Contribution ID: 9b7ebb1c-d3bd-45d6-89d8-513117466a4e
Date: 03/09/2020 22:53:17

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).

* 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"

Standing Committee of European Doctors (CPME)

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?	○	○	○	◉	○

* **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

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.	◉	○	○	○	○

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.	◉	○	○	○	○

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	○	◉	○	○	○
2) Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics	○	◉	○	○	○
3) Promote dynamic regulation and policy learning in current regulatory framework	○	◉	○	○	○

4) Ensure that data security and ethical considerations are embedded in the governance of data within the Network	◉	○	○	○	○
5) Map the use and needs of data analytics for veterinary medicines and support a streamlined approach across borders within the EEA	○	◉	○	○	○

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.	○	◉	○	○	○
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.	◉	○	○	○	○
3) Enable and leverage research and innovation in regulatory science	◉	○	○	○	○

4) Enhance collaboration with medical device experts, notified bodies and academic groups	◉	○	○	○	○

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.	◉	○	○	○	○
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	◉	○	○	○	○
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	◉	○	○	○	○

4) Define pull incentives for new and old antibacterial agents, including investigating support for new business models and not-for-profit development	◉	○	○	○	○
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	○	◉	○	○	○
6) Improve regulatory preparedness for emerging health threats	◉	○	○	○	○

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)	◉	○	○	○	○
2) Enhance inspector capacity building at EU and international level to address the problem of APIs, new technologies and continuous manufacturing	○	◉	○	○	○

3) Reinforce the responsibility for product quality by harmonising and reinforcing guidance to facilitate a coherent approach to the standards by regulators and industries	◉	○	○	○	○
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.	◉	○	○	○	○
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.	○	◉	○	○	○

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	○	◉	○	○	○
2) Strive for operational excellence, building on the work done in the current strategy	○	◉	○	○	○

3) Achieve a sustainable financial and governance model for the network	◉	○	○	○	○
4) Develop a digital strategy to drive digital business transformation	○	◉	○	○	○
5) Enable quick, consistent and adequate response to public and animal health challenges	◉	○	○	○	○

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:

European doctors agree that there is a need to increase transparency and overview of the marketing status of centrally authorised medicines.

We also recognise a need for structural changes. The EMA should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply.

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.

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.

As to increasing availability of medicines through optimisation of regulatory path, including evidence planning, European doctors believe that all kind of revisions of the procedures for accelerated medicines' development, new means of their assessments, and fast approval and market access must be undertaken cautiously to adequately take patient benefit and safety aspects into consideration.

Please also consult the CPME Policy on Medicine Shortages (https://bit.ly/3a5qGZZ).

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:

In the context of the discussed paradigm shift from focusing on pre-approval activities to strengthening post-approval activities using real world data, European doctors underline the importance of gathering robust evidence before the approval of any new medicine not to put patients health at risk.

Moreover, a critical reflection on which data is relevant for drug development processes needs to be undertaken.

Real-world data can provide useful supplementary information in the context of marketing authorisation processes and in particular post approval surveillance activities. However, it is important to have in place appropriate framework ensuring the quality, robustness, reliability and usefulness of collected data.

What is more, European doctors consider of utmost importance to guarantee the confidentiality and privacy of patient data. It requires the existence of an appropriate data governance model based on the WMA Declaration of Helsinki (https://bit.ly/3fJJeAh) and the WMA Declaration of Taipei (https://bit.ly /2XBBQ3z).

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 3: Innovation

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

- ◉ Yes
- ○ No

Comments on objectives of the strategic theme area:

The network should support ambitious EU research programme.

In light of the recent proposal of the Council of the EU to cut funding for the Horizon Europe programme that could have a considerable impact on health research and innovation, European doctors would like to emphasise the importance of ensuring sufficient resources for medical research, especially in the areas of unmet needs (e.g. antimicrobial resistance (AMR), Alzheimer or dementia).

The network should aim at improving innovation agenda that is not always driven by public health needs. Consequently, the neglected, low-profile areas of “market failures” and unmet medical needs (requiring clearer and stricter definition) are not sufficiently addressed.

Moreover, 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).

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.

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:

Along with the European Commission's Pharmaceutical Strategy for Europe, the network's strategy should prioritise tackling AMR and contribute to keeping AMR high on the EU and national policy agendas.

It is important to support Member States' efforts in the implementation of AMR One Health National Action Plans (NAPs), which are aligned with the Global Action Plan on AMR and make use of the proposed ECDC /EFSA/EMA harmonised outcome indicators to measure progress in the reduction of antimicrobials use and AMR in humans and animals.

European doctors also recognise a need for a dedicated EU fund or funds earmarked from the current EU budget to support Member States in developing and implementing One Health AMR NAPs.

We would also like to emphasise that prevention must be in 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.

Building on the comment made in the previous section, we believe 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.

Moreover, non-market-based mechanisms to address market failures in other fields of biomedical R&D should also be explored.

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

If yes, please elaborate which ones and provide details on how these could be considered.

CPME takes part in the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) and soon will host the Joint Action's deliverables related to healthcare professionals at its website - cpme.eu.

CPME will shortly publish a report on medical doctors' knowledge, attitudes and behaviours on antibiotics, antibiotic use and antibiotic resistance. The report has been prepared by the Danish Medical Association, CPME member, that analysed data on roughly 7300 medical doctors' answers from the ECDC survey conducted between January and May 2019 (https://bit.ly/2DNnRQY).

CPME takes part in the organisation of the ECDC European Antibiotic Awarness Day (EAAD).

In terms of promoting "One Health" approach to AMR, CPME along with medical students and other professional and student organisations representing the dentists and the veterinarians sent a joint letter in May 2017 to the Deans of medical, dental and veterinary schools across Europe inviting them to work collaboratively under the 'One Health' concept to tackle current and future challenges for the three professions.

The joint letter was the basis for organising the first One Health workshop organised in Paris in December 2018 discussing the situation in France, Belgium, Luxembourg and the Netherlands.
Following this successful first debate and teamed up by the pharmacists and pharmacy students we organised the second workshop in Warsaw – this time bringing together participants from Poland, Czech Republic, Hungary and Slovakia. The third workshop will take place in 2021.

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 5: Supply chain challenges

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

- ◉ Yes
- ○ No

Comments on objectives of the strategic theme area:

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. 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.

What is more, 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.

Please also consult the CPME Policy on Medicine Shortages (https://bit.ly/3a5qGZZ).

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 6: Sustainability of the Network and operational excellence

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

- ◉ Yes
- ○ No

Comments on objectives of the strategic theme area:

Question 7: Are you undertaking concrete actions in this field that could support or complement EMA/HMA network activities?

- ○ Yes
- ◉ No

Question 8: Are you undertaking concrete actions in this field?

- ○ 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)

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)

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)

Background Documents

european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

Contact

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