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# Towards the European medicines agencies network strategy 2028 (EMANS 2028)

Reflection paper

# Contents

# Abbreviations

| | |
|---|---|
| ACT EU | Accelerating Clinical Trials in the EU |
| AI | Artificial intelligence |
| API | Active pharmaceutical ingredient |
| AMR | Antimicrobial resistance |
| BDSG | Big Data Steering Group |
| CESP | Common European Submission Portal |
| CHESSMEN | Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network |
| CTCG | Clinical Trials Coordination Group |
| CTIS | Clinical Trial Information System |
| DARWIN EU | Data Analysis and Real World Interrogation Network |
| DG HERA | Directorate-General Health Emergency Preparedness and Response Authority |
| EC | European Commission |
| EHDS | European Health Data Space |
| EIC | European Innovation Council |
| EIT | European Institute of Innovation and Technology |
| EMA | European Medicines Agency |
| EMANS | European medicines agencies network strategy |
| ESG | Electronic submission gateway |
| ESMP | European Shortages Monitoring Platform |
| ETF | Emergency Task Force |
| EU | European Union |
| EUCAST | European Committee on Antimicrobial Susceptibility Testing |
| EU-IN | EU-Innovation Network |
| EU-JAMRAI | European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections |
| EU-NTC | EU Network Training Centre |
| EU-SRS | European Substance Registration System |
| EURIPID | The European Integrated Price Information Database |
| FAO | Food and Agriculture Organization |
| GDP | Good distribution practice |

| | |
|---|---|
| GMP | Good manufacturing practice |
| HMA | Head of Medicines Agencies |
| HTA | Health technology assessment |
| HTACG | Member State Coordination Group on Health Technology Assessment |
| ICMRA | International Coalition of Medicines Regulatory Authorities |
| IDMP | Identification of medicinal products |
| IHI | Innovative Health Initiative |
| IHSI | International Horizon Scanning Initiative |
| ISO | International Organization for Standardization |
| ITF | Innovation Task Force |
| JPIAMR | Joint Programming Initiative on Antimicrobial Resistance |
| MAH | Marketing authorisation holder |
| MCM | Medical countermeasure |
| MSSG | Steering Group on Shortages and Safety of Medicinal Products |
| NCA | National competent authority |
| NCAPR | National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers |
| NPAG | Network Portfolio Advisory Group |
| NTWP | Novel Therapies and Technologies Working Party |
| OECD | Organisation for Economic Co-operation and Development |
| OHHLEP | One Health High-Level Expert Panel |
| OSOA | One substance, one assessment |
| PED | Patient experience data |
| PMDA | Pharmaceuticals and Medical Devices Agency (Japan) |
| PQKMS | Pharmaceutical Quality Knowledge Management System |
| QIG | Quality Innovation Group |
| RAGNA | Regulatory Agencies Global Network against AMR |
| R&D | Research and development |
| ROG | Regulatory Optimisation Group |
| RSS | Regulatory science strategy |
| SAWP | Scientific Advice Working Party |
| SME | Small and medium-sized enterprise |

| | |
|---|---|
| SoHO | Substances of Human Origin |
| SPOC WP | Single Point of Contact Working Party |
| SPOR | substance, product, organisation and referential |
| TATFAR | Transatlantic Taskforce on Antimicrobial Resistance |
| TEHDAS2 | Towards European Health Data Space 2 |
| TF AAM | Task Force on Availability of Authorised Medicines for Human and Veterinary Use |
| UNEP | United Nations Environmental Programme |
| US FDA | United States Food & Drug Administration |
| VetCAST | Veterinary subcommittee of the European Committee on Antimicrobial Susceptibility Testing |
| WHO | World Health Organization |
| WOAH | World Organisation for Animal Health |
| XEVMPD | Extended EudraVigilance medicinal product dictionary |

# Introduction

In the last quarter of 2020, the European medicines regulatory network published its five-year strategy covering the period from 2021 to 2025 (EMANS 2025)[1] under the overarching theme 'protecting public health at a time of rapid change.'

EMANS 2025 set out how the network will continue to foster the development and supply of medicines, taking advantage of developments in science, medicine and digital technologies and tackling health threats, such as the COVID-19 pandemic.

The strategy had six themes or priority focus areas: 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 and 6) sustainability of the network and operational excellence.

### Updating EMANS 2025

In December 2023, the network published its mid-term report showing the progress made in implementing the strategy.[2] Following the publication of the mid-term report, the network started work on reviewing the scope of the strategy to cover the network's goals and objectives up to 2028.

While the COVID-19 pandemic had already started by the time EMANS 2025 was published, the pandemic brought about further changes in how the network deals with health threats. The EU enacted new legislation[3] to handle health threats and established the Directorate-General Health Emergency Preparedness and Response (DG HERA) to improve the EU's preparedness. In addition, technological advances, particularly in the area of artificial intelligence (AI), occurred more rapidly than originally anticipated and are significantly changing the regulatory landscape. The regulatory landscape will undergo further changes in the coming years as the European Union revises its pharmaceutical legislation in what will be 'the largest reform in over 20 years'.[4]

The approach taken for the updated strategy (EMANS 2028) recognises the urgent need to adapt to these developments. The network decided to update EMANS 2025 to cover the period up to 2028, taking into account the fact that some of the changes, most notably, the revision of the EU pharmaceutical legislation are still underway. While EMANS 2028 cannot pre-empt the legislative changes or make assumptions about what they will be, it can help the network to take preparatory steps to be in the best position to implement them smoothly.

As a first step to updating EMANS 2025, the Heads of Medicines Agencies (HMA) and the European Medicine's Agency (EMA) produced this reflection paper which the network used as a basis for developing EMANS 2028. EMANS 2028 will be available for public consultation before its final adoption. (See section 7. ).

[1] https://www.ema.europa.eu/en/documents/report/european-union-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf
[2] https://www.ema.europa.eu/en/documents/report/european-medicines-agencies-network-strategy-2025-mid-point-report-q2-2023_en.pdf
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2022:020:TOC
[4] https://ec.europa.eu/commission/presscorner/detail/en/IP_23_1843

**Strategic focus areas for EMANS 2028**

In addition to updating EMANS 2025, EMANS 2028 will also cover strategic aspects of EMA's regulatory science strategy (RSS) [5] primarily within theme 3, thereby bringing together the overall strategy of the European medicines regulatory network into a single document.

