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Final programming document 2026–2028

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Foreword

I am pleased to present the European Medicines Agency's (hereinafter EMA or the Agency) Single programming document for 2026–2028, which sets out our priorities, challenges, and goals for the next three years, alongside the final work programme for 2026.

As we close EMA's 30th anniversary year and look ahead to the decades to come, the Agency is re-energised by a new vision:

A fast path from innovation to safe and effective medicines

This vision reflects our commitment to safeguarding public and animal health while fostering innovation in medicines regulation. The coming years will be pivotal for the Agency and the European medicines regulatory network as we prepare for the implementation of the new pharmaceutical legislation — the most significant review in more than 20 years. These changes will require adaptation of our processes, close collaboration with our partners and a forward-looking approach to ensure fast access to safe, effective, and high-quality medicines for patients across Europe.

The European pharmaceutical legal landscape continues to evolve at an unprecedented pace: beyond the implementation of the new pharmaceutical legislation, EMA must be prepared for other changes on the horizon, including the entry into force of the One Substance, One Assessment package and European Health Data Space Regulation (EHDS), as well as other legislative proposals such as the Critical Medicines Act, the Biotech Act, and the revision of the Medical Devices and In Vitro Diagnostics Regulations.

Our multi-annual programme is anchored in the European medicines agencies network strategy to 2028 (EMANS), which guides our transformation across six strategic areas: improving accessibility of medicines; leveraging data, digitalisation and AI; advancing regulatory science, innovation and competitiveness; strengthening preparedness to address antimicrobial resistance and other health threats; ensuring availability and supply of medicines; and securing the sustainability of the Network. These priorities reflect the evolving scientific, technological, and societal landscape and positions EMA and its regulatory partners within the Network to respond effectively to emerging challenges.

To help target our efforts in 2026, EMA has identified three focus areas: building on the proposed legislative changes to 'Reimagine EMA', supporting innovation for public and animal health, and ensuring that we invest in our staff and the Network of tomorrow. We see a unique opportunity to adapt our regulatory system to deal with rapid scientific and technological advances, as well as to increase efficiency through smart digitalisation and use of artificial intelligence. We will further enhance our early development support to enable new medicines to be authorised in the EU as rapidly as possible.

Key to enabling these ambitions is our dedicated workforce. We will continue to invest in our staff and the expertise in our network, building capacity and capability to fully embrace the challenges and opportunities that lie ahead.

We do this in a context where the need to reinforce trust in science and institutions has never been greater. This means we need to work harder than ever with our partners and stakeholders and we have to embrace new ways of communication to reach different audiences, particularly younger generations who will be key to developing and maintaining our future approaches. Together with the Network, we will uphold the principles of transparency, scientific excellence, and trust that form the foundation of the European medicines regulatory system. Engaging with stakeholders continues to be a

priority for EMA — not only with patients, consumers, healthcare professionals and academics, but also with international regulators.

I am confident that, through these collective efforts, EMA will continue to protect public and animal health while supporting innovation and competitiveness in Europe's life sciences sector.

Finally, I need to highlight that the current 2026–28 Single programming document reflects activities and initiatives that EMA will implement on the basis of the available knowledge at the time of drafting. However, should pieces of legislation with significant impact on the Agency's activities be published in the period following the mailing of this document to the Management Board, then the Agency may come back to the Board in the course of 2026 with a proposal for an amended/updated Single programming document.

Emer Cooke, Executive Director

List of acronyms

Term/abbreviation	Definition
3R	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
3RsWP	3Rs Working Party
ACAA	Agreement between EU and Israel
ACE	Analytics Centre of Excellence
ACPC	Advisory Committee on Procurement and Contracts
ACT EU	Accelerating Clinical Trials in the EU
AD	Administrator category post
ADR	Adverse Drug Reaction
ADRA	CVMP's dosage review and adjustment of selected veterinary antibiotics project
AE	Adverse Event
AF	Advisory function
AI	Artificial Intelligence
AMA	African Medicines Agency
AMEG	EMA CHMP/CVMP Antimicrobial Advice Ad Hoc Expert Group
AMLAC	Regulatory agency for medicines in Latin America and the Caribbean
AMR	Antimicrobial resistance
API	Active Pharmaceutical Ingredient
API	Application programming interface
AST	Assistant category post
ASU	Antimicrobial sales and use
ATD	EMA Access to Documents
ATMP	Advanced Therapy Medicinal Product
AUDA	African Union Development Agency
BEMP	Best Environmental Management Practice for the Public Administration Sector
BREEAM	Building Research Establishment Environmental Assessment Method
BTP	SAP Business Technology Platform

Term/abbreviation	Definition
CA	Contract agent
CAP	Centrally Authorised Product
CAT	EMA Committee for Advanced Therapies
CBRN	Chemical, Biological, Radiological and Nuclear
CCI	Commercially confidential information
CDP	EMA Clinical Data Publication
CECP	Clinical Evaluation Consultation Procedure
CEPI	Coalition for Epidemic Preparedness Innovations
CGREA	Central Government Real Estate Agency
CHMP	EMA Committee for Medicinal Products for Human Use
CMC	Chemistry Manufacturing and Controls
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
COMP	EMA Committee for Orphan Medicinal Products
CORC	Collaborative Open Research Consortium
COSO	Committee of Sponsoring Organizations of the Treadway Commission
CoUP	Compilation of Union Procedures on Inspections and Exchange of Information
COVID-19	Coronavirus disease 2019
CRM	Customer Relationship Management
CRO	Contract Research Organisation
CRP	Collaborative registration procedure
CT	Clinical trial
CTCG	Clinical trial Coordination Group
CTD	Common Technical Document – see eCTD
CTFG	Clinical Trial Facilitation Group
CTIS	Clinical Trials Information System
CTR	Clinical Trial Regulation
CVMP	EMA Committee for Veterinary Medicinal Products
DARWIN	Data Analytics and Real World Interrogation Network
DG	Directorate-General

Term/abbreviation	Definition
DG ECHO	European Commission Civil Protection and Humanitarian Aid Operations department
DG ENEST	European Commission Directorate-General for Enlargement and the Eastern Neighbourhood
DG ENV	European Commission Directorate-General for Environment
DG HERA	European Commission Directorate-General Health Emergency Preparedness and Response Authority
DG DIGIT	European Commission Directorate-General for Digital Services
DG INTPA	European Commission Directorate-General for International Partnerships
DG SANTE	European Commission Directorate-General for Health and Food Safety
DIA	Drug Information Association
DPO	Data Protection Officer
EAB	EMA Architecture Board
EC	European Commission
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECP	European Commission Priority
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European Environment Agency
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EIC	European Innovation Council
ELM	Engineered living materials
EMA	European Medicines Agency
EMANS	European medicines agencies network strategy
EMAS	EU Eco-Management and Audit Scheme
EMP-TC	Evaluation of Medicinal Products Technical Committee
EMRN	European medicines regulatory network

