



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"

Association of European Cancer Leagues (ECL)

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.

1. Regulatory aspects of medicine approval such as the use of adaptive pathways, orphan designation and paediatric investigation plan should be more elaborated in the strategy
2. Efforts should be increased towards centralisation of clinical trial management to avoid multiple smaller trials with the same drugs in the different MS.
3. Necessary changes (of legislation and practice) in the wake of desired empowerment of the Agency to deal with pressing issues (in the wake of shortcomings identified during the pandemic as well as review of legislation, pharmaceutical strategy delivery etc.)

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 type="radio"/>	<input checked="" 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 checked="" type="radio"/>	<input 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 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 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 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 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 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 checked="" type="radio"/>	<input 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 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 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 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 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 type="radio"/>				
6) Improve regulatory preparedness for emerging health threats	<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 checked="" 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 checked="" 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 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 checked="" type="radio"/>	<input 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 checked="" type="radio"/>	<input type="radio"/>	<input 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 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:

Indeed, to address medicine shortages, it is important to:

- Strengthen the existing EU pharmaceutical legislative framework to improve notification of medicines shortages and reinforce obligations of the market Authorisation Holders (MAHs) and wholesalers to supply the market;
- Ensure timely delivery of the Commission study on medicine shortages and include an assessment of the impact of shortages on patients (incl. health outcomes and associated costs) among its objectives; Ensure patient safety and efficacy of their treatment are at the core of shortage prevention and management
- Publish new EU guidance elaborating on cases when free movement of medicines may be restricted in order to prevent and address medicine shortages;
- Publish new EU guidance on prudent procurement practices to help prevent occurrence of shortages in generic medicines;

To enable access to quality medicines:

- Ensure high quality benefit-risk assessment of patient-relevant endpoints before granting market access to medicines, stressing the need for surrogate endpoints in clinical trials to be accompanied by hard endpoints reflecting improvements in overall survival and quality-of-life measures;
- Demand systematic collection and submission of real-world evidence (including overall survival, adverse reactions and quality-of-life improvements) once the medicine enters the market and its timely re-assessment, where appropriate;

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

- Yes
 No

If yes, please specify

Please remember to specify if a particular comment relates specifically to the human or veterinary part.

- Adaptive pathways and conditional approvals - ensure it does not come at the cost of patient/citizen safety (same with use of medicines and vaccine in crisis such as COVID-19 pandemic)
- Preventing misuse of orphan medicine status and regulatory incentives (e.g., use for personalised treatments for more prevalent diseases)
- Less prevalent use of PIP waiver for paediatric medicines - introducing the 'mechanism of action principle'

It is important to differentiate shortages of cheap/essential medicines caused by supply chain disruptions ect. and unavailability of innovative medicines due to commercial aspects, including a high price

Please see ECL's Position Paper on EU Pharmaceutical Strategy with recommendations for the following areas: medicine shortages, R&D and Clinical Trials, regulatory approvals, orphan & paediatric medicines, international collaboration in HS, HTA and P&R here: <https://www.europeancancerleagues.org/wp-content/uploads/ECL-Pharma-Strategy-Position-Paper-August-2020.pdf>

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.

- ECL is eligible organisation of the EMA PCWP
- ECL can further provide expertise via the ECL Access to Medicines Task Force, consisting of 20 staff members of national cancer societies working in the field of medicines, research and advocacy
- ECL can provide national contacts to EMA/HMA and national/local cancer societies can provide connections with patients and further expertise related to cancer care in the MS

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

- Yes
 No

If yes, please provide details of the ongoing or planned initiatives.

- Planned commission study on root causes of medicine shortages
- Commission study on orphan and paediatric medicines incentives
- EU Pharmaceutical Strategy
- EU4Health programme
- Horizon Europe
- Europe's Beating Cancer Plan
- Private-public partnerships e.g., IMI and Innovative Health Initiative

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:

Healthcare data should not be regarded as a commercial commodity

To ensure robust and non-bias data/evidence for health decision-making (including approval, HTA and reimbursement decisions), the EMA should play a role in securing the quality of the health data (incl. access to raw data, data validity). Therefore, the role of the EMA in this field should be enhanced, particularly ahead of the upcoming European Health Data Space file.

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

- Yes
- No

If yes, please specify

Please remember to specify if a particular comment relates specifically to the human or veterinary part.

- Ensuring research results and data sets from all clinical trials submitted to the EMA for marketing authorisation are publicly available, in order to build trust in the EU's regulatory framework and foster further research concerning a product's efficacy and safety

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

If yes, please provide details of the ongoing or planned initiatives.

- European Health Data Space
- EU4Health
- Horizon Europe
- PPPs

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:

Stress should be on:

- Ensuring full implementation of the Clinical Trial Regulation as soon as possible;
- Pooling resources and enhance collaboration throughout the entire medicines access pathway, to prepare health systems for (i) the arrival of new medicines and technologies, (ii) conducting high quality HTA and (iii) sharing information about prices and pricing and reimbursement strategies, in order to enhance countries' ability to (a) prioritise medicines with higher clinical value, (b) review and adjust prices based on new evidence, and (c) effectively negotiate the prices of medicines.
- Granting market access via adaptive pathways and accelerated approval schemes only in cases of unmet medical need, as intended, and prevent their misuse in cases where sufficient evidence for market approval is lacking;
- Address challenges of pharmaceutical and diagnostic co-development in personalised medicines by developing transparent European guidelines on trial designs, statistical methodology, authorisation processes, and clinical use;
- Setting up rigorous design of clinical trials using real world data, with appropriate analytic approaches, to minimise the inherent risk of bias in such studies to avoid decision making based on flawed results;
- Advancing the methodology and setting up trials in the area of personalised medicine in close collaboration with decision-makers, and further support for research into personalised medicine, to provide insight into their outcomes and reduce uncertainty over their use.
- Ensuring the quality of medicines and good manufacturing practice is not compromised by regulatory flexibility measures put in place by the Commission in the times of COVID-19 pandemic and other public health emergencies.

