HMA
Heads of Medicines Agencies

EMA
EUROPEAN MEDICINES AGENCY

European medicines agencies network strategy to 2025

Final report

An agency of the European Union

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Foreword by Emer Cooke and María Lamas

2021 to 2025 was no ordinary five-year period. It was a time when Europe's resilience and scientific ambition were put to the test. It was a time when we needed to manage uncertainty, supply chain vulnerabilities and rapid technological developments. It was a time for collective action to strengthen preparedness and advance innovation.

Emer Cooke, EMA Executive Director

María Lamas, Chair of HMA Management Group

The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) set out their strategy to 2025 during the COVID-19 public health emergency. We are delighted, 5 years on, to be in a position to announce that we have made real and tangible progress.

We are not only now better prepared to help protect the public in times of emergency but we have also emerged stronger as a network. We have learnt many lessons and have delivered across six priority focus areas:

- Availability and accessibility of medicines
- Data analytics, digital tools and digital transformation
- Innovation
- Antimicrobial resistance and other emerging health threats
- Supply chain challenges
- Sustainability of the network and operational excellence

This was also a time of unprecedented change in the pharmaceutical legislative landscape. We had the extension of EMA's legal mandate, partly as a response to COVID-19, the implementation of the veterinary medicines regulation and new proposals for major legislative changes in the shape of the pharmaceutical reform.

We saw the emergence of artificial intelligence as a widely available tool, which has started to transform working practices across the network.

And we had the opportunity to celebrate EMA's 30-year anniversary, an uplifting moment to reflect on how far we have come on our journey of collaboration, as well as our collective achievements in implementing EMANS 2025.

This report describes what we achieved together over these five years. Great strides were made by drawing on expertise from across the network and by working closely with stakeholders, including the general public, patients, developers, researchers and healthcare professionals.

Of all the learnings from implementing this strategy, one stands out: that the network must be able to adapt efficiently to a changing landscape, as we did during the COVID-19 public health emergency, and must be ready to seize the opportunities arising from technological and other advances.

The achievements described in this report have informed our next strategy (EMANS 2028), adopted in March 2026 under the overarching theme of 'seizing opportunities in a changing medicines landscape'.

We are proud of how our network has evolved over the last 5 five years and are looking forward to delivering on the transformative opportunities that lie ahead.

Introduction

Initially published in 2020, EMANS 2025 is the main strategy guiding the delivery of the operational, regulatory and scientific output of the European Medicines Agency and the national competent authorities for medicines in the EU. The strategy sets out goals and priorities for the years 2021 to 2025 to give strategic direction to the work of the European Medicines Regulatory Network.

The strategy outlined six priority focus areas, with clear strategic goals and objectives for each area. The actions to fulfil the goals and objectives were incorporated by EMA and the HMA into their respective work plans and programming documents.

The implementation of EMANS 2025 also took place in the context of the regulatory science strategy to 2025. The EMANS 2025 mid-point report already detailed key achievements from the implementation of EMANS 2025, including those related to the regulatory science strategy, up to June 2023.

The current report describes the main achievements of the network in implementing the strategy from January 2021 to the end of 2025. The structure follows the goals and objectives originally defined in the strategy.

For each objective, the report has a section 'Follow-up actions in EMANS 2028' which describes further related activities the network will carry out as it implements the next strategy (EMANS 2028) from 2026 to 2028.

Highlights of the main achievements for each strategic focus area

Availability and accessibility of medicines

> Over the lifetime of EMANS to 2025, we experienced unforeseen and highly complex challenges impacting medicines availability. This only served to underscore the importance of the network's strategic and coordinated approaches to strengthen supply and address associated vulnerabilities. Doing so is critically important not only for regulatory systems, but also for health systems and ultimately for the patients we serve. We, as regulators, remain committed to these efforts and look forward to continuing this work under EMANS to 2028, supported by evolving and strengthened legal frameworks.
>
> **Lorraine Nolan,**
> Former Chair of EMA Management Board, former Chief Executive of Irish Health Products Regulatory Authority (HPRA), HMA

> The regulatory decision is one step towards access to medicines for patients in national healthcare systems. EMANS to 2025 was the foundation for technical work with HTA bodies and payers to enable the generation of evidence addressing the different assessment context. Furthermore, it facilitated the preparation for the regulatory/HTA interface under the HTA Regulation. Now that this legal framework is in operation, we can bring our collaboration to the next level, in the interest of patients in need of new medicines.
>
> **Michael Berntgen,**
> Michael Berntgen, Head of Scientific Evidence Generation Department, EMA

Goal 1

Strengthen the availability of medicines to protect the health of European citizens and animals.

Objectives

- Identify the specific root causes of shortages of medicines for human and veterinary use and develop strategies to improve prevention and management of shortages (a better understanding of the specific causes for shortages of generics/off-patent products vis-à-vis products still under patent protection is essential). Based on the outcome of a study of the causes, the aim is to identify and suggest areas where changes to EU or national legislation could improve supply.
- Foster the awareness among the public and healthcare professionals of the approval standards, safety, effectiveness and immunogenicity of similar biological products to facilitate the uptake of biosimilars in healthcare systems.
- Improve coordination of information and actions, including implementation of best practices, of EU regulatory authorities, stakeholders and international partners.
- Empower EMA with sufficient capacity to monitor and coordinate medicines' availability and supply. EMA should also coordinate the activities of the EMRN in order to ensure availability of critical medicines in the EU and the European Economic Area (EEA) by supporting increase of production capacity to meet demand.
- Increase transparency on availability/launch of medicines to facilitate targeted regulatory actions and communication with patients, healthcare professionals and health technology assessment (HTA) bodies.

Achievements

Root causes of shortages, prevention and management

- Collaboration between EMA/HMA and the Joint Action on Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network (CHESSMEN) was expanded to avoid potential duplication of work.
- CHESSMEN WP5 report on the root causes of shortages was finalised and work transferred to the Medicine Shortages Single Point of Contact (SPOC) Working Party. An approach on harmonisation of root cause classification was agreed in December 2025.
- The MSSG toolkit on recommendations on tackling shortages of medicinal products was published in October 2023.
- Shortage Prevention and Mitigation Plans (SPMPs) templates were produced and published on 18 June 2024. The SPMP Pilot started in December 2024 and was completed in September 2025. The accompanying pilot report was published in December 2025.
- A good practice guide for industry on prevention of human medicinal product shortages was published in Q2 of 2023.
- A good practice guide for prevention of shortages of medicines for human use for patients and healthcare professional organisations was published in 2022.

Monitoring and coordination of medicines availability and supply

- The European Shortages Monitoring Platform (ESMP) was launched for the routine reporting of shortages for centrally authorised products by industry and for the reporting of industry and regulators' crisis and MSSG-led preparedness. The platform went live in January 2025.
- MSSG recommendations to strengthen supply chains of critical medicinal products were published in April 2024.
- EMA's extended mandate on the availability and supply of medicines became applicable. The Executive Steering Group on Shortages and Safety of Medicinal Products (also known as the Medicines Shortages Steering Group, MSSG), the operational SPOC Working Party, which supports the work of the MSSG and a network of Single Points of Contact in companies (iSPOC) were established to monitor shortages and availability issues.
- Joint recommendations were issued by the European Commission (EC), HMA and the EMA for actions to avoid shortages of key antibiotics used to treat respiratory infections for European patients in the 2023/2024 winter season. For the following autumn/winter seasons 2024/2025 and 2025/2026, EMA and SPOC WP continued to closely monitor the supply and availability of antibiotics across the EU/EEA and stayed in close cooperation with companies.
- The EC, HMA and EMA published the first version of the Union list of critical medicines in December 2023. Subsequently, the second version of the list was published in

December 2024 and the first annual update to the second version of the list published in December 2025.

- The Veterinary Strategic Focus Group set up a subgroup on Availability and Shortages to clearly define the availability and shortage issues related to veterinary medicines and recommend regulatory solutions to these issues.
- The HMA/EMA multi-stakeholder workshop on shortages of human and veterinary medicines was held on 1-2 March 2023.

Coordination and best practices

- A joint ICMRA-industry virtual workshop was held on 20 July 2023, during which participants discussed their experience of involvement in pilot programmes facilitating collaborative regulatory evaluation of post-approval changes, as well as the future direction of ICMRA's Pharmaceutical Quality Knowledge Management project. A further virtual workshop was held on 19 September 2025, allowing in-depth discussions on learnings arising from the pilots and longer term plans for associated collaborative regulatory processes.

Medicines information/communication

- As part of work to implement ePI for EU medicines, an electronic product information (ePI) Common Standard for human medicines was developed. User-testing of ePI was also completed and the ePI pilot report published.
- A joint statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU was published by the HMA and EMA, with an accompanying Questions & Answers document.
- Initial work has been done towards building the biosimilar toolkits for Member States.
- An analysis of responses to a survey on multilingual packaging was undertaken, with subsequent update of the CMDh Best Practice Guide on Multilingual Packaging finalised in 2024.
- In 2022, CMDv revised its Best practice guide for the processing of SmPC, labelling and package leaflet and the preparation of multilingual/-country packaging provided in support of MRP/DCP/SRP and variations to improve product availability.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Further improve the ability of the network to anticipate, prevent and mitigate medicines shortages in collaboration and coordination with relevant stakeholders.
- Further review the root cause classification/categories of shortages, taking into consideration stakeholders' input.
- Identify and evaluate vulnerabilities in the supply chains of critical medicines via the establishment of a vulnerability assessment methodology as outlined in the new pharmaceutical legislation.

- Further review shortage prevention and mitigation plans and the pilot phase in the context of the new pharmaceutical legislation.
- Further assess the marketing status systems to identify additional activities (including communication activities).
- Define the veterinary availability/shortages issues and recommend regulatory solutions to resolve these issues. (This activity is to be carried out by the Veterinary Strategy Focus Group subgroup on availability and shortages.)
- Continue developing information materials on biosimilars to support Member States' toolkits.
- Continue quantifying the scale of the impact of shortages of veterinary medicines at the multi-stakeholder level.
- Implement prioritised use cases in accordance with the EU Veterinary Big Data Workplan. (Use cases on the availability of veterinary medicines include real-time monitoring of shortages and identification of treatment alternatives.)

Goal 2

Optimise the path from development, evaluation through to access for beneficial medicines (innovative and follow-on) through collaboration between medicines regulators and other decision-makers.

Objectives

- Develop better scientific evidence which serves different decision makers along the decision chain (regulators, health technology assessment (HTA) bodies and payers), including evidence to support post-licensing follow-up of medicinal products, thereby using a life-cycle approach to evidence generation and the possibility to adjust decisions based on new evidence.
- Develop clear and enhanced communication for patients, healthcare professionals, veterinarians and animal owners as well as downstream decision makers about the regulatory assessment including information gap inherent for medicinal products approved on the basis of limited scientific data and secondary endpoints (e.g. orphans, limited market veterinary medicinal products).
- Develop new metrics for accessibility of medicines that better represent real patient access to newly authorised medicinal products in different markets.
- Foster alignment of national implementation of compassionate use programmes to promote equity in access for patients during late-stage development and improved utilisation of data from such programmes to support later decision making.

Achievements

- Operations in relation to the HTA Regulation were implemented, particularly regarding the sharing of information from the centralised procedure to support joint clinical assessments of medicines as well as the initiation of parallel joint scientific consultations on medicinal product developments. Furthermore, the first forecasting reports for medicines and devices were provided, and additional experts (patients, carers and clinicians) to support HTA-related activities were identified.
- In April 2025, EMA and the Heads of HTA Agencies Group published a joint position paper on understanding evidence challenges, managing uncertainties and exploring potential solutions (Joint HTAb-regulatory perspectives).
- A multi-stakeholder workshop on patient experience data took place with a view to discussing ways to improve the collection and use of patient experience data to achieve a more patient-centred medicine development and regulation.
- A PCWP/HCPWP annual meeting took place to explore the intersection between regulatory and HTA assessments and its role in access.
- HTA representatives participated as members of many initiatives and structures, such as the DARWIN EU Advisory Board and the Network Data Steering Group. They also regularly participated in workshops related to evidence planning, such as the Workshop on external controls.
- Bilateral discussions to foster mutual understanding of perspectives on evidence for decision making through EMA/EUnetHTA21 took place, including a dedicated meeting with a focus on ATMP assessment in Q1 2023.
- Parallel joint scientific consultation work involving the Scientific Advice Working Party (SAWP) and EUnetHTA21 progressed, with transitional arrangements for parallel scientific advice in the interim period made available.
- Multi-topic technical engagement between regulators and HTA bodies occurred at European level with a view to supporting the implementation of the new HTA Regulation and joint reporting about the achievements under the work plan.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Continue contributing to the successful implementation of the HTA Regulation, in collaboration with the Member State Coordination Group on HTA (HTACG) and the HTA secretariat provided by the European Commission.
  - Sharing of information from the centralised procedures of medicinal product applications that are in scope of joint clinical assessment production by the HTACG.
  - Provision of parallel joint scientific consultation for medicines and for devices.
  - Supporting the identification of emerging health technologies including collaborative work on horizon scanning.

  - Enabling the delivery under the Implementing Regulation on exchange of information with EMA.
  - Progressing joint scientific and technical work of horizontal nature.
- Continue the work on patient experience data (PED):
  - Finalise the consultation on the PED reflection paper and define any further action.
  - Evaluate the usefulness of the dedicated sections on PED introduced in the CHMP assessment report template.
  - Continue to monitor progress on the action plan on PED.
- Publish a framework to review the evidence needs for decisions leading to access for innovative medicines that address unmet medical needs and have received specific support from a regulatory perspective.

Data analytics, digital tools and digital transformation

> By unlocking the value of data and AI, together we strengthen medicines regulation and advance the EMANS 2028 strategy across all its themes, enabling the accelerated delivery of safe and effective medicines for patients and animals across Europe.

Karl Broich,
President of the German Federal Institute for Drugs and Medical Devices (BfArM), HMA

> By building stronger data governance, interoperable systems and trustworthy AI into the heart of medicines regulation, we are creating a future where data driven decisions bring benefits for patients.

Peter Arlett,
Head of Data Analytics and Methods Taskforce, EMA

Goal 1

Enable access to and analysis of routine healthcare data, enable analysis of individual patient data from clinical trials and promote standardisation of targeted data.