Term/abbreviation	Definition
EMS	Environmental management system
EMWP	European Medicines Web Portal
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
END	Seconded national expert (Experts nationaux détachés)
ENS	Early Notification System
EPAA	European Partnership for Alternative Approaches to Animal Testing
EPAR	European public assessment report
EPPO	European Public Prosecutors Office
ERA	Environmental Risk Assessment
ESEC	EMA European Specialised Expert Community
ESMP	European Shortages Monitoring Platform
ESUAvet	European Sales and Use of Antimicrobials for Veterinary Medicine
ETF	EMA Emergency Task Force
EU	European Union
EU DPR	Regulation (EU) 2018/1725 – data protection rules for EU institutions
EU DQF	EU Data Quality Framework
EU4Health	EU4Health programme
EUDA	European Union Drugs Agency
EUDPR	EU Data Protection Regulation
EU-IN	EU-Innovation Network
EU-M4all	EU Medicines for all
EU NTC	EU Network Training Centre
EU-OSHA	European Agency for Safety and Health at Work
EUR	Euro
EURS	European Review System for eCTDs
EV	EudraVigilance
EVMPD	EudraVigilance Medicinal Products Dictionary
EXB	EMA Executive Board
EXTM	Exceptional Transparency Measures
FAIR	Findable, accessible, interoperable and reusable

Term/abbreviation	Definition
FDA	Food and Drug Administration
FG	Function Group (for contract agent staff)
FHIR	Fast Healthcare Interoperability Resources
FTE	Full-time equivalent
FWC	Framework contract
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GDPR	General Data Protection Regulation
GLP	Good Laboratory Practice
GMDP	Good manufacturing and distribution practice
GMP	Good Manufacturing Practice
GVP	Good Pharmacovigilance Practices
HC	Health Canada
HCP	Healthcare Professional
HCPWP	EMA Healthcare Professionals' Working Party
HESI	Health and Environmental Sciences Institute
HMA	Heads of Medicines Agencies
HMPC	EMA Committee on Herbal Medicinal Products
HR	Human resources
HTA	Health Technology Assessment
HTACG	Member State Coordination Group on HTA
ICDRA	International Conference of Drug Regulatory Authorities
ICF	Internal control framework
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
ICSR	Individual Case Safety Report
ICT	Information and communication technologies
IHI	Innovation Health Initiative
IMRWG3Rs	International Medicines Regulators' Working Group on 3Rs

Term/abbreviation	Definition
IncreaseNET	Joint Action Supporting the increased capacity and competence building of the EU medicines regulatory network
IPA	Instrument for Pre-accession Assistance
IPRP	International Pharmaceutical Regulators Programme
IQM	integrated quality management
IRIS	Not an abbreviation. Refers to the regulatory & scientific information management platform between EMA and stakeholders
ISO	International Organisation for Standardisation
ISPOR	Professional Society for Health Economics and Outcomes Research
IT	Information technology
ITF	EMA Innovation Task Force
IVDR	EU In vitro Diagnostic medical devices Regulation
IWG	Inspectors Working Group
JAP	HMA/EMA Joint Audit Plan
JCA	Joint Clinical Assessment
JCASG	Joint Clinical Assessment subgroup
JIACRA	Joint Inter-agency Antimicrobial Consumption and Resistance Analysis
JRC	European Commission's Joint Research Centre
JSC	Joint Scientific Consultation
JSCSG	Joint Scientific Consultations Steering Group
KPI	Key Performance Indicator
LACE	Lean-Agile Centre of Excellence
LMS	EU Network Training Centre Learning Management System
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
MAV+	Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies
MAWP	Multi-annual work plan
MB	EMA Management Board
MCMs	Medical countermeasures

Term/abbreviation	Definition
MD	Medical device
MDR	EU Medical Devices Regulation
MDSSG	EMA Medical Devices Shortages Steering Group
MHLW/PMDA	Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency, Japan
MLM	Medical literature monitoring
MLT	Medicines Leadership Team
MON VS	Monitoring value stream
MRA	Mutual Recognition Agreement
MRL	Maximum Residue Limit
mRNA	Messenger RNA
MS	Member State of the European Union
MSSG	EMA Medicines Shortages Steering Group
MTA VS	Managing the Agency value stream
MVP	Minimum viable product
MWP	EMA CHMP Methodology Working Party
NAMs	New approach methodologies
NAP	Nationally Authorised Product
NAPs	Nationally Authorised Products
NATO	North Atlantic Treaty Organization
NC3Rs	National Centre for the Replacement, Refinement and Reduction of Animals in Research (UK)
NCA	National competent authority
NCAPR	National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers
NDSG	Network Data Steering Group
NEPAD	New Partnership for Africa's Development
NET	IncreaseNET - Joint Action - Supporting the increased capacity and competence building of the EU medicines regulatory network
NFR	New Fee Regulation
NGO	Non-governmental organisation
NICTAC	Network ICT Advisory Committee

Term/abbreviation	Definition
NIH	National Institutes of Health
NIS	Non-Interventional Study
NL	The Netherlands
NN	Net negative
NP	Net positive
NPAG	Network Portfolio Advisory Group
NPL	New pharmaceutical legislation
NTWP	EMA CVMP Novel Therapies and Technologies Working Party
OECD	Organisation for Economic Co-operation and Development
OHHLEP	One Health High-Level Expert Panel
OLAF	European Anti-Fraud Office
OMCL	Official Medicines Control Laboratory
OPAD	Other post-authorisation data
OPEN	Opening our Procedures at EMA to Non-EU authorities
PB	EMA Portfolio Board
PCWP	EMA Patients' and Consumers' Working Party
PDCO	EMA Paediatric Committee
PECP	Performance Evaluation Consultation Procedure
PED	Patient Experience Data
PHE	Public Health Emergency
PI	Product information
PIC/s	Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric Investigation Plan
PLM VS	Product Lifecycle Management value stream
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma Master File
PMS	Post-Marketing Surveillance
PNEC	Predicted no effect concentration
PPD	Protected personal data
PQKM	ICMRA Product Quality Knowledge Management (PQKM) initiative

Term/abbreviation	Definition
PRAC	EMA Pharmacovigilance Risk Assessment Committee
PRIME	EMA Priority Medicines scheme
PSUR	Periodic Safety Update Report
PTM	Portfolio and technology meetings
PUI	Product User Interface
PUMA	Paediatric Use Marketing Authorisation
QAT	Quality control, assurance and acceptance testing
QIG	Quality Innovation Group
R&D VS	Research and Development Management value stream
RAGNA	Regulatory Agencies Global Network against Antimicrobial Resistance
RFI	EMA Request for Information
RMP	Risk Management Plan
RMR	Reaction Monitoring Report
ROG	Regulatory Optimisation Group
RPM	Regulatory Procedure Management
RSRN	Regulatory Science Research Needs
RWD	Real-world data
RWE	Real-world evidence
SA	Scientific advice
SAFe	Scaled Agile Framework
SAP	Statistical Analysis Plan
SAWP	EMA CHMP Scientific Advice Working Party
SC	Secretary
SES	Staff engagement survey
SIA	AI Specialised Interest Area
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SISAQOL	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints in Cancer Clinical Trials
SLA	Service level agreement
SME	Small and Medium sized enterprises

Term/abbreviation	Definition
SMS	Substance Management Service
SNE	Seconded national expert
SNSA	Simultaneous National Scientific Advice
SPC	Summary of Product Characteristics for veterinary medicines
SPD	Single programming document
SPOC	Single Point of Contact
SPOR	Substance, Product, Organisation and Referential
SRD	Sectoral Reference Document
SSA	EMA Signal and Safety Analytics
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TB	Tuberculosis
TC	Technical Committee
TCO2e	Tonnes of Carbon Dioxide equivalent
TEMA	Temporary emergency marketing authorisation
TLM	Technology Lifecycle Management and Information Security value stream
UK	United Kingdom
ULCM	Union list of critical medicines
UPD	Union Product Database
US/USA	United States of America
UX	User experience
VAMFs	Vaccine antigen master file
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	ECDC/EMA Vaccine Monitoring Platform
VMP	Veterinary medicinal product
VNRA	Variation Not Requiring Assessment
vPTMF	Vaccine platform technology master file
VS	Value stream
VSM	Voluntary Solidarity Mechanism
WEEE	Waste electrical and electronic equipment

Term/abbreviation	Definition
WG	Working Group
WHO	World Health Organization
WOAH	World Organisation for Animal Health
WP	Working party
XEVMPD	Extended EudraVigilance medicinal product dictionary
XML	Extensible Markup Language

Mission statement

Mission

The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

Vision

A fast path from innovation to safe and effective medicines.

