision on what is an UMN due to differing legal mandates, governance, and processes among regulators, HTA bodies, and payers. Any deliberation on UMN should foster innovation and better patient access, not hinder it, particularly as the potential to meet an UMN is a condition for eligibility to many expedited regulatory pathways. Although following an inflexible definition is unlikely to keep pace with scientific advances, EFPIA believes that EMA should follow a consistent approach to consider UMN without taking affordability into account
Conduct research to better understand accessibility for medicines addressing unmet needs and how evidence requirements affect decision outcomes.	Answer: ○ High priority ○ Medium priority ◉ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Through their respective mandates and remits, among other roles, regulators speak for scientific, pharmacological advancement, balancing efficacy and safety, and progressing innovation; HTA bodies speak for promoting health-care system interests and medicine use effectiveness; payers speak for efficiencies and budgetary effectiveness: the context and perspectives of those decisions are different. While all have patients at the centre of their decision-making activities, it’s vital that the patient voice is actively considered when making decisions. Involving patients requires that participants have been provided with the necessary capacity and skills

Continue collaborative work on methodologies for the generation of evidence that is also relevant for health technology assessments.	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Fostering dialogue and collaboration between regulators and HTA bodies may be valuable. The network should take a cooperative approach, supporting JSC and encouraging the use of all data sources and innovative technologies for evidence generation. Scientific rigor and independence of MAA reviews should be ensured. Methodologies used by HTA bodies vary and the regulatory network could help to standardise the HTA methodology with the evolving regulatory methodologies to have a positive impact on medicines' access. The network should also promote acceptance of novel and innovative clinical trial designs to help ensure EU does not fall behind or become an afterthought

Strategic Theme area 2: Leveraging data, digitalisation, and artificial intelligence

Question 4: **How would you rate each objective in terms of priority?**

Embed the use of EU healthcare data from diverse populations in the network's processes and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, e.g. genomic data)	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports the use of data from a range of populations and types. This can partly be achieved through consistent data access rules under the EHDS Regulation. The rules should foster innovation while not compromising, patient privacy, IP rights and commercially sensitive information. With the availability of new technologies and data sources, the strategy should include provisions to enhance expertise and readiness to handle these. To support initiatives in new areas, overarching cross-domain regulatory guidance is needed that provide direction but remain flexible enough to allow developers to use innovative approaches to generate the necessary evidence for decision-making

Ensure a high level of interoperability, standardisation and quality of data addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports greater interoperability, standards, quality, and tools to increase shared trust and confidence in data use throughout the lifecycle. PMS as a single source of truth should be prioritised. Regarding the routine use of IPD from clinical trials, clarity is needed on the purpose, types of, and resources for data analysis. We encourage collaboration with other regulators who are already routinely assessing IPD. EFPIA encourages that appropriate level of data granularity is accounted for to support unbiased, quality datasets for AI models and algorithms. Interoperability is crucial to monitor supply. Safeguarding data from cyber breaches is essential for trust and compliance
Reinforce the network's digital infrastructure in line with the Network Portfolio Vision to drive the digital transformation of the network's scientific and regulatory processes	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports using digital technology and AI to transform the work of the network and industry in regulatory processes. To maximize efficiency and quality, transparency on actions and shared learnings between regulators and industry, and collaboration on designing solutions is encouraged. We propose developing a clear vision of digital regulatory processes and a roadmap of initiatives alongside regular updates on how authorities leverage AI and new IT tools. Global alignment on data standards is also needed. IT tools can support the scientific continuum across EU NCAs making procedures more agile while addressing potential vulnerabilities
Foster a culture of continuous experimentation and innovation across the network	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* A culture of continuous experimentation and innovation is crucial in particular to realize practical innovations such as harmonized implementation of electronic package information. The potential for the network to use cloud technology to streamline administrative tasks and maintenance submissions should support freeing-up resource capacity while ensuring the continued availability of existing products on the market

