



Public consultation on European Medicines Agencies Network Strategy to 2025

Fields marked with * are mandatory.



Introduction

The purpose of this public consultation is to seek views from EMA's and HMA's stakeholders, partners and the general public on the proposed joint [European Medicines Agencies Network Strategy to 2025](#) 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, 2021-2025.

The views being sought on the proposed strategy refer both to the extent and nature of the broader strategic theme areas and goals. We also seek your views on whether the specific underlying objectives proposed are the most appropriate to achieve these goals.

The strategy will be aligned with the broader [Pharmaceutical Strategy for Europe](#) being developed by the European Commission and its actions will seek to provide synergies with actions developed under the Pharmaceutical Strategy where their subject matter overlaps. Wherever matters of policy or potential legislative change are referred to, these should be understood as supporting the development and implementation of the broader Pharmaceutical Strategy, where the ultimate responsibility for such matters will lie.

The questionnaire has been launched on 6 July 2020, to enable stakeholder feedback to be collected on the draft network strategy and will remain open throughout the consultation period until **4 September 2020**. In case of any queries, please contact: EMRN2025strategy@ema.europa.eu.

Completing the questionnaire

This questionnaire should be completed once you have read [the draft joint strategy document](#). The survey is divided into a general section on the whole document and then focuses on each strategic theme area. 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.

Data Protection

By participating in this survey, your submission will be assessed by EMA and HMA. EMA collects and stores your personal data for the purpose of this survey. Requests for contributions to be published in an anonymised form, can be sent to the data controller ([S-DataController@ema.europa.eu](mailto:DataController@ema.europa.eu)).

* Name

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Stakeholder Information

* **Question 1: What stakeholder, partner or group do you represent:**

- Individual member of the public
- Patient or Consumer Organisation
- Healthcare professional organisation
- Learned society
- Farming and animal owner organisation
- Academic researcher
- Healthcare professional

- Veterinarian
- European research infrastructure
- Research funder
- Other scientific organisation
- EU Regulatory partner / EU Institution
- Health technology assessment body
- Payer
- Pharmaceutical industry
- Non-EU regulator / Non-EU regulatory body
- Other

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

If not applicable, please insert "n/a"

European Federation of Nurses Associations - EFN

Overall strategy

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

Please select one or both options, as applicable

- Human
- Veterinary

Question 3: Having read the proposed strategy, how would you rate it in general terms?

Answer the following question on a scale of 1-5, where 5 indicates highly satisfied and 1 highly dissatisfied

	1. Highly Dissatisfied	2. Dissatisfied	3. Neutral	4. Satisfied	5. Highly satisfied
* What are your overall impressions of the EMAN Strategy to 2025?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

*** Question 4: Are there any significant elements missing in this strategy?**

Please note that the strategy aims to focus on major areas of interest for the next five years and it is not intended to cover all activities undertaken by the Network.

- Yes
- No

If yes, please provide further details.

- To strengthen the importance of frontline healthcare nurses to be able to prescribe medicines in all EU countries
- A focus to fight antimicrobial resistance
- A focus on vaccination and prevention, linking it to the nursing workforce and other healthcare professions

Question 5: The following is to allow more detailed feedback on prioritisation of the joint EMA/HMA goals for each strategic theme, which will also help shape the future application of resources. Your further input is therefore highly appreciated. Please choose for each row the option which most closely reflects your opinion. For areas outside your interest or experience, please leave blank.

Should you wish to comment on any of the goals and their underlying objectives, there is an option to do so.

Strategic Theme area 1: Availability and accessibility of medicines

	Very important	Important	Moderately important	Less important	Not important
1) Strengthen the availability of medicines to protect the health of European citizens, via: efficient and targeted regulatory measures, made possible through an in-depth understanding the root causes of unavailability of patented and off-patent products; identification of possible challenges in implementing legislation, removal of national barriers, increased coordination of the EMRN, sharing and implementation of best practices including stakeholders and increased transparency are the essential steps towards this goal.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>2) Optimise the path from development, evaluation through to access for innovative and beneficial medicines through collaboration between medicines regulators and other decision makers in the areas of: evidence planning, including post-licensing evidence; engagement in review of evidence and methodologies, respecting remits of the various players; collaboration on horizon scanning. As a result of this work, medicines that address unmet medical needs should have broader and earlier access coverage.</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Strategic Theme area 2: Data analytics, digital tools and digital transformation

	Very important	Important	Moderately important	Less important	Not important
<p>1) Enable access to and analysis of routine healthcare data and promote standardisation of targeted data</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>2) Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>3) Promote dynamic regulation and policy learning in current regulatory framework</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Ensure that data security and ethical considerations are embedded in the governance of data within the Network	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Map the use and needs of data analytics for veterinary medicines and support a streamlined approach across borders within the EEA	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Strategic Theme area 3: Innovation