Legal mandate

The European Medicines Agency is the European Union (EU) agency responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human and veterinary use.

The Agency provides the Member States and the institutions of the EU with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of applicable EU legislation.

The EU rules governing veterinary and human medicines are set out in Regulation (EU) 2019/6 and Directive 2001/83/EC respectively. They provide the legal framework for the authorisation, manufacture, pharmacovigilance and distribution of medicines in the EU. The centralised authorisation procedure for human and veterinary medicines is based on Regulation (EC) No 726/2004, which established the European Medicines Agency (EMA), and Regulation (EU) 2019/6.

In 2010, a package of legislation was adopted whose main aim is to reinforce pharmacovigilance in the EU. This was supplemented by further legislation in 2012. The main legal acts in this area are: Regulation (EU) No 1235/2010 and Regulation (EU) No 1027/2012 amending, as regards pharmacovigilance, Regulation (EC) No 726/2004; Directive 2010/84/EU and Directive 2012/26/EU amending, as regards pharmacovigilance, Directive 2001/83/EC. Commission Implementing Regulation No 520/2012, which concerns operational aspects of implementing the new legislation.

In 2017, the Regulations on Medical Devices (Regulation (EU) 2017/745) and on In Vitro Diagnostic Devices (Regulation (EU) 2017/746) changed the European legal framework for medical devices, introducing new responsibilities for the European Medicines Agency and national competent authorities through the issuing of scientific opinions related to consultation procedures initiated by notified bodies on specific categories of medical devices.

In 2018, a new legislation governing veterinary medicinal products and repealing Directive 2001/82/EC was adopted. The new Veterinary Medicines Regulation (Regulation (EU) 2019/6) modernises the existing rules on the authorisation and use of veterinary medicinal products in the European Union (EU). It became applicable on 28 January 2022. It contains new measures for increasing the availability and safety of veterinary medicinal products and to support the EU action against antimicrobial resistance. The Agency continues to work closely with the European Commission and other EU partners to finalise the implementation of the new Regulation.

In 2022, the Agency's legal mandate was extended by Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and

medical devices. This Regulation formalises and strengthens the Agency's role in crisis response, provides a legal basis for the Agency's activities on shortages of medicines and medical devices, and endows EMA with the management of Expert Panels on Medical Devices. Lastly, the Regulation provides a legal basis for DARWIN EU®.

In 2024 and 2025, following the adoption of Regulation (EU) 1938/2024 the Agency has started to liaise with the Substances of Human Origin (SoHO) Coordination Board on authorisations and supervisory activities concerning the implementation of the Plasma Master File (PMF) certification pursuant to Directive 2011/83/EC to support the harmonised implementation of standards and technical guidelines.

In 2025, the Regulation on Health Technology Assessment (HTA), Regulation (EU) 2021/2282, became applicable. This Regulation mandates the European Medicines Agency to collaborate with the newly established HTA Coordination Group, in the context of parallel Joint Scientific Consultation, exchange of information related to their Joint Clinical Assessment, as well as contribution to the identification of emerging health technologies, for medicinal products and medical devices.

Principal activities

Working with the Member States and the European Commission as partners in a European medicines regulatory network, the European Medicines Agency:

- Provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;
- Applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;
- Implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;
- Provides scientific advice and incentives to support the development and improve the availability of innovative new medicines;
- Recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;
- Involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- Publishes impartial and comprehensible information about medicines and their use;
- Develops best practice for medicines evaluation and supervision in Europe and contributes, alongside the Member States and the European Commission, to the harmonisation of regulatory standards on the international level;
- Provides scientific support to the timely development of high-quality, safe and effective medicines during public health emergencies;
- Monitors and mitigates shortages of medicines and medical devices during a public health emergency;
- Ensures the functioning of expert panels to assess high-risk medical devices and in vitro diagnostic medical devices, and advises on crisis preparation and management;

- Provides scientific opinions related to the consultation procedures initiated by notified bodies on specific categories of medical devices, in accordance with the provisions of the revised legislative framework on medical devices and in vitro diagnostics (MDR/IVDR); e.g. companion diagnostics, devices incorporating a medicinal substance with ancillary action to that of the device, devices composed of substances that are systemically absorbed by the human body;
- Consult with the European Commission in the process of issuing decisions under Article 4(1) of the MDR/IVDR, specifically in deliberating on the possible regulatory status as a device of products involving medicinal products, human tissues and cells – basis: Article 4(4);
- Cooperates with the European Commission and the Member State Coordination Group on HTA (HTACG) by exchanging information in the context of joint clinical assessments, joint scientific consultations, and the identification of emerging health technologies, for medicinal products and medical devices;
- Liaises with the Substances of Human Origin Coordination Board on authorisations and supervisory activities concerning the implementation of the Plasma Master File certification.

Guiding principles

We are strongly committed to public and animal health, taking into account the One Health approach.

We make independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in our field.

We support research and innovation to stimulate development of better medicines and seek to support European competitiveness.

We value the contribution of our partners and stakeholders to our work.

We assure continual improvement of our processes and procedures, in accordance with recognised quality standards.

We adhere to high standards of professional and personal integrity.

We communicate in an open, transparent manner with all our partners, stakeholders and colleagues.

We promote the wellbeing, motivation, and ongoing professional development of every member of the Agency.

We have a vision to be a climate-friendly and resource-efficient organisation.

Part I: General context

For the 2026–2028 planning exercise, the Agency continues to maintain its focus on key investments to address upcoming challenges and opportunities. The Agency aims to ensure preparedness for the implementation of the revised pharmaceutical legislation and to continue its transition into a digitally enabled and data-driven regulator. The changes brought by the revised pharmaceutical legislation will represent the most significant shifts in the Agency's operating environment since its inception. Additionally, the continuous investment by partners and stakeholders in new data sources and disruptive technologies (e.g. real-world data and artificial intelligence) is expected to keep influencing the current and future Agency's operating landscape. The 2026 work programme reflects the initiatives the Agency will take to address these changes. Considering the evolving external environment, the following section presents the key aspects that influence the general context in which the Agency operates:

EU Medicines regulatory network – resourcing and committees' workload: the sustainability of the European medicines regulatory network (EMRN), which is increasingly challenged by resources constraints, economic pressures and technological disparities, remains a key aspect characterising the general context in which the Agency operates. As highlighted throughout this document, the Agency's products portfolio has been steadily growing over the past years. This growth translates not only into additional workload for the Agency but also for its scientific committees, which have seen a significant intensification of demands. While scientific committees are under increasing pressure to evaluate submissions and provide scientific opinions, persistent resourcing constraints across Member States and EMA remain a threat for the continuity of regulatory functions, prompting the need for innovative cross-resourcing models and strategic workforce planning solutions. This situation is expected to be further exacerbated in the future in view of the growing number of advanced therapy medicinal products, combination products, etc. Technological imbalances within the network underscore the urgency of harmonised digital infrastructure and capacity-building. Simultaneously, the EMRN must adapt to legislative shifts, including the revised pharmaceutical law and AI regulation, while maintaining cybersecurity and data governance standards. While the Agency remains committed to keep prioritising process improvement, digitalisation, resource optimisation and capacity building in its forthcoming planning cycles, it must be recognised that at present, network resourcing and committees' workload remain significant challenges and more must be done to ensure the sustainability of the European regulatory system in both the short and longer term. Investing in these areas is a strategic imperative to ensure that the European regulatory network remains resilient, adaptive, and capable of delivering its mission of safeguarding public and animal health while fostering innovation in an increasingly complex environment.