This reflection paper builds on the strategic focus areas from EMANS 2025 with some changes made to increase the focus on topics such as competitiveness and artificial intelligence. The theme of availability is now considered alongside the theme of supply.

While the strategy applies to both human and veterinary medicines, some of the goals and objectives in the focus areas may apply only to human or veterinary medicines. Where this is the case, it is made clear in the text.

| **Updated strategic focus areas or themes for EMANS 2028** |
| --- |
| • Accessibility<br>• Leveraging data, digitisation and artificial intelligence<br>• Regulatory science, innovation and competitiveness<br>• Antimicrobial resistance and other health threats<br>• Availability and supply<br>• Sustainability of the network |

EMANS 2028 will feed into the network's core work of evaluating medicines for authorisation and monitoring their safety. The EU's robust pharmacovigilance system, for example, stands to gain from goals such as improvements in network processes and how the network seizes the opportunities presented by the advances in data analytics and artificial intelligence. Furthermore, improvements in evidence generation (linked to efforts to improve innovation and accessibility) can lead to benefits in how the network evaluates medicines before and after authorisation.

An important transversal theme is capacity building. For the network to achieve its strategic aims it is important that it has the resources and the personnel required for its tasks, from inspecting manufacturing sites and overseeing the supply chain to applying the latest digital tools and supporting innovation. This is emphasised in the section on sustainability (section 6. ) but is a transversal theme cutting across all focus areas.

Also key to achieving the strategic goals of EMANS 2028 will be the collaboration between the network and its stakeholders. From improving accessibility to harnessing innovation and addressing information needs of the public, the network will rely on its work with international partners, as well as patients and healthcare professionals, industry and academia for the successful implementation of the strategy. This too is highlighted in the section on sustainability.

# 1. Accessibility

This reflection paper distinguishes between accessibility and the closely related concept availability (see section 5. ). For human medicines, a medicine is considered accessible when it has gone through the necessary steps towards approval and reimbursement by healthcare systems, i.e. it has been

[5] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

authorised by regulators and evaluated positively by other relevant authorities such as health technology assessment (HTA) bodies and payers.

HTA bodies as well as payers consider factors such as effectiveness compared to alternative treatments and affordability to determine whether a medicine is of sufficient value to be taken up by national health systems. This means that there are situations where a medicine may have a marketing authorisation but, for all intents and purposes, is not accessible to patients.

If a medicine is accessible, it is only considered 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. Though the two concepts of accessibility and availability are related to the same goal (ensuring patients have medicines they need), the distinction is necessary because improving accessibility and availability requires distinct sets of actions.

Accessibility and availability, along with affordability, are key drivers for the ongoing revision of the EU pharmaceutical legislation, and it is important that the network is ready to implement the relevant provisions once it is enacted.

With respect to accessibility, the new Regulation on Health Technology Assessment (Regulation (EU) 2021/2282 or the HTA Regulation) will come into application in January 2025 providing a framework for EU-level clinical assessment of medicinal products and medical devices to inform national decision making on access. Cooperation and information exchange with EMA is recognised in the Regulation, and regulators will consequently contribute to its successful implementation.

In addressing the issue of accessibility, it is important to acknowledge that healthcare systems need to make important choices, given the limited resources available in terms of personnel and funding. Collaborating with HTA bodies and payers can enable broader, faster and more equal access across the EU for both innovative and off-patents medicines and ensure that the development and evaluation stages generate the kind of evidence that also serves their needs.

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

## *1.1. Challenges*

Given that a main goal of the network is to facilitate the path from authorisation to approval by HTA bodies and payers, the key challenge is the generation of evidence these bodies need for their decision making.

It is clear that the evidentiary requirements need to be carefully considered, taking into account the increased complexity of healthcare solutions patients are faced with in terms of administration and funding and taking a life-cycle approach to evidence generation with the possibility of adjusting decisions as new evidence is generated.

There is also a need to focus on streamlining the development of biosimilar medicines as well as complex generic medicines, through dialogue on evidence needs and by promoting public trust and uptake of these medicines. In this context, international efforts to integrate behavioural evidence into public health programmes and policies are noted.[6]

It will also be important to take account of advances in the use of real-world data and patient experience data (PED), which can complement clinical data obtained at the pre-marketing stage. In

[6] https://www.who.int/news/item/12-11-2021-joint-research-centre-and-world-health-organization-join-forces-to-use-behavioural-insights-for-public-health

addition, there is a need to increase the transparency surrounding the evidence on which both marketing authorisation decisions and HTA decisions are made and to create a framework that makes the path from development to accessibility more predictable.

Importantly, the network needs to come to a common understanding of unmet medical needs, a concept that HTA bodies and payers also use in their national decision-making.

## *1.2. Opportunities*

The network is in a good position to build on its current interactions with HTA bodies and payers. Early discussions on evidence needs through parallel scientific advice are recognised pillars and will be strengthened through the new system under the HTA Regulation. The network is also working closely with HTA bodies and payers in EMA's lifecycle management initiatives (e.g. the Data Analysis and Real-World Interrogation Network (DARWIN EU)). The network should also build on its consultation with these bodies, as well as national authorities responsible for medical devices, to define evidence needs for combinations of medicines with devices and digital technologies and other complex healthcare solutions.

Furthermore, opportunities brought about by the HTA Regulation provide a framework for greater collaboration between regulators and HTA bodies on methodological and scientific guidelines, as well as research towards new methodologies and evidence requirements. The latter should be underpinned by information exchange with the European-level HTA network under the HTA Regulation, as well as regional healthcare payer organisations in relation to preparedness / horizon scanning.

## *1.3. Goals and objectives*

Having considered the current situation and possible new developments in the coming years, the network will focus on two main goals and specific objectives for achieving them.

- **Optimise the path to accessibility by working with other decision makers (HTA bodies and payers).**
  - Contribute to the successful implementation of the HTA Regulation.
  - Foster the generation of robust scientific evidence to serve different decision makers (regulators, HTA bodies and payers).
  - Enhance communication with other decision makers about the scientific considerations leading to regulatory outcomes.
- **Deepen engagement with healthcare policy makers on initiatives and research relevant to sustain health technology accessibility.**
  - 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.
  - Conduct research to better understand accessibility for medicines addressing unmet needs and how evidence requirements affect decision outcomes.
  - Continue collaborative work on methodologies for the generation of evidence that is also relevant for health technology assessments.

