*The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.*

# CPME response to the Public consultation on European Medicines Agencies Network Strategy to 2028

On 7 November 2024, the CPME Board adopted the 'CPME response to the Public consultation on European Medicines Agencies Network Strategy to 2028' (CPME 2024/151).

# 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"

Standing Committee of European Doctors (CPME)

* **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

*** 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. | ◉ | ○ | ○ | ○ | ○ |

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| 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 |
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| 1) Contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach. | ◉ | ○ | ○ | ○ | ○ |

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| 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 |
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| 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.

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

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## Strategic Theme area 1: Accessibility

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

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| Contribute to the successful implementation of the HTA Regulation. | Answer:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>The new HTA Regulation will come into effect in January 2025 and EMA should support its successful implementation, together with healthcare professionals, patients and other stakeholders. |
| Foster the generation of robust scientific evidence to serve different decision makers (regulators, HTA bodies and payers). | Answer:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>We believe that a better integration between HTA and scientific approaches right from the start is needed in order to address real unmet medical needs of the patients, ensure a better positioning of medicinal products in the therapeutic strategy but also ensure the sustainability of healthcare systems. |

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| Enhance communication with other decision makers about the scientific considerations leading to regulatory outcomes. | Answer:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| 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:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>The network, along with other stakeholders, should engage in the discussion on establishing a common definition of “innovative medicine” as the one that meets a previously unmet or inadequately met, substantive health need and offers enhanced effectiveness or other incremental benefit relative to existing therapeutic alternatives (see OECD report on Pharmaceutical Innovation and Access to Medicines, November 2018, https://bit.ly/3gFrNIA). |
| Conduct research to better understand accessibility for medicines addressing unmet needs and how evidence requirements affect decision outcomes. | Answer:<br>( ) High priority<br>(●) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Continue collaborative work on methodologies for the generation of evidence that is also relevant for health technology assessments. | Answer:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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

Question 6: **How would you rate each objective in terms of priority?**

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| 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:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>With the emergence of artificial intelligence, new cybersecurity threats will emerge and those need to be considered. Data quality from different sources is also a challenge, as well as common criteria to collect patent experience data. |
| 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:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>Ensuring that the network data assets are appropriately managed is essential to generate trust and to serve as an example for the EHDS. EMA should also support the idea that ICT professionals working for the network abide to ethically-based codes of conduct and be subject to regulatory oversight and disciplinary sanctions. This would ensure that these specialists have an up-to-date competence, relevant to their field, and that they comply with professional obligations, reflecting a win-win strategic policy approach. |
| 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:<br>○ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Foster a culture of continuous experimentation and innovation across the network | Answer:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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| Leverage experimentation and technological advances in AI to support the digital business transformation of the EU network | Answer:<br>○ High priority<br>○ Medium priority<br>◉ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Harness the potential of AI throughout the medicines' lifecycle | Answer:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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

Question 6: **How would you rate each objective in terms of priority?**

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| Continue to support innovation and the integration of scientific and technological advancements in the development of human and veterinary medicines | Answer:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| 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:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Facilitate the implementation of novel manufacturing technologies and analytical techniques | Answer:<br>○ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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| 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:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Foster innovation and the improved planning and conduct of clinical trials and emerging clinical data generation | Answer:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>Innovation in clinical trial design must adhere to the same quality, safety and ethics criteria as established trials. |
| 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:<br>( ) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Develop network-led partnerships with key stakeholders (e.g. academia and industry) to deliver impactful progress in regulatory science and provide training | Answer:<br>( ) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| 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:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>The network could also encourage the inclusion of pro-public safeguards, such as transparency regarding public contributions and clauses on accessibility and affordability in all kinds of public-private cooperation that includes public funding. Such an approach should also be promoted at national level, where a significant amount of public resources is also dedicated to supporting early stages of biomedical research. |

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| 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:<br>(•) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

## Strategic Theme area 4: Antimicrobial resistance and other health threats

Question 6: **How would you rate each objective in terms of priority?**

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| 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:<br>(•) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>Collection and reporting of sales and use data for animals should be enhanced. We support the prevention of overuse of antibiotics in agriculture and environmental contamination leading to antimicrobial resistance must be a priority. Routine preventive use of antibiotics for healthy groups of animals must be banned. The use of critically important antimicrobials in agriculture and food production must be restricted.<br><br>We also defend that sale, including online, of over-the-counter antibiotics must be effectively banned in all Member States. European and national level controls must ensure compliance, adhering to current legislation. |

