HMA
Heads of Medicines Agencies

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EUROPEAN MEDICINES AGENCY

# Seizing opportunities in a changing medicines landscape

## The European medicines agencies network strategy 2028

An agency of the European Union

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# A strategy for changing times

## Foreword by Emer Cooke, EMA Executive Director and María Jesús Lamas Díaz, Chair of HMA Management Group

**In the last quarter of 2020, the European medicines agencies network – comprising national competent authorities (NCAs) and the European Medicines Agency (EMA) – published its five-year strategy covering the period from 2021 to 2025. The strategy (EMANS 2025) has now undergone an update to cover the period up to 2028.**

Under the overarching theme 'protecting public health at a time of rapid change', EMANS 2025 set out how the network aimed to continue fostering the development and supply of much needed medicines in the EU. Since then, several changes to the regulatory and technological landscape have occurred, some more rapidly than anticipated. In the wake of the COVID-19 pandemic, the EU enacted new legislation to handle public health emergencies and established the Directorate-General Health Emergency Preparedness and Response Authority (DG HERA) to improve the EU's preparedness.

**Emer Cooke**, Executive Director, European Medicines Agency

Technological advances, particularly in the area of artificial intelligence (AI), brought opportunities to transform the way medicines are developed and regulated across the network. Furthermore, the EU made steps to revise its pharmaceutical legislation in what will be the largest reform of EU medicines regulation in decades.

These and other changes herald a brighter future for EU medicines regulation, and it was necessary to review and update EMANS 2025 if we are to seize the opportunities they present.

While EMANS 2028 cannot pre-empt the legislative changes, this strategy will help prepare the network for the revisions to the pharmaceutical legislation and further changes to the technological and regulatory landscape.

EMANS 2028 will also guide the network as it seizes opportunities and meets the challenges of the near future, including preparing for and responding to public health emergencies and threats such as antimicrobial resistance.

**María Jesús Lamas Díaz**, Chair, Head of Medicines Agencies Management Group

As with EMANS 2025, the overarching theme of EMANS 2028 is that of change – rapid, somewhat unpredictable but nonetheless full of promise. These changes drive many of the considerations in the six focus areas or themes. The themes for the most part apply to innovative medicines as well as off-patent medicines, such as generic and biosimilar medicines. We have chosen these themes with a view to supporting our core work of evaluating human and veterinary medicines as we promote the development of medicines and ensure they reach those who need them.

Underpinning the entire strategy is the 'One Health' approach to protecting public health. One Health is an integrated approach that aims to sustainably balance and optimise the health of humans, animals and ecosystems. The network recognises that this approach is essential for dealing with global threats, because the health of humans, domestic and wild animals, plants and the wider environment are – and have always been – closely entwined.

In implementing this strategy, it will be necessary to take account of important legislative and policy developments in areas such as environmental sustainability, the European Green Deal and the single assessment of substances.