Leverage experimentation and technological advances in AI to support the digital business transformation of the EU network	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA encourages the network to share experiences and initiate dialogue with the industry regarding the implementation of digital technologies, fostering an exchange of learnings. It should ensure alignment with appropriate regulatory standards, providing a robust framework that can be revised over time as the field evolves. This approach will enable companies to invest confidently in new technologies, knowing that innovation is encouraged without compromising patient protection and the integrity of the digital marketplace
Harness the potential of AI throughout the medicines' lifecycle	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA recommends adopting a flexible and practical approach towards harnessing the full potential of AI to strengthen regulatory decision making. We recommend the network develops Q&A documents for this fast-moving field, in addition to hosting public discussion and mutual information sharing of the developing practices in industry and regulators. EFPIA believes that transparency in AI use for regulatory processes is crucial to help showcase how ethical AI use has been validated. EFPIA also supports cross-collaboration among teams and regulators to leverage AI safely and responsibly for patients' interests

Strategic Theme area 3: Regulatory science, innovation, and competitiveness

Question 4: **How would you rate each objective in terms of priority?**

Continue to support innovation and the integration of scientific and technological advancements in the development of human and veterinary medicines	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports the goal to maintain the EU's competitiveness in developing innovative products and attracting & promoting R&D. We agree with the need to address complexity, funding, and innovation fragmentation in the EU. There is a need to support sustainable innovation in Europe and facilitate the adoption of scientific and technological advancements in medicine development and manufacturing through regulatory guidance. Maintaining a competitive environment for developing devices/diagnostics requires flexible & pragmatic implementation of the regulations and alignment with the CTReg. The EU framework needs to keep up with other regions so EU patients can receive the same benefits
In collaboration with other EU bodies, implement a model for efficient, timely and coordinated EU horizon scanning for human and veterinary medicines that address the needs of regulators, HTA bodies and payers, supported by digital tools and AI	Answer: ( ) High priority (•) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* The EU must foster communication and collaboration among stakeholders to prevent working in silos. EFPIA stresses the need for coherent legislative frameworks to avoid fragmentation among new EU agencies like those focused on the AI Data Act and ERA. Horizon scanning should lead to upskilling and preparing healthcare systems for novel technologies. Methodologies must be adapted for all reviewers to understand modern technologies. Establishing guardrails around collaborations is crucial due to different remits and decision contexts. Ensuring a comprehensive view is key to reducing complexity and fostering novel solutions, with attention to coherence at both EU and Member State levels

Facilitate the implementation of novel manufacturing technologies and analytical techniques	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* The strategy explains that “(s)uch innovations may require novel manufacturing technologies and delivery approaches, including nanotechnology, 3D printing, decentralised in situ manufacturing and the greater use of medical device/medicinal product combinations and related diagnostics”. EFPIA concurs and wishes to see many of these innovations better encouraged, supported and occurring with greater frequency in the EU
Support the generation of high-quality evidence in quality, non-clinical and clinical domains by researchers and sponsors from early development stages and provide timely scientific and/or regulatory advice	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* The strategy underscores the network's role in enhancing EU competitiveness by supporting innovators. A robust, well-resourced network is vital for fostering innovation; thus, EU regulators should have a strong plan to hire and retain staff with the right expertise and provide ongoing training to ensure consistent approaches across the network. Collaboration globally is crucial for supporting future innovation and should also be emphasized to help build capacity. EFPIA stresses the continued need for timely, iterative, and integrated dialogue between medicine developers and regulators to ensure optimal development plans

Foster innovation and the improved planning and conduct of clinical trials and emerging clinical data generation	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EU needs a clinical research framework that supports faster, smarter, and more patient-centric clinical trials, but barriers exist within today's EU CT ecosystem. EFPIA believes a more European approach to the oversight of clinical trials should be introduced, including alignment on the requirements for CTAs, incorporating scientific and technological advancements and mechanisms for engaging with NCAs. A sense of urgency is needed to reverse the EU's decline in clinical research, including an assessment of the CT Regulation and taking action to ease the conduct of multi-country CTs. EFPIA also emphasizes the need to consider complex, innovative quality and non-clinical domains
Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation in collaboration with other EU initiatives and institutions e.g. JRC.	Answer: ( ) High priority (•) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* This objective is important to stimulate and foster non-clinical models that will ultimately streamline R&D. As urged by the revision of the pharma legislation, collaboration among EU scientific authorities and bodies regarding the scientific assessment of relevant substances, exchange of data and information, and development of coherent scientific methodologies, including the 3Rs for animal testing, is key. This approach should take into account the specificities of the assessment of medicinal products. Additionally, it is crucial to ensure an aligned international approach to facilitate an overall reduction in the use of animal models