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| 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:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>In the context of the revision of the general pharmaceutical legislation, we welcome the use of ePI as a complementary tool to current paper leaflets to increase citizens' access to objective and neutral information at home. We advocate that the electronic product information (ePI) should never replace the paper version included in medicine packets but remain complementary. |
| In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests | Answer:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>We would also like to emphasize that prevention must be at the heart of all AMR-related actions. The network should support efforts to ensure high standards of infection prevention and control in all sectors and across all Member States.<br><br>Healthcare professionals must have access to fast and efficient point-of-care diagnostics to support prudent prescribing, and only in exceptional circumstances should antibiotics be prescribed without laboratory or point-of-care diagnostics. |
| 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:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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| Provide guidance on regulatory pathways for phages and other innovative products in human and veterinary medicine, engaging with relevant stakeholders | Answer:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Engage stakeholders in pipeline discussions with a view to facilitating the development and eventual authorisation of relevant products | Answer:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>An end-to-end approach to the development of new antibiotics is needed, supported by an innovative incentive model to decouple the revenue from the novel antibiotic from the quantity sold. Examples of such incentives are market entry rewards, guarantees for minimum turnover and milestone payments. See CPME Policy on AMR (https://shorturl.at/H1o94). |
| 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:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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| Support the European Commission and Member States in the implementation of new business models for antimicrobials (particularly antibiotics), including eligibility assessment | Answer:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>The network should support the development of new needs-driven models to finance and stimulate antibiotic R&D, which ensure both responsible use and equitable and affordable access to quality antibiotics.<br>Moreover, non-market-based mechanisms to address market failures in other fields of biomedical R&D should also be explored.<br>CPME recommends deleting the transfer exclusivity voucher from the pharmaceutical legislation, and instead focusing on investing EU and Member States efforts in non-legislative tools, such as incentives under development within DG HERA and payment models successfully tested in some EU countries (https://shorturl.at/SaTFX, page 19). |
| Refine regulatory activities to increase preparedness and harmonise approaches for investigating medicinal products during emergencies, including for conducting timely clinical trials during emergencies | Answer:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| 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:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Expand the international alignment on regulatory requirements from quadrilateral (FDA-Health Canada-PMDA-EMA) agreements to achieve more global consensus | Answer:<br>( ) High priority<br>(●) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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| 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:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Explore ways to better inform the public about medicines for health threats to engender trust in the medicines and the regulatory system | Answer:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

## Strategic Theme area 5: Availability and supply of medicines

Question 6: **How would you rate each objective in terms of priority?**

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| 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:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>In the context of the revision of the general pharmaceutical legislation, CPME welcomes the strong focus on addressing medicine shortages and strengthening security of supply. Earlier notifications of shortages and withdrawals are positive proposal, as well as strengthened cooperation and monitoring by the EMA and competent authorities. We also welcome an obligation for marketing authorization holders for having in place shortage prevention plans to all medicines and a possibility to transfer marketing authorisation to another party in case of withdrawal. |

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| Improve coordination of activities related to improving availability of human medicines and implement best practices in conjunction with stakeholders and international partners | Answer:<br>(•) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>It should be also examined for which products it would be beneficial to relocate production to Europe. In such cases, it can be incentivised by the revision of tendering procedures to include the criterion of supply chain resilience, especially the location of the production sites. One solution could be the creation of a label “medicine made in Europe” which could be used as a requirement in tendering procedures. Besides the reshoring of production, it should be also explored how to diversify supply sources located externally. More data must be gathered on supply chain risks to establish exactly where their vulnerabilities lie and how its resilience can be strengthened. |
| 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:<br>(•) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>Medicine shortages can be addressed by measures related to their distribution that include stockpiling or restricting parallel trade. When needed, stockpiling of medicines should take place at EU level. National stockpiling should only be introduced when not endangering neighbouring countries, regions or health care facilities with patients in need of the stockpiled medication. To prevent a shortage, stockpiling for essential medicines should be introduced lasting at least four weeks in hospitals and two to three months in wholesalers’ inventories. Please see the continuation of the reply under "Any other comments" marked with *. |