Pharma law revision: on 26 April 2023, the European Commission published its proposal for a comprehensive reform of the EU pharmaceutical legislation, marking the most significant overhaul since the establishment of the European Medicines Agency (EMA). The reform includes revisions to Directive 2001/83/EC and Regulation (EC) No 726/2004 (the 'general pharmaceutical legislation'), as well as updates to Regulation (EC) No 1901/2006 on paediatric medicines and Regulation (EC) No 141/2000 on orphan medicines. This legislative package aims to improve access and affordability of medicines, enhance supply security, foster innovation and competitiveness, promote environmental sustainability, and strengthen the EU's response to antimicrobial resistance (AMR). For the Agency and the Network this reform offers a framework to implement strategic ambitions outlined in the European medicines agencies network strategy to 2028 (EMANS) but also requires significant operational

adjustments. The Agency must prepare for a shift in its committee functioning, more agile regulatory processes, and increased transparency expectations.

Financial situation and global instability: the broader EU financial landscape is put under pressure by competing budgetary demands, including military and energy security spending, while global trade instability and rising trade tariffs further complicate the outlook. These dynamics may lead to reduced pharmaceutical industry investments leading to fewer regulatory submissions, particularly for high-cost or innovative therapies that national payers may deem unaffordable. Such a trend could erode EMA's fee-based revenue model, especially if companies delay or withdraw product launches, or opt not to submit a marketing authorisation application due to market access challenges. While these trends may become more visible in the medium to long-term the Agency should continue to maintain transparency in its cost structures, monitor industry trends closely, and advocate for sustainable funding mechanisms for its expanding public health responsibilities.

Communications and stakeholders' engagement: the COVID-19 pandemic marked a turning point for EMA's transparency and communication activities, setting new expectations for openness, responsiveness, and public trust. As the Agency moves forward, the proposed revision of the EU pharmaceutical legislation reinforces the need for a robust communication framework that ensures high levels of transparency and stakeholder engagement. This strengthens the need for stepping up engagement and communication activities with local actors. In an era shaped by digital transformation and evolving public expectations, when international and government bodies face increasingly a lack of trust – especially among younger generations – EMA will explore ways to leverage its partnership with trusted healthcare actors, to counter misinformation, enhance health literacy and remain a trusted hub for scientific and evidence-based information.

Data management: the strategic importance of data as a core asset for EMA is increasingly evident. With the forthcoming European Health Data Space (EHDS) regulation, which will provide a harmonised framework for the secondary use of health data, establishing clear standards, governance mechanisms, and interoperability requirements, the Agency can enhance its ability to access and reuse high-quality, cross-border health data for regulatory decision-making, public health monitoring, and innovation. However, turning this vast and complex data into actionable information requires robust data governance, advanced analytics capabilities, and skilled personnel. Moreover, the Agency continues to invest in infrastructure and tools that support the integration of real-world evidence into regulatory processes as this becomes increasingly accepted as a complement to clinical trial data. Ensuring the sustainability of these efforts will depend on EMA's ability to attract digital talent, upskill its workforce, and embed a culture of data-informed decision-making across the organisation.

Digitalisation of society and AI: technology development offers significant opportunities to enhance the efficiency, agility, and robustness of regulatory processes. Digital tools can streamline data collection, automate routine tasks, and improve the traceability and transparency of regulatory decisions. AI, particularly in the form of machine learning and predictive analytics, can enable the identification of complex patterns in large datasets, supporting more informed and timely regulatory decision-making. However, these advancements also introduce new challenges, like ensuring the quality, reliability, and interoperability of digital data on one side, as well as implementing a robust governance framework for the responsible use of AI to mitigate risks such as algorithmic bias, data privacy breaches, and cybersecurity threats. Lastly, to fully harness the benefits of digitalisation, the Agency must invest in upskilling its workforce, modernising its infrastructure, and establishing clear protocols for the ethical and secure use of emerging technologies.

International environment: as the war in Ukraine has accelerated EU enlargement discussions, with Ukraine and Moldova advancing in their accession processes, EMA must remain agile and prepared to scale up enlargement-related activities by drawing on past experiences while adapting to today's more

complex geopolitical context. While the implementation of the Windsor Framework has begun to stabilise EU-UK regulatory cooperation, uncertainties remain with regard to the UK's evolving pharmaceutical legislation. At global level the Agency should continue to assert its relevance by engaging with international regulators and broader regulatory initiatives such as Project Orbis and ACCESS, while supporting in close collaboration with the European Commission the EU's expanding health diplomacy, including partnerships with the African Medicines Agency.

Legislative revisions: the EU regulatory landscape is undergoing significant transformation and not only the revised pharma law, but also other pieces of EU legislations will impact EMA in the coming years, across multiple domains. Initiatives like the AI act, the Cyber Security Regulation, the Biotech Act, the European Health Data Space (EHDS), the Variation Regulation and its guidelines and a possible revision of the MDR/IVDR Regulation will have significant effect on how the Agency operates. These changes will improve the efficiency and competitiveness of the regulatory framework and may create new tasks for EMA and will necessitate interaction with entities at both EU and Member State levels. These developments offer an unprecedented opportunity to simplify and modernise the regulatory environment, along with considerations on EMA's role and the rapid and efficient adaptation to a context of a new and pioneering technological landscape, such as the need for new IT systems.

Part II: Multi-annual programming 2026–2028

Multi-annual work programme

The EMA Multi-annual work programme 2026–2028 has been developed to deliver the new EMA vision of *A fast path from innovation to safe and effective medicines*. The document clusters the Agency's activities around 2 blocks:

A. **Statutory activities.** This block encompasses different areas of work: **1)** Product-related activities supporting the development, evaluation, and monitoring of medicines to ensure their safety, efficacy, and quality. This includes pre-authorisation guidance, scientific advice, regulatory assessments, and collaboration with stakeholders to facilitate timely access to safe, effective treatments for patients. **2)** Horizontal public health activities **3)** Corporate activities.

B. **Strategic transformation.** This block includes: **1)** Specific time-bound multi-annual goals and objectives included in the overall Network strategy to 2028. The EMANS to 2028 strategy supports the core work of evaluating human and veterinary medicines, while promoting the development of new medicines and ensure that they reach patients. **2)** Digitalisation and Network Portfolio activities, aiming at enhancing efficiency and effectiveness of the current operations.