Objectives

- Deliver a sustainable platform to access and analyse healthcare data from across the EU (DARWIN EU).
- Pilot the analysis of individual patient data from clinical trials in initial marketing authorisation assessments with a view to a targeted roll-out of such analyses.
- Establish collaborations with external stakeholders (including patients, academia, non-governmental organisation and industry) and with international regulatory authorities on big data initiatives.
- Establish an EU framework for data quality, discoverability and representativeness through agreement on meta-data for regulatory purposes, a standardisation roadmap and registers of real-world data sources and of observational studies.

Achievements

DARWIN/RWE

- DARWIN EU was established as the main pathway to generate real world evidence (RWE) and support EMA's scientific committees as well as the work of national competent authorities, the European Centre for Disease Prevention and Control, health technology assessment bodies and payers.

  By the end of the reporting period DARWIN EU had 40 data partners with access to data from over 290 million patients across 18 countries and more than 110 studies had been initiated to supporting regulatory decision-making and public health. Study protocols and reports of all DARWIN EU studies are publicly available in the HMA-EMA Catalogue of RWD studies.

  DARWIN EU participated in the EHDS2 pilot with a use case on coagulopathy and COVID-19 (EUPAS107315).

- Reports on conducting studies with Real World Data (RWD) were published annually. The third report was published in June 2025, based on experience gathered between February 2024 and February 2025, highlighting the EMRN's continued efforts to better integrate RWE into regulatory decisions as well as learnings not only from studies conducted via DARWIN EU but also from other pathways used to generate RWE. Throughout the years, it shows an increased proportion of feasible studies, an annual increase in studies being conducted and completed, a shorter duration of DARWIN EU studies and the support to a broad range of stakeholders.

- Progress in convergence with international partners on RWD/RWE was essential throughout the reporting period.

  At ICH level, the reflection paper on "Pursuing Opportunities for Harmonization in Using Real-World Data to Generate Real-World Evidence, with a focus on Effectiveness of Medicines" was adopted in 2024. The reflection paper was co-developed by EMA, FDA and Health Canada following a joint statement by ICMRA calling for international collaboration in generating and using RWE in regulatory decision making. The ICH M14 Guideline on general principles on planning, designing, analysing, and reporting of non-interventional studies that utilise Real-World Data for safety assessment of medicines was then published in September 2025; and to further enable the integration of RWE into regulatory submissions and decision-making, a concept paper proposing the development of a new ICH guideline on RWD/RWE terminologies, metadata, and assessment principles with a focus on effectiveness (aka ICH E23) was adopted by ICH management committee in November 2025.

  Under the umbrella of ICMRA, a new working group on RWE for public health emergencies, co-chaired by EMA and Health Canada, continued activities from the former COVID-19 RWE and Observational Studies Working Group and was a global forum for regulators to enhance the efficiency of responses to public health emergencies by conducting collaborative studies based on RWD. The first two collaborative studies (one on the use of glucagon-like peptide-1 receptor agonists and one on background incidence rates of adverse events of special interest to support early stages of vaccine safety signal evaluation) started in 2025. The findings and lessons learnt are expected to be published in 2026.

Other data analytics initiatives

- The clinical study data pilot (formerly known as raw data pilot) was launched in 2022 and continued during the reporting period to investigate the benefits of visualising and analysing clinical study data to support the scientific assessment of medicinal products. Based on the initial insights from the pilot including early evidence of the potential for such data analysis to speed up the authorisation of new medicines (see pilot interim report), the pilot's duration was extended and pilot participation requests from pharmaceutical industry continue to be accepted to date. As of December 2025, 13 regulatory procedures have been selected for the pilot. Support for marketing authorisation holders (MAHs) was important and in 2023 EMA published the application of EMA's transparency principles to the raw data proof-of-concept pilot.
- The digital transformation of clinical trial information was strengthened with initiatives such as the digital protocol (ICH M11). The final ICH M11 guideline, clinical study protocol template and technical specifications was adopted in December 2025.
- The EMA proof of concept study to evaluate implementation of the standard for exchange of non-clinical data (SEND) was launched in 2023 and was completed at the end of 2025. As of December 2025, SEND data for 27 marketing authorisation applications were received and for 15 of them the SEND data were analysed.
- To continue to keep abreast with technological and methodological changes, the utility of mobile health data and social media data to support regulatory decision-making was explored.

EU framework for data quality, discoverability and representativeness

- The first EU data quality framework for EU medicines regulation was developed with the MWP and published in 2023. To understand the quality of the data used for real-world evidence generation, the Network Data Steering Group (NDSG) endorsed the RWD quality chapter of the EU Data Quality Framework for EU medicines regulation. The final version of the RWD quality chapter will be published in 2026, offering insights on key considerations for RWD quality including practical recommendations, metrics to assess data quality dimensions and a guideline on assessing data quality in relation to a research question.
- To support the preparation and implementation of the European Health Data Space (EHDS), collaboration was launched with the QUANTUM project for HealthData@EU, aiming to design and develop a data quality and utility label for the EHDS.
- The HMA-EMA catalogues of real-world data sources and studies were launched in February 2024 to help medicines regulators, researchers and pharmaceutical companies to identify the most suitable data sources to address specific research questions and support the assessment of study protocols and results. Aligning with 'FAIR' data principles, they use an agreed set of metadata to describe and connect data sources to studies based on the metadata list for real-world data sources and studies published in June 2025. Users of the catalogues are supported by the Good practice guide for the use of the HMA-EMA catalogues of real-world data sources and studies. As of December 2025, the RWD catalogues contained 272 registered data sources and 3,235 studies.

Collaboration with external stakeholders and partners

- Collaborations were established during the reporting period, and several multi-stakeholder events were organized each year via the annual multi-stakeholder data and AI forums, and complemented by specialized workshops (e.g. workshops on RWE, data quality, registries, pharmacogenomic, patient experience data, signal detection and PMS) and workshops supported by the EMA Methodology Working Party (MWP) and ACT EU.
- In the area of AI, collaborations included, at European Union level, the EU Agencies Network Working Group on AI and the European Specialised Expert Community (ESEC) of the EMA Methodology Working Party (MWP) which is now fully established and provides a forum for collaboration and knowledge sharing across the network.

Artificial Intelligence

- A common set of 10 guiding principles to inform and enhance the use of AI for generating evidence across the medicinal product lifecycle was drafted in close collaboration with the US Food and Drug Administration (FDA), and was adopted by NDSG at the end of 2025.
- The guiding principles on the use of large language models (LLM) in regulatory science and for medicines regulatory activities were published in September 2024 and are now available to help the network staff on how to use large language models in their work.

- The first annual report of the European medicines regulatory network's AI observatory was published in July 2025 compiling the network's experience with AI during 2024. The report is supported by two other related documents: a compilation of examples of AI use in medicine regulation and a horizon scanning short report.
- The Network Data Steering Group (NDSG) endorsed the network's AI research priorities in 2025.
- The NDSG has also adopted a network AI tools framework to support the sharing and development of AI tools across the network (human and veterinary domain) and to foster collaboration, integration and reusability of AI tools and models.
- The NDSG continued to be a place to discuss national AI initiatives in the medicines' lifecycle and for regulatory science. In 2025, a series of workshops with national competent authorities (human and veterinary domains) were organised to collect 61 AI use cases (covering 3 main AI capabilities: drafting and summarization of information; validation and quality assurance; and knowledge mining and retrieving of information) and to discuss existing or potential solutions and concepts that could be used for their implementation.
- In collaboration with the network, EMA worked on developing AI agents and, in March 2024, EMA launched the first AI-enabled knowledge mining tool called Scientific Explorer for EU regulators. The tool enabled easy, focused and precise search of regulatory scientific information from network's sources to support decision-making and simplify processes. The first releases focused on scientific advice procedures for human medicines and veterinary medicines.
- Finally, in 2025, a group focused on AI was established to facilitate open dialogue with industry stakeholders (human and veterinary domains) on the development and use of AI in the medicines' lifecycle. The first meeting took place in November 2025.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Maximise the generation, interoperability, use and exchange of data to support EU decision-making in the context of key EU legislative initiatives.
- Conduct of RWD studies, align with international partners on RWE, launch DARWIN EU 2 and continue strategic engagement on RWE, collaborating with key stakeholders including HTA bodies and health data access bodies.
- Collaboration with EC on the implementation of the new pharmaceutical legislation and transition to systematic receipt and analysis of individual patient clinical study data for centrally authorised products.
- Continue to support the voluntary submission of SEND data and prepare EMRN for wider uptake.
- Publish additional data quality chapters, i.e. on adverse drug reaction data and on medicinal product PMS master data.
- Advance identifying upcoming data and tool trends in science, technology and regulation and gather stakeholder insights through a dedicated workshop in 2027.

- Continue to explore analysis of additional data types, such as mobile health data, social media, genomics and patient experience data, to complement clinical trial data analysis and support regulatory decision-making.
- Continue collaborating on data and AI with external stakeholders, e.g. via multi-stakeholder specialised workshops/forums.
- Publication of the network's AI research priorities adopted by the NDSG.
- Realise the network vision on AI across all EMANS focus areas, including:
  - Roll out of AI guidance in the medicines lifecycle, with MWP (including AI in clinical development and AI in pharmacovigilance)
  - A roadmap for further guidance development on AI to the network, in alignment with the Biotech Act
  - Continued support in the evaluation of AI in medicines lifecycle
  - Roadmap on continued support to the deployment of AI solutions across the EMRN, including, REGULUS and Scientific Explorer
  - Strengthen collaboration with IncreaseNet programme.
  - Promote network sharing of AI solutions and approach for AI training.

Goal 2

Build sustainable capability and capacity within the network

Objectives

- Build EU network capability to analyse big data.
- Digitally transform the EU network's scientific and regulatory processes to enable use of digital tools and analytics and create supporting digital infrastructure, for example, to support the uptake and review of big data (from electronic health record (eHR), registries, devices etc.).

Achievements

- Activities have been performed to ensure the governance (prioritisation, funding and coordination) of the Network Portfolio. Since the implementation of Agile governance in 2021, several quarterly Agile ceremonies have been organised (18 Quarterly Strategic Portfolio Review and Quarterly Portfolio Sync ceremonies, 19 Planning Interval ceremonies and 19 System Demos). The Portfolio Objectives have been updated to align with EMANS 2028.
- EMA's Agile transformation was advanced further to support the delivery of the Network Portfolio and wider digital initiatives. Agile methods are increasingly

embedded in portfolio management and delivery, with clearer roles and processes, strengthened capabilities and expanded training resources and support. Agile practices are also being piloted in emerging areas, including HR and implementation of the New Pharmaceutical Legislation, helping to test and extend Agile ways of working beyond core digital initiatives. Through these efforts, EMA is further strengthening collaboration across the network and supporting more iterative, value-driven delivery of initiatives.

- The network's involvement in the development of digital systems has been strengthened since the launch of Agile governance, with 11 network product owners and 58 network subject matter experts across 12 product teams between 2022 and 2025.

DigiLab/experimentation runway

- Establishment of the Digital Innovation Lab (DigiLab) and expansion of the Analytics Centre of Excellence (ACE) within EMA, as a set of activities to discover, experiment with and develop digital solutions that have the potential to support core business and support functions across EMA.
- Digital Innovation Lab (DigiLab)/Analytics Centre of Excellence (ACE) have continued to explore experimentation opportunities and deliver automations.
- Efficiencies gained through the launch of new automation and analytical tools from the ACE team across a number of business areas where activities are performed manually, such as:
  - the new Certificate Processing System which enables the submission, prepayment and generation of medicine certificates faster using a process that is fully digital.
  - (Invented) name review process. The Phonetic and Orthographic Name Similarity Algorithm (PONSA) is a pilot tool available to EMA and NCAs with potential high value for the network and industry that increases consistency, accuracy, and reliability in the similarity screening of reviewing proposed invented names for human medicinal products following the centralized procedure.
  - periodic safety update reports submission process. The EU reference dates list tool for EMA significantly increases operational efficiency, reduces data management challenges by consolidating the list of active substances and submission of periodic safety update reports and provides automated reporting
  - Digitalise stakeholder engagement by further developing the QR code technology into digital business cards for EMA colleagues who represent EMA in various forums, environmentally friendly alternative to paper versions.
  - Automating financial data processing and repetitive tasks: most notable being the PDF Vendor Invoicing that reduces manual work by automating the processing of 200 invoices and 300 emails per month.
  - Translation Automation of Annex I. Designed to save time and reduce costs, the translation Automation of Annex I internal application streamlines the translation process for Annex I referral documents.

- Controlled experiments with AI technologies including AI agents were conducted to explore where these technologies could be used at EMA for further efficiency and productivity gains to support strategic goals.
- EMA's first virtual reality powered training was launched to raise cybersecurity awareness using innovative and engaging approaches.
- In June 2025 DigiLab led on the setting up of an experimentation runway to bridge experimentation efforts to the Network Portfolio and foster innovation and transparency of the work of decentralised innovation teams. Within first 6 months, 7 decentralized innovation teams have been onboarded, and the work of 17 prototypes and pilots in the areas of analytics, AI and robotics process automations have been coordinated.
- In November 2025, DigiLab also delivered the first successful experimentation to scale up through the Network Portfolio. The Early Notification System is a secure and user-friendly portal that supports exchange of safety notifications within the EU regulatory network.
- EMA's management practices were further developed internally and with respect to the network and stakeholders through a Change Management Centre of Expertise tasked with building and improving EMA's competence and establishing tools and services. This is to ensure readiness and long-term adoption of digital and other changes.
- An updated and simplified change management toolkit was released in 2025, and a change management governance framework was implemented, including support to integration of change management practices for strategic transformations such as implementation of SAFe Agile at EMA.

Digital academy

- Delivery of a digital academy at EMA to support the development of digital skills, increase digital literacy, capability and capacity and raise awareness of digital topics at all levels. Thirteen modules have now been launched on topics such as digital mindset, digital wellbeing, artificial intelligence, robotic process automation, cloud computing, design thinking and LEAN.
- AI literacy modules (6 in total) were launched for EMA staff in Q4/2025.