Develop network-led partnerships with key stakeholders (e.g. academia and industry) to deliver impactful progress in regulatory science and provide training	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA agrees with the network that revising the EU pharmaceutical legislation offers a unique chance to modernize and future-proof the regulatory framework to address challenges although EFPIA believes that some of the proposals need further modification to achieve this aim. Revising the legislation is only one available approach to evolving the regulatory framework so that it is suitable to bring future innovations to patients. EFPIA stresses the need for multistakeholder collaboration in translating regulatory research into useful tools for drug development and to improve the current practices. Both the EMA and national authorities have an important role in endorsing these tools
Enhance the regulatory competence of researchers and developers from academia, hospitals and SMEs to facilitate the translation of research into innovative medicines through direct support and pre-competitive research collaborations	Answer: ( ) High priority (●) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA encourages the Network to continue supporting knowledge exchange with academia, hospitals, SMEs, and other non-commercial researchers on regulatory science to facilitate the translation of research into brining innovative medicines to patients and healthcare systems. It is important to highlight the need for, and encourage participation in, pre-competitive collaborations, such as those under the IHI, to ensure they produce outcomes that translate into regulatory acceptability and ultimately become part of the development toolbox

Increase collaboration with medical device experts, notified bodies, ethics and patient communities, HTA bodies and the Substances of Human Origin (SoHO) network in conjunction with the European Commission to support development and authorisation of combination products	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Using novel technologies, new therapies being developed are increasingly more complex. Therefore, a closer collaboration among stakeholders involved in medical devices and combination product development is important to create a more efficient innovation ecosystem. The fragmented EU regulatory framework for combination products poses complexity, unpredictability, and inefficiency challenges. Reforms should streamline requirements while ensuring patient safety. EU's competitiveness is hindered by duplicated processes for drug device combinations. The network should support removing national requirements and creating a single regulatory process for CTAs and MAAs for combination products

Strategic Theme area 4: Antimicrobial resistance and other health threats

Question 4: **How would you rate each objective in terms of priority?**

Continue to implement the requirements for the mandatory collection and reporting of sales and use data for antimicrobials in animals, and improve access to information and data and communicate the findings	Answer: ( ) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum*

Modernise the product information of existing antibiotics for veterinary use and consider additional options for guiding prescribing practices. For human medicines, take account of ongoing initiatives, while incorporating relevant new provisions in the new pharmaceutical legislation	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* An opportunity to modernize product information is to implement personalized electronic patient information. Easy access to electronic versions of patient information, personalized to the patient and from a trusted source, with the latest scientific and patient-friendly information is critical. This ensures the correct use of medicines, promotes understanding of their safety and benefits, helps patients adhere to their treatment, and thus promotes better outcomes and reduces medicine waste – especially important for antibiotics. Improved stewardship should include educating patients and HCPs for a better understanding of when and why antimicrobials should or should not be used
In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum*
Develop, update, and promote regulatory guidance on antimicrobial use in animals to guarantee therapeutic options and minimise the impact of antimicrobial resistance while also support the development, implementation and uptake of guidance for human medicines	Answer: ○ High priority ○ Medium priority ◉ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum*
Provide guidance on regulatory pathways for phages and other innovative products in human and veterinary medicine, engaging with relevant stakeholders	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum*

Engage stakeholders in pipeline discussions with a view to facilitating the development and eventual authorisation of relevant products	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA concurs with this objective since we understand the value of regulators' input to innovators during pipeline/portfolio meetings. Early interactions with regulators are key to support innovation in Europe. There is a need to adjust PRIME in support of a streamlined development of antimicrobial products and to extend eligibility to include extension of indications
Provide systematic support to developers of new antimicrobials, including antibacterials and alternatives to the use of antimicrobials, mainly through the ETF, and for veterinary medicines through the Innovation Task Force (ITF) and veterinary medicines Scientific Advice Working Party	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA fully supports the network's suggestion that a Transferable Exclusivity Voucher, proposed in the pharma legislative review, could be a possible incentive for antimicrobial development. There is an urgent need to introduce a sustainable pull mechanism in the legislation to restore the antimicrobial pipeline. EFPIA also questions why systematic support for antimicrobial developers is routed through the Emergency Task Force, which focuses on public health emergencies. This group has too narrow a focus for antimicrobial resistance, an ongoing concern that should be addressed by one of the other working groups
Support the European Commission and Member States in the implementation of new business models for antimicrobials (particularly antibiotics), including eligibility assessment	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA underscores the need for robust support in defining eligibility criteria essential to the effective implementation of pull incentives for antimicrobial R&D, notably through the transferable exclusivity voucher, if introduced following the pharma legislation revision. Collaboration between the EMA and the European Commission will be crucial to ensure these incentives are applied in a streamlined and impactful manner, fostering innovation while addressing urgent antimicrobial needs