A) Statutory activities

1. Product related activities

1.1. Evaluation and supervision of human medicines

1.1.1. Pre-authorisation activities

Pre-authorisation support aims to facilitate and improve the availability of safe and effective medicinal products for patients and healthcare professionals by supporting innovation and research. This is achieved by several activities and incentives offered to companies prior to submitting applications for marketing authorisation. The assistance and support are provided by the Agency through its scientific committees, as well as in collaboration with health technology assessment (HTA) bodies and international partners. The main **activity** areas in this domain include the following:

Scientific advice and protocol assistance. To facilitate the product-development process, the Agency provides scientific advice (initial and follow-up) to sponsors on all products and issues related to the development of medicines. In the case of orphan medicinal products, the Agency provides advice in the form of protocol assistance, which can include advice on the significant benefit of a product. Patient representatives are increasingly involved in these procedures. Parallel scientific advice can be provided by the Agency with the HTA Coordination Group. The Agency also provides advice and opinions on the qualification of innovative development methods, such as biomarkers. Scientific advice is also provided jointly with US FDA (parallel advice).

Supporting the development of PRIority MEdicines. PRIME is a scheme to reinforce scientific and regulatory support to new medicines addressing a major public health need in an effort to stimulate innovation, optimise their development and facilitate an accelerated assessment.

Orphan medicinal product designation and related maintenance procedures. To foster the availability of medicines for rare diseases, the Agency gives its opinion on the designation of medicinal products as orphan products and on maintenance of this status at the time of marketing authorisation. The designation status granted by the European Commission allows sponsors and marketing authorisation holders to benefit from several important incentives designed to encourage the development of products which, for economic reasons, would otherwise not be pursued.

Development of medicines for children. To improve the availability of medicinal products specifically authorised for children, the Agency issues decisions on paediatric investigation plans (PIPs), with or without deferrals or, where justified, agrees to waivers. When the studies or measures are completed, EMA verifies their compliance with key elements contained in the agreed PIPs. The Agency also issues decisions on requests for modification of a previously agreed PIP. An agreed PIP leads to information on the paediatric use of medicines being included in a centralised or national marketing authorisation procedure (for new or already authorised medicinal products), or in a paediatric-use marketing authorisation (PUMA) for off-patent products.

Classification and certification of advanced therapy medicinal products (ATMPs). The Agency issues a scientific recommendation, after consultation with the European Commission, on whether a given product based on genes, cells, or tissues, falls, on scientific grounds, within the definition of an advanced therapy medicinal product (ATMP classification). Where relevant, the Agency may consult with advisory bodies established under other relevant Union legislation, such as the SoHO Coordination Board. The Agency also carries out a scientific evaluation of quality data and, when available, non-clinical data, for advanced therapy products under development by small and medium-sized enterprises. Subject to this evaluation, the Agency may issue a certificate confirming the extent to which the available data comply with the standards that apply for evaluating a marketing authorisation application (ATMP certification).

Supporting the development of medicines for specific target populations. In addition to the aspects linked to the development of medicines for children (see above), this includes increasing focus on geriatric patients and pregnant and lactating women. Changes in the world's demographic composition draw increasing attention to the health needs of the very old and frail population. The Agency encourages research and development of medicines for a real-life population, with a particular emphasis on areas of unmet need, such as frailty, on formulations and packaging adapted to the ageing population, and on challenges posed by co-morbidities and multiple medications. Equally, the Agency encourages the generation of evidence on the use and safety of medicines for pregnant and breastfeeding women to enable better decision-making on medical treatment for women who are planning to have a child, are pregnant, or wish to breastfeed and will work on a more defined strategy over the year.

Antimicrobial resistance. The Agency, through its Emergency Task Force (ETF), has launched a pilot initiative to provide scientific advice specifically focused on antimicrobial resistance (AMR). This pilot targets key areas including bacterial vaccines, tuberculosis (TB), and treatments for multidrug-resistant infections.

1.1.2. Initial evaluation

Initial evaluation refers to the process of scientific assessment of medicines submitted for centralised marketing authorisation. It also covers the provision of scientific opinions, in cooperation with the World Health Organization (WHO), on medicinal products for human use that are intended exclusively for markets outside of the European Union (EU-M4all previously known as Article 58 procedure). The complexity of the assessments needed to authorise a medicine increases with the advance of

technological, methodological, and scientific knowledge, for personalised medicines in particular. Targeted and personalised medicine approaches are increasingly being used as an integrated package of tailor-made healthcare solutions comprising elements of pharmaceuticals and devices that address in the best possible way the needs of individual patients. The responsibility of maintaining an excellent quality of outputs calls for continuous training within the regulatory network and the involvement of external independent experts, including patient representatives, which contribute to medicines assessment either through scientific advisory groups or dedicated ad hoc expert groups. The Agency coordinates and performs (through its committees) the scientific evaluation of applications for marketing authorisation, including risk management plans, and issues opinions that form the basis for the European Commission's decision to grant an EU-wide marketing authorisation. The opinions are based on balancing a medicine's desired effects ('benefits') against the undesired effects ('risks'). Weighing the benefits and risks of a medicine is based on the evaluation of a large amount of data relating to the quality, safety and efficacy of a medicine. Scientific guidelines are developed to guide applicants with regard to the requirements for demonstrating the quality, safety and efficacy of a medicine. The scientific review on which the Agency's opinion is based is documented in an assessment report, which is made publicly available as a European public assessment report (EPAR).

EMA is piloting the use of individual patient-level data from clinical studies in marketing authorisation evaluations, aiming to gain a deeper understanding of the evidence, thereby improving the of regulatory decisions. This work will inform the implementation of new pharmaceutical legislation which is anticipated to require systematic submission of these data in dossiers of new medicines. These efforts are accompanied by the development of EU-level standards for data quality, representativeness, and metadata, and by collaboration with stakeholders to promote methodological consistency.

1.1.3. Post-authorisation activities

Post-authorisation activities include all the activities performed by the Agency to maintain authorised medicines on the market and ensure that products on the EU market are kept up to date with scientific advances and in line with the needs of authorisation holders. Activities covered in this area include those described below.

Variations to marketing authorisations. These can be either minor (type IA or IB) or major (type II) changes to the product information and dossier with regard to the quality, safety, and efficacy of the authorised product, including new or extended therapeutic indications and risk-management plans.

Applications for line extensions of marketing authorisations. These include fundamental changes to the medicinal product, such as changes to the active substance, changes to the strength, pharmaceutical form, or route of administration of the medicinal product.

Maintenance activities. These include follow-up on certain obligations and measures that marketing authorisation holders need to fulfil following the granting of marketing authorisations (MAs). These include reassessment and renewal of MAs, post-authorisation measures, transfers of MAs, and Article 61(3) notifications.

1.1.4. Referrals

Referrals are initiated for centrally and nationally authorised products, either in cases where there is concern over the safety or benefit-risk balance of a medicine or a class of medicines, disagreement among Member States on the use of the medicine, a community interest, or in order to obtain harmonisation within the Union of the conditions of authorisation for products already authorised by Member States. In a referral, the Agency conducts a scientific assessment of a medicine (or class of

medicines) and makes a recommendation for a harmonised position across the EU. Depending on the type of procedure, the outcome will be implemented by the Member States, or the European Commission will issue a decision to all Member States reflecting the measures to take to implement the Agency's recommendation.

Referrals can be started by the Commission, any Member State, EMA or by the marketing authorisation holder that markets the medicine.

1.1.5. Pharmacovigilance activities

Pharmacovigilance covers the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions (ADRs) or any other medicine-related problem.

The Agency coordinates the EU pharmacovigilance system that connects the systems of each national competent authority and operates pharmacovigilance processes that support both the EU pharmacovigilance system and the recommendations and opinions of the EMA committees on the benefits and risks of medicines. Pharmacovigilance activities are integrated with many aspects of the Agency's processes, including initial evaluation (for centrally authorised procedures), periodic safety update reports, post-authorisation referrals, signal management, inspections and data management, and therefore related items are found also in those sections of this document.