For activities related to the EU Network training Centre (EU NTC), see the section 'Sustainability of the network and operational excellence'.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Leverage digitalisation, experimentation and innovation to deliver optimised regulatory processes.
- Reinforce the scientific and regulatory capacity and capability of the network.
- Establish a shared operating model to support network activities and collaboration.

Goal 3

Promote dynamic regulation and policy learning within the current regulatory framework.

Objectives

- Modernise the delivery of scientific advice at central and national level by developing network skills and processes.

Achievements

- National competent authorities from Denmark, Germany, the Netherlands, Portugal, Spain, and Sweden collaborated in 2022, sharing good practice in data and analysis: Principles on 'Clusters of Excellence' were agreed, and the clusters of excellence discussion paper was published in 2023.
- Training programs were rolled out to the network in partnership with the EU NTC via its platform during the reporting period, in close collaboration with the MWP and scientific expertise from the relevant ESEC SIAs. For activities related to the EU NTC, see the section 'Sustainability of the network and operational excellence'.
- The Methodology Working Party was established and issued its 3-year workplan, updated annually. The methodology European Specialist Expert Community (ESEC) was also established with, to date, more than 289 experts from more than 21 European countries as well as EMA, bringing together a broad range of expertise organized in specialised interest areas (SIAs) that includes AI & data science, biostatistics, clinical pharmacology, modelling & simulation, pharmacogenomics and RWD. Some of the key achievements on data and guidance development include:
  - A roadmap to produce guidance for the EU network on RWE to support regulatory decision-making,
  - the reflection paper on use of real-world data in non-interventional studies to generate real-world evidence for regulatory purposes,
  - the draft concept paper on the development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making,
  - the draft concept paper on the guideline revision on good pharmacogenomic practice,
  - the reflection paper on the use of artificial intelligence (AI) in the medicinal product lifecycle,
  - Support to development of ICH guidelines. In addition to the ICH M11 and M14 guidelines, the draft ICH M15 guideline on general principles for model-informed drug development was adopted (and published in early 2026).

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Endorse the AI training strategy and roll out AI training material to the network, starting with AI literacy training and data protection training.
- Strengthen collaboration with IncreaseNet programme and partnership with EU NTC on training related activities (RWE, biostatistics, data science, genomics) and roll out of additional training modules.
- Support network knowledge-sharing activities, e.g. through ESEC and SIAs.
- Collaborate with MWP on stakeholders' guidance and align with international initiatives (notably relevant ICH guidelines).

Goal 4

Ensure that data security and ethical considerations are embedded in the governance of data within the network.

Objectives

- Ensure data are managed and analysed within a secure and ethical governance framework.

Achievements

- The European Medicines Agencies Network data strategy was published in October 2025, providing the vision, principles and objectives for implementing effective data management within the EMRN data ecosystem.
- The European Medicines Regulatory Network Data Standardisation Strategy was published in 2022 to support the development of globally applicable standards for the human and veterinary regulatory domains.
- The review of the network data governance was strengthened. The Big Data Steering Group (BDSG) operated between 2020 and 2024 (mandate and membership) and the Network Data Steering Group (NDSG) was established in 2025 (mandate and membership). The work of the groups were guided by their workplan, informed by stakeholders and partners feedback and updated annually (the latest version of the workplan is NDSG workplan 2026-2028). It included the publication of the first in Europe artificial intelligence workplan to 2028, setting out a collaborative and coordinated strategy to maximise the benefits of AI to stakeholders while managing the risks.
- Both groups supported the preparation for a changing policy environment with the future European Health Data Space (EHDS) and the revised pharmaceutical strategy for Europe via regular updates from the European Commission, participation to

various fora and workshops and collaboration with the Joint Action Towards the European Health Data Space. They provided a place to discuss and learn from the European regulatory science projects and from the European commission research activities in the field of Big Data and RWE, including the HORIZON-HLTH-2022-TOOL projects.

- The European Veterinary Big Data strategy 2022 - 2027 was adopted in 2022, followed by the EU Veterinary Big Data Workplan to 2022-2025 which was adopted in 2023. Key achievements included:
  - Completion of the 'Big Data in Veterinary Medicines Regulation: A Data Landscape Analysis' study
  - The roll out of the Union Product Database (UPD) data quality framework
  - The establishment of the veterinary data hub, a multi-disciplinary team of network experts from Belgium, France, Germany, Portugal, Spain and Sweden.
  - The organisation of the annual veterinary big data stakeholder forum.
- On data protection, a series of training webinars were delivered to experts from Members States. The DARWIN EU data protection impact assessment was completed and lessons learned have been shared with the network of NCA data protection officers.
- To foster data interoperability, support to the EMRN for the implementation of the Interoperable Europe Act was explored with NDSG and the EMA's first interoperability assessment report was published in October 2025.
- NDSG recognised the PMS system as a shared source of product master data for all EU medicinal products supporting EU-wide use cases. In 2025, NDSG progressed the work on implementation within the network and published strategic recommendations for human master data implementation and data management. These included input from the EMA-HMA Regulatory Optimisation Group (ROG) to support effective and efficient implementation and use.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Annual update and publication of the NDSG workplan to 2028.
- Organise public consultation on the revised EU Veterinary Big Data Workplan.
- Continued support to the implementation of the EHDS, Towards the European Health Data Space Joint Action 2 , the revised pharmaceutical strategy for Europe, and other key legislative initiatives, notably the forthcoming European Biotech Act and its implications and opportunities on data.
- Strengthen network data analytics capabilities, e.g. publication of the EMRN data analytics framework.
- Strengthen network data governance through data cataloguing and data quality, for example, by:

  - Rolling out the EMRN critical data assets catalogue in preparation of EHDS and EMRN use cases.
  - Improving data quality and maturity assessment for the EMRN critical data assets.
- Strengthen interoperability of the network data and progress with harmonisation of the implementation of master data and related data standards within the network, for example, by:
  - Progressing towards discontinuation of the extended EudraVigilance medicinal product dictionary, with PMS as single repository of product data.
  - Agreeing on model for EMRN working arrangements for medicinal product PMS data management.
  - Piloting the public release to stakeholders of medicinal product PMS master data (via API).
  - Agreeing on recommendations for substance SMS master data implementation.

Innovation

Regulatory science drives the integration of cutting-edge science and technology into innovation of medicines for both humans and animals, which would not be possible without multi-stakeholder collaboration. Regulatory frameworks, scientific guidance, and support mechanisms evolve to help researchers and, above all, to meet the needs of patients and animals who remain at the heart of everything we do throughout the entire lifecycle of medicines. All these efforts aim to close the gap between research and clinical practice, often referred to as the “valley of death,” ensuring that scientific advances truly reach and benefit both people and animals.

María Lamas,
Chair of HMA Management Group, Executive Director of the Spanish Agency of Medicines and Medical Devices (AEMPS), HMA

> From anticipation of early concepts to execution and impact, regulators are not just a step in the medicines innovation lifecycle—we are an integral part of it. By using regulatory science as a catalyst of progress, we work collaboratively to bring purpose, efficiency and predictability to a highly dynamic research and innovation ecosystem. In doing so, we help reinforce the EU's leadership in medicins innovation and strengthen its global competitiveness."
>
> **Emmanuel Cormier,**
> Head of Regulatory Science and Innovation Task Force, EMA

Goal 1

Catalyse the integration of science and technology in medicines development and ensure that the network has sufficient competences to support innovators in various phases of medicines development.

Objectives

- Support the integration of scientific and technological progress in the development of medicines (e.g., precision medicine, biomarkers, 'omics and ATMPs) and ultimately into patient treatment.
- Transform the regulatory framework for veterinary medicines to support innovation and successful implementation of the veterinary medicines regulation.
- Implement an EU-level model for efficient, timely and coordinated horizon scanning and priority setting that fulfils the needs of both regulators and HTA-bodies and payers.
- Facilitate the implementation of novel manufacturing technologies.

Achievements

Advanced Therapies Medicinal Products (ATMPs)

- The Quality Innovation Group was established.
- Quality Innovation Group (QIG) conducted a survey and ITF reviewed novel technologies.
- Launch of pilot providing enhanced support to academic ATMP development.

- ATMP cluster meetings held with the United States Food and Drug Administration (FDA), the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and Health Canada.
- Between 1 January 2020 and 31 December 2023, almost half of PRIME designated products were ATMPs, demonstrating the high support provided to these products.
- Dedicated training modules delivered on navigating the regulatory requirements and scientific advice for ATMPs.

EU IN borderline classification group (BLCG)

- Provision of input into the revision of the pharmaceutical legislation which included a proposed mechanism for a scientific opinion at EMA level as to whether a borderline product is or is not a medicinal product.
- Regular meetings held to discuss borderline classification cases raised by NCAs.
- Inclusion of representatives from other networks (e.g. medical devices, substances of human origin (SoHO))
- SoHO based therapies webinar on classification of faecal microbiota transplantation (products co-organised by EU-IN BLCG and SoHO team (DG Sante) in May 2025.

Support mechanisms and Simultaneous National Scientific Advice (SNSA)

- An R&D platform industry stakeholders focus group was established and since then multiple meetings organised.
- Establishment of an EU-IN horizon scanning as a systematic activity and delivery of several published or internal reports on topics of high regulatory interest via engagement with external horizon scanning initiatives, including initiatives of ICMRA, International Horizon Scanning Initiative (IHSI), World Health Organization (WHO) and Joint Research Centre (JRC).
- The Working Group on Pharmaceuticals in the Environment is carrying out activities to implement the EU strategic approach and best practices published in 2025. A new HMA group to continue the work of this working group created in November 2025.
- Engagement with ICMRA and establishment of an AI Working Group.
- Publications on the development of biomarkers from discovery to regulatory qualification for drug development.
- SNSA project pilot offered consolidated scientific advice from more than one NCA with a single-entry point. Phase 2 of the SNSA pilot was finalised, an optimized procedure was developed, and an action plan was established for the future implementation of a more flexible approach at which the NCA would play a more prominent role. Information about the project pilot was published on EU-IN webpages on the EMA and HMA websites including procedural guidance, common application form and templates and new documents will be published in the future related with the new updated procedure.

- Support for developers via Innovation Task Force (ITF) and Business Pipeline Meetings (BPM) is in place, expanding early points of contacts for technologies and methods related to drug development. The number of support meetings increased overall, with a high proportion focused on technology.
- EMA membership in the Science and Innovation Panel of the Innovative Health Initiative (IHI).
- Contributions provided to IHI calls launched in the following fields:
  - Personalised oncology (innovative people-centred, multi-modal therapies against cancer).
  - An innovative decision-support system for improved care pathways for patients with neurodegenerative diseases and comorbidities.
  - Cardiovascular diseases (improved prediction, prevention, diagnosis and monitoring).
  - Next generation imaging and image-guided diagnosis and therapy for cancer.
  - Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need.
- Horizon scanning reports on artificial intelligence, on genome editing and on nanotechnology-based medicines were published. In order to reach a broader audience, the findings and key recommendations included within the genome editing and within the nanotechnology-based medicines were published in a Nature Reviews Drug Discovery paper and on a Nature Reviews materials paper, respectively. A report assessing international horizon scanning signals by JRC and WHO was published.
- Identification of new technologies via horizon scanning, ITF and scientific advice activities.

Innovative manufacturing

- Agreement with US FDA so that FDA and QIG will work closely to advance and align regulatory thinking in the area of advanced manufacturing.
- Two listen-and-learn focus group meetings with industry, academia and international partners took place in March and November 2023.
- Regular updates have been provided at the relevant Working Parties (Biologics and Quality Working Parties) and GMDP inspectors Working Group (IWG) aiming to share experiences and learnings with the network. Guidance is being developed as regulatory understanding on the priority topics evolves, in the form of a Q&A on process models and a Q&A on decentralised manufacturing.

Product specific support

- Development support for applicants through one-to-one meetings with applicants and ITF contributions. Topics included decentralised manufacturing for ATMPs; alternative sterilisation methods to help ensure supply and avoid shortages, continuous manufacturing for vaccines etc.

- Scientific advice on use of robots for aseptic filling, AI for visual inspection of sterile products and decentralised manufacturing of ATMPs.
- Joint visit with FDA's Center for Biologics Evaluation and Research to an EU vaccine manufacturing facility using novel facility designs and extensive automation aiming to allow flexibility in manufacturing and rapid increase in manufacturing capacity to meet demand.

Veterinary medicines

- The Novel Therapies & Technologies working party (NTWP) of the veterinary domain has been set up and is currently producing guidance on the efficacy of cell therapies and is also working on the safety of nanomedicines. Members from the human domain within the NTWP are also involved in the drafting of the guidance.
- An Environmental Risk Assessment European Specialised Expert Community (ERA ESEC) has been created for sharing of information between experts in the environmental risk assessment area. The ESEC is relevant for veterinary medicines, but also for human medicines. The foundation for an ESEC on novel therapies and technologies has been established and will be fully implemented in the short term.
- Guidance for the implementation of the Regulation produced before the implementation date, consisting of over 50 documents, many of which concern biologicals/immunologicals.
- The CVMP worked with the European Food Safety Authority (EFSA) on risk assessment with a view to aligning the methodology for estimating consumer exposure to residues, including dual-use substances. A draft guideline "Development of a harmonised approach to exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides residues in food of animal origin" has been approved by the CVMP and EFSA. It has gone through a consultation period and is currently under revision.
- Novel Therapies and Technologies Working Party (NTWP) continued to update and publish scientific guidance on the requirements for the development of novel therapy veterinary medicines.
- EU NTC training for veterinary assessors.
- Several ITF meetings supported veterinary medicines developers throughout the development lifecycle of novel therapies.
- The CVMP continued to deliver advice to the EC on implementing and delegated acts. The network is also finishing the work to implement some of the new provisions of the legislation like those for limited markets or exceptional circumstances.
- The efficacy of the EMA policy on minor-use-minor-species was assessed via a questionnaire to stakeholders.
- A study of chronic toxicity studies performed in dogs used for the setting of maximum residue limits (MRLs) for substances used in Veterinary Medicinal Products (VMPs).
- Training and webinars with stakeholders were held at EMA and at national level about the functionality of the Union Pharmacovigilance Database, adverse events reporting

and recording and the signal management process. Guidance was published in November 2025.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period 2026-2028.