# The six themes in EMANS 2028

**Accessibility**

**Leveraging data, digitalisation and artificial intelligence**

**Regulatory science, innovation and competitiveness**

**Antimicrobial resistance and other health threats**

**Availability and supply**

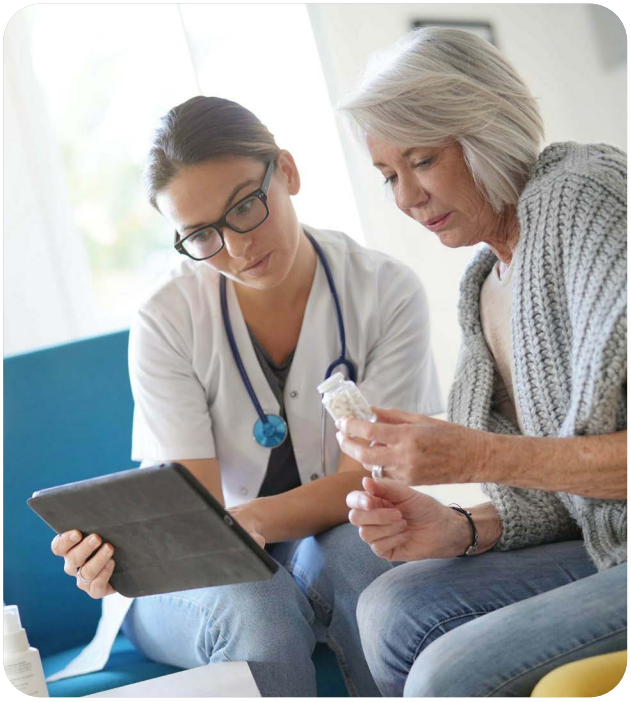
**Sustainability of the network**

# 1. Accessibility

## The path to accessibility

**A medicine is accessible to patients when it has gone through the necessary stages towards approval and reimbursement by healthcare systems, i.e. it has been authorised by regulators (via EMA or NCAs) and then evaluated positively by other relevant authorities such as health technology assessment (HTA) bodies and payers. This means that there will be instances when a medicine is authorised but, for all intents and purposes, is not accessible to patients.**

The network aims to facilitate the path to accessibility. One way to achieve this is by ensuring that evidence generated during the development, authorisation and post-authorisation stages is relevant for HTA bodies and payers. Collaborating with HTA bodies, including the Heads of HTA Agencies Group (HAG), and payers is therefore key to generating such evidence. Equally important is ensuring that these bodies (as well as patients and healthcare professionals) are aware of scientific considerations behind regulatory outcomes (e.g. those concerning orphan medicines, biosimilar medicinal products and conditional marketing authorisations).



The new HTA Regulation[1] provides for cooperation and the exchange of information between regulators and HTA bodies working within their respective remits, and the successful implementation of the regulation is an important part of the network's strategy. Furthermore, the network will work more closely with other policy makers, including governmental bodies, such as health ministries, and payers. Areas of cooperation to be covered include research and horizon scanning activities related to accessibility. Research topics may include, for example, the impact of evidence requirements – pre- and post authorisation – on decision outcomes.

## Accessibility versus availability

For human medicines, EMANS 2028 distinguishes between accessibility and the closely related concept of availability. A medicine only becomes 'available' when it is placed on the market and manufactured in sufficient quantities so that it can be delivered to patients who may benefit from it (see theme 5).

Problems with accessibility and availability also occur with veterinary medicines, but the underlying causes may be different from those affecting human medicines and may require different solutions. The section on theme 5 also covers aspects related to veterinary medicines.

It is important that efforts to improve the accessibility and availability of medicines apply to both innovative medicines and off-patent medicines such as generics and biosimilars.

1 Regulation (EU) 2021/2282

## Goals for accessibility

| Goals | How we will achieve them |
|---|---|
| **Optimise the path to accessibility by working with other decision makers (HTA bodies and payers) (1.1)** | • Contribute to the successful implementation of the HTA Regulation (1.1.1)<br>• Foster the generation of robust scientific evidence to serve different decision makers (regulators, HTA bodies and payers) (1.1.2)<br>• Enhance communication with other decision makers about the scientific considerations leading to regulatory outcomes for both innovative and off-patent medicines (1.1.3) |
| **Deepen engagement with healthcare policy makers on initiatives and research relevant to sustaining health technology accessibility (1.2)** | • Contribute to initiatives exploring the perspective different stakeholders have about unmet medical needs and how they inform considerations about clinical significance, significant benefit and major contributions to patient care (1.2.1)<br>• Conduct research to better understand accessibility for medicines addressing unmet needs and how evidence requirements affect decision outcomes (1.2.2)<br>• Continue collaborative work on methodologies for the generation of evidence that is also relevant for health technology assessments (1.2.3) |

# 2. Leveraging data, digitalisation and artificial intelligence

## Leveraging data

**Over the past few years, the network has been processing an increasing amount of data as it discharges its everyday functions, monitoring the safety and efficacy of medicines, generating real-world evidence and contributing to EU-wide health policies.**

This technology-driven explosion of data is both an opportunity and a challenge, an opportunity to better support decision making and a challenge to ensure that data used to support decision making are as meaningful and unbiased as possible and that attendant risks, including security and confidentiality risks, are kept to a minimum. The network is already making efforts to strengthen data governance and ensure that data from one partner in the network are in a form that can be used by other partners (so called 'interoperability'). Implementing and harmonising master data and related data standards within the network will also be essential to strengthen interoperability of network data and to deliver stakeholder benefits.