Refine regulatory activities to increase preparedness and harmonise approaches for investigating medicinal products during emergencies, including for conducting timely clinical trials during emergencies	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* It is important to reflect on the learnings of COVID-19 and streamline the regulatory pathways to approve investigational medicinal products for prevention and treatment during emergencies. During the pandemic It was demonstrated that existing pathways can be optimised, reliance implemented, and administrative burden reduced. In addition, EFPIA recognises the need for regulators to help build clinical trial networks so that all evidence generated from clinical trials during emergencies contributes to the scientific understanding of the emergency
Respond to health threats that could be related to climate and environmental changes, using the One Health approach as defined by OHHLEP when applicable and in close collaboration with other Union agencies	Answer: ( ) High priority (•) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* The strategy notes that this objective connects to the EU's strategic approach to pharmaceuticals in the environment and the ongoing review of the EU Water framework directive. Public-private partnerships should be supported and the industry involved to work towards common solutions on depolluting the environment, especially when pollution emerges from pharmaceutical products. At the same time, other factors of pollution should be explored (e. g., improper disposal of medicines). Finally, any depollution framework such as EPR schemes based on polluter-pays principle should be fair and proportionate to the specificities of medicines
Expand the international alignment on regulatory requirements from quadrilateral (FDA-Health Canada-PMDA-EMA) agreements to achieve more global consensus	Answer: ( ) High priority (•) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* International alignment and convergence are key to accelerate access to innovative medicines. If there is no opportunity for that, reliance approaches should be considered and used

Adopt necessary regulatory flexibilities to support the development and authorisation of countermeasures for use in emergencies, including those caused by chemical, biological, radiation and nuclear threats	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* The EU network should reflect on potential threats and possibilities of increasing regulatory flexibilities and reliance
Explore ways to better inform the public about medicines for health threats to engender trust in the medicines and the regulatory system	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA recognises the efforts already made in this area and believe they should be sustained. These actions help to inform the public about medicines for health threats and enhance public trust. A continued partnership with Industry on this initiative is also needed

Strategic Theme area 5: Availability and supply of medicines

Question 4: **How would you rate each objective in terms of priority?**

Identify specific root causes of shortages for human and veterinary medicines and develop harmonised strategies to improve the prevention and management of shortages, particularly for critical medicines	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Shortages can have varied and product-specific root causes. Cumulative requirements from the EU Green Deal and substance restrictions can disrupt supply chains. Tailored measures are essential due to varying supply constraints across TAs and countries. Stakeholder collaboration is necessary. A unified definition of Critical Medicines at country and Union level with a harmonized list and clear demand definitions can strengthen an EU-wide approach. Harmonizing shortage definitions, data-sets, and interoperable systems, with risk-based approaches, are needed to address shortages. Shortage prevention plans should focus on critical medicines and not be mandatory for all medicines

Improve coordination of activities related to improving availability of human medicines and implement best practices in conjunction with stakeholders and international partners	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA agrees regulators must work closely with MAH, manufacturers, and international partners to manage shortages and oversee supply chains. A coordinated, structured, and reliable approach to discuss and plan for future public health emergencies is needed. Fragmented policies across countries create hurdles in the supply chain, increasing the risk of shortages. Companies need evidence-based information on Member States' demand, as supply may exceed demand for some medications considered in short supply by other Member States. The use of ICMRA's PQKMS project is supported. Regulatory flexibility should also allow distribution of packs from other EU Member States
Work with the European Commission to coordinate national and EU strategies for human medicines, including stockpiling, to reduce possible impact of national measures on availability of medicines in other countries	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Measures to mitigate shortages should be proportionate and provide efficient, workable solutions for public health needs. Disproportionate national stockpiling or extraordinary demand increases can harm other countries, especially if safety stocks are blocked and multiple countries enforce them simultaneously. This approach is unsustainable. If safety stocks are necessary, they should be managed at a EU level, aligning with the solidarity principle and replacing national requirements. An EU safety stock policy, with EU-owned strategic reserves is more efficient, minimizing costs and optimizing supply allocation through cross-border flows