### *1.4. Ongoing initiatives and activities*

The following initiatives and activities were considered in the development of the network's goals and objectives.

| **Network initiatives and activities – accessibility** |
|---|
| • Implementation of the HTA Regulation<br>• EU initiatives on making medicines more affordable(e.g. the European Integrated Price Information Database (EURIPID) project)<br>• Activities under the auspices of the National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR) to enable healthcare payer collaboration<br>• World Health Organization (WHO)/Europe Access to Novel Medicines Platform<br>• Activities of the Organisation for Economic Co-operation and Development (OECD) with respect to access to medicines<br>• The International Horizon Scanning Initiative (IHSI)<br>• Engagement with HTA bodies and payers in EMA's lifecycle management initiatives (e.g. DARWIN, Big Data Steering Group (BDSG) activities and AI initiatives)<br>• Consultation of HTA and payers to define evidence needs for combinations of medicines with devices and digital technologies and other complex healthcare solutions<br>• Work on patient experience data (PED)<br>• Stakeholder survey on biosimilar information needs and interchangeability and development of communication toolkit |

# 2. Leveraging data, digitalisation and artificial intelligence

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 is as meaningful and unbiased as possible and that attendant risks, including security and confidentiality risks, are kept to a minimum. To this end, the network is already making efforts to strengthen data governance, share more data across the network and ensure that data from the one partner in the network is in a form that can be used by other partners (so called 'interoperability').

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

AI is a prime example of such emerging technologies. Since EMANS 2025, the availability and use of AI has become more common place. The network aims to harness the full potential of AI not only to strengthen regulatory decision making but also to increase personal productivity and efficiency of network processes.

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

## *2.1. Challenges*

Managing the continuous increase in the volume and complexity of data from various sources ('Big Data') is a key challenge for the network. Due the rapid advances in access to healthcare data, technology and methodologies, the network will also need to continuously adapt its regulatory standards and guidance on the use of patient-level healthcare data and artificial intelligence. As the field evolves at speed, it is important that guidelines keep abreast of changes and embrace diverse populations.

The network will also need to significantly expand its technological capability and capacity and to attract more personnel with skill sets in areas such as advanced analytics, including artificial intelligence.

There are also non-technological challenges, for example maintaining public trust in the use of AI by industry and regulators. In addition, the use of data and the digital transformation of the network's processes must be in accordance not only with legal requirements such as those concerning data protection but should also accord with societal values and ethical considerations. Engaging with stakeholders will be key in successfully using technology such as AI in the network's processes in a way that engenders trust.

## *2.2. Opportunities*

The challenges notwithstanding, the network has made significant progress over the past few years. The European Health Data Space (EHDS) Regulation and AI act have provisions to alleviate some of the challenges. Furthermore, the successful delivery of the Big Data Steering Group workplan, the adoption of the multi-annual AI workplan to 2028, the adoption of the European Veterinary Big Data strategy 2022- 2027, the delivery of the EU Veterinary Big Data workplan to 2025 and the development of EMA's reflection paper on the use of AI in the medicinal product life cycle are demonstrations of the continuous efforts of the network to realise the full potential of evidence generation and AI in regulatory decision-making. These efforts have also included international collaboration where key progress was made in the area of real-word evidence.

Several initiatives have also been launched or rolled out by national competent authorities and EMA to use and experiment with AI, particularly in the area of large language models. The Accelerating Clinical Trials in the EU (ACT EU) initiative will also contribute to the increased use of data, digitalisation and AI in the EU network by supporting smarter clinical trials through regulatory, technological and process innovation.

In the meantime, the Horizon Europe Health cluster will continue investing in multistakeholder collaborative projects to improve and protect citizens' health until 2027 by generating new knowledge and developing innovative solutions. Outcomes of such projects can benefit the EU regulatory network and its help in its goal to leverage data, digitalisation and AI.

The HTA Regulation could also provide further opportunities to strengthen the access and use of data to support decision-making.

Finally, the HMA/EMA Regulatory Optimisation Group (ROG) can provide strategic input (including problem statements and business cases) on relevant topics to the Network Portfolio Advisory Group (NPAG), which in turn provides recommendations to the EMA Portfolio Board and Agile Value Streams.

## 2.3. Goals and objectives

Having considered the current situation with respect to leveraging data, digitalisation and artificial intelligence and possible new developments in the coming years, the network will focus on three main goals and specific objectives for achieving them.

- **Maximise the generation, interoperability, use and exchange of data to support EU decision-making.**
  - Embed the use of EU healthcare data from diverse populations in the network's processes[7] and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, e.g. genomic data).
  - Ensure a high level of interoperability, standardisation and quality of data addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed.
- **Leverage digitalisation, experimentation and innovation to deliver optimised regulatory processes.**
  - Reinforce the network's digital infrastructure in line with the Network Portfolio Vision to drive digital transformation of the network's scientific and regulatory processes.
  - Foster a culture of continuous experimentation and innovation across the network.
- **Realise the network vision on AI across all EMANS focus areas.**
  - Leverage experimentation and technological advances in AI to support the digital business transformation of the EU network.
  - Harness the potential of AI throughout the medicines' lifecycle.

## 2.4. Ongoing initiatives and activities

The following initiatives and activities were considered in the development of the network's goals and objectives.

| Network initiatives and activities – Leveraging data, digitalisation and artificial intelligence |
|---|
| • Implementation of the Big Data Steering Group workplan 2023-2025, the multiannual AI workplan to 2028 and the European Veterinary Big Data strategy 2022-2027<br>• The European Commission's initiatives relating to digital transformation of healthcare in the Digital Single Market<br>• European activities related to artificial intelligence (including activities of the high-level expert group on AI and the AI Act)<br>• The European Health Data Space (and its joint action Towards European Health Data Space 2 (TEHDAS2) and related projects)<br>• The European Strategy for Data |

[7] This includes leveraging data through EHDS and DARWIN EU and analysis of individual patient data from clinical trials.