As part of its strategy, the network also aims to maximise the use of data and evidence generation to support decision making. One example of this approach is the intention to embed the routine use of EU healthcare data in the network's processes, including data from the Data Analysis and Real World Interrogation Network (DARWIN EU) and individual patient data from clinical trials. Legislation for a European Health Data Space (EHDS) will also reinforce the framework for generating evidence for EU decision making in the future.

In all these activities, the network is committed to ensuring that data use complies with the EU Data Protection Regulation and all applicable data protection, privacy and cybersecurity requirements in the EU.

As the network makes progress in its use and generation of data, it is also important to stress that marketing authorisation holders and applicants remain responsible for generating the necessary data to support or justify their applications.

## Digital transformation and artificial intelligence

A key element of the network's strategy centres around digital transformation, using digital technology to increase efficiency and automate many of the network's processes. This will involve continuous experimentation as the network explores and makes use of emerging technologies.

Artificial intelligence (AI) is a prime example of such emerging technologies. Since the adoption of EMANS 2025, the use of AI has become more commonplace and the network aims to harness the full potential of AI across all the EMANS themes.

The use of digital technology and AI has the potential to transform the network's core work of evaluating human and veterinary medicines for authorisation and monitoring their safety. For veterinary medicines, the network will push ahead with its vision to implement new digital solutions in its European veterinary big data strategy.

In the area of public engagement, the network is working to make public information more accessible with its electronic product information initiative which aims to make the summary of product characteristics and package leaflet more accessible to stakeholders.

## Goals for leveraging data, digitalisation and artificial intelligence

| Goals | How we will achieve them |
|---|---|
| **Maximise the generation, interoperability, use and exchange of data to support EU decision making in the context of key EU legislative initiatives (notably, the EHDS and new pharmaceutical legislation) (2.1)** | • Embed the use of EU healthcare data from diverse populations in the network's processes, including in support of the EHDS implementation, and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, such as genomic data) (2.1.1)<br>• Ensure a high level of interoperability (including through the use of master data), standardisation and quality of data, addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed (2.1.2) |
| **Leverage digitalisation, experimentation and innovation to deliver optimised regulatory processes (2.2)** | • Reinforce the network's digital infrastructure in line with the Network Portfolio Vision to drive the digital transformation of the network's scientific and regulatory processes (2.2.1)<br>• Foster a culture of continuous experimentation and innovation across the network (2.2.2) |
| **Realise the network vision on AI across all EMANS focus areas (2.3)** | • Leverage experimentation and technological advances in AI to support the digital business transformation of the EU network (2.3.1)<br>• Harness the potential of AI throughout the medicines' lifecycle (2.3.2) |

# 3. Regulatory science, innovation and competitiveness

## Regulatory science

**Regulatory science plays a critical role in public health by bridging the gap between scientific research and the practical application of that research in regulatory decision making.**

To bridge that gap, the network has long realised that it needs to help create a favourable regulatory and research environment to increase the likelihood that innovations result in the successful development of new treatments or repurposing of existing ones.

For both medicines and medical devices, taking steps to deepen and foster communication and collaboration with stakeholders, such as clinicians, academics, medical devices experts, notified bodies, ethics committees and patients organisations, small and medium-sized enterprises (SMEs), research groups, industry and incubators can help harness expertise and talents across the EU.