- Continue fostering interaction and collaboration with different stakeholders (academia, research institutes, industry, funding bodies, SMEs, etc). This collaboration is highlighted in every activity.
- Organise joint workshops promoting EU innovation framework and competitiveness.
- Continue to progress workplans of relevant groups (QIG, Novel Therapies & Technologies Working Party, EU-IN and ICMRA).
- Publish and disseminate horizon scanning reports on identified and prioritised trends and further optimise horizon scanning methodology involving relevant stakeholders.
- Collaborate with FDA on topics of mutual interest, considering joint scientific advice, reviews of marketing authorisation applications and guidance when relevant.

Goal 2

Foster collaborative evidence generation, improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTA and pricing and reimbursement authorities.

Objectives

- Foster innovation in clinical trials and develop the regulatory framework for emerging clinical data generation.
- Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation and invest in special population initiatives.
- Develop further the collaboration of various groups involved with scientific advice and/or regulatory guidance.

Achievements

Clinical Trial Information System (CTIS)

- Launch of the Clinical Trial Information System (CTIS) enabling the mandatory applicability of the Clinical Trial Regulation (CTR) in January 2023.
- Online training programme dedicated to sponsors and member states was developed; CTIS training materials also available.
- Public consultation on CTIS transparency rules in May 2023, culminating in revised CTIS transparency rules adopted in October 2023.

- The Clinical Trials Coordination Group (CTCG) was reorganized and integrated with SAWP, EU-IN, ACT EU and facilitated by INNO governance meetings.
- The Emergency Task Force (ETF) and European Commission hosted an event, in June 2023, to collect insights and suggestions for possible EU-level actions to improve the way clinical trials are set up and conducted in the European Union (EU) during public health emergencies.
- Launch of the Clinical Trial Regulation collaborate initiative, anchored to ACT EU to facilitate optimised Member State and NCA ethics collaboration on clinical trial authorisation under CTR.
- Launch of the COMBINE project by NCAs and European Commission to address the challenges at the interface of the Clinical Trial Regulation and the EU Medical Device Regulation 2017/745 and In Vitro Diagnostic Regulation 2017/746 (CTR/MDR/IVDR), with links to the multi-stakeholder platform (MSP) and EMA activity in clinical trials and medical devices.
- Onboarding of the user community on the use of CTIS with a variety of stakeholder events to enhance quality of clinical trial application (CTA) submission.
- CTIS became a registered data provider for the WHO International Clinical Trials Registry Platform in May 2023.
- Facilitation of assessors' community collaboration (at an assessors' round table).
- Publication of monthly key performance indicators (KPIs) to monitor the European clinical trials environment and launch of annual sponsor surveys to identify issues with the Clinical Trial Regulation and develop tailored solutions.
- EU-IN meeting in Madrid in 2022 was successful in reinforcing collaboration between different groups (INNO collaboration). There were also increasing interactions and the delivery of an academic workshop.

Accelerating Clinical Trials in the EU (ACT EU)

- The ACT EU programme was set up and later transitioned into an early delivery mode with a revised work plan for 2023 to 2026 covering 11 priority actions.
- The ACT EU Steering Group was established, with adoption of its mandate and membership;
- A priority action on clinical trials in public health emergencies was created to facilitate, together with Member State NCAs and ethics committees, the rapid approval of clinical trials when an emergency is declared.
- A Q&A on complex clinical trials was published and a recommendation paper on decentralised elements in CTs was issued in Dec 2022.
- Multi-stakeholder events were embedded as part of the ACT EU activity, including workshops on ICH E6 (R3), and clinical trial methodologies in 2023.
- Training strategy has been available since 2022, setting out high-level objectives for the development of a training curriculum, with completion of the regulatory training needs assessment and gap analysis in 2023.

- Two pilots aimed at improving the quality of applications for clinical trials were launched: Pre-clinical trial application advice (Pre-CTA) and consolidated scientific advice (SAWP-CTCG). Twenty pre-clinical trial applications (CTAs) and 11 SAWP-CTCG applications submitted as part of two ongoing pilot studies.
- Public consultation on the multi-stakeholder platform (MSP) to improve clinical trials in the EU was launched in February 2023, and the kick-off meeting of the MSP occurred in June 2023.
- An open call for nominations to create the Multi-stakeholder Platform Advisory Group concluded in November 2023 to provide both strategic and operational input to the programme.
- ACT EU Steering Group prioritised support for academic sponsors conducting multinational clinical trials and delivered a clinical trials data analytics research agenda as key areas for additional EU public funding.

Regulatory framework

- The GCP regulatory oversight modernised to enable decentralised models of clinical trials coupled with direct digital data accrual.
- Development and adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance at EU and international level.
- Set up of focus group on qualification of novel methodologies during 2022 focusing on horizon scanning for future methodologies (including digital endpoints) and on identification of additional expertise needs and necessary improvements in the qualification process.
- Qualification of digital technologies and transfer of learnings to future guidance development. (Publication of draft CHMP opinion for stride velocity 95th centile measured by a valid and suitable wearable device, as primary endpoint in Duchenne muscular dystrophy clinical trials for public consultation).
- EMA expert base expanded in the areas of digital, biomechanics and devices.
- Progress on DARWIN EU (see the section ‘Data analytics, digital tools and digital transformation’).

Non-clinical models and 3Rs

- Launch of the 3Rs Working Party supporting qualification of new alternative 3R-compliant methods/models including in silico and novel in vitro assays.
- Launch of a specific ITF platform to discuss methodologies that minimise animal testing during medicines development.
- Implementation of the revised carcinogenicity guideline ICH S1(R1), which seeks to reduce the number of in vivo studies performed via a scientific weight-of-evidence approach with:
  - Systematic review of organ-on-chip technology in medicines development: state-of-the-art and gaps to be addressed for purposes of qualifying the methods.

  - Implementation of the ICH M7(R2) guideline for the evaluation and control of mutagenic impurities.
- 3Rs Working Party (3RsWP) public sessions to present work plan and priorities of the WP in March 2024, April 2025
- Support given to the EC Roadmap towards phasing out of animal testing for chemical safety assessment
- Agreement on terms of reference for International Medicines Regulators Working Group 3Rs and the creation of supporting drafting groups, operational expert groups and ESECs.
- Continuous revision of existing scientific guidelines on the acceptance and implementation of 3Rs for human and veterinary medicines.
- Ongoing drafting of new guidelines.
- The INNO group has continued its cross-group collaboration, defining a workplan, sharing updates from the different groups.
- To support data driven decision-making and advanced analytics, access to state-of-the-art software packages and databases has been obtained and is available to EMA staff and the network. Lhasa software aims to aid regulatory and scientific review by providing tools for predicting safety and quality properties in medicines development, combined with in silico software packages for advanced analytics (e.g., Derek Nexus, Kaptis, Sarah Nexus).

Modelling, simulation and extrapolation

- Inclusion in the Methodology Working Party 3-year work programme:
  - Application of new methodologies such as extrapolation and modelling and simulation through the HTA consortium (EMA/EUnetHTA21 work plan) in progress.
  - Initiation of ICH guideline drafting work (ICH M15) – general principles for model-informed drug development.
  - Q&A on PD1/PD-L1 drafted and Q&A published in Q1 2023.
  - Technical advice to research funders on this topic area.

Special populations

- Strategic initiative in maternal-fetal health and advancing access through better understanding and communication of benefits, risks, and uncertainties of medicines use in pregnancy and breastfeeding.
- The ICH Assembly endorsed the proposal for a new efficacy topic (E21) on “Inclusion of Pregnant and Breastfeeding Individuals in Clinical Trials”.
- Development and implementation of an algorithm to identify pregnancy-related spontaneous reports in EudraVigilance in support of enhanced signal detection for this population. The algorithm is a substantial improvement over the MedDRA SMQ used thus far and has been adopted by the WHO.

- The start of CONSIGN (Covid-19 infectiON and medicineS In pregnancy), an EU-led global study of the impact of COVID and its treatments in pregnancy. EMA is leading on the meta-analysis of RWE data sources, to which the US Centres for Disease Control and Prevention, US FDA, Health Canada, the Saudi Food and Drug Administration and academic and clinical centres from around the globe contribute with the view to expanding to other conditions in the future.
- An EMA-FDA-Medicines & Healthcare products Regulatory Agency regulatory cluster has been set up and is meeting monthly to collaborate on strategy development and implementation on medicines in pregnancy and breastfeeding, as well as product-specific discussions between EMA and FDA.
- COMP expert group meeting was held and paper published on orphan condition nomenclature for inherited retinal dystrophies.
- Erythromycin project for intestinal motility using the ongoing DARWIN EU drug utilisation study of medicines with prokinetic properties in children and adults diagnosed with gastroparesis.

Scientific advice/regulatory guidance

- The EU-IN workplan included the Simultaneous National Scientific Advice (SNSA) project with a clear focus on clinical trials applications.
- Two pilots aimed at improving the quality of applications for clinical trials were launched: Pre Clinical Trial Applications) Pre-CTA and SAWP-CTCG

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Continue to progress workplans of relevant groups (CTCG, ACT EU, EU-IN, SAWP and HTACG).
- Continue the effective implementation of 3Rs principles through the 3Rs Working Group since it remains a high priority for many stakeholders.
- Facilitate Member State cooperation on national scientific advice.

Goal 3

Enable and leverage research and innovation in regulatory science.

Objectives

- Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science.

Achievements

- Several multi-stakeholder meetings have been organised:
  - 'Shaping a European innovation ecosystem: EU-Innovation Network multi-stakeholder meeting', held in Madrid, Spain, in September 2023.
  - 'Strengthening life-sciences innovation across Europe: EU-IN conference' held in Dublin, Ireland, in November 2023.
  - 'Translating innovation into access for ATMPs: third EU-Innovation network multi-stakeholder meeting' held in Rome, Italy, in November 2024.
- EU-IN representatives actively participated in ACT EU priority action 10, focussed on the development of a clinical trials training curriculum. ACT EU priority action 10 completed the mapping of the training needs of academia and SMEs in clinical trials via a survey. The analysis of the responses was completed in June 2025.
- A technical document on regulatory support for researchers at national and European levels has been developed and will be published in 2026.
- The EMA/HMA European Platform for Regulatory Science Research was launched in March 2025. The participants were researchers from academia, public and not-for-profit institutions, and regulators. Two meetings held in May and September 2025.
- A notice for expression of interest has been published by the Italian Medicines Agency to identify universities or research institutes (public or private) that could develop and deliver training courses for the European Medicines Regulatory Network through the EU NTC platform.
- Publication of an update (14 July 2025) to EMA's Regulatory Science Research Needs (RSRN).
- Systematic engagement with research funders across Europe, including European Commission's Directorate General for Research and Innovation and Innovative Health Initiative.
- Coordinated involvement in regulatory science projects on RWD for regulatory decision-making, AI, obesity, mental health, biomarkers non-cancer authorised medicines, pragmatic trials.
- Best practices for collaboration with academia identified and to be implemented by NCAs.
- Completion of a study of the experience of the EMA with involvement in multi-stakeholder regulatory science research projects based on semi-structured interviews of staff members and project coordinators.
- Contribution to the draft Strategic Research and Innovation agenda of the forthcoming European Partnership Animal health and welfare.
- The Strengthening Training of Academia in Regulatory Sciences (STARS), a project of the European Commission concluded with all deliverables achieved. The Common Strategy of STARS had 21 recommendations. EU IN promoted the implementation of

these recommendations through different channels (ACT EU priority actions, IncreaseNET).

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Continue to identify opportunities for engagement to influence the launch of funding calls.
- Continue to develop network coordination in individual regulatory science research projects through the EU Innovation Network (EU-IN).
- Broaden the scope of stakeholder involvement, including with academia, industry and funding bodies.

Goal 4

Enhance collaboration with other stakeholders including medical device experts, notified bodies, SMEs and research/academic groups.

Objectives

- Increase collaboration with medical device authorities and notified bodies, exchange knowledge and facilitate collaboration and sharing of expertise to ensure effective and appropriate regulation of combination products.
- Promote early interaction with academia, researchers and SMEs with views to increasing awareness of regulatory requirements and facilitating the translation of relevant research into authorised medicinal products and ultimately into clinical practice.

Achievements

- Launch of a Combination Products Operational Group, in collaboration with the European Commission, to bring together experts from devices and medicines competent authorities, as well as notified bodies. The aim of this group is to facilitate dialogue, enhance mutual understanding and reflect on potential solutions within the current framework, regarding regulatory challenges at the interplay of pharmaceutical and medical device frameworks for combination products and consultations procedures.
- Companion diagnostic expert group established by the CHMP to support and enhance EMA's regulatory and scientific input into the evaluation of applications for personalised medicines and companion diagnostic consultations.
- Establishment of scientific advice by Expamed to manufacturers of high-risk device and piloting of Expamed development support to orphan devices.

- EMA's contribution to all projects of the COMBINE programme.
- Ad-hoc interactions with representatives of the Notified Body Coordination Group-Medical Devices to share experience with the provision of notified body opinion (Medical Devices Regulation, Article 117) in the context of marketing authorisation for combination products.
- Engagement with stakeholders continued, including on repurposing with the finalisation of the EU Repurposing Project pilot (report published in July 2025). To increase the visibility of the findings and recommendations there were also published in Nature Reviews Drug Discovery.

Knowledge and expertise exchange

- The Digital Academy was launched, a digital skills framework developed and introductory modules in a number of topic areas now available. Modules on other digital topics including artificial intelligence under development (see the section' Data analytics, digital tools and digital transformation.'
- Surveys for HMA and Leaning Management System users on training needs and priorities in the network.
- Access to product information modules provided to a small number of African regulators, as part of the collaboration between EMA and the African Medicines Agency.
- Contract signed with an external consultant for development of a learning design and development toolkit for curriculum steering groups and course developers.
- Ongoing work with the service provider to improve the reporting analytics of the LMS.
- Interactions initiated with EU-IN (training in new areas of innovation), and PIC/S (training in good manufacturing practice). Discussions also initiated on future of learning topics – implementation of the multi annual work programme (MAWP) topics, interactions with external organisations, new areas, interactions with academia.
- Engagement with academia to develop regulatory training modules, including describing innovation of new medicines and their progression from laboratory to patient:
  - Publication of video tutorial on "How to apply and benefit from an orphan drug designation" with European Infrastructure for Translational Research (EATRIS).
  - EMA and the European Clinical Research Infrastructure Network joint training session - Implementation of the Clinical Trial Regulation (EU) No 536/2014 for academia.
  - Webinar for small and medium-sized enterprises (SMEs) and academia on the Clinical Trials Regulation and the CTIS.