Improve transparency and communication on both the launch of medicinal products and shortages with relevant stakeholders, including patients, healthcare professionals and HTA bodies	Answer: ○ High priority ○ Medium priority ◉ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Effective communication around possible shortages avoids panic hoarding of medicines. Regular dialogue with authorities and demand creators prevents last-minute requests for additional supplies and ensures transparency of the supply chain. Once medicines reach wholesalers, there is no visibility on whether they are delivered to patients as needed or moved to other countries, creating an imbalance between supply and demand forecasts that MAHs cannot supervise. Regulators should work closely with wholesalers and parallel traders to avoid supply distortions. Standardizing the definition and reporting of supply interruptions will streamline efforts to address actual shortages
Ensure sufficient numbers of trained inspectors are continuously available to perform legal duties (see section on sustainability of the network)	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* The different Mutual Recognition Agreements on GMP inspections between the EU and third countries have resulted in important improvements in GMP site inspection efficiencies and have helped to manage the limited inspector capacity across the EU. These international mutual recognition agreements should be expanded to other product types, such as biologics (e g vaccines, plasma-derived medicinal products,), and cell and gene therapies, and other countries and regions. Furthermore, the reliance approach as proposed in the revision of the pharma legislation will facilitate targeting resources
Use risk-based inspection planning, alternative inspection methodology and collaboration with international partners to better target oversight of the supply chain, including for key finished product and API manufacturers	Answer: ◉ High priority ○ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Risk-based inspection planning can help to focus on where the problems are and help to reduce bureaucracy. Approaches could include elements such as reducing the length of inspections and the number of topics to be covered, based on prior available knowledge about the site / products / process. A further approach could be to focus the inspection on sites or subject matter not yet inspected by other inspectorates. As part of these necessary activities, the use of reliance agreements and hybrid inspections as well as development of Mutual Recognition Agreements should have an important place

Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines in the supply chain	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Counterfeit and illegally compounded medicines pose a significant threat to patients' health and safety. These unlawful medicines may contain incorrect or insufficient ingredients, rendering them ineffective or even deadly. EFPIA is committed to promoting access to safe and efficacious medicines, raising awareness about the dangers of counterfeit medicines, and combating unsafe medicines. Leveraging systems established as a result of the Falsified Medicines Directive to increase supply visibility and create an alerting system on low supply would be a significant step forward in supply chain policies
Keep GMP requirements updated in light of technological progress in manufacturing, (e.g. Digital, IA and other technological systems).	Answer: ◉ High priority ○ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA agrees that GMPs can improve and support manufacturers by providing principles of what to do. EFPIA also supports the update of GMP requirements in light of technological progress in manufacturing. However, there is a risk of overregulation if regulatory guidance is updated to reflect every technique, especially in a rapidly changing environment. It is also important to consider that GMP requirements are globally harmonized and this needs to be maintained, especially since many companies operate globally
Improve and inter-link information in current databases (e.g. EudraGMDP)	Answer: ◉ High priority ○ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports the development of an interoperable IT monitoring and prevention tool, linking the ESMP with the EMVS. This interoperability will provide real-time data to assess shortages and identify targeted solutions. The EMVS stores information on the number of packs supplied by manufacturers, dispensed in pharmacies and hospitals, exported or imported, and stock levels at the Member State level. This goal should also include better interoperability between the ESMP, SPOR master data, and national shortages reporting, while harmonizing data-sets