**Network initiatives and activities – Leveraging data, digitalisation and artificial intelligence**

- Work to implement the veterinary medicines regulation (Regulation (EU) 2019/6) in relation to pharmacoepidemiology, signal detection and antimicrobial resistance, which will benefit significantly from use of big data and AI
- Implementation of international data standards like International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) across Europe and progress in implementing usage of substance, product, organisation and referential (SPOR) master data throughout the network
- Implementation and further development of the European Substance Registration System (EU - SRS)
- Initiatives on e-submission of clinical trial applications and simplification, modernisation, and improvement of the Clinical Trial Information System (CTIS)

# 3. Regulatory science, innovation and competitiveness

Innovation in the pharmaceutical sciences is a major factor determining the types of promising new medicines that will be available to EU citizens in the future. Today, advances from transformational research in biomedical science are yielding new treatment opportunities at an ever-increasing pace. Editing of the genetic code and functions of cells has already brought new and effective treatments against cancer and other major diseases, while developments in advanced therapy medicinal products offer more opportunities to address unmet medical needs.

Biomarkers identified from genomic, proteomic, metabolic and microbiomic data, as well as clinical and imaging data, offer the possibility of tailoring treatments at a personalised level in a more targeted way (personalised medicine). Such innovations may require novel manufacturing technologies and delivery approaches, including nanotechnology, 3D printing, decentralised in situ manufacturing and the greater use of medical device/medicinal product combinations and related diagnostics.

The network has long realised that it has a key role to play in creating a conducive regulatory environment to increase the likelihood that innovations result in the successful development of medicines, and the integration and uptake of these medicines within the healthcare systems, including medicines to address health threats, such as antimicrobial resistance (see section 4. ).

Experience has shown that developers benefit from dialogue and support at various stages of development, and working with developers early in medicines development can ensure that appropriate evidence is generated for regulators and other decision makers to evaluate medicines (see section 1. ).

In the area of medical devices and combination product development, closer collaboration involving various stakeholders (including clinicians, academics, medical devices experts, notified bodies, ethics and patients committees, small and medium-sized enterprises (SMEs), research groups, industry and incubators) will help harness expertise and talents across the EU, leading to a more efficient ecosystem for innovation and product development. An example of such collaboration can be seen in the COMBINE project, which aims to analyse the root causes of challenges faced by sponsors in conducting clinical studies of medicines alongside performance studies of diagnostics or clinical investigations of medical devices, and to identify potential solutions to these challenges.

Innovation also applies to clinical trials. ACT EU and similar initiatives aim to transform the initiation, design and execution of clinical trials to promote the development of high-quality, safe, and effective medicines, while better integrating clinical research into the European health system. In this context, the Clinical Trials Information System (CTIS) remains an essential tool for implementing the Clinical Trials Regulation, supporting Europe as a key destination for clinical trials. Ongoing efforts will focus on simplifying, modernising and improving the system's user experience. In addition to fostering innovation in the conduct of clinical trials, the network also aims to contribute to medicines' innovation through more efficient evidence generation.

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. In addition, the network will support initiatives aimed at making pharmaceutical production more environmentally sustainable.

For innovation to thrive in the EU, it is important to have a competitive environment. The European Commission and national competition authorities help foster competition in the EU as well as enhancing the overall competitiveness of the region. The network also has a role to play by providing support to innovators and ensuring that the regulatory framework is conducive to research and the development and manufacturing of medicines.

## *3.1. Challenges*

A key challenge concerns resources within the network to support innovation. The network must urgently address the challenge of acquiring relevant scientific expertise and keeping abreast of innovations in research and development, such as advances in precision/personalised medicines and manufacturing and analytical technologies.

The network will need to carefully consider factors inhibiting the successful development of medicines in the EU, which may include regulatory complexity, lack of adequate funding and too much fragmentation in the innovation ecosystem.

The network also needs to find ways to reduce the therapeutic gap with respect to the unmet medical need for veterinary medicines in cases where there are no authorised veterinary medicines.

Other challenges are more strategic and may require input from outside the network, for example finding ways to maintain EU's global competitiveness as a place for developing innovative products and attracting research and development.

## *3.2. Opportunities*

The revision of the EU pharmaceutical legislation provides a unique opportunity to modernise and future proof the regulatory framework to address some of the challenges noted above.

Other areas where work is underway include the repurposing of authorised medicines; early collaboration and dialogue with stakeholders with respect to regulatory and scientific requirements; and horizon scanning and activities to future proof the network and innovation ecosystem.

The EU's competitiveness and role in public health innovation also bodes well for the network's effort to boost R&D and investment in the EU, as do recent proposals from the European Commission to boost biotechnology and biomanufacturing in the EU.[8]

There are also opportunities linked to Europe's Beating Cancer Plan, which launched seven EU Networks of Expertise for cancer care focusing on areas that require cross-border collaboration, such

[8] https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1570

as -omics technologies. In addition, the European Commission supports the 24 European Reference Networks that bring together European hospital centres to tackle rare, low prevalence, and complex diseases.

## 3.3. Goals and objectives

Having considered the current situation with respect to regulatory science, innovation and competitiveness, including the challenges and opportunities, the network will focus on three main goals and specific objectives for achieving them.

- **Promote the integration of advancing science and technology in medicines development and manufacturing.**
  - Continue to support innovation and the integration of scientific and technological advancements in the development of human and veterinary medicines.
  - In collaboration with other EU bodies, implement a model for efficient, timely and coordinated EU horizon scanning for human and veterinary medicines that addresses the needs of regulators HTA bodies and payers, supported by digital tools and AI.
  - Facilitate the implementation of novel manufacturing technologies and analytical techniques.
- **Foster generation of high quality and impactful evidence with particular focus on clinical trials.**
  - Support the generation of high-quality evidence in quality, non-clinical and clinical domains by researchers and sponsors from early development stages and provide timely scientific and/or regulatory advice.
  - Foster innovation and the improved planning and conduct of clinical trials and emerging clinical data generation
  - 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.
- **Promote stakeholder cooperation to accelerate the translation of innovation into therapies, facilitate the repurposing of existing therapies and increase EU competitiveness.**
  - Develop network-led partnerships with key stakeholders (academia and industry) to deliver impactful progress in regulatory science and provide training.
  - 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.
  - Increase collaboration with medical device experts, notified bodies, ethics and patient communities, HTA bodies and the Substances of Human Origin (SoHO) network in conjunction with the European Commission to support development and authorisation of combination products.