For information on additional achievements related to EU-NTC see the section 'Sustainability of the network and operational excellence'.

Medical devices and combination products

- Establishment and operation of the medical devices expert panels (Expamed), with the creation of a list of experts and the thematic mapping of expertise.
- Establishment of a process for multi-stakeholder scientific advice to support development of medicine-device combinations, qualification methodologies and the use of companion diagnostics.
- Engagement with industry in the context of the R&D platform meeting resulted in following outcomes:
  - Industry (including the MedTech industry) agreed to provide an in-depth analysis of scope/remit as well as typical types of questions that would be subject to such scientific advice.
  - Pilot launch of scientific advice for selected medical device products.
  - Agreement that EMA will consider future engagement opportunities on the refinement of the integrated pathways concept.
- A process to consult medical device authorities and/or notified bodies (as applicable) for device-related aspects throughout the product lifecycle was developed, including post-authorisation safety related events.
- Collaborative interactions with the EC's Medical Device Coordination Group and the Notified Body Coordination Group (NBCG) have been established to develop procedural guidance in the lifecycle management.
- Internal EMA Digital Therapeutics Matrix established to monitor, share and discuss cases. Existing EMA support platforms to developers (i.e. Innovation Task Force, scientific advice and qualification of novel methodologies) are available to developers. Amendments to ITF, scientific advice and qualification of novel methodologies scope/procedure/expertise are being discussed and implemented (e.g. Focus Group on QoNM as part of the R&D stakeholder platform and EMA workshop on the qualification of novel methodologies in March 2023).

Early interaction with academia, researchers and SMEs

- Implementation of strengthening training of academia in regulatory science recommendations on early stakeholder interactions, including encouraging early interaction with researchers and developers (facilitated by national innovation offices or the EMA's ITF) as well as highlighting the availability of other regulatory support pathways and mechanisms.
- Engaged with European Commission Directorate-General Research & Innovation, Directorate-General for Health and Food Safety (DG SANTE), Directorate-General for Communications Networks, Content and Technology (DG CONNECT), the Innovative Health Initiative, the Committee on the Environment, Public Health and Food Safety (ENVI) Agencies and Member State funding agencies to propose and issue calls to establish research collaborations:
  - Evaluation of 30 consortia requests for involvement of EMA regulatory scientists in their projects.

- EMA subject matter expert support to consortia in form of advisory role in (n=5), participation (n=1), and recommendations for regulatory services (n=9).
- Published research and evaluation of the impact of pharmacovigilance and risk management planning.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Continue to develop workplans of relevant groups (EMA Single Programming Document and EU-IN) engaging a wide range of stakeholders (researchers and developers from academia, hospitals and SMEs, industry, funding bodies, medical device experts, notified bodies, ethics committees and patient communities, HTA bodies and the Substances of Human Origin (SoHO) network and device stakeholders).
- Promote stakeholder interactions to address regulatory requirements of complex products within the 'integrated pathways project'.

Antimicrobial resistance and other emerging health threats

> Current and future threats to public and animal health, such as antibiotic resistance or other emerging health threats, must immediately be identified and addressed preventively. Our joint strategy based on the "One Health approach" is essential for an early and successful intervention.

Thomas Heberer,
Head of Division of Veterinary Medicinal Products, German Federal Office of Consumer Protection and Food Safety (BVL), HMA

> To tackle the problem of antimicrobial resistance and to stay ready for future public health emergencies, we need to have a pipeline of medical countermeasures on the shelf and ready to go. EU regulators are proactively supporting developers and creating a conducive environment for innovation.

Marco Cavaleri,
HMA Head of Public Health Threats Department, EMA

Goal 1

Provide high quality information on antimicrobial consumption and surveillance data on antimicrobial resistance.

Objectives

- Implement the requirements for the mandatory collection of sales and use data for antimicrobials used in animals, spread knowledge and ensure better access to data in line with the veterinary medicines regulation.
- Foster more robust surveillance systems in the EU for both antimicrobial consumption and emergence of resistance in veterinary and human medicine, in order to foster analyses of the potential relationships between antimicrobial consumption and AMR and of co-selection of AMR by use of biocides and feed additives.

Achievements

- The European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG) was established in 2023 to advise EMA on technical aspects, the Member States on operational aspects and CVMP on scientific aspects related to collection, analysis and reporting of antimicrobial sales and use data. This body is also the mechanism for Member States' approval of EMA reports on sales and use of antimicrobials in veterinary medicine ('ESUAvet reports').
- Development of a manual for Member States for establishing a data quality management plan for the collection of antimicrobial sales and use data under Regulation (EU) 2019/6 and its delegated and implementing regulations by the respective subgroup.
- The guideline on indicators and denominators was developed, with the latter finalised and published in October 2023.
- The first ESUAvet report – 'European sales and use of antimicrobials for veterinary medicine - Annual surveillance report for 2023' – was published in March 2025.
- The second ESUAvet report – 'European sales and use of antimicrobials for veterinary medicine - Annual surveillance report for 2024' – was published in December 2025.
- The new ESUAvet interactive dashboard was launched in December 2025 to provide access to antimicrobial VMP sales data, empowering stakeholders, from policymakers to the general public, to explore and understand trends in veterinary antimicrobial consumption patterns to support decision-making. This was launched alongside another interactive dashboard that contains historical ESVAC data.
- The third joint inter-agency antimicrobial consumption and resistance analysis report was published in 2021, and the fourth in 2024. They are based on data provided by EMA, ECDC, and EFSA surveillance and monitoring systems.

- Technical improvement of Antimicrobial Sales and Use Platform and further development of guidelines and support documents (e.g. Antimicrobial Sales and Use platform User Guide, Antimicrobial Sales and Use Power BI Application Guide, Antimicrobial Sales and Use technical implementation protocol).
- Information and communication campaigns for national-level data reporters, and the provision of national support documents, websites, webinars, etc.
- Organisation of various webinars on relevant topics such as quality management and data handling.
- Solving data quality issues in the Union Product Database (UPD) by different approaches (e.g. Data Quality Framework, Template reviewing by MSs).
- Successful implementation of IT systems for sales and use data collection (Step 1 at national level).
- Provision of EMA scientific advice, with input of experts nominated by HMA for the following:
  - Commission Delegated Regulation (EU) 2021/578 on requirements for the collection of data on the volume of sales and on the use of antimicrobial medicinal products in animals.
  - Commission Implementing Regulation (EU) 2022/209 establishing the format of the data to be collected and reported on volume of sales and on use of antimicrobial medicinal products in animals.
- EMA has completed the IT development of the antimicrobial Sales and Use data system, which was designed, built and tested in close collaboration with Member State experts. The system is now fully operational and ready to receive annual data submissions from Member States, supporting the implementation of the legal requirements in line with the established timelines and deliverables. The transition was further supported by a dedicated change liaison programme that assisted Member States in developing or adapting their national systems for collecting antimicrobial sales and use data. With the development phase finalised, EMA's IT activities are now focused on system maintenance, ensuring stability through minor improvements and timely bug fixes.
- At Member State level, the HMA Working Group on the "implementation of use data collection by animal species" provides guidance to all veterinary NCAs on the transfer of data, ensuring data quality management, and on communication.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- 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.
- Constant improvement of data quality, especially in the use data sector, exchange of experiences between Member States through the ESUAvet Working Group.

Goal 2

Contribute to responsible use of antimicrobials and effective regulatory antimicrobial stewardship.

Objectives

- Modernise the summaries of product characteristics (SmPC) of old antibiotics for human and veterinary use.
- Define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests.

Achievements

- As part of the implementation of Regulation (EU) 2019/6, the following achievements of the EMA, with the support of Member States' experts, contributed to the responsible use of antibacterials and effective regulatory antimicrobial stewardship:
  - The Dosage Review and Adjustment of Established Veterinary Antibiotics (ADRA) project aligns with the reflection paper, which highlights the development of non-experimental approaches to refine the dosage regimens of established veterinary antibiotics. With respect to this project, the ADRA Temporary Working Party was established. Work has started with the first combination: Veterinary Medicinal Products (VMPs) containing amoxicillin (as a single active substance) in pigs for use in drinking water or in feed, for respiratory indications
  - First scientific report by five EU health and environment agencies – EFSA, ECDC, ECHA, EEA and EMA – supported by the Joint Research Centre, published on the 'Impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus* spp.'
  - Based on the comments received on the concept paper, the development of a reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals is ongoing and planned to be published for public consultation in 2026.
- Based on the EMA's advice on legislation defining criteria for the designation of antimicrobials to be reserved for human use and on recommendations for inclusion of medicines in a list of antimicrobials reserved for human use, the Commission Delegated Regulation (EU) 2021/1760 and the Commission Implementing Regulation (EU) 2022/1255 were published respectively.
- Commission Implementing Regulation (EU) 2024/1973 was adopted and is based on the Scientific advice under Article 107(6) of Regulation (EU) 2019/6. This is a new EU rule that sets out which antimicrobials are not allowed to be used—or can only be used under strict conditions—when treating animals.

- Scientific advice under Article 115(5) of Regulation (EU) 2019/6 on veterinary medicinal products, regarding the list of substances which are essential for the treatment of equine species and for which the withdrawal period for equine species shall be six months (Equine advice) was adopted. Based on this advice, the Commission Implementing Regulation (EU) 2025/901 was adopted.
- Federation of Veterinarians of Europe and EMA webinars were organised, in collaboration with CVMP members, on the regulation of veterinary medicinal products to clarify and provide a deeper understanding of the new rules for veterinarians, staff of competent authorities, and officials. Topics include restrictions on the conditions for using certain antimicrobials under the "cascade".
- The Article 31 referral for old antibiotics for human use was restarted in 2023 after a pause due to the COVID-19 pandemic.
- A reflection on the best strategy to ensure appropriate use of human antibiotics and to inform prescribers has taken place.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Modernise the product information of existing antibiotics for veterinary use and consider additional options for guiding prescribing practices.
- For human medicines, take account of ongoing initiatives on EU product information, while incorporating relevant new provisions in the new pharmaceutical legislation.
- Progress on exploring alternatives to referrals for human antibiotics in order to have an impact on use.
- In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics for human use to support the development of improved diagnostic tests.
- Provide joint scientific advice with an expert panel for in vitro diagnostics related to AMR
- Continuously raise awareness of AMR through education, best practice-sharing and training.
- Finalisation of the reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals is planned to be published in 2026 for public consultation.
- Start internal and external discussion on potentially considering AMR-related diagnostics as high risk (category 4).
- On the veterinary side, in follow-up to the above-mentioned ADRA-project on dosage review and adjustment of selected veterinary antibiotics.

Goal 3

Ensure regulatory tools are available that guarantee therapeutic options while minimising impact of antimicrobial resistance on public health and the environment

Objectives

- Promote guidance on antimicrobial use by adapting existing and creating new guidelines and finalise the Agency approach to antimicrobial resistance in the environment.

Achievements

- The CVMP published the 'Guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals'. The Committee started working on a similar guideline for non-food-producing animals. The paper was published for public consultation.
- A joint EMA/HMA AMR workshop was held on 18 October 2023 at the high-level meeting of the Spanish Presidency of the EU with a focus on communication strategies needed to raise awareness among professionals and the general public.
- The CVMP started the development of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment resulting from the use of a VMP by publishing a paper for public consultation.
- The CVMP is working on the revision of the 'Reflection paper on the use of macrolides, lincosamides and streptogramins in animals in the European Union: development of resistance and impact on public and animal health' based on the published concept paper. The draft reflection paper will be published for public consultation in 2026.
- AMR event 'Combatting Antimicrobial Resistance - Strategies and Challenges' was held on 20 - 21 November 2023 in Berlin organised by the Federal Office of Consumer Protection and Food Safety in Germany.
- Building on the updated advice on the impact on public health and animal health of the use of antibiotics in animals (categorisation of antimicrobials), EMA published a concise infographic in all official EU languages to help guide veterinarians in clinical decision-making. This infographic was revised in 2025 to align with the list of antimicrobials reserved for treatment of certain infections in humans (Commission Implementing Regulation (EU) 2022/1255)
- Cooperation with other stringent regulators at the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) and within a quarterly dedicated cluster (involving EMA, FDA, Health Canada and PMDA) in which a number of important aspects are discussed, including AMR-relevant new drug developments (in terms of regulatory expectations).

- Other guidelines, human and veterinary, were worked on by EMA, with concept papers developed and released for consultation and feedback taken into account during ongoing guideline development. These include:
  - The guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in food-producing animals.
  - The reflection paper on the use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union: development of resistance and impact on human and animal health.
  - A reflection paper on antimicrobial resistance in the environment: considerations for current and future risk assessment of VMP was published.
  - The guideline on the clinical evaluation of antifungal agents for the treatment and prophylaxis of invasive fungal disease, which is being updated.
- Communication on available tools, like the updated Antimicrobial Advice Ad Hoc Expert Group categorisation, to stakeholders to ensure proper implementation in cooperation with the Working Group of Communication Professionals. These include:
  - Federation of Veterinarians of Europe and the EMA, in collaboration with selected CVMP members, run webinars on the VMP-Reg to clarify and deepen understanding of the new rules for veterinarians, competent authority staff, and officials. Topics included data collection on the sales and use of antimicrobials, the EMA's categorisation of antibiotics for veterinary use, restrictions on the use of certain antimicrobials in animals, and the conditions for using certain antimicrobials under the "cascade".
  - Activities to streamline the different communication activities in the medicines agencies network (e.g. for the annual World Antimicrobial Awareness Week).

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Develop, update, and promote further 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.

Goal 4

Define pull incentives for new and old antimicrobial agents.

Objectives

- Define value of new antimicrobial agents to inform new business models and cooperate in the establishment of new business models, including the exploration of incentives for continuous manufacturing of old antibiotics in the European medicines agencies network strategy to 2025.