## Clinical trials and manufacturing

Innovation also applies to clinical trials and manufacturing. With respect to clinical trials, the network aims to foster innovation in the conduct of trials, aligning with the Accelerating Clinical Trials in the EU (ACT EU) initiative, and to contribute to medicines' innovation through the most efficient generation of robust evidence. The Clinical Trials Information System (CTIS) remains an essential tool for implementing the Clinical Trials Regulation[2], supporting Europe as a key destination for clinical trials. Ongoing efforts will focus on simplifying, modernising and improving the system's user experience. Alongside innovations in clinical trials, the network will continue to leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation.

In the area of manufacturing, the network aims to support the application of innovative approaches to the design, manufacture and quality control of medicines not only to produce new medicines but also to improve the supply of existing ones.

## Fostering competitiveness

For innovation to thrive in the EU, it is important to boost competitiveness. The network has a role to play by bolstering support for innovators, developers and other involved actors, such as funding bodies, and ensuring that the regulatory framework is conducive to research and the development and manufacturing of medicines. The network will also identify opportunities presented by the new legislation to strengthen the EU's competitiveness, including legislation which may impact research and development, such as the EU Biotech Act and the Critical Medicines Act.

Finally, as the European Union makes strides in the area of environmental sustainability, it is important that the network promotes environmentally sustainable practices in pharmaceutical development, manufacturing and the use and disposal of medicines in line with other initiatives related to the Green Deal and the Net-Zero Industry Act.

2 Regulation (EU) No 536/2014

## Goals for regulatory science, innovation and competitiveness

| Goals | How we will achieve them |
|---|---|
| **Promote the future-proofing of the EU innovation ecosystem by monitoring and integrating advancing science and technology in medicines development and manufacturing (3.1)** | • Continue to support innovation and enable integration and adaptation of scientific and technological advancements in the development of human and veterinary medicines in a timely manner (3.1.1)<br>• In collaboration with other EU bodies, implement a model for efficient, timely and coordinated EU horizon scanning for human and veterinary medicines to inform the development of regulatory tools and approaches and identify areas where additional expertise is needed (3.1.2)<br>• Facilitate the development and implementation of novel manufacturing technologies and analytical techniques, including with a view to facilitating the adoption of more sustainable practices with a reduced carbon footprint (3.1.3) |
| **Foster generation of high-quality and impactful evidence with particular focus on clinical trials (3.2)** | • Support the generation of high-quality evidence in quality, non-clinical (including non-animal methods) and clinical domains by researchers and sponsors from early development stages and provide timely and more accessible scientific and/or regulatory advice (3.2.1)<br>• Foster innovation and the improved planning and conduct of clinical trials and emerging clinical data generation (including the integration of real-world data) in conjunction with activities related to theme 2 (3.2.2)<br>• Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation in collaboration with other EU initiatives and institutions (e.g. the Joint Research Centre) and align approaches internationally (e.g. with International Coalition of Medicines Regulatory Authorities (ICMRA)) (3.2.3) |
| **Promote stakeholder cooperation to accelerate the translation of innovation into therapies, facilitate the repurposing of existing therapies and increase EU competitiveness (3.3)** | • Develop network-led partnerships with key stakeholders (e.g. academia, industry and funding bodies) to deliver impactful progress in regulatory science and research and provide training (3.3.1)<br>• Enhance the regulatory competence of researchers and developers from academia, hospitals and small and medium-sized enterprises (SMEs) to facilitate the translation of research into innovative medicines through direct support and pre-competitive research collaborations (3.3.2)<br>• Increase collaboration with medical device experts, notified bodies, ethics committees and patient communities, HTA bodies and the Substances of Human Origin network in conjunction with the European Commission to support development and authorisation of combination products (3.3.3) |

# 4. Antimicrobial resistance and other health threats

**Antimicrobial resistance (AMR) is a prime example of a global threat facing the European Union. To manage the threat, the network must promote the responsible use of antimicrobials in humans and animals. Further work is also required to provide incentives for the development of antimicrobials, and the network faces the paradoxical challenge of seeking the development of new products that it hopes will not be needed. International collaboration is crucial here, given the global causes and effects of AMR and the urgent need to pool expertise.**

Other threats that require the continuous attention of the network include biological threats, such as outbreaks and pandemics, as well as chemical, radiological and nuclear threats.