## 3.4. Ongoing initiatives and activities

The following initiatives and activities were considered in the development of the network's goals and objectives.

**Network initiatives and activities – innovation and competitiveness**

- Network group work plans for the EU-Innovation Network (EU-IN), Clinical Trials Coordination Group (CTCG), Scientific Advice Working Party (SAWP), Quality Innovation Group (QIG), INNO group, EU Network Training Centre (EU-NTC) and Novel Therapies and Technologies Working Party (NTWP)
- ACT EU and other initiatives (e.g. Clinical Trial Regulation Collaborate initiative)
- Implementation of legislation in force /work on legislative proposals with respect to the medical devices regulation, In vitro diagnostic medical devices regulation, clinical trial regulation, HTA regulation, veterinary medicines regulation, SoHO regulation, AI act and one substance, one assessment (OSOA)
- Work on the roadmap on phasing out animal testing in chemical safety assessment
- NCA activities with academia
- NCA involvement and engagement with regulatory science research projects and technology transfer offices, Horizon Europe and its initiatives like Innovative Health Initiative (IHI), the European Innovation Council (EIC), the European Institute of Innovation and Technology (EIT), the Critical Path Institute and the EU-Innovation Network
- European Reference Networks
- Europe's Beating Cancer Plan which launched EU Networks of Expertise for cancer care, EU Network of National Comprehensive Cancer Centres)
- Partnership for the Assessment of Risks from Chemicals
- Ongoing initiatives on horizon scanning
- Repurposing project
- Parallel consultation between Regulatory Authorities and the Member State Coordination Group on HTA (HTACG)
- International collaboration within the International Coalition of Medicines Regulatory Authorities (ICMRA)
- European Platform for Regulatory Science Research
- EC communication on boosting biotechnology and biomanufacturing in the EU, leading to a potential EU Biotech Act[9]
- EU4Health programme /Joint actions: IncreaseNET

# 4. Antimicrobial resistance and other health threats

The EU has adopted the One Health approach, as defined by the One Health High-Level Expert Panel (OHHLEP), to address health threats. One Health is an integrated, unifying strategy that seeks to sustainably balance and optimize the health of people, animals and ecosystems. In today's interconnected world, this approach is essential to prevent, prepare for and respond to global threats.

[9] https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffc-411b-8cd6-b52417514cb3_en

A prime example of such threats is antimicrobial resistance (AMR). In the EU alone AMR causes more than 35,000 human deaths per year while the global toll is estimated to amount to 1.27 million human deaths annually. If the emergence and spread of AMR continues unabated, the annual number of deaths worldwide is expected to be in the millions, making AMR a more common cause of death than cancer by 2050.[10][11]

To manage the AMR threat, the network must promote the responsible use of antimicrobials in both the human and veterinary sectors while supporting the development of new antimicrobial agents and alternatives to the use of antimicrobials. International collaboration is crucial here given the global causes and effects of AMR and the urgent need to pool expertise as well as collaboration with other EU scientific agencies following the One Health approach[12].

Additionally, it is essential to consider the gendered aspects of health threats and the use of antimicrobials for effective interventions. Differences in biological factors, social roles and access to resources can significantly impact the prevalence, experience, and management of health issues.

On the veterinary side, since EMANS 2025 the veterinary medicines regulation (Regulation (EU) 2019/6) has become applicable, and rules regarding the use of antimicrobials in animals and reserving certain antimicrobials for humans have been strengthened.

A step-wise approach to developing and expanding the systems collecting and reporting antimicrobial use data by animal species and by certain animal species categories is being implemented in line with legislative requirements. This requires additional support in terms of system expansion and analytical tools. The network needs to continue to improve the prevention and treatment of infectious diseases in animals and to promote better use and regulation of existing antibiotics. It also needs to provide a pathway for the development of new antibiotics for veterinary use.

There are also biological threats to public health beyond AMR that the network will have to face and for which the network will need to find enduring solutions. As the COVID-19 pandemic illustrated, viral outbreaks in one part of the globe can spread rapidly causing death and severe illness as well as economic disruption. The world was still dealing from the consequences of the pandemic when an outbreak of mpox occurred and quickly spread around the world. Still other health threats will be non-biological in nature. Chemical, radiological, and nuclear threats, including bioterrorism, natural disasters and chemical attacks, need the continuous attention of the network.

Preparing for health threats requires new approaches for providing regulatory support for the development of innovative products, such as phages and microbiome-based products. The need to support innovative SMEs and academic groups is also greater, and international cooperation is more critical. With respect to the latter, the network can build on its collaboration with regulators such as those in North America and Japan and expand these efforts globally by participating in initiatives such as Regulatory Agencies Global Network against AMR (RAGNA) and FAO-UNEP-WHO-WOAH Quadripartite activities.

Within the network, the Emergency Task Force (ETF), formed at the beginning of the COVID-19 pandemic, handles regulatory activities concerned with public health emergencies and health threats. At the European Commission, DG HERA, established as a direct consequence of the lessons learned from the COVID-19 pandemic, is working to ensure a robust Union response to serious cross-border health threats including securing medical countermeasures (MCMs).

[10] https://health.ec.europa.eu/system/files/2020-01/amr_2017_action-plan_0.pdf
[11] Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050 - ScienceDirect
[12] Cross-agency One Health task force framework for action

## 4.1. Challenges

The provision of regulatory support for innovative products such as phages and microbiome products as well as support to SMEs, academic groups and clinical trial networks continues to be important to help address AMR (see section 3. ). This applies to both human and veterinary medicines.

Further work is required to provide incentives for antimicrobial development where the network faces the paradoxical challenge of seeking the development of new products that it hopes would not be used or would be used as sparingly as possible. Different ideas have emerged in recent years (e.g. 'Netflix' model and models that guaranteed revenue), and the Transferable Exclusivity Voucher is proposed in the pharmaceutical legislative review as a possible tool. These are important given the fact that the market volume for antibiotics is highly unpredictable and may not be attractive for potential developers of new antimicrobials.