Achievements

- Key aspects of this strategic goal have been incorporated into the new revision of the pharmaceutical legislation.
- Technical ongoing work with the European Commission on the proposed pull incentives.
- Discussion on pros and cons of different business models in the context of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), Member States' initiatives such as European Union Joint Action on AMR and Healthcare-Associated Infections (JAMRAI) and G7/20 Working group on incentives (hosted by Global AMR R&D Hub).

Goal 5

Foster dialogue with developers of new antimicrobial agents and alternatives to traditional antimicrobials.

Objectives

- Foster development of new antimicrobials, including new antibacterials for human use, define regulatory pathways for phages and other innovative products in human and veterinary medicine and engage with relevant stakeholders to discuss the issue effectively.

Achievements

- AMR is a focus area for the EU network, with high-level meetings held to bring stakeholders together to focus on relevant issues, including innovation and alternative treatments.
- Guidelines and respective dedicated trainings to support the authorisation of antimicrobial VMPs or products that can help to reduce the use of antimicrobials were published, e.g. on:
  - quality, safety and efficacy of bacteriophages
  - evaluation of benefit-risk balance of veterinary VMPs
  - clinical trials with immunological VMPs
  - requirements for the production and control of immunological VMPs

  - data requirements for vaccine platform technology master files
  - data requirements for vaccine antigen master files
  - data requirements for multi-strain dossiers for inactivated veterinary vaccines
  - data requirements for authorisation of immunological VMPs in exceptional circumstances
  - data requirements for adjuvants in vaccines for veterinary use
- The reflection paper on promoting the authorisation of alternatives to antimicrobials (products that can help to reduce the use of antimicrobials) in the EU was finalised and published in 2021.
- A reflection paper on the application of Article 40(5) of VMP-Reg for certain categories of variations was published in 2025. This paper clarifies the circumstances and types of data required to demonstrate a reduction in antimicrobial resistance and provides guidance on variations to marketing authorisations that could benefit from an additional four years of data protection (Article 40(5)).
- AMR was also a main topic at the HMA II meeting in Uppsala and several other meetings.
- EMA contributed to a 2022 OECD briefing note on antimicrobial resistance in the EU/EEA.
- EMA participation at the policy brief 'How can the EU support sustainable innovation and access to effective antibiotics?' produced by the European Observatory on Health Systems and Policies with the Swedish Presidency of the Council of the EU.
- For the discussion of these issues in a global context, the Regulatory Agencies Global Network against AMR (RAGNA) was initiated by the Swedish Presidency in cooperation with the World Health Organization (WHO) in June 2023.
- Regulatory cluster teleconferences on bacteriophages for human use have started and progressed to the proposal for a working group within TATFAR. Mapping of clinical research and support via funded research will be explored.
- EMA promoted the use of available regulatory tools to expedite antibacterial agent development and of alternative therapeutic approaches, which can be adapted if necessary. The Emergency Task Force has increased its outreach to developers in this area (early dialogue with developers of medicines meeting unmet medical need) and early dialogue in general with EMA.
- A report from the TATFAR meeting on phages for human use has been published in *Nature Communications*.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Continue discussions on the future regulatory pathways in connection with the new pharmaceutical legislation for medicines for human use, keeping the veterinary side involved.

- Workshop on bacteriophages to discuss how to advance regulatory pathways in light of the new pharmaceutical legislation planned for Q4 2026.
- CVMP will publish concept papers outlining quality and safety expectations for RNA interference and RNA antisense therapies, as well as for mRNA vaccines for veterinary use. These papers will form the basis for future guidelines and help prepare the regulatory system for next-generation veterinary medicines.

Goal 6

Improve regulatory preparedness for emerging health threats.

Objectives

- Refine regulatory activities between epidemics to increase preparedness and harmonise regulatory framework and approaches for investigation of medicinal products during emergencies.

Achievements

- With the reinforced role of the EMA (in line with Regulation (EU) 2022/123), the now permanent Emergency Task Force (ETF) was established (see also the section 'Sustainability of the network and operational excellence'). The ETF is regularly engaging with developers and provided scientific advice on medicines that could address a public health emergency.
- The EMA emerging health threats plan was updated in February 2023.
- EMA transparency measures for medicines addressing public health emergencies published in Jan 2023.
- The ETF's role in preparedness has been established. Scientific advice procedures have been progressed in several areas related to health threats.
- Regulatory review of the evidence of medical countermeasure products to support HERA and Member States in stockpiling and joint procurement have started.
- Collaboration with EU and Member State bodies related to chemical, biological, radiological and nuclear risk mitigation has progressed. A workshop with EU consortia such as Counteract has been held at EMA.
- A workshop on clinical trials during public health emergencies was held at EMA, leading to a proposal for a coordinating committee to prioritise studies and funding for CTs during emergencies and in peace time. It has also led to the addition of a priority action for clinical trials during emergencies in ACT EU.
- A workshop on generating clinical evidence for treatment and prevention of long-COVID was hosted by EMA with the inclusion of patient representatives, clinicians and international stakeholders.

- A workshop on endpoints and clinical trial design for antivirals for respiratory viruses (EMA workshop on primary efficacy endpoints for antivirals and monoclonal antibodies intended for the treatment of COVID-19 and influenza and a workshop on non-clinical models to support approval of medical countermeasures before emergencies have taken place (EMA workshop: Non-clinical data for regulatory decision-making on the efficacy of medical countermeasures.
- The COVID-19 Lessons Learned report was published on 1 December 2023.
- New models of clinical investigations explored, e.g. at workshop on controlled human infection models and clinical trial design.
- The use of non-clinical models assessed for approval of chemical, biological, radiological, and nuclear medical countermeasures, e.g. workshop on non-clinical models and alternatives.
- Guidance documents issued on clinical treatments in the context of biological and chemical deliberate release.
- Collaboration with WHO and international partners on key viral families and collaborative open research consortia.
- Provision of support to clinical trial networks in the EU and globally on epidemics and pandemics response.
- Medical countermeasures mapped for different health threats.
- Engagement with the Health Security Committee, the newly created Advisory Committee for Public Health Emergency, HERA and the European Civil Protection and Humanitarian Aid Operations on priorities for R&D and stockpiling of medical countermeasures.
- The streamlining of regulatory and ethics approval for clinical trials in emergencies was advanced through ACT EU, leading to the launch of the scientific advice of the ETF in conjunction with Clinical Trials Coordination Group and the Ethics Advisory Group.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Consolidate perspectives on approval of medical countermeasures when clinical efficacy trials are not feasible before an actual emergency, via drafting an ETF reflection paper
- Advance and finalise guidance documents for antivirals for respiratory viruses, influenza vaccines, vaccines for orthopoxviruses, tuberculosis treatment and antifungal agents.
- Advance portfolio of options for clinical investigations of medical countermeasures during emergencies.
- Provide joint scientific advice with an expert panel for in vitro diagnostics for pathogens of epidemic and pandemic potential.

- Issue clinical treatment recommendations for radionuclear threats.
- Embed the One Health principles and expand monitoring of health threats related to climate and environmental changes.

Supply chain challenges

> The COVID-19 public health emergency highlighted enduring vulnerabilities in pharmaceutical supply chains, reinforced by ongoing geopolitical and economic pressures. Ensuring the continuous availability of medicinal products and APIs remains a critical priority for the European regulatory network. This need was addressed by strengthening the reliability of evidence available to regulators, enhancing supply chain transparency, and reinforcing harmonised, risk-based regulatory and inspection approaches. It is important to reinforce these measures in order to support informed decision-making, to enhance traceability of medicines throughout the supply chain, build inspector capacity and contribute to a more resilient and sustainable availability of medicinal products across the European Union, already preparing to respond to the new provisions of the pharmaceutical reform.

Rui Santos Ivo,
Chair of EMA Management Board, President of the Portuguese National Authority of Medicines and Health Products (INFARMED), HMA

> Through strengthened traceability systems, enhanced inspectorate capacity, and deeper international cooperation, EMA and the national competent authorities are reinforcing the security and oversight of the medicines supply chain, ensuring that falsified products are kept out, manufacturers are consistently and effectively supervised, and regulatory decisions are supported by more reliable, interoperable data.
>
> **Brendan Cuddy,**
> Lead Scientific Officer and GMDP IWG Chair, EMA

Goal 1

Enhance traceability, oversight and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs) and excipients.

Objectives

- Improve and inter-link information in current/existing databases to provide supply chain compliance overview.
- Tackle falsified medicines; prevent presence of falsified medicines in the supply chain by strengthening inspections of manufacturers' application of safety features and of the repository systems.

Achievements

- Work is ongoing on the Product Management Service (PMS) which will make available product data on all authorised medicinal products in the EU, including both CAPs and NAPs, in ISO IDMP-compatible format.
- The Good Manufacturing Practice (GMP)/Good Distribution Practice (GDP) Inspectors Working Group (GMDP IWG) has established a GDP Drafting Group in 2024 to provide clarifications to existing guidance for wholesale distributors authorisation (WDA) holders when performing risk assessment on the verification of authenticity of medicinal products at risk of falsifications. The GDP DG will also update existing and develop new Compilation of Union Procedures to support harmonisation between member states.
- Work has continued with the extension of the Joint Audit Programme to cover Good Distribution Practice. The GDP Drafting Group held a joint meeting with the EU4H11 subgroup working on harmonisation and implementation of JAP for GDP on 20-21 March 2025.

- The entry into force of Regulation (EU) 2019/6 on veterinary medicinal products has extended Good Distribution Practice to veterinary medicines and active substances used in veterinary medicine.
- Scientific advice providing the principles of GDP to be incorporated into implementing acts was adopted through the GMDP IWG and the CVMP. The GMDP IWG has developed the template for the wholesale distributors authorisation for veterinary medicine for use by EU authorities.
- Work has been concluded on finished products and active pharmaceutical ingredients.
- A pilot programme for co-operation and reliance with partner authorities, relying upon GMP inspection reports of PIC/s authorities for GMP verification has successfully concluded.
- Co-operation and reliance with partner authorities on the inspection of API manufacturers through the API Programme and the inspection of third country manufacturers of medicinal products is ongoing.
- The EudraGMDP database was integrated with the Organisational Management System so that there is only a single controlled version of the name and address of manufacturers, importers and distributors of medicines for human and veterinary use, improving the quality of supply chain compliance information available.
- The strengthening of inspectorate capacities has been taken up within the Joint Action EU4H 11 included in the EU4Health Programme funded by the European Commission. The Joint Action EU4H 11 aims at strengthening capacities of EEA GMP/GDP inspectorates with respect to Good Distribution Practice. It has proceeded along 4 key action areas identified in the network strategy:
  - Strengthening the Joint Audit Programme (JAP) for EEA GMP inspectorates: The Joint Action EU4H 11 has started work on optimising training and qualification processes for auditors as well as the JAP procedure. Furthermore, the co-financing of costs related to JAP activities supports member states' participation in the Joint Audit Programme.
  - Two training sessions performed in March 2022, and October 2023 related to JAP audits for training of JAP auditors.
  - Reviewing the national implementation of the European GDP legislation and guidelines and developing a proposal to add GDP to the existing Joint Audit Programme. By promoting collaboration between EEA GDP inspectorates, the Joint Action will strengthen the EEA GDP inspectorates' network and work towards a harmonization of GDP inspections standards.
  - Strengthening EEA inspectors' capacities by establishing harmonised training and qualification processes for GMP inspectors, in cooperation with the PIC/S Inspectorates' Academy.
- Strengthening the supply chain also focuses on the co-operation and reliance with partner authorities on the inspection of API manufacturers that is ongoing through the API Programme and the inspection of third country manufacturers of medicinal products through the establishment of a new pilot programme evaluating and relying

upon inspection reports of PIC/s authorities for GMP verification, that began in October 2022.

- The implementation of the objective to provide a supply chain compliance overview has also been linked with the work on shortages (as the latter may also require a rapid analysis of the manufacturing sites of products affected by shortages). This is intended to develop a European concept model to monitor and manage medicines shortages, taking into consideration existing tools/good practices developed at EU MS level in order to achieve an efficient merging of the available systems and information sources of MSs with an inclusive approach. (See the section 'Availability and accessibility of medicines').
- A report has been prepared on a SWOT analysis of the current state of IT solutions in the EU and Member States. Main findings include as weaknesses missing information on stocks and demand as well as forecasts and production plans.
- Work Package 7 of CHESSMEN Joint Action has also been progressing in development of identification of best practice solutions and minimum common datasets by making a survey to collect information from the Member States existing systems related to shortage situations. This survey also included technical questions for a complete overview of the multitude of different systems (e.g. service portals, platforms and networks). A report has been written from the results of the survey.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines in the supply chain.

Goal 2

Enhance inspector capacity building at EU and international level.

Objectives

- Enhance capacity building of EU inspectors and assessors in order to harmonise approaches to regulatory inspections procedures to address requirements and challenges of APIs, medicinal products, excipients, new technologies and continuous manufacturing.
- Promote a more tailored supervision of API manufacturers through assessment and inspection of their API development and risk management practices in technology transfer; increase supervision of sites that produce medicinal products for a significant number of EEA markets or very significant numbers of products, with dedicated cooperative supervision between MSs and strategic partners for these sites.

Achievements

- A first GMDP IWG inspector training strategy was drafted and adopted by the GMDP IWG.
- The GMDP IWG established a drafting group for inspector training.
- The GMDP IWG together with EMA established an expert community of GMP inspectors to facilitate interaction and exchange of information between inspectors across the EEA.
- Funding was secured through EU NCT to cover trainee inspector participation at inspector training events held in the EU.
- A pilot programme of joint inspector training visits initiated through GMDP IWG has been accepted for funding through EU4Health JA No. 11.
- Inspector training on the new GMP Annex 1 was secured through PIC/s. A series of training videos covering the main changes introduced with the new version of Annex 1 has been prepared and has been made available through PIC/s. A follow-up survey to confirm future topics for GMP inspectors' training on Annex 1 was completed.
- Five GMP Inspector training events were held in 2025 with support from EU4H Joint Action and from EU NTC. Training materials have been made available on the EU NTC platform.
- The Joint Inspector Training Visits programme supported by the EU4H Joint Action has continued in 2025 with several observed inspections to support training and capacity development.
- With respect to the supervision of API manufacturers, a risk-based tool on pre-approval API inspections was developed and discussed at the GMDP IWG. It was agreed to pause this work until the publication of the new pharma legislation that will provide a legal basis for risk-based inspection of API manufacturers.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Ensure sufficient numbers of trained inspectors are continuously available to perform legal duties.
- 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.