Within the network, the Emergency Task Force (ETF), formed at the beginning of the COVID-19 pandemic, helps handle regulatory activities concerned with public health emergencies and health threats. At the European Commission, DG HERA and DG SANTE (the Directorate-General for Health and Food Safety) are working to ensure a robust Union response to serious cross-border health threats.

AMR and other health threats can only be adequately addressed by following a One Health approach recognising that the health of humans, domestic and wild animals, plants and the wider environment are closely entwined.

## Goals for antimicrobial resistance and other health threats

| Goals | How we will achieve them |
|---|---|
| **Contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach (4.1)** | • Continue to implement the requirements for the mandatory collection and reporting of sales and use data for antimicrobials in animals and for improving access to information and data and communicating the findings (4.1.1)<br>• Modernise the product information of existing antibiotics for veterinary use and consider additional options for guiding prescribing practices in accordance with the terms of their marketing authorisation. For human medicines, take account of ongoing initiatives while incorporating relevant new provisions in the new pharmaceutical legislation (4.1.2)<br>• In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests (4.1.3)<br>• Develop, update and promote regulatory guidance on antimicrobial use in animals to guarantee therapeutic options and minimise the impact of antimicrobial resistance while also supporting the development, implementation and uptake of guidance for human medicines (4.1.4) |

| | |
|---|---|
| **Support development of new antimicrobial agents and alternatives to the use of antimicrobials in collaboration with international partners (4.2)** | • Provide guidance on regulatory pathways for phages and other innovative products in human and veterinary medicine, engaging with relevant stakeholders (4.2.1)<br>• Engage stakeholders in pipeline discussions with a view to facilitating the development and eventual authorisation of relevant products, including vaccines (4.2.2)<br>• Provide systematic support to developers of new antimicrobials for human use, including vaccines, antibacterials and alternatives to the use of antimicrobials, mainly through the ETF, and for veterinary medicines through the Innovation Task Force (ITF) and veterinary medicines Scientific Advice Working Party (4.2.3)<br>• Support the European Commission and Member States in the implementation of new business models for antimicrobials (particularly antibacterial agents), including eligibility assessment (4.2.4) |
| **Strengthen regulatory preparedness for health threats (4.3)** | • Refine regulatory activities to increase preparedness and harmonise approaches for investigating medicinal products during emergencies, including approaches for conducting timely clinical trials during emergencies (4.3.1)<br>• Respond to health threats that could be related to climate and environmental changes using the One Health approach, as defined by the One Health High-Level Expert Panel (OHHLEP), when applicable, and in close collaboration with other Union agencies (4.3.2)<br>• Expand international alignment on regulatory requirements from quadrilateral (US FDA-Health Canada-PMDA[3]-EMA) agreements to achieve more global consensus (4.3.3)<br>• Adopt necessary regulatory flexibilities to support the development and authorisation of countermeasures for use in emergencies, including those caused by chemical, biological, radiation and nuclear threats (4.3.4)<br>• Explore ways to better inform the public about medicines for health threats to engender trust in medicines and the regulatory system (4.3.5) |

3 Japan's Pharmaceuticals and Medical Devices Agency

# 5. Availability and supply of medicines

## A shared responsibility

**Repeated shortages of vital medicines, particularly those for severe and chronic illnesses, put the health of the public at risk and erode public trust in the regulatory system.**

Preventing these shortages is a shared responsibility. In their role managing shortages and overseeing supply chains, regulators must work closely with marketing authorisation holders and manufacturers, many of whom operate outside the EU, as well as with international partners, who are working to protect the supply of medicines in their territories. Regulators must also work closely with healthcare professionals, including physicians and pharmacists, wholesalers and patients who all play a role in managing the impact of shortages.