There also remains the need to foster multidisciplinary dialogue between human and veterinary stakeholders and for increased involvement of regulators.

There remains a challenge in finding a pathway to market new veterinary antimicrobials after establishing a list of antimicrobials reserved for human use.[13]

Another critical challenge is integrating gender considerations into regulatory frameworks and clinical trials. Overlooking gender differences in disease prevalence, treatment efficacy and side effects may lead to potential gaps in medicine effectiveness and safety.

In combating health threats, the network must also take measures to ensure that the public have access to reliable information about medicines aimed at tackling the threats. Mistrust of regulatory systems and medicines in general can hamper efforts to protect the public. During the COVID-19 pandemic, vaccine hesitancy, partly caused by misconceptions about the COVID-19 vaccines, was a challenge for the regulatory network and vaccination authorities.

In addition to the current challenges, the network will have to consider the effect of environmental, demographic and climate changes. Such changes can result, for example in the spread of vector-borne diseases like dengue fever in Europe, bringing new or exacerbating health threats.

## 4.2. Opportunities

With the high-level of international attention on AMR in 2024 due to the United Nations General Assembly meeting and the progress made under EMANS 2025, the network has the opportunity to build on its achievements and the strengthened collaboration among EU agencies working on AMR.

Experience so far with the ETF allows the network to better support the development of new innovative medicinal products, e.g. phages, and vaccines. This support should also extend to academia, clinical trial networks, the European Committee on Antimicrobial Susceptibility Testing (EUCAST) and its veterinary subcommittee (VetCAST) and relevant European professional bodies.

Likewise, the increased interaction with international partners, particularly in North America and Japan, can serve as a model for expanding and working more closely with regulators in other regions of the world.

[13] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11653-Drug-resistance-list-of-antimicrobial-medicines-reserved-for-treating-humans_en

## *4.3. Goals and objectives*

Having considered the current situation with antimicrobial resistance and other health threats, the network will focus on three main goals and specific objectives for achieving them.

- **Contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach.**
  - 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.
  - Modernise the product information of existing antibiotics for veterinary use or consider additional options for guiding prescribing practices. For human medicines, take account of ongoing initiatives, while incorporating relevant new provisions in the new pharmaceutical legislation.
  - In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests.
  - Develop, update, and promote 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.
- **Support development of new antimicrobial agents and alternatives to the use of antimicrobials in collaboration with international partners**
  - Provide guidance on regulatory pathways for phages and other innovative products in human and veterinary medicine, engaging with relevant stakeholders
  - Engage stakeholders in pipeline discussions with a view to facilitating the development and eventual authorisation of relevant products.
  - Provide systematic support to developers of new antimicrobials, including 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
  - Support the European Commission and Member States in the implementation of new business models for antimicrobials (particularly antibiotics), including eligibility assessment
- **Strengthen regulatory preparedness for health threats.**
  - Refine regulatory activities to increase preparedness and harmonise approaches for investigating medicinal products during emergencies, including for conducting timely clinical trials during emergencies.
  - Respond to health threats that could be related to climate and environmental changes, using the One Health approach, as defined by OHHLEP, when applicable and in close collaboration with other Union agencies.
  - Expand the international alignment on regulatory requirements from quadrilateral (US FDA-Health Canada-PMDA-EMA) agreements to achieve more global consensus.
  - 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

- Explore ways to better inform the public about medicines for health threats to engender trust in the medicines and the regulatory system.

## *4.4. Ongoing initiatives and activities*

The following initiatives and activities were considered in the development of the network's goals and objectives.

| **Network initiatives and activities – Antimicrobial resistance and other health threats** |
|---|
| • The preparations for the UN General Assembly High-Level Meeting on antimicrobial resistance in 2024 |
| • The June 2023 Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, which referenced the interagency AMR working group |
| • Cross-agency One Health task force framework for action |
| • The EU Farm to Fork strategy setting sales reduction targets for antimicrobials in farmed animals and aquaculture under the European Green Deal |
| • Continuing the implementation of the veterinary medicines regulation, Regulation (EU) 2019/6, including the step-wise approach to reporting antimicrobial use data |
| • The European One Health Action Plan (2017) and, the Council Recommendation (2023) Implementation of actions on AMR in EMA's Regulatory Science Strategy to 2025 |
| • Work of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) |
| • The Regulatory Agencies Global Network against AMR (RAGNA) initiative |
| • The Quadripartite (FAO, UNEP, WHO, and WOAH) work on AMR |
| • EMA-FDA-Health Canada-PMDA joint activities on alignment on regulatory requirements for new antibacterial/antifungal agents for human use |
| • Activities under Commission (e.g. DG HERA including Joint Procurements, MCMs pipeline support and clinical trials in emergencies |
| • The DARWIN EU projects analysing health data from human medicine, specifically for antimicrobials |
| • The initiatives on preparing for emerging health threats proposed by the EU under the umbrella of the EU4Health and RescEU programmes |
| • EU AMR specific initiatives and programmes such as EU JAMRAI 2 and JPIAMR, the European Partnership on Animal Health, and the EU Partnership for One Health AMR |
| • Activities in relation to independent international research on intervention and implementation research in low- and middle-income countries, the International Centre for Antimicrobial Resistance Solutions, and the independent international network Action on Antibiotic Resistance |
| • The EU's strategic approach to pharmaceuticals in the environment and the ongoing (2024) review of the EU Water framework directive |
| • Activities related to the Global AMR R&D Hub |
| • The European Vaccination Information Portal |

# 5. Availability and supply

Prevention and mitigation of medicines shortages is a shared responsibility of all stakeholders, and regulators must ensure they comply with their legal obligations in terms of market supply and monitor supply interruptions.

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. In recent years the availability of medicines has been a concern within the EU, with medicines for cancer, infections and disorders of the nervous system accounting for more than half of those in short supply.[14]

In their role managing shortages and overseeing supply chains, regulators must work closely with marketing authorisation holders and manufacturers, many of whom operate from outside the EU, as well as with international partners, themselves 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 play a role in managing the impact of shortages.

Within regulatory authorities, dedicated teams are involved in protecting supply chains through inspections and enforcement of manufacturing and distribution standards, monitoring shortages and communicating with and advising stakeholders. They also manage supply disruptions, which occur on a daily basis across the EU, as well as the risk of falsified medicines entering the supply chain, which is sometimes but not always linked to shortages.

