



# 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](mailto: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

Amandine Oset

\* Email

amandine.oset@echamp.eu

## Stakeholder Information

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

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

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

**\* Please specify:**

Please select one option that best describes your organisation

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

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

If not applicable, please insert "n/a"

European Coalition on Homeopathic & Anthroposophic Medicinal Products

## Overall strategy

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**\* 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 checked="" type="radio"/>	<input 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.**











We note that the strategy aims to focus on major areas of interest and is not intended to cover all activities undertaken by the Network. However, even though we are not aware of significant missing elements, we wish to stress the importance of striking a better balance between curative treatments and preventative care and propose that this should be reflected in the fundament of the strategy. In its report on access to medicines (2018/C263/02), the European Parliament demands that patients “have access to the healthcare and treatment options of their choice.....including complementary and alternative therapies and medicines”. The current regulatory framework serves the patients’ needs in this area, ensuring the quality and safety of these products, while at the same time giving patients access to medicines of their choice. Traditional and complementary medicines have a valuable role to play alongside conventional medicines in tackling the unique health challenges that Europe is now facing. We ask the Network to acknowledge the need for a better balance between the focus on prevention and the focus on cure and gives its support so that the full potential of these products be further explored and exploited, not overlooked. The WHO Global Report on Traditional and Complementary Medicine 2019 provides valuable information for policy makers “...for capitalizing on the potential contribution of T & CM to health and well-being.”

**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
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<p>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.</p>					
<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>					

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

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

**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"/>

<p>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</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>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</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>4) Define pull incentives for new and old antibacterial agents, including investigating support for new business models and not-for-profit development</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>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</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>6) Improve regulatory preparedness for emerging health threats</p>	<input type="radio"/>	<input checked="" 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 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 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 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 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 type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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**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 checked="" type="radio"/>	<input 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 type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
4) Develop a digital strategy to drive digital business transformation	<input type="radio"/>	<input checked="" 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 type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

## Strategic focus areas

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**\* 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
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## **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:

An inclusive strategy for the utilisation of real world data should not be limited to the treatment of unmet medical needs but should also help improve understanding of treatment outcomes for established medicines including traditional and complementary medicines, leading to better decisions on the role they can play in meeting patients' needs. Recognising that the lack of required personnel and competences will be a challenge in dealing with this strategic goal, we take this opportunity to ask the Network to give due consideration to including competence in data analysis of product effectiveness and performance in the area of traditional and complementary (human and veterinary) medicines, in line with the WHO Astana declaration in October 2018 on primary health care.

**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
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## **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:**

There is universal consensus that AMR is one of the major global threats to the public and animal health environment and that it demands a “One health approach”. The six main goals defined by the Network to address this problem are appropriate and realistic. We are pleased to see that emphasis will be placed on exploring alternative approaches to treatment of infectious diseases. We would like refer to the Joint Programming Initiative on Antimicrobial Resistance (<https://www.jpiamr.eu/supportedprojects/fourth-joint-callresult/>) which addresses the role of Complementary and Alternative Medicine treatment strategies in supporting the appropriate use of antibiotics.

**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

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**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 \(https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1242-Pharmaceutical-Strategy-Timely-patient-access-to-affordable-medicines/public-consultation\)](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1242-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**

EMRN2025strategy@ema.europa.eu