The network's strategy for improving the availability of medicines involves identifying root causes of shortages and developing harmonised strategies for preventing and managing them, coordinating activities within and outside the network to effectively tackle shortages, and reinforcing the oversight and protection of the supply chain.

The network will also collaborate with the European Commission to support future initiatives, including those related to the Critical Medicines Act.

## Availability of veterinary medicines

Ensuring the availability of medicines for animals is a particular challenge due to the large number of species for which treatments are needed and the fact that medicines availability fluctuates across the EU. Given the importance of animal health and how animal and human health are intertwined, the network will address specific factors hindering the availability of veterinary medicines.

## Inspection capacity

In the years ahead, it is crucial that the network has sufficient numbers of trained inspectors continuously available to perform legal duties relating to regulatory inspection procedures. It is also imperative that they are adequately trained to deal with challenges they could encounter during inspections, particularly in countries outside the EU with different legal frameworks.

## Goals for availability and supply

| Goals | How we will achieve them |
|---|---|
| **Strengthen the availability of medicines to protect public and animal health (5.1)** | • Identify specific root causes of shortages for human and veterinary medicines and develop harmonised strategies to improve the prevention and management of shortages, particularly for critical medicines (5.1.1)<br>• Improve coordination of activities related to improving availability of human medicines and implement best practices in conjunction with stakeholders and international partners (5.1.2)<br>• Work with the European Commission to coordinate national and EU strategies for human medicines, including stockpiling, to reduce the possible impact of national measures on availability of medicines in other countries (5.1.3)<br>• Improve transparency and balanced communication on both the launch of medicinal products and shortages with relevant stakeholders, including patients, healthcare professionals and HTA bodies (5.1.4) |
| **Reinforce the oversight and protection of the supply chain and increase inspector capacity (5.2)** | • Ensure sufficient numbers of trained inspectors are continuously available to perform legal duties (see theme 6) (5.2.1)<br>• Use risk-based inspection planning, alternative inspection methodologies and collaboration with international partners to better target oversight of the supply chain, including for key finished product and active pharmaceutical ingredient (API) manufacturers (5.2.2)<br>• Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines into the supply chain (5.2.3)<br>• Keep good manufacturing practice (GMP) requirements updated in light of technological progress in manufacturing (e.g. with respect to digital, AI and other technological systems) (5.2.4)<br>• Improve and interlink information in current databases (e.g. EudraGMDP) (5.2.5) |

# 6. Sustainability of the network

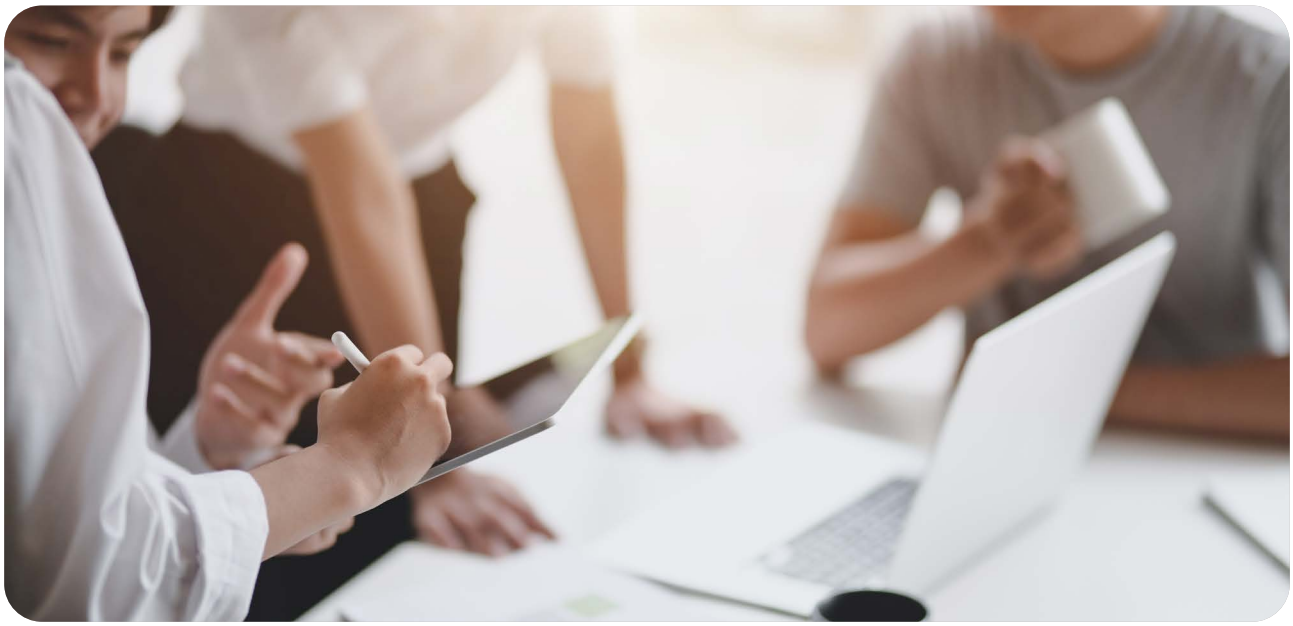
**Protecting public health is a long-term objective and it is important that the network is able to pursue its goals in the long as well as the short and medium term. This means having adequate resources, including funding and expertise, business processes and IT capabilities as well as efficient governance structures that plan for and are capable of executing long-term projects.**