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| Improve transparency and communication on both the launch of medicinal products and shortages with relevant stakeholders, including patients, healthcare professionals and HTA bodies | Answer:<br>(●) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>European doctors believe that strengthening regulation of the supply chain could help in tackling medicine shortages. The pharmaceutical companies supplying medicines on the EU market should be able to demonstrate that their supply chain is resilient to a variety of shocks, including by not being overly exposed to one country or region, and provide a contingency plans to help identify risks early on and promote mitigation measures. Moreover, the supply and reporting obligations must be strengthened and enforced. The rest of the answer is under "Any other comments" marked with **. |
| Ensure sufficient numbers of trained inspectors are continuously available to perform legal duties (see section on sustainability of the network) | Answer:<br>( ) High priority<br>(●) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| 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:<br>( ) High priority<br>(●) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines in the supply chain | Answer:<br>( ) High priority<br>(●) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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| Keep GMP requirements updated in light of technological progress in manufacturing, (e.g. Digital, IA and other technological systems). | Answer:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Improve and inter-link information in current databases (e.g. EudraGMDP) | Answer:<br>○ High priority<br>◉ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

## Strategic Theme area 6: Sustainability of the network

Question 6: **How would you rate each objective in terms of priority?**

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| 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:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Explore ways to improve efficiency by creating centres of excellence and allocating NCA resources more strategically | Answer:<br>◉ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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| Build the network's capability to carry out the digital transformation of its scientific and regulatory processes, ways of working and tools | Answer:<br>(•) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>Ensure appropriate human oversight and human in the loop throughout the different digitalisation processes. |
| For human medicines, prepare for the implementation of new legislation combined with the modernisation and consolidation of IT systems | Answer:<br>(•) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| For veterinary medicines, continue to build on the progress achieved in implementing the veterinary regulation and align IT solutions across sectors | Answer:<br>( ) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*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:<br>( ) High priority<br>(•) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

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| 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:<br>○ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Enhance capacity of the network through international convergence, information and work sharing and multilateral cooperation | Answer:<br>○ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| 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:<br>○ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |
| Support the establishment of the African Medicines Agency, strengthening cooperation between European, African and international partners | Answer:<br>○ High priority<br>○ Medium priority<br>○ Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum* |

| | | |
|---|---|---|
| Develop and implement a framework for communication and engagement to address information needs of the public and counter mis/disinformation | Answer:<br>(•) High priority<br>( ) Medium priority<br>( ) Low priority | (Optional) Please provide any specific comments you have.<br>*700 character(s) maximum*<br>This is an important activity to be carried out by EMA, which should be connected also to digital health literacy. |

# 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*

• CPME believes the EU can contribute to ensuring equal access to medicines in all Member States by subjecting the granting of the marketing authorisation to a commitment on the part of pharmaceutical companies that once authorised, medicinal products will be launched in all EU countries at the same time.
• In the context of the revision of the general pharmaceutical legislation, we advocate that access to medicines for patients should not be determined by where they live. Therefore, we call for an obligation for marketing authorisation holders to, in good faith, file for pricing and reimbursement of a medicine upon a request by a Member State as a step towards more equitable access for patients.
• Improved communication about shortages and alternatives for prescribers is also a good development in the revision of the pharmaceutical legislation. Nevertheless, the security of supply could be further improved by establishing mandatory safety stocks of critical medicines at the company level.
• With the emergence of artificial intelligence, new cybersecurity threats will emerge and need to be considered.
* To increase the EU's resilience to external emergencies, stockpiling of medicines within the supply chain and at EU level under coordination of an EU agency allowing for targeted interventions. Please see https://www.cpme.eu/api/documents/adopted/2020/4/cpme.2020-005.FINAL_.CPME_.Policy.on_.Medicine.Shortages.pdf
** European doctors believe the current pharmaceutical legislation should be clarified. An early warning system should be introduced obliging all stakeholders in the supply chain to report any shortages at national and at EU level.

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