The area covers:

- GVP evaluation of safety specifications for products in the context of initial marketing authorisation, benefit-risk evaluation and risk management activities;
- periodic safety update reports (PSURs), and oversight risk-management plans and of post-authorisation studies;
- using epidemiology based on real-world data to study populations, diseases and the performance of medicines for the assessment of the safety and performance of medicines once placed on the market;
- management of adverse drug reaction reports, i.e. cooperation with NCAs in the management of safety signals for centrally authorised products and nationally authorised products, and of emerging safety issues and (safety) incidents;
- coordination of safety communications;
- publication of lists of products, including EU reference dates (for PSURs), products under additional monitoring and withdrawn products;
- coordination of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), which builds capacity in the delivery of post-authorisation studies;
- development and maintenance of good pharmacovigilance practices (GVP) and standards for the system, as well as development and implementation of evidence-based process improvements and updates to GVP.

1.1.6. Cooperation with the HTA Coordination Group

The Agency has the legal responsibility to cooperate with the Member State Coordination Group on Health Technology Assessment (HTA Coordination Group, HTACG) under the HTA Regulation (Regulation (EU) 2021/2282). Collaboration with Member States is crucial for HTA cooperation and

WHO's efforts on affordable innovation, which may require further engagement by EMA and support to enhance access to medicines. In this context, exchange of information between the Agency and the HTACG, its sub-groups as well as the HTA secretariat, provided by the European Commission, is required in the following areas:

Conduct of parallel Joint Scientific Consultation (parallel JSC) together with the HTACG. When developers request advice and guidance on their prospective development plan, they have the possibility to request this from the Agency and the HTACG in parallel. Synchronised processes and aligned tools (such as single briefing book and joint discussion meetings) facilitate such parallel JSC.

Provision of information for the conduct of Joint Clinical Assessment (JCA) by the HTACG. The Agency notifies the HTA secretariat about submitted applications that are in scope of JCA, provides relevant information at milestones during the assessment as well as submits the final outcomes of the regulatory reviews. Timeframe for the joint clinical assessments of medicinal products is linked to the timeframe of the centralised marketing authorisation procedure as indicated in Regulation (EC) No 726/2004.

Support the preparation of reports on emerging health technologies. The Agency provides relevant forecasting and pipeline data to support the preparation of reports by the HTACG on emerging health technologies expected to have a major impact on patients, public health or healthcare systems, in complementarity with and possibly building on horizon scanning intelligence gathered by the Commission Directorate-General Health Emergency Preparedness and Response Authority (DG HERA).

In scope of this cooperation are medicinal products throughout the lifecycle as well as expert panel activities for medical devices including in vitro diagnostics. The distinctive remits of the Agency and the HTACG, respectively, are preserved in all cooperation activities.

1.2. Evaluation and supervision of veterinary medicines

1.2.1. Pre-authorisation activities

Pre-authorisation support refers to the services provided prior to submission of a marketing authorisation application and aims to facilitate the development of veterinary medicines. Activities in this area cover the following:

Scientific advice. To facilitate development of new veterinary medicines, the Agency provides scientific advice to applicants during the research and development phase of veterinary medicinal products on aspects relating to quality, safety or efficacy of these products, and on the establishment of maximum residue limits.

Support for authorisation of **products for limited markets**. To stimulate development of new veterinary medicines intended for limited markets, the Agency provides support to applicants intending to submit applications for products for limited markets via direct advice and relevant guidance development.

Support development of **emerging therapies and technologies**. To proactively identify scientific, legal, and regulatory issues of emerging therapies and technologies, the Agency provides a discussion platform for early dialogue with applicants within the context of the Innovation Task Force and has also established the Novel Therapies and Technologies Working Party (NTWP) to create guidance in this area.

Product classification advice. To address uncertainties in terms of product classification by providing guidance and clarity to stakeholders from the viewpoint of 1) whether a veterinary medicinal product (VMP) is a non-biological, biological or immunological VMP and 2) whether a VMP is a novel therapy product. The guiding principle is to ensure that the dossier contains information that will allow for adequate assessment of the product.

Vaccine availability. Vaccination is one of the most effective tools for preventing animal diseases and for promoting animal health and welfare, safe food production and public health. Despite their importance, there are often challenges to ensuring that suitable veterinary vaccines are available in a timely manner on the European Union (EU) market. The European Medicines Agency (EMA) and its partners in the European medicines regulatory network are discussing how to ensure continuous availability of veterinary vaccines.

1.2.2. Initial evaluation

Initial evaluation refers to the process of scientific assessment of applications for veterinary medicines submitted for marketing authorisation through the centralised procedure. The following activities are included in this domain:

Initial evaluation. The initial evaluation phase includes pre-submission discussions with future applicants, scientific evaluation of applications, and issuing an opinion to the European Commission. The Commission grants the marketing authorisation, following which the Agency makes available the public assessment report, product information and other relevant documents on the Veterinary Medicines information website.

Establishment of MRLs. The use of veterinary medicinal products in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. Before a veterinary medicinal product can be authorised, the safety of its residues must be evaluated. The Agency recommends maximum residue limits (MRLs) for pharmacologically active substances used in

veterinary medicines, as well as for certain biocidal products used in animal husbandry, to ensure consumer safety with regard to foodstuffs of animal origin, including meat, fish, milk, eggs and honey. Once adopted by the Commission, these maximum residue limits become legally enforceable European standards.

1.2.3. Post-authorisation activities

Post-authorisation activities include all the activities performed by the Agency to maintain centrally authorised medicines on the market and ensure that products on the EU market are kept up to date with scientific advances and are in line with the needs of authorisation holders. Activities covered in this area include the following:

Variations to marketing authorisations. The Veterinary Regulation classifies the variations as to requiring assessment or not requiring assessment. The variations not requiring assessment are submitted directly into the Union products database (UPD), whereas the variation requiring assessment need to be submitted for assessment to the Agency.

Maintenance activities. These include, but are not limited to, follow-up on certain obligations that marketing authorisation holders need to fulfil following the granting of marketing authorisation, 1- or 5-year re-examination of certain marketing authorisations, as well as marketing authorisation transfers when the legal entity of the marketing authorisation holder changes.

1.2.4. Arbitrations and referrals

The Agency conducts referral and arbitration procedures.

Arbitration procedures are initiated for nationally authorised products because of disagreements between Member States on the harmonisation of their summaries of product characteristics.

Referrals are initiated regarding centrally and nationally authorised products to obtain harmonisation within the Union of the conditions of authorisation for products already authorised by Member States, or in cases where there is a Union interest, or in cases where there are other safety-related issues. In a referral, the Agency conducts a scientific assessment of a medicine (or class of medicines) and makes a recommendation for a harmonised position across the EU. The European Commission then issues a decision to all Member States reflecting the measures to take to implement the Agency's recommendation.

Referrals can be started by the Commission, any Member State, EMA or by the marketing authorisation holder.

1.2.5. Pharmacovigilance activities

Pharmacovigilance covers the science and activities relating to the detection, assessment, understanding and prevention of suspected adverse events related to a medicinal product. Pharmacovigilance aims to ensure that post-authorisation safety monitoring and effective risk-management are continuously applied to veterinary medicines throughout the EU.