It also requires managing the network's workload to ensure that the regulatory system is not under undue strain and finding ways to build capacity and capabilities to deal efficiently with the increasing complexity of medicines and technologies. Reinforcing the capacity and capability of the network is a key part of the entire strategy.

The workload of the network is driven in large part by the number and timing of submissions from marketing authorisation holders and applicants, which can be made centrally, through the mutual recognition and decentralised procedures or via the purely national route. A key challenge is to allocate resources for the various procedures more strategically across the network (e.g. based on type of product or procedure).

Establishing a shared operating model to support the network's activities and using technology to transform its processes will therefore be key to building a more sustainable network. Equally important is strengthening cooperation with international partners, e.g. via ICMRA, which will improve the ability of the network (and its partners) to deal with regulatory challenges which are increasingly global in nature.

To achieve its aim of protecting public health, the network must also engage effectively with stakeholders. Working with the public, patients and healthcare professionals is crucial because these stakeholders need to be adequately informed about the medicines they use or prescribe and because trust in the regulatory system is necessary to counter mis- and disinformation and 'anti-science' narratives. In addition, the network should continue to strengthen its engagement with medicines developers, including academia, to achieve its aims of increasing accessibility and availability of much needed medicines.



## Goals for sustainability

| Goals | How we will achieve them |
|---|---|
| **Reinforce the scientific and regulatory capacity and capability of the network (6.1)** | • Ensure the network has the capacity and capability to support innovation and the use of new methodologies, AI and data analytics and to be equipped for the new pharmaceutical legislation (6.1.1)<br>• Explore ways to improve efficiency by creating centres of excellence and allocating NCA resources more strategically (6.1.2)<br>• Build the network's capability to carry out the digital transformation of its scientific and regulatory processes, knowledge management, ways of working and tools (6.1.3) |
| **Establish a shared operating model to support network activities and collaboration (6.2)** | • For human medicines, prepare for the implementation of new legislation combined with the modernisation and consolidation of IT systems (6.2.1)<br>• For veterinary medicines, continue to build on the progress achieved in implementing the veterinary regulation and align IT solutions across sectors (6.2.2)<br>• Explore opportunities for shared data, process and technology initiatives, including AI, and establish a model for joint EMA/HMA sponsorship of such initiatives (6.2.3)<br>• Contribute to the implementation of the new EMA fee regulation[4] and regularly monitor and adjust the cost-based system for fees and NCA remuneration (6.2.4) |
| **Strengthen public and stakeholder engagement and global convergence with international partners (6.3)** | • Enhance the capacity of the network through international convergence, information and work sharing and multilateral cooperation (6.3.1)<br>• Together with the European Commission, strengthen international collaboration to perform legal duties relating to inspections and to face global challenges related to new methodologies and continuous manufacturing (6.3.2)<br>• Strengthen cooperation between European and international partners and support the regulatory systems in EU candidate countries and the African Medicines Agency (6.3.3)<br>• Develop and implement a framework for communication and engagement with stakeholders to address information needs of the public and counter mis- and disinformation (6.3.4) |