Strategic Theme area 6: Sustainability of the network

Question 4: **How would you rate each objective in terms of priority?**

Ensure the network has the capacity and capability to support innovation and the use of new methodologies, AI and data analytics and to be equipped for the new pharmaceutical legislation	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Capacity building is highlighted as a key theme; this aligns with EFPIA's regulatory policy priorities. The need for adequate resources, including funding, expertise, business processes, IT capabilities, and efficient governance for long-term projects are critical. EFPIA advocates for a robust, well-resourced regulatory network to achieve Europe's health and life science strategy goals. The use of AI, data analytics, and digitalisation should be explored as another transversal theme. Additionally, EFPIA also calls for more efficient resource use, in particular to reset the level of resource needed for lifecycle management activities and redeploy those resources to support innovation
Explore ways to improve efficiency by creating centres of excellence and allocating NCA resources more strategically	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* Creative solutions are needed to address EU regulatory resourcing constraints and this should be prioritised. EFPIA supports advancing multi-national assessment teams and OPEN. Establishing centres of excellence is of interest and could concentrate specialized knowledge leading to higher quality assessments and faster decision-making. Establishing a CoE approach should be evaluated to understand its added value, its impact on streamlined decision-making, and the risks to network resiliency. It should also not hinder the use of experts from across the EU during regulatory processes; one of the EU regulatory framework's strengths

Build the network's capability to carry out the digital transformation of its scientific and regulatory processes, ways of working and tools	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* It is crucial to develop well-equipped regulators with the network needing experts who understand science, regulation, and digital technologies at their interfaces. Although this expertise is rare, NCAs should use the fee increase to address this challenge through access to appropriate education and training pathways. New technology and IT tools enable qualified assessors to work with more agility and cohesion, creating strong knowledge management and institutional memory. By freeing resources from administrative tasks, the network can focus on complex regulatory activities. Modernizing processes with contemporary IT tools will benefit the entire EU regulatory network and healthcare overall
For human medicines, prepare for the implementation of new legislation combined with the modernisation and consolidation of IT systems	Answer: (●) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supported the revision of the EMA Fees Regulation to ensure the modernisation and sustainability of the regulatory system, allowing adaptability for emerging technologies that will address the future needs of healthcare systems across Europe. Along with fee generating activities, the Network should also receive a balance of public funding for upskilling staff and investing in infrastructure; essential network activities that are not fee-for-service based. IT systems and platform evolution would need to be coherent and well connected to avoid further layers of complexities in the EU system
For veterinary medicines, continue to build on the progress achieved in implementing the veterinary regulation and align IT solutions across sectors	Answer: ( ) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum*

Explore opportunities for shared data, process and technology initiatives and establish a model for joint EMA /HMA sponsorship for such initiatives	Answer: ○ High priority ◉ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports the IncreaseNET initiative to enhance the network's capabilities, including training on the contributions of GMP inspectors. The streamlining of the variations framework is crucial to improve efficiency and speed; the updated regulation and guidance better accounts for technical advances in development and manufacturing capacities. System evolution is necessary to facilitate continual improvement of manufacturing processes within today's global supply chains. EMA and HMA should work together to foster a culture of proportionality in clinical trial assessments to improve efficiency by reducing duplication of work
Contribute to the implementation of the new EMA fee regulation [1] and regularly monitor and adjust the cost-based system for fees and NCA remuneration	Answer: ◉ High priority ○ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* The new Fees Regulation aligns with EFPIA's principles of transparency, fairness, proportionality, sustainability, simplicity, and flexibility. EFPIA supports its goals to streamline the system, simplify the fee structure, provide a sound financial basis for EMA operations, remunerate NCAs for their contributions, and future-proof the system. EFPIA also urges Member States to ensure the fees actually fund the work of the NCAs to the EU regulatory framework
Enhance capacity of the network through international convergence, information and work sharing and multilateral cooperation	Answer: ◉ High priority ○ Medium priority ○ Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA agrees with the action to strengthen cooperation with international partners to address global regulatory challenges. The network has a 'gold standard' multi-country convergence and reliance model, providing valuable insights and leadership. EMA should leverage its experience to shape new models and expand international convergence opportunities. The EU's experience with reliance, especially in post-approval areas, supports sustainability but the focus should be on general international convergence. EMA should advocate for reliance on inspection outcomes and work with HMA to foster a culture of proportionality