	Very important	Important	Moderately important	Less important	Not important
1) Catalyse the integration of science and technology in medicines development and ensure that the network has sufficient competences to support innovators in various phases of medicines development.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Foster collaborative evidence generation - improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTAs, and pricing and reimbursement authorities.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) Enable and leverage research and innovation in regulatory science	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Enhance collaboration with medical device experts, notified bodies and academic groups	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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Strategic Theme area 4: Antimicrobial resistance and other emerging health threats

	Very important	Important	Moderately important	Less important	Not important
1) Provide high quality information on antimicrobial consumption and surveillance data on antimicrobial resistance in animals and humans in support of policy development.	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Contribute to responsible use of antibacterial agents and effective regulatory antimicrobial stewardship in human and veterinary sectors by putting in place strategies to improve their use by patients, healthcare professionals and national authorities	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3) Ensure regulatory tools are available that guarantee therapeutic options (with a focus on veterinary medicines) while minimising impact of antimicrobial resistance on public health and the environment	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4) Define pull incentives for new and old antibacterial agents, including investigating support for new business models and not-for-profit development	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Foster dialogue with developers of new antibacterial agents and alternatives to traditional antimicrobials, to streamline their development and provide adequate guidance in both human and veterinary medicine	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6) Improve regulatory preparedness for emerging health threats	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Strategic Theme area 5: Supply chain challenges

	Very important	Important	Moderately important	Less important	Not important
1) Enhance traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Enhance inspector capacity building at EU and international level to address the problem of APIs, new technologies and continuous manufacturing	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3) Reinforce the responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4) Encourage supply chain resilience and review long-term risks resulting from dependency on limited number of manufacturers and sites, to ensure continuity of supply and availability of medicinal products.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Analyse the possible implications of new manufacturing technologies in order to regulate the new supply chains needed to manufacture and distribute new types of medicinal products for human and veterinary use.	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Strategic Theme area 6: Sustainability of the Network and operational excellence

	Very important	Important	Moderately important	Less important	Not important
1) Reinforce scientific and regulatory capacity and capability of the network	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2) Strive for operational excellence, building on the work done in the current strategy	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3) Achieve a sustainable financial and governance model for the network	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4) Develop a digital strategy to drive digital business transformation	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5) Enable quick, consistent and adequate response to public and animal health challenges	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Strategic focus areas

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

Please select as many choices as applicable.

- 1. Availability and accessibility of medicines
- 2. Data analytics, digital tools and digital transformation
- 3. Innovation
- 4. Antimicrobial resistance and other emerging health threats
- 5. Supply chain challenges
- 6. Sustainability of the Network and operational excellence

Strategic Theme area 1: Availability and accessibility of medicines

Question 6: Do the objectives adequately address the challenges ahead?

- Yes
- No

Comments on objectives of the strategic theme area:

Other than the accessibility of medicines, the strategy should address the role of general care nursing prescribing medicines.

Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- Yes

No

Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

Yes

No

Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

Yes

No

Strategic Theme area 2: Data analytics, digital tools and digital transformation

Question 6: Do the objectives adequately address the challenges ahead?

Yes

No

Comments on objectives of the strategic theme area:

The digital transformation of healthcare, pharmaceuticals and medications plan will also have an effect on the future developments of Electronic Health Records - please see the two ongoing Horizon 2020 projects InteropEHRate (http://www.efnweb.be/?page_id=10684) and Smart4Health (http://www.efnweb.be/?page_id=10687).

Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

Yes

No

Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

Yes

No

Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

Yes

No

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

Question 6: Do the objectives adequately address the challenges ahead?

- Yes
- No

Comments on objectives of the strategic theme area:

A greater emphasis on patient safety and general care nurses should be given. Particularly given that nurses are the most trusted healthcare professionals of all, and they are in a privileged position to combat AMR at the frontline of healthcare.

Question 7: Are there any other challenges that should be addressed by the EMA/HMA network in this area?

- Yes
- No

Question 8: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- Yes
- No

Question 9: Are there any other ongoing or planned initiatives that should be considered for this proposed strategic theme area?

- Yes
- No

Any other comments

Please feel free to provide any other additional comments not provided in the previous questions

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 \(https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/eu-medicines-agencies-network-strategy\)](https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/eu-medicines-agencies-network-strategy)

[European Medicines Agencies Network Strategy to 2025 \(https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf\)](https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf)

[Pharmaceutical Strategy for Europe \(https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12422-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines/public-consultation\)](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12422-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines/public-consultation)

Background Documents

[european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf](#)

Contact

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