The Agency has a coordinating role in the EU pharmacovigilance system and operates services and processes to support veterinary pharmacovigilance activities. The Agency also provides guidance and recommendations to stakeholders on the safe and effective use of veterinary medicines. Activities covered by the Agency include: management of EudraVigilance Veterinary, the database containing information on suspected adverse events to veterinary medicines which have been authorised in the European Economic Area (EEA), coordination of the assessment of the signal management process

performed by national competent authorities, coordination of safety communication, development and maintenance of good pharmacovigilance practice guidelines, coordination of pharmacovigilance inspections.

1.3. Horizontal and other product related activities

1.3.1. Inspections and compliance

This area covers several activities to ensure that medicinal products in the EU are developed, produced and monitored in accordance with the EU good practice standards and comply with the requirements and conditions established in the marketing authorisation. The area covers human and veterinary medicines. Activities covered include the following:

Coordination of inspections. The Agency coordinates inspections to verify compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) and good pharmacovigilance practice (GVP), and with certain other aspects of the supervision of authorised medicinal products in use in the EU. Inspections are initiated following the request of the CHMP or CVMP in connection with the assessment of marketing authorisation applications or the ongoing supervision of authorised products. Similarly, the Agency coordinates inspections of blood establishments within the plasma master file (PMF) certification framework.

Harmonisation of inspection standards and practices. The Agency contributes to the harmonisation of inspection standards and practices within the European Union and with international partner authorities, including the Pharmaceutical Inspection Co-operation Scheme (PIC/S), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Coalition of Medicines Regulatory Authorities (ICMRA). The Agency is collaborating with international partners and engages with key manufacturing third countries to increase awareness and facilitate the application of internationally agreed Quality and GxP standards globally. The Good Manufacturing and Distribution Practice Inspectors Working Group (GMDP IWG) supports the drafting of harmonised guidelines, work related to Mutual Recognition Agreements, how legislation impacts GMP inspection activity and harmonisation of GMP inspections, the harmonisation of inspection standards and practices through a quality system within the European Union. The Joint Audit Programme (JAP) forms an essential part of the quality system adopted by GMP inspectorates in the European Economic Area (EEA), aiming to ensure consistency of GMP standards and a harmonised approach throughout Europe. A subgroup of the GMDP IWG, the Compliance Group, oversees the audit programme.

Quality defects. The Agency is the primary contact point for the notification of suspected quality defects affecting centrally authorised products. It coordinates the investigation, evaluation, and follow-up of the suspected defects in collaboration with the rapporteur Member State and supervisory authority, to agree, with the necessary urgency, on the implementation of appropriate actions, including communication, in the interest of public health.

Sampling and testing programme. The Agency operates a sampling and testing programme to supervise the quality of centrally authorised medicinal products placed on the market and to check compliance of these products with their authorised specifications. Sampling from the market in different Member States is carried out by national inspectorates and testing is performed by Official Medicines Control Laboratories (OMCL), coordinated through the European Directorate for the Quality of Medicines & HealthCare (EDQM). The Agency is responsible for the selection of products to be sampled and the follow-up of any findings with the relevant marketing authorisation holders and rapporteurs.

Certificates. The Agency issues electronic certificates of medicinal products, in accordance with WHO requirements, to support the work of health authorities outside the European Union, especially in developing countries. Certificates are issued by the Agency, on behalf of the European Commission, to confirm the marketing authorisation status and GMP compliance of the manufacturing sites of products

authorised by the Commission through the centralised procedure, or of products for which a marketing authorisation application has been submitted to the Agency.

Parallel distribution. Parallel distribution is the distribution of a centrally authorised medicinal product from one Member State to another by a pharmaceutical company, independent of the marketing authorisation holder. The Agency checks compliance of products distributed in parallel with the conditions laid down in Union legislation on medicinal products and the marketing authorisation of the product.

Mitigation of supply shortages. Past years saw cases of global supply shortages of medicines. Quality defects or GMP non-compliance have been identified as one of the root causes. This has led to the development of recommendations to minimise the risks of such shortages occurring in the future, as well as mitigate the impact of shortages that do occur. The Agency continues to promote proactive risk-management by manufacturers and marketing authorisation holders and, within its scope, instilling controls to ensure product quality and supply continuity.

Pharmaceutical waste. The Agency contributes to the ad hoc working group of the Pharmaceutical Committee on the EU strategic approach on pharmaceuticals in the environment, tasked with identifying ways of reducing pharmaceutical waste. Within its scope, it continues to recommend measures for reducing pharmaceutical waste such as the extension of expiry dates where stability data permits and the review of pack sizes.

Manufacturing strategy. In line with novel manufacturing approaches, the manufacture of novel therapies, and in preparation for Pharma 4.0, the Agency has increased its focus on the supervision of such activities, whilst also ensuring the fostering of growth in this area. This is also in line with efforts from regulators in other regions, in particular the US. The establishment of the Quality Innovation Group (QIG), which is co-lead by the Inspections and Quality offices, will allow for more proactive engagement with the network and industry to understand novel manufacturing technologies, and help determine how to best regulate these activities

1.3.2. Committees, working parties, and expert management

The scientific opinion-making of the Agency for human and veterinary medicines is done primarily through committees and working parties. The Agency has seven scientific committees, each focusing on a specific area of work. Six committees provide scientific opinions regarding human medicines (CHMP, COMP, PDCO, HMPC, CAT and PRAC), and one focuses on veterinary medicines (CVMP). The Agency's committees typically meet monthly, and the Agency provides all support for organising and conducting these meetings.

The activities within this domain include the following:

Scientific Coordination Board. The Scientific Coordination Board (SciCoBo) is composed of the chairs of the scientific committees, CMDh/v and the Scientific Advice Working Parties (h/v), the Emergency Task Force (ETF), the Clinical Trial Coordination Group (CTCG), as well as members of the Agency's senior management. The SciCoBo has a strategic role and a coordination role which are closely linked. Strategically, it is responsible for identifying key priorities where new or enhanced engagement is essential to the continued success of the Agency's mission and consequently essential to shape and influence the vision for the next EU medicines agencies network strategy. It analyses trends in science, technology and regulatory science tools captured by horizon scanning with a view to generating and overseeing the implementation of regulatory science. Regarding its coordination role, it ensures there is sufficient coordination between the committees, to increase the robustness and

predictability of the outcomes of benefit-risk assessments, and application of consistent standards across the lifecycle of medicines.

Committees Secretariat. The Committees Secretariat provides organisational, secretarial and budget management for the operation of the Agency's scientific committees, as well as necessary technical, legal and regulatory support to the committees. It includes coordinating adequate scientific support and leadership across the Agency, as well as ensuring coordination and communication across scientific committees, working parties and scientific advisory groups, and facilitating interactions between these groups. In addition, the Committees Secretariat coordinates work-plan proposals and prioritisation, according to the impact of work on committees and strategic priorities set in the work programme of the Agency.

The Agency also provides the **secretariat for the Co-ordination Group for Mutual Recognition and Decentralised Procedures**, Human (CMDh) and Veterinary (CMDv), including also regulatory and legal support.

Working parties secretariat. This covers organisational, secretarial, and budget management for the operation of the Agency's working parties and scientific advisory groups.

Expert management. The Agency manages a database of more than 4,500 experts involved in the Agency's regulatory and scientific activities ensuring application of the Agency policies on declaration of conflicts of interest and transparency.

Herbal medicinal products. The Agency provides scientific opinions on questions relating to herbal medicines, establishes European Union herbal monographs for traditional and well-established-use herbal medicines, and drafts entries to the European Union list of herbal substances, preparations, and combinations thereof for use in traditional herbal medicinal products. The monographs and herbal-specific scientific and regulatory guidance documents prepared by the Agency facilitate the granting of traditional use registrations and well-established-use marketing authorisations for herbal medicines, allowing them to be placed onto the EU market.