Goal 3

Reinforce the responsibility for product quality by harmonising and reinforcing guidance.

Objectives

- Develop EU level data integrity guidance.
- Ensure a stable EU-GMP regulatory framework with predictable outcomes by promoting and improving the understanding of EU GMP requirements and preparedness by third country manufacturers and their supervisory authorities. Foster an environmentally friendly level playing field.

Achievements

- A draft Chapter 4 (Documentation) of the EU GMP Guide as well as a draft Annex 11 (Computerised Systems) guideline, incorporating rules concerning data integrity was published for stakeholder consultation by the European Commission in July 2025. The consultation concluded in October 2025. The comments received from stakeholders are now being evaluated.
- Work on revision of GMP guidelines (apart from the ATMP GMP guideline) was carried out in collaboration with PIC/s to promote and improve understanding of EU GMP requirements.
- A draft Chapter 1 (Pharmaceutical Quality System) of the GMP guide was published for stakeholder consultation in September 2025. The consultation concluded in December 2025. The comments received from stakeholders are now being evaluated.
- A draft Annex 22 (Artificial Intelligence) covering use and validation of artificial intelligence was published for stakeholder consultation by the European Commission in July 2025. The consultation concluded in October 2025. The comments received from stakeholders are now being evaluated.
- A concept paper proposing revision to the GMP guideline for ATMPs was published in May 2025. A draft updated guideline is now being prepared taking into account comments received.
- Three concept papers proposing revision to Annex 3 (Radiopharmaceuticals), Annex 6 (Medicinal Gases) and Annex 15 (Validation) of the GMP Guideline were published for stakeholder consultation in December 2025.
- The Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group (GMDP IWG) has developed scientific advice for GMP implementing acts for veterinary medicines and active substances in relation to proposed extension of environmental measures to good manufacturing practice.
- New Annex 1 “Manufacture of Sterile Medicinal Products” and Annex 21 “Importation of Medicinal Products” were published in 2022. Annex 1 entered into force in August 2023, and Annex 21 entered into force in August 2022.
- A concept paper to revise Annex 11 incorporating existing data integrity guidance questions and answers was published in November 2022.

Follow-up actions in EMANS 2028:

The following activities will be carried out in the next strategy period from 2026 to 2028:

- 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).

Goal 4

Encourage supply chain resilience and review long-term risks resulting from dependency on limited number of manufacturers and sites.

Objectives

- Enhance the reliability of evidence available to regulators for informing the decision-making process on the supply chain and promote supply chain resilience and reliability of supply of APIs and medicinal products.

Achievements

- The reliability of evidence for decision making on the supply chains has been enhanced by:
  - Strengthening the documentation and data integrity requirements for manufacturers and importers in Annex 11, 22 and Chapter 4 of GMP Guidelines.
  - Training of GMP inspectors on documentation and data integrity requirements carried out in 2025.
  - The GMDP IWG's ongoing revision of the Compilation of Union Procedures on risk-based inspection planning.
  - Finalisation of the reliance pilot, which has allowed the use of inspection reports from PIC/s authorities to inform the decision-making process.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Use risk-based inspection planning, alternative inspection methodology and collaboration with international partners to better target oversight of the supply chains, including for key finished product and API manufacturers.

Goal 5

Analyse the possible implications of new manufacturing technologies and adapt the regulatory framework to accommodate innovation in manufacturing and distribution.

Objectives

- Analyse the regulatory system with respect to new technologies and new tools used in manufacturing and in supply chain management and control; identify opportunities to improve supply chain resilience.

Achievements

- For achievements under this objective, please also refer to section 3 on Innovation, in particular achievements under the Quality Innovation Group.
- A draft Annex 22 covering validation of artificial intelligence was published for stakeholder consultation by the European Commission in July 2025. The consultation concluded in October 2025. The comments received from stakeholders are now being evaluated.
- Questions and answers on the use of X-ray sterilization were published by EMA in October 2023.
- Questions and answers on the use of 3D printing were adopted by the GMDP IWG in November 2025.

Follow-up actions in EMANS 2028:

The following activity will be carried out in the next strategy period 2026 to 2028:

- 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).

Sustainability of the network and operational excellence

“We will strengthen the network’s capability to deliver digital transformation in the implementation of new human and veterinary legislation. By leveraging shared data, processes, technologies—including AI—and enhanced work sharing, the network will improve efficiency, international convergence and responsiveness to public information needs, while actively countering mis- and disinformation to protect patient safety and wellbeing.

Runa Hauksdottir Hvannberg,
Executive Director of the Icelandic Medicines Agency (IMA), HMA

“Ensuring that patients have reliable access to medicines, even during times of crisis, is a key priority for the European Medicines Regulatory Network. Through EMANS 2025, we have reinforced this foundation by strengthening our scientific and regulatory capacity, enhancing operational excellence and digital transformation, and bolstering our crisis-response capabilities. The improved coordination on critical shortages and assessments of vulnerabilities in essential supply chains have increased our resilience, ensuring we remain prepared to protect public and animal health in an increasingly complex supply and crisis landscape.

Alberto Gañán Jiménez,
Head of Committees and Quality Assurance, EMA

Goal 1

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

Objectives

- Ensure 'fit-for-purpose' scientific capability of the network.
- Prepare for and implement the veterinary medicines Regulation.

Achievements

- The IncreaseNET initiative was launched in January 2024 to address the capacity and capability of the network. As part of the initiative, the following actions were undertaken:
  - The areas for training development were selected (ATMPs; chemistry, manufacturing and controls; biologicals; pharmacokinetics; modelling and simulation; clinical trials and statistics); learning outcomes and objectives for these areas were developed; and an Introduction program for newly recruited assessors was developed and launched in the EU NTC platform in June 2024. The first module on Biostatistics was launched in November 2025.
  - The on-the-job training and -coaching program were successfully developed, implemented, and reviewed. The program kicked off with CHMP procedures in June 2024 and was extended to PRAC procedures in May 2025.
  - Two innovation-related surveys were shared with NCAs, the first to screen unmet needs or practices already in place at NCAs in terms of assessment/training on innovation topics and the second to collect best practices in innovation support. In addition, a grid of criteria for assessing the impact of new technologies on the organization of NCAs was drawn up and Toolkits to facilitate NCAs' interaction with academia and SMEs were developed.
  - Collaboration was undertaken with EMA/HMA bodies: the European Union Network Training Centre (EU NTC), the Committee for Medical Products for Human Use (CHMP), Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), Committee for Advanced Therapies (CAT), Biologics Working Party (BWP), EU Innovation Network (EU-IN), Accelerating Clinical Trials in the European Union (ACT-EU), Strategic Resource Oversight Group (SROG).
- A new expertise-based governance model for working parties of CHMP was implemented to optimise the use of available expertise in the network. The new model fosters harmonised best practices in the management of the working parties and groups in order to deliver the strategic, tactical and operational goals.

- A number of activities were undertaken by the HMA-EMA Strategic Resource Oversight group, such as oversight of NCA capacity and resource allocation vs forecasting and introduction of an annex to the letter of intent to facilitate rapporteurship bidding.
- The first-ever Assessors Day was held at the EMA premises on 5 – 6 November 2025 which attracted nearly 120 participants from 28 different NCAs across 4 scientific disciplines (clinical, non-clinical, quality and pharmacovigilance). The overall feedback received was overwhelmingly positive with 98% of participants indicating they were satisfied or very satisfied.
- Finalisation of the pilot for direct payment of external experts by EMA to be part of rapporteur/co-rapporteur assessment teams for marketing authorisation applications with 2 participating NCAs. As a result, EMA in agreement with HMA/SROG will offer this possibility to NCAs when the required resources cannot be provided from within the network, e.g. through MNATs.
- An additional project leader was onboarded and toolkit for making online courses is being rolled out.

Network Training Centre (EU NTC)

- A new strategy for the EU Network Training Centre (EU NTC) was developed, aligned to EMANS strategic goals that foresees further strengthening of the EU NTC, greater use of innovative learning approaches and expansion to new audiences.
- Close collaboration with regulatory partners in the EU Medicines Regulatory Network to support capacity and capability building initiatives such as EU4H Joint Actions (e.g. IncreaseNET and EU4H Joint Action 11 to strengthen EU/EEA NCAs – Medicines Inspectorates).
- A new NCA remuneration scheme for development and delivery of priority training services was adopted by the Management Board in June 2023. Following the completion of a successful pilot at the end of 2024 where experts from the network were remunerated for 25 training modules, the scope of the scheme was updated and the levels of remuneration, increased, as endorsed by the Management Board in October 2025.
- An EU NTC learning and development toolkit was developed and launched in 2023 with the aim to streamline the support to course owners and curriculum developers and increase the pedagogical quality of learning interventions.
- A number of course design workshops led by the EU NTC core team took place in order to support EMA and network course owners in the design and development of training courses. The value of these workshops can be illustrated by the successful data integrity training course organised in 2025, which featured a blended learning approach including eLearning, practical case studies and for the first time, virtual reality training for network participants.
- Improvements in the EU NTC Learning Management System (LMS) to enhance user experience.
- New domain for international regulators set up in the EU NTC LMS providing access to specific courses in the EU NTC training catalogue to countries participating in the

Instrument for Pre-accession Assistance programme as well as to African regulators in the context of the African Medicines Agency project.

- A publicly available EU NTC portal providing visibility of all EU NTC learning offers was launched in January 2024.
- Training programs were rolled out to the network under the leadership of Theme 2 and the Network data steering group and in partnership with the EU Network Training Centre (EU NTC) via its platform during the reporting period, in close collaboration with the MWP and scientific expertise from the relevant ESEC SIAs:
  - Roll out of the Big Data Training Signpost to provide a helpful resource listing all existing EU NTC training in biostatistics, pharmacoepidemiology, data science and pharmacogenomics.
  - Roll out pharmacoepidemiology and RWE training curriculum. It is complemented by the Real-World Academy, a series of webinars to share and build knowledge on RWE generation and its use and facilitate the interpretation and use of study results for regulatory decisions.
  - Launch of the genomics curriculum, with a focus on pharmacogenomics and roll out of first module on 'Introduction to Human Genetics'.
  - Launch of the data science curriculum, including training modules on big data, data management and data visualization, AI, data quality and omics.
  - Launch of the biostatistics curriculum, in collaboration with the EU4Health Joint Action IncreaseNet (e.g. on adaptive trial designs) and as part of the development of reflection papers and guidelines.
  - The establishment of an AI training curriculum under the framework of the EU NTC was agreed in 2025, including data protection training in the context of AI. It will also provide the overarching framework for the AI training developed for the EMRN, for example under initiatives such as the EU4Health Joint Action supporting the increased capacity and competence building of the EU medicines regulatory network (EU4Health Joint Action IncreaseNET).
  - Organisation of 2 AI masterclasses on the use of large language models and hands on training on the guiding principles on the use of large language models for the EU network in 2024.

Network Portfolio

- The establishment of the Veterinary Union Product Database (UPD), serving as a single source of information on all authorised veterinary medicines and their availability in European Union (EU) and European Economic Area (EEA) Member States. UPD is required by the Veterinary Medicines Regulation (Regulation (EU) 2019/6), which became applicable on 28 January 2022.
- EMA has implemented and continues to embed Agile delivery practices in digital transformation to bring greater flexibility, transparency and efficiency to network portfolio delivery. Work is ongoing in Agile Product Teams including PMS (Product Management Services) and strategic engagement with network and industry

stakeholders in portfolio ceremonies via face-to-face meetings. This approach also aims to strengthen alignment of the delivery of the network portfolio with wider strategic digital transformation initiatives. EMA established a Lean Agile Centre of Excellence in January 2023 to further mature and evolve the Agile ways of working, to optimise delivery.

- Delivery of a collaboration tool for expert panels for medical devices, in support of the EMA's extended mandate related to medical devices.
- Development of the EU standard for electronic product information (ePI) and pilot capabilities for the authoring and publication of ePI for centralised and nationally authorised products in the EU. A pilot project was carried out for a set of CAPs and NAPs to test the business process and develop guidance for inclusion of ePI in regulatory procedures. In user acceptance testing with companies and service providers, participants successfully created, validated and imported ePI at the Product Lifecycle Management portal, positively signalling the readiness of industry to provide ePI to regulators at a future go live date (see the section 'Availability and accessibility of medicines'.
- Delivery of good clinical practice (GCP) and good pharmacovigilance practice (GVP) inspections management on the IRIS regulatory procedure management platform. This brings efficiencies and a modernised and collaborative way of working.
- Implementation of iSPOC registration for the identification of focus points of contact during public health emergencies and major events in support of medicine shortages Regulation (Regulation (EU) 2022/123).
- Delivery of new capabilities in the Experts Management Tool to support the management of experts working with EMA.
- Work started and is ongoing on implementation of ISO IDMP standards in PMS, an essential foundation for high quality shared data across the EMRN.
- Delivered enhancements to the Common Repository, including improved security features, a key system in the evaluation and assessment process.
- Delivery of signal and safety analytics minimum viable product in December 2025 to EMA pharmacovigilance office and selected NCAs. Wider roll-out to NCAs planned for 2026.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Continue the implementation of IncreaseNet.
- Further discuss and implement initiatives to increase the capacity and capabilities of the network at HMA/EMA Strategic Resource Oversight Group.
- Continue to roll out the Network Portfolio workplan based on 5 value streams.
- The HMA-EMA SROG to consider general actions to address the network capacity constraints by increasing oversight of capacity and capability of the NCAs to undertake upcoming work and specific actions for identified shortfalls.

Goal 2

Strive for operational excellence, building on the work done in the current strategy.

Objectives

- Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations.
- Introduce governance and IT process improvements to further professionalise prioritising, budgeting, securing, provisioning and running of technology services.

Achievements

- Regulatory optimisation of the mutual recognition and decentralised procedures for human and veterinary medicines is ongoing with the coordination groups for mutual recognition and decentralised procedures (CMDh and CMDv).

  The CMDh initiated a pilot in Q3 2025 for the exchange of information on bioequivalence studies (contract research organisation and protocol number) and finished product manufacturers via the Common Tracking System database to allow identification of “same” dossier and re-use of existing assessments (IncreaseNET task 7.5).