It is also important to reduce critical dependencies on active pharmaceutical ingredients (APIs) from third countries and the network remains prepared to support any initiatives aimed at addressing this issue.

Recently, regulatory authorities have had to contend with acute shortages related to the off-label use of medicines, partly fuelled by social media and trends in the wider society, underscoring the need to continue engaging with the media.

Given that the causes of most shortages are invariably cross-national, regulatory authorities in the EU increasingly work together to manage and prevent shortages. The Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) plays a key role in managing shortages at the EU level. Established in March 2022 in accordance with the Regulation on EMA's Reinforced Role (Regulation (EU) 2022/123), the group has several responsibilities including providing recommendations on actions to be taken at EU level relating to medicine shortages and monitoring the availability of critical medicines. Similarly, the Executive Steering Group on Shortages of Medical Devices (MDSSG) ensures the network can respond to supply issues with medical devices.

With respect to veterinary medicines, the extent of shortages is not currently known but work is underway to improve the availability of medicines for pets, livestock and other animals in the EU.

Availability in this reflection paper refers to the delivery and supply of authorised medicines to patients and animal owners, and differs from the term accessibility, which relates to the post-authorisation evaluation and approval of medicines by authorities like HTA bodies and payers so that they can be delivered to patients (see section1. ). As noted in section 1, the situation is different in the area of veterinary medicines, where the same HTA process does not occur.

This strategic focus area covers how the network intends to improve the timely availability and supply of medicines in the EU and to prevent shortages and manage them when they occur.

[14] https://www.europarl.europa.eu/topics/en/article/20200709STO83006/medicine-shortages-in-the-eu-causes-and-solutions

## 5.1. Challenges

The root causes of shortages are increasingly complex, and it is important that the network gain a better understanding of the risks posed by the growing outsourcing trends throughout the manufacturing chain (for active pharmaceutical ingredients (APIs) as well as raw materials) and the increasing complexity of distribution systems. Excessive market consolidation and price erosion also contribute towards the occurrence of medicines shortages.

Managing shortages takes up significant resources of the network and requires the adoption of measures in different areas. These include the establishment of dedicated teams, adoption of reports on the need for harmonisation of EU-wide definitions and procedures on shortage management and shortage notification systems, the setting up of stakeholder dialogue platforms, implementation of greater transparency measures and sharing of data and information between parties, implementation of effective preventive strategies, the introduction of greater regulatory flexibilities and diversification in procurement.

Increasing the resources available for good manufacturing practice (GMP) inspections and ensuring interoperability between databases used to provide oversight of the supply chain, such as EudraGMDP, the Organisation Management Service and Product Management Service, are possible means for addressing the challenges.

As several initiatives are already underway to respond to shortages in the EU, there is a need to ensure alignment across the various initiatives to avoid duplication and to ensure that recommendations and activities arising from them suit the needs of the network. Coordination of the work under the MSSG and Single Point of Contact Working Party (SPOC WP) will be crucial.

For veterinary medicines, the extent of shortages is not fully known but the manufacture and distribution of veterinary medicines face some similar hurdles seen with human medicines. In addition, problems with availability may be complicated by the large number of animal species for which medicines are required. Tackling these problems and implementing Regulation (EU) 2019/6 on veterinary medicinal products (which extends good distribution practice (GDP) to veterinary medicines and active substances) are priorities for the network in the years ahead.

Additionally, technological advances, not only in the area of AI but also novel manufacturing technologies, pose further challenges for competent authorities, including challenges related to the assessment and inspection of new emerging technologies and the use of new informatic tools in the management of all processes related to GxP. It is vitally important to empower assessors and inspectors with skills and competencies relating to these new technologies.

## 5.2. Opportunities

On the legislative front, the revision of the EU pharmaceutical legislation for human medicines as well as extension of EMA's mandate could provide a number of distinct opportunities. There is an opportunity to establish a more proactive approach to managing the availability of medicinal products and help clarify obligations of stakeholders in terms of notification and supply responsibilities and, most importantly, in terms of safeguarding patients' rights. There could also be a legal basis for supervision of GDP activities, reliance on trusted third country supervisory systems, risk-based API inspection, authorisation of decentralised manufacturing facilities and the introduction of an EMA pharmaceutical inspectorate.

Ongoing initiatives and activities such as development of the European Shortages Monitoring Platform for human medicines can address the need for greater transparency and oversight of medicines shortages and the supply chain through the adoption of digital solutions. Other initiatives, such as

ICMRA's Pharmaceutical Quality Knowledge Management System (PQKMS) project, will be key for strengthening cooperation and harmonisation across and beyond the network.

The network can also harness its communication skills and resources to engage with the public to keep them informed about availability issues that might affect them, while discouraging actions that may exacerbate shortages situations. Engaging with the public may also increase public awareness of the intricacies of the medicines supply chain, as well as the roles and responsibilities of the various stakeholders involved. An example of the importance of communication with stakeholders is in the area of biosimilar medicines where EU and national authorities are raising awareness among the public and healthcare professionals which could help prevent shortages by reducing overreliance on a small number of biological medicines.

## *5.3. Goals and objectives*

Having considered the current situation with regard to the availability and supply in the EU and possible new developments in the coming years, the network will focus on two main goals and specific objectives for achieving them.