4 Regulation (EU) 2024/568 on fees and charges payable to EMA

# Beyond EMANS 2028

**EMANS 2028 is the product of many months of collaboration between a group of experts from NCAs (under the auspices of the HMA) and EMA. The group decided on the themes and what had changed since the adoption of EMANS 2025, formed drafting groups to discuss challenges and opportunities in each focus area, and then worked on the goals for the network along with the objectives for achieving them. Notes from the months-long deliberations are available in a reflection paper, the text of which formed the basis of the initial draft of EMANS 2028.**

The preparation of the strategy also took into account feedback from a public consultation. Over a two-month period, several stakeholders, including industry, patients, healthcare professional organisations, researchers, animal welfare organisations and public bodies, were able to share their opinions on the draft strategy and on what the priorities should be in the coming years. A multi-stakeholder webinar subsequently took place ahead of the finalisation.

In implementing this strategy, it is important for the network to have a shared vision of what the situation will be in the EU for users of medicines and all its stakeholders as we approach 2028 and beyond.

## A vision for the near future

This strategy paints a vision for 2028 and beyond of an EU where:

- The pathway to accessibility is efficient and predictable due to greater collaboration with all stakeholders, especially HTA bodies, payers and policy makers.
- The network has kept abreast of advances in digitalisation and AI and is making progress in transforming its scientific and regulatory processes.
- The network has taken impactful action to accelerate the translation of innovation into medicines development and improve competitiveness relative to other parts of the world.
- The network has made appreciable progress in tackling the threat posed by antimicrobial resistance and has increased preparedness for other threats.
- Fewer patients and users of animal medicines face the problem of acute and long-term shortages, particularly of critical medicines.
- The network is on a better footing with respect to available resources and has increased its productivity, taking full advantage of technological advances.

In the coming years, the network will evaluate its progress in each focus area by assessing how it achieves the individual goals and objectives set out in this strategy. Importantly, the network stands ready to adapt its approaches as necessary in response to advances in science and technology and to seize new opportunities that arise in the future.

# List of abbreviations

| | |
|---|---|
| **ACT EU** | Accelerating Clinical Trials in the EU |
| **AI** | Artificial intelligence |
| **AMR** | Antimicrobial resistance |
| **API** | Active pharmaceutical ingredient |
| **CTIS** | Clinical Trials Information System |
| **DARWIN EU** | Data Analysis and Real World Interrogation Network |
| **DG HERA** | Directorate-General Health Emergency Preparedness and Response Authority |
| **DG SANTE** | Directorate-General for Health and Food Safety |
| **EMA** | European Medicines Agency |
| **EMANS** | European Medicines Agencies Network Strategy |
| **EHDS** | European Health Data Space |
| **ETF** | Emergency Task Force |
| **GMP** | Good manufacturing practice |
| **HAG** | Heads of HTA Agencies Group |
| **HMA** | Heads of Medicines Agency |
| **HTA** | Health technology assessment |
| **ICMRA** | International Coalition of Medicines Regulatory Authorities |
| **IT** | Information technology |
| **ITF** | Innovation Task Force |
| **NCA** | National competent authority |
| **OHHLEP** | One Health High-Level Expert Panel |
| **PMDA** | Pharmaceuticals and Medical Devices Agency (Japan) |
| **SMEs** | Small and medium-sized enterprises |
| **US FDA** | United States Food and Drug Administration |

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