Together with the European Commission, strengthen international collaboration to perform legal duties relating to inspections and to face global challenges related to new methodologies and continuous manufacturing	Answer: (•) High priority ( ) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* EFPIA supports convergence, work-sharing, and reliance for all aspects of a product's lifecycle, including inspections and import testing under MRAs with a focus on using existing dialogues to enhance international regulatory collaboration. The concept of global regulatory assessments and collaborative evaluation should be explored potentially facilitated by cloud-based platforms. Elements of Good Regulatory Practice and effective decision-making should be included in FTAs with third countries. ICMRA's PQKMS project will be key for strengthening cooperation, harmonization across and beyond the network, and better global regulatory convergence along with regulatory harmonisation through ICH
Support the establishment of the African Medicines Agency, strengthening cooperation between European, African and international partners	Answer: ( ) High priority (•) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum* As the burden of most commonly occurring communicable and non-communicable diseases shifts to low-middle income countries mainly in Africa, EFPIA is supportive of EMA's intent to aid the formation of the African Medicines Agency by sharing knowledge and expertise gained from the European National/Mutual recognition procedures as well as the centralized procedures. We encourage EMA to consider including other LMICs in the knowledge and expertise sharing as they might benefit from the EU experience as well
Develop and implement a framework for communication and engagement to address information needs of the public and counter mis /disinformation	Answer: ( ) High priority (•) Medium priority ( ) Low priority	(Optional) Please provide any specific comments you have. *700 character(s) maximum*

Overall strategy

Question 5: Having read the proposed strategy, what is your overall impression?

	Very positive	Positive	Neutral	Negative	Very negative
* What is your overall impression?	( )	(•)	( )	( )	( )

Any other comments *(optional)*

If you have any additional elements or further comments not highlighted in previous sections, please provide them here. Otherwise leave blank.

3000 character(s) maximum

The EU regulatory framework needs to be globally competitive and able to deliver future innovation to patients. The revised strategy and the revision of GPL contain positive provisions but it remains unclear if they will achieve this future proofing goal; competitiveness aspects could be better addressed. Although the proposed strategy incorporates future looking themes to advance regulatory science and preparing for the knowns and unknowns, it is not possible to anticipate every opportunity, risk, or scenario and we are concerned the strategy does not capture the complexity of future products and their manufacture.

The AMR section does not mention vaccines. They are now recognised as an essential component in the fight against AMR and regulatory agilities are needed to accelerate availability of AMR relevant vaccines Such omission, at a time when evidence of vaccines' impact on AMR is compelling, is a risk public health cannot afford to take. We recommend references to vaccines as crucial to address AMR, that they are currently underutilized in the AMR fight, and include a goal to introduce regulatory agilities and support development for AMR vaccines.

EFPIA is revising our regulatory strategy to deliver ambitious goals that will ensure the EU regulatory framework becomes more competitive and adaptive, while supporting innovation, enabling digital transformation and leveraging every opportunity to simplify, with patients/improving public health at its centre. Many of our key themes align with the strategy objectives including Improving the CT ecosystem, ensuring use of novel evidence and methodologies to generate evidence supports all decision-making, manufacturing/quality innovation, the interface between the drug and device/diagnostic regulatory frameworks, and ensuring a sustainable EU regulatory framework. There are several focus areas for EFPIA that do not appear to be addressed within the strategy and we recommend further consideration for their inclusion. These are simplification through digitalisation of the variations framework, the interface of the chemical and environmental legislation with the medicines framework, and establishing a more dynamic approach to assessing evidence for MAs as the evidence becomes available

We concur with the plan to sunset the strategy in 2028. At that time, it will be critical to conduct an evaluation of the progress made and enable another public consultation of the next strategic plan that will incorporate the GPL changes. Innovative medicine developers need the certainty and predictability that a roadmap provides even when disease, science, technology, innovation, and the political environment are all facing uncertainties

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

EU Medicines Agencies Network Strategy to 2028 (https://www.ema.europa.eu/en/documents/other/seizing-opportunities-changing-medicines-landscape-european-medicines-agencies-network-strategy-2028-draft_en.pdf)

Background Documents

EU Medicines Agencies Network Strategy to 2025

European medicines agencies network strategy to 2025: Mid-point report to Q2 2023

Reflection paper for EU Medicines Agencies Network Strategy to 2028

Contact

Contact Form