- **Strengthen the availability of medicines to protect the health of European citizens and animals.**
  - 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.
  - Improve coordination of activities related to improving availability of human medicines and implement best practices in conjunction with stakeholders and international partners.
  - 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.
  - Improve transparency and communication on both the launch of medicinal products and shortages with relevant stakeholders, including patients, healthcare professionals and HTA bodies.
- **Reinforce the oversight and protection of the supply chain and increase inspector capacity.**
  - Ensure sufficient numbers of trained inspectors are continuously available to perform legal duties (see section on sustainability of the network)
  - Use risk-based inspection planning, alternative inspection methodology and collaboration with international partners to better target oversight of the supply chain, including for key finished product and API manufacturers
  - Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines in the supply chain
  - Keep good manufacturing practice (GMP) requirements updated in light of technological progress in manufacturing (e.g. with respect to digital, IA and other technological systems).
  - Improve and inter-link information in current databases (e.g. EudraGMDP)

### *5.4. Ongoing initiatives and activities*

The following initiatives and activities were considered in the development of the network's goals and objectives.

| **Network initiatives and activities – availability and supply** |
| --- |
| • Ongoing and planned joint actions such as the Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (CHESSMEN), Joint Action on regulatory flexibilities, European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI)<br>• EC communication on shortages<br>• Additional legislative, cross-sectoral and cross-cutting developments<br>• Work of groups including Critical Medicines Alliance, Task Force on Availability of Authorised Medicines for Human and Veterinary Use (TF AAM), SPOC WP, Steering Group on Shortages and Safety of Medicinal Products (MSSG)<br>• Development of European Shortages Monitoring Platform (ESMP)<br>• Strengthening of multistakeholder approach<br>• ICMRA PQKM project<br>• International collaboration, including work related to the establishment of the African Medicines Agency<br>• Recognition of the EU network as a WHO listed authority<br>• Healthcare professional and patient communications<br>• Development of training for inspectorates |

# 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 system is not under undue strain and finding ways to build capacity and capabilities in order 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 current strategy and one that affects all EMANS focus areas.

A sustainable network must also be able to respond adequately to public health challenges, including during emergencies, and work closely with its stakeholders to ensure that it achieves its public health aims. Working with stakeholders is also crucial because the public needs to be adequately informed about medicines in order to counter mis/disinformation and 'anti-science' narratives.

## 6.1. Challenges

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 or through the mutual recognition and decentralised procedures or via the purely national route. A key challenge therefore is balancing this workload in the various procedures in a way that uses the network's resources most efficiently.

For the network to achieve its strategic aims it is important that it has the resources and the personnel required for its tasks, from inspecting manufacturing sites and overseeing the supply chain to applying the latest digital tools and supporting innovation. The network must assess its resource needs in all strategic focus areas and take action to address them while adopting new technologies and approaches to improve efficiency.

On the efficiency front, there is also an increased need to streamline interactions with stakeholders, given the multiple entry points and standards for stakeholder interaction within the network (e.g. the Common European Submission Portal (CESP), electronic submission gateway (ESG), extended EudraVigilance medicinal product dictionary (XEVMPD)) and to enable the seamless exchange of regulatory information with industry stakeholders using internationally agreed data and standards.

## 6.2. Opportunities

Developments on the legislative front provide a number of opportunities to improve the sustainability of the network. For human medicines, the proposed new legislative framework can drive improvements related to changes to the centralised procedure and reorganisation of EMA committees, which combined with the modernisation and consolidation of IT systems can help to address the emerging needs of the network.

With respect to the network's workload, there is an opportunity in the coming years to agree on ways to allocate work within the network more efficiently, for example through the establishment of centres of excellence, which will develop expertise for certain types of procedure and products.

For veterinary medicines, the network will continue to build on the progress achieved implementing Regulation (EU) 2019/6 and strive for continued alignment of IT solutions across sectors.

The network also has the opportunity to build on its extensive collaboration with international partners. By working closely with international partners and pooling resources and expertise, the network can better achieve its short- and long-term goals.

Experience to date has confirmed the importance of the network being able to communicate and engage with its stakeholders. The lessons learnt during COVID-19 have also confirmed that strong communication and engagement is key for the network to achieve its objectives more effectively. The complexity of the EU system with several national authorities and its multi-lingual nature needs to be considered when planning communication-related activities to ensure that the Union speaks with one voice in a coordinated manner. The emergence of AI and other innovative digital tools, however, offers many opportunities to overcome the more technical obstacles.

## 6.3. Goals and objectives

Having considered the current situation and possible new developments in the coming years, the network will focus on the three main goals and specific objectives for achieving them.

- **Reinforce scientific and regulatory capacity and capability of the network.**

- 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.
- Explore ways to improve efficiency by creating centres of excellence and allocating NCA resources more strategically.
- Build the network's capability to carry out the digital transformation of its scientific and regulatory processes, ways of working and tools.

- **Establish a shared operating model to support network activities and collaboration.**
  - For human medicines, prepare for the implementation of new legislation combined with the modernisation and consolidation of IT systems.
  - For veterinary medicines, continue to build on the progress achieved in implementing the veterinary regulation and align IT solutions across sectors
  - Explore opportunities for shared data, process and technology initiatives and establish a model for joint EMA/HMA sponsorship for such initiatives.
  - Contribute to the application of the new EMA fee regulation and the regular monitoring and adjustment of the cost-based system for fees and NCA remuneration.
- **Strengthen public and stakeholder engagement and global convergence with international partners.**
  - Enhance capacity on the network through international convergence, information and work sharing and multilateral cooperation.
  - Together with the European Commission, strengthen international collaboration to perform legal duties relating to inspections and face global challenges related to new methodologies and continuous manufacturing.
  - Support the establishment of the African Medicines Agency, strengthening cooperation between European, African and international partners.
  - Develop and implement a framework for communication and engagement to address information needs of the public and counter mis/disinformation.

## *6.4. Ongoing initiatives and activities*

The following initiatives and activities were considered in the development of the network's goals and objectives.

| **Network initiatives and activities – sustainability of the network** |
| --- |
| • The implementation of veterinary medicines regulation (Regulation (EU) 2019/6) |
| • Work related to the Network Portfolio roadmap 2023-2025 and final programming document 2024-2026 |
| • Revision of the EU variation regulation for human medicines (Regulation (EU) 1234/2008) |
| • Implementation of the regulation on fees and charges payable to EMA (Regulation (EU) 2024/568) |

| Network initiatives and activities – sustainability of the network |
| --- |
| • EU4Health Joint Action on capacity building of the European Medicines Agencies Network - IncreaseNET<br>• Initiatives of the EU Network Training Centre (EU-NTC) concerned with training and sharing good practices across the network<br>• The European Vaccination Information Portal |

# 7. Next steps: preparing EMANS 2028

The drafting of this reflection paper was the first step in the development of EMANS 2028. The paper served as a basis for preparing draft text of EMANS 2028 which the network is making available for public consultation.

The EMANS 2028 text will be finalised between December 2024 and March 2025, after which HMA and EMA's Management Board will sign off on the final strategy. The final EMANS 2028 will be published in beginning of the second quarter of 2025.