  Pursuant to Articles 69 to 72 of Regulation (EU) 2019/6, the CMDv set up a procedure for harmonisation of SmPCs of nationally authorised veterinary medicinal products (reference products and their generics and hybrids). The CMDv concluded the SmPC harmonisation exercise 2023; the exercise 2024 is being finalised.

- For the centralised procedure, several optimisation initiatives have been introduced to improve the management of assessment reports during evaluation.

  New Day 80 clinical, non-clinical, and quality report templates have been introduced and used by assessors as part of the CHMP assessment report revamp project.

  A pilot involving applicants completing the Day 80 clinical and non-clinical reports has been conducted, with 11 pilots completed and feedback under review; a draft report will be shared by end of 2025.

  Collaboration between EMA, NCAs, and industry continues through focus groups to support template development and co-authoring on SharePoint.

- The rapporteurship bidding model has been reviewed with involvement of the HMA EMA Operational Resource Planning and Oversight Group. The new model fosters collaboration within the network in situations of resource constraints.
- Regulatory Optimisation Group (ROG) activities have been reactivated. ROG provided strategic input to the Network Portfolio Advisory Group.

The ROG established the NCAs Business Representatives Community to support the Network Portfolio by strengthening the NCA business representation in the network IT developments. The Community's goals are to align EMA and NCAs tactically, improve the governance model through empowering network POs and SMEs, and support Agile operational delivery across the network. The Business Community meets on a quarterly base.

The ROG continues its work on Product Management Service (PMS) with a focus on addressing the quality gap concerning NCAs product legacy data and strengthening the trust in PMS among network and industry stakeholders. A proposal for feasibility study of EU-wide PMS data qualification has been developed and initiated with 20 NCAs participating in the analysis.

- Successful implementation of IRIS at EMA for all centralised post authorisation procedures in Q1 2025.
- Benchmarking of medicines agencies exercise of NCAs and EMA has been conducted in Q1-Q2 2023 to identify strengths, best practices and any opportunities for improvement in the agencies. The results are stored in a central database which serves as a tool to share best practices across the network.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

- Extend IRIS implementation to marketing authorisation applications including pre-submission activities, maximum residue limit (V), ATMP certification (H).
- Explore possibility of piloting the database reporting of certain Type IA scopes
- Conclude ongoing initiatives on the centralised procedure.

Goal 3

Achieve a sustainable financial and governance model for the network.

Objectives

- Contribute to the revision of the current fee regulation and implement the final legislation.

Achievements

- New fee regulation was adopted in February 2024 and entered into force on 1 January 2025. The new cost-based fee regulation will provide financial sustainability for the Agency and the network while providing administrative simplification based on a leaner fee structure.

- IT systems and the EMA's internal processes were adapted on time for the entry into force.
- The Management Board adopted a decision on the common format for time reporting for the agreed procedure types to be included in the first round of monitoring exercise.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period 2026-2028:

- Continuation of monitoring exercise, coordination with EC for preparation of special report to align the fee regulation to new legal proposals (e.g. new pharmaceutical legislation, Medical Device Regulation/In Vitro Diagnostics Regulation, Biotech Act).

Goal 4

Develop a digital strategy to drive digital business transformation.

Objectives

- Establish an IT operating model and services, in support of the digital strategy and digital business transformation.

Achievements

- EMA has continued to deliver on IT systems and on experimentation and automation through its Analytics Centre of Excellence and Digital Innovation Lab (DigiLab) (see Theme 2 on data analytics, digital tools and digital transformation).
- Human Variation electronic application forms (eAFs) became available for all centralised and national products. Use of a web-based eAF for non-centrally authorised products started in October 2024. The use was limited to CAPs and EMA led work-sharing applications until the end of 2024. It was extended to non-centralised procedures on 1 January 2025.
- Successful launch of new regulatory procedure management capabilities in IRIS for all post authorisation procedures and ongoing work for pre-authorisation.
- Launch of a new product data management (PMS) interface to allow industry, regulators and the general public to view product data held by EMA in PMS. In Q1 2025, the enrichment capability of PMS was launched, enabling MAHs to submit data on manufacturers, manufacturing business operations and structured data on pack sizes to support the European Shortages Monitoring Platform (ESMP). In Q3 2025, these capabilities were expanded allowing the submission of large volumes of data directly from MAHs systems, via the PMS application programming interface (API) enabling faster and more streamlined sharing of data between MAHs and EMA.

- To ensure NCA readiness, EMA also delivered data services for mapping the product data from NCA databases to PMS as well as monthly NCA webinars to enable community generated solutions.

Follow-up actions in EMANS 2028

The following activities will be carried out in the next strategy period from 2026 to 2028:

Next steps in PMS

- Facilitate public access and transparency as well as stabilise and improve PMS data quality by delivering:
  - Export of the public dynamic reports, allowing the general public to export PMS public data from the Product User Interface in a simpler/excel format.
  - PMS public read API, allowing public to access/read PMS public data in a programmatic machine-to-machine interface.
  - Data quality improvements, prioritising migration/integration technical fixes; implementing data quality reports to monitor issues and carrying out targeted fixes/cleaning.
  - Continued improvements to capabilities to enable the decommissioning of SIAMED and XEVMPD, simplifying the data flows/integration and technical landscape.

Next steps in ePI

- Incorporate ePI into routine regulatory procedures, by delivering:
  - Outstanding critical feature
  - Business processes for centrally and non-centrally authorised medicines
  - Enhanced performance and stability
  - Testing, engagement and change management.

Goal 5

Enable quick, consistent and adequate response to public and animal health challenges.

Objectives

- Build further capacity and capability within the network to support crisis management.

Achievements

- EMA supported the coordinated management of critical shortages and shortages of CAPs, working with national competent authorities in the SPOC Working Party and the executive MSSG.
- A voluntary solidarity mechanism was established in October 2023. The voluntary solidarity mechanism was piloted from October 2023 to June 2025 and is now fully operational. Seven voluntary solidarity mechanism procedures were launched in 2024 and six were launched in 2025.
- EMA and MSSG followed the developments in the Critical Medicines Alliance and in 2025 finalised a vulnerability assessment methodology to identify vulnerabilities in the supply chains of critical medicines. This methodology was adopted by MSSG in November 2025 and will be piloted in 2026 in preparation for the new pharmaceutical legislation and Critical Medicines Act. The methodology was published and can be found here.
- With respect to medical devices, EMA finalised the development of the Critical Medical Devices IT system in July 2023. In June 2023, the Agency published the Methodology for the establishment of the "public health emergency critical medical devices list".
- The MSSG adopted the list of 'main therapeutic groups' (MTGs) of medicinal products necessary for emergency care, surgeries and intensive care on 7 July 2022. The list was established with support of the SPOC WP and other relevant groups and aims to support the setting up of any future lists of critical medicines needed to respond to a public health emergency or major event.
- During the public health emergencies of COVID-19 and MPOX the MSSG adopted the list of critical medicines for the COVID-19 public health emergency and the list of critical medicines for mpox public health emergency in May 2023. The lists are no longer active and the enhanced monitoring requirements no longer apply after the World Health Organization (WHO) declared an end of the public health emergencies.

Regulatory innovation and flexibilities

- Complementary to those referred to in the MSSG toolkit, the EC adopted an amendment of the Variations Regulation introducing measures that will support regulatory simplification and flexibility (e.g. mandatory work-sharing and annual submission for type IA variations).
- Joint meetings of the HMA Working Group on Crisis Management Affairs, Working Group on Communication Professionals, Working Group of Quality Managers, Clinical Trial Coordination Group and World Green Economy Organization were held in April and July 2023.
- Establishment of the ETF in March 2022 with an initial focus on COVID-19 and mpox, which shifted into preparedness activities for public health threats following the end of the public health emergencies (see section 'Antimicrobial resistance and other emerging health threats').

Follow-up actions in EMANS 2028

- Actions regarding health threats and medicines availability during disruptions will be followed up under Themes 4 and 5 in EMANS 2028.

Conclusions and next steps

With the adoption of this report the European medicines agencies network has concluded its implementation of EMANS 2025. Over the period of its implementation, the network made strides in all key focus areas while dealing with the COVID-19 pandemic.

The network is now implementing a new strategy (EMANS 2028), which takes into account experience gained during the implementation of EMANS 2025. As detailed in the report, many of the activities carried out as part of EMANS 2025 will be followed up as part of the new strategy. The new strategy not only builds on the success of EMANS 2025, but it will also help the network to seize new opportunities (for example, in relation to artificial intelligence) and to adapt to changes in the pharmaceutical landscape, including the new pharmaceutical legislation.

As with EMANS 2025, the network will report on the implementation of EMANS 2028 and the follow-up actions described in this report.

Glossary

3Rs	Principles relating to the use of animals in medicines testing (Refine testing to reduce the harm to the animal, reduce the numbers of animals required and replace animal testing wherever and whenever it is possible)
AI	Artificial intelligence
ACE	Analytics Centre of Excellence
ACT EU	Accelerating Clinical Trials in the EU (ACT EU)
ADRA	Adjustment of established veterinary antibiotics
AMR	Antimicrobial resistance
API	Active pharmaceutical ingredient
ATMP	Advanced therapy medicinal product
BDSG	Big Data Steering Group
BPM	Business pipeline meetings
CAP	Centrally authorised product
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures – human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - veterinary
COMP	EMA's Committee for Orphan Medicinal Products
CTA	Clinical trial application
CTIS	Clinical Trial Information System
CTCG	Clinical Trials Coordination Group
CTR	Clinical trial regulation
CVMP	Committee for Veterinary Medicinal Products
DARWIN EU	Data Analysis and Real World Interrogation Network, an EU platform to access and analyse healthcare data from across the European Union
DCP	Decentralised procedure
DG CONNECT	European Commission Directorate-General for Communications Networks, Content and Technology
DG RTD	European Commission Directorate General for Research and Innovation

DG SANTE	European Commission Directorate General for Health and Food Safety
DigiLab	EMA's Digital Innovation Lab
eAF	Electronic application form
EATRIS	European Infrastructure for Translational Research
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECRIN	European Clinical Research Infrastructure Network
EEA	European Economic Area
EFSA	European Food Safety Authority
EHDS	European Health Data Space
eHR	Electronic health record
EMA	European Medicines Agency
EMANS	European medicines agencies network strategy
EMRN	European Medicines Regulatory Network
ENVI	European Parliament Committee on the Environment, Public Health and Food Safety
ePI	Electronic product information
ESEC	European Specialist Expert Community
ESUAvet	European Sales and Use of Antimicrobials in veterinary medicine
ESUAvet WG	European Sales and Use of Antimicrobials in veterinary medicine Working Group
ETF	Emergency Task Force
EU	European Union
EU-IN	EU-Innovation Network. A collaboration between the EU NCAs and EMA, aimed at fostering medicines innovation and early development of new medicines
EUnetHTA	European Network for Health Technology Assessment. A collaboration between HTA bodies across Europe
FDA	Food and Drug Administration (USA)
GCP	Good clinical practice
GDP	Good distribution practice
GMDP IWG	GMP/GDP Inspectors Working Group
GMP	Good manufacturing practice

GVP	Good pharmacovigilance practices
HERA	Health Emergency Preparedness and Response
HMA	Heads of Medicines Agencies
HTA	Health technology assessment
HTACG	Member State Coordination Group on HTA
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
IDMP	European Identification of Medicinal Products, a suite of standards developed by ISO
IHI	Innovative Health Initiative
IHSI	International Horizon Scanning Initiative
IRIS	EMA's online Regulatory and Scientific Information Management Platform
ISO	International Organization for Standardization
iSPOC	Industry Single Points of Contact
IT	Information technology
ITF	Innovation Task Force
JA CHESSMEN	Joint Action on Coordination and Harmonisation of the Existing Systems against Shortages of Medicines
JAMRAI	European Union Joint Action on AMR and Healthcare-Associated Infections
JAP	Joint Audit Programme
JRC	Joint Research Centre
KPI	Key performance indicator
LMS	Learning management system
MAH	Marketing authorisation holder
MDCG	Medical Devices Coordination Group
MDR	EU Medical Device Regulation (2017/745)
MRLs	Maximum residue limits
MRP	Mutual recognition procedure
MS	Member State (of the European Union)
MSP	Multi-stakeholder platform

MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MWP	Methodology Working Party
NAP	Nationally authorised product
NBCG	Notified Body Coordination Group
NCA	National competent authority, one of the national medicines regulators that form part of the Network
NDSG	Network Data Steering Group
NGOs	Non-governmental organisations
NTC	Network Training Centre
OECD	Organisation for Economic Co-operation and Development
PCWP/HCPWP	EMA's Patients and Consumers Working Party and Health Care Professionals Working Party
PED	Patient experience Data
PIC/S	Pharmaceutical Inspection Co-operation Scheme, an informal co-operative arrangement for regulators on Good Manufacturing Practice (GMP) of human and veterinary medicines
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMS	Product Management Service (PMS)
PRAC	EMA's Pharmacovigilance Risk Assessment Committee
PRIME	Priority Medicines Scheme (EMA)
QIG	Quality Innovation Group
QoNM	Qualification of novel methodologies
QR code	Quick response code
RAGNA	Regulatory Agencies Global Network against AMR
ROG	Regulatory Optimisation Group
R&D	Research & development
RWD	Real word data
RWE	Real world evidence
Saudi FDA	Saudi Food and Drug Authority
SAWP	Scientific Advisory Working Party
SEND	Standard for exchange of non-clinical data
SIA	Specialised interest areas
SME	Small to medium-sized enterprise

SmPC	Summary of product characteristics
SNSA	Simultaneous national scientific advice (pilot project of the EU Innovation Network)
SoHO	Substances of human origin
SPMP	Shortage prevention and mitigation plan
SROG	Strategic Resource Oversight Group
SPOC	Single point of contact
SRP	Subsequent recognition procedure
STARS	Strengthening Training of Academia in Regulatory Sciences, a project of the European Commission
TAFTAR	Transatlantic Taskforce on Antimicrobial Resistance
UPD	Union Product Database
VMP	Veterinary medicinal product
WGQM	Working Group of Quality Managers
WGEO	World Green Economy Organization
WHO	World Health Organization

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