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

- Yes
- No

If yes, please specify

Please remember to specify if a particular comment relates specifically to the human or veterinary part.

Additionally, it is necessary to

- compare novel treatments to each other and to the standards of care (use of comparative trials)
- Incentivise novel clinical trial designs and research on treatments that are neglected by the pharmaceutical industry, such as:
 - i. Treatment optimisation research to identify the optimal dosage and duration of existing treatments, both for the benefit of patients and to guarantee the sustainability of healthcare systems;
 - ii. Drug re-purposing research to find new applications of well-established, effective and widely available generic medicines;
 - iii. Multimodality combination treatments
- Support independent (non-profit) clinical research that ultimately demonstrates the added therapeutic value for patients (overall survival and quality of life);

There is a need to increase competition for commercial development by extending the role of public, academic and non-profit research from basic research to market-ready products.

This approach might be particularly promising in the field of gene and cell therapy, where treatments are tailor-made to fit the genetic profile of an individual patient. In order to achieve success, legislation related to marketing of products would need to include public research entities and non-profit organisations. In addition, the EMA and national medicines agencies should evaluate clinical evidence provided by public researchers and non-profit organisations, e.g., related to new indications. Subsequently, it is necessary to work with sponsors to enable extension of the product to new indications based on additional data from public/non-profit research, and thus enabling off-label use to become on-label.

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.

- ECL is eligible organisation, actively participating in the EMA PCWP
- ECL can further provide expertise via the ECL Access to Medicines Task Force, consisting of 20 staff members of national cancer societies working in the field of medicines, research and advocacy
- ECL can provide national contacts to EMA/HMA and national/local cancer societies can provide connections with patients and further expertise related to cancer care in the MS

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

- Yes
- No

If yes, please provide details of the ongoing or planned initiatives.

- Implementation of Clinical trials regulation
- Enhanced cooperation between medicines agencies, HTA and payers on scientific advice from early product development
- EU Pharmaceutical Strategy
- it is important not to duplicate efforts, voluntary initiatives under Beneluxa, IHSI, EUNetHTA and HTA regulation progress need to be taken into account

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:

ECL recommends to:

- Require all medicines marketed in more than one EU Member state to have accompanying concrete and legally binding European shortage management and prevention plans in order to switch from crisis management to an upstream approach;
- Create early warnings systems on medicine shortage at both national and European level; set up a permanent system for monitoring medicine shortages in the EU by building on experience set up under the SPOC system (ensure the system focuses on both prevention and crises management of shortages)

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

If yes, please provide details of the ongoing or planned initiatives.

- Possible launch an EU Joint Action focusing on the prevention of, and solutions to, medicine shortages to give medicine agencies space to exchange best practice and draw plans as the agenda of EMA/HMA does not have the capacity to tackle the entire spectrum of issues

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:

ECL would like to underline the need for sustainability and growth of the agency to answer the high demand while maintaining the quality of assessments

Increased resources from the EU budget would be desirable in order to decrease high dependency on industry fees

Cooperation with other regulatory, HTA, P&R agencies, notified bodies and non-EU meds agencies, particularly MHRA is key

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

See full set of ECL's recommendations to the EU Pharmaceutica Strategy here: <https://www.europecancerleagues.org/wp-content/uploads/ECL-Pharma-Strategy-Position-Paper-August-2020.pdf>

ECL's recommendations related to orphan & paediatric medicines:

1. Setting clear and transparent criteria for sustaining orphan designation at the time of marketing authorisation by the EMA based on significant benefit and prevention of misuse and overuse of the orphan status (incl. evergreening and salami slicing);
2. The Commission's recent move to provide free scientific advice to academics working on rare disease therapeutics is welcome. It should consider what other non-regulatory incentives might be offered to organisations under the Regulation;
3. Ensuring the right balance between awarding incentives in orphan medicine development, particularly where there exist no treatment alternatives, and preventing unintended effects on affordability (e.g., by revoking market exclusivity when a medicine has generated sufficient return on investment; or evaluating the benefit-risk ratio of extended market and data exclusivity);
4. Ensuring criteria for orphan designation exclude eligibility of personalised treatments for more prevalent diseases and prevent proliferation of market exclusivity and other incentives;
5. All awarded incentives for orphan medicines (and other areas including paediatric medicines, antimicrobials etc.) should be evaluated periodically to assess whether they have reached the intended effect and not posed obstacles to patient access to these products;
6. Introducing the 'mechanism of action principle' in the Paediatric Regulation, to prevent granting of PIP waivers when an adult cancer has no paediatric iteration (e.g., lung cancer treatments) but the drug's mechanism of action (such as targeting a specific genetic variation) is plausibly beneficial for some paediatric cancers, thereby reducing the ratio of waivers to PIPs in the long-run;
7. Introducing regulatory requirements and rewards for early PIP completion that will establish an evidence base for the paediatric population, even if the adult development program is aborted. Currently, new medicines showing promise for children are not adequately researched after a medicine fails to show potential in an adult indication;
8. Allowing inclusion of adolescents in paediatric phase I, II and III trials where relevant (e.g., for adolescents with paediatric cancer type or biological targets);

9. Considering alignment and synergies with global initiatives on paediatric medicine development – including the recently introduced RACE for Children Act.

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

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