Scientific guideline development. To facilitate the development of medicinal products and guide applicants in their medicines' development planning, the Agency, through its working parties, prepares and reviews guidelines on a variety of scientific topics relevant for the development of medicines. The guidelines take into consideration the latest scientific developments and the knowledge derived from product assessments within the Agency, and contain detailed requirements for the demonstration of quality, safety and efficacy for specific diseases or conditions. They are consulted upon with stakeholders, adopted by the Agency's scientific committees and made available on the Agency's corporate website. Transfer of knowledge accumulated from medicines evaluation through state-of-the-art recommendations of the guidelines is a key activity of the Agency. In particular, in relation to vaccines and therapeutics, the Agency keeps updating scientific guidelines to reflect the regulatory and scientific developments made during the pandemic.

Meeting management. Meeting management encompasses the organisation of EMA meetings, conferences, workshops and training courses, including those under the EU enlargement programme. The Agency organises travel and accommodation arrangements for delegates, while also providing assistance with logistical and administrative issues.

1.3.3. Medical devices

EMA has distinct regulatory responsibilities per category of medical device, including in vitro diagnostics. They are as follows:

Medicines used in combination with a medical device. EMA assesses the safety and effectiveness of medicines used in combination with a medical device. This is part of a centralised procedure application for the medicinal product.

Medical devices with an ancillary medicinal substance. The notified body must seek EMA's scientific opinion on the quality and safety of the ancillary substance under the mandatory scope of the centralised procedure, including authorised medicinal substances derived from human blood or plasma. For all other medicinal substances, the notified body can ask for the opinion of a national competent authority or EMA.

Companion diagnostics ('in vitro diagnostics'). The notified body must seek EMA's scientific opinion on the suitability of the companion diagnostic to the medicinal product if the latter falls within the scope of the centralised procedure.

Medical devices made of substances that are systemically absorbed. The notified body must seek the scientific opinion of a competent authority. EMA provides scientific opinions on the compliance of the substance with the requirements laid down in Annex I to Directive 2001/83/EC.

High-risk medical devices. EMA supports the medical device expert panels that provide opinions and views to notified bodies on the scientific assessment of certain high-risk medical devices and in vitro diagnostics.

Support to development. EMA pilots the advice to manufacturers on clinical development of high-risk medical devices that has been extended to support the development and status designation of orphan medical devices. EMA also guides the regulatory requirements for a medicinal product with an integrated medical device and considers the use of medicinal products in combination with a medical device when issuing scientific advice for medicinal products. Through these activities, EMA fosters the cooperation with medical device authorities and notified bodies for a more integrated evaluation of medicines and medical devices used in combination. EMA also fosters the development of medical device training for regulators in the context of use of medicines.

1.3.4. Data governance and data management

EMA's data related activities are driven by growing importance of data and are aligned with EU wide strategic and legal initiatives including the European Strategy for Data and European Health Data Space (EHDS) with the aim of unlocking the value of data for better patient and animal health outcomes. EMA is committed to support the EC on EHDS implementation to maximise the benefits for public health.

The Agency places strategic importance on data governance and data management as foundational pillars in its transformation into a data driven regulator. This continuous work involves establishing robust governance structures, improving the findability, interoperability and quality of data, and enhancing the capacity to generate insights that inform regulatory decisions.

Data strategy and governance. Collaboration and harmonisation across European medicines regulatory network (EMRN) is maintained through the joint HMA EMA Network Data Steering Group , guided by its workplan 2025–2028, which includes initiatives in artificial intelligence. The Agency will continue the ongoing efforts to further progress with the implementation of the European Medicines Agencies Network Data Strategy. This strategy sets out the agreed EMRN vision, principles to be followed and goals to be met to maximise the value of the data managed by the EMRN. Through this collaborative approach, the strategy aims to enhance the network's ability to protect public health while fostering innovation in medicines development and regulation. Transforming the EMRN into a

data-driven regulatory ecosystem that promotes innovation, efficiency, and better coordinated decision-making remains a priority.

Data governance oversight is provided by the EMA Data Board, and supported through close collaboration with the NDSG, to ensure that data are managed securely, ethically and in compliance with EU and international guidelines and standards. The EMA data board also coordinates the development and adoption of new international data standards and data guidelines developed through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) work groups. In line with the FAIR principles of data governance: ensuring findability, accessibility, interoperability and reuse of data, the Agency will deliver an EMA and Network data catalogue.

Data analytics. A data analytics framework will be developed to support an Agency-wide, structured approach to leveraging regulatory and healthcare data for better processes and better decisions. This will include dashboarding and as well-advanced analytics including artificial intelligence (AI). EMA is investing in analytical capabilities and embedding data driven methodologies into its core operations to support the objectives of the European medicines agencies network strategy to 2028.

Data management. These services are essential for secure, efficient and user-friendly data exchanges between the Agency and its partners, in line with agreed governance policies. Clear reporting on data management activities and measures of data quality have been implemented, ensuring accessible, catalogued data with known levels of quality. Open standards like FHIR and VICH facilitate data exchanges, and modern, scalable application programming interfaces (API) are provided both within EMA systems and across the Network.

Data quality. As part of its approach to data quality for Network critical data assets, EMA leads the development of the **EU Data Quality Framework** (EU DQF) including RWD and ADR data dedicated chapters. This framework provides a common, standardised approach to assessing the quality of data used in medicine regulation supporting consistent and evidence-based benefit-risk decisions. Data quality is considered a key focus area to ensure data accuracy, completeness and consistency. Monitoring continues from data collection through data-reuse and data analysis.

EudraVigilance (EV) and Article 57 databases management. The Agency further supports the scientific assessment and the continuous monitoring of medicines through:

- the collection, management and analysis of the data from EudraVigilance (EV) and Article 57 databases of authorised medicines products. These data underpin key pharmacovigilance activities such as signal detection and ADR reporting.
- Medical Literature Monitoring (MLM). This service is an important source of information for identifying suspected adverse reactions to authorised medicines. Ongoing efforts continue to enhance the quality and consistency of data reported to EV resulting in strengthening of the safety monitoring of medicines.

To ensure effective use of the EV system the Agency continuously supports stakeholders through training, guidance and manuals.

Advancing regulatory data management and platform implementation. The Agency is dedicated to empowering the network by delivering high-quality master data on Substances, Products, Organisations, and Referentials (SPOR), ensuring that stakeholders can rely on high quality data to support all regulatory activities. This is in line with EMA's long-term vision of enabling efficient regulatory processes and decision-making through consistent and standardised data. Moreover, EMA will continue efforts to establish a unified data foundation for the Network, covering all core regulatory master data. This work is crucial for leveraging shared, reusable data across the Network. The Product

Management Service (PMS) is on track to become the key reference data source for all medicinal product data in the European Economic Area (EEA). The Network and the Agency now have a consistent source of truth for all regulatory master data and crucial data assets. In this context, the Agency will continue striving towards full implementation of Data Platform. The goal is to share data through a data platform approach, initially serving internal consumers and later extending to external consumers. This strategy supports improved data management processes, aiding efficient regulatory operations and decision-making. The Data Platform will:

- facilitate the dissemination of trusted, high-quality information. Through it the Agency aims to develop general public-facing solutions to make available electronic health data sets for controlled consumption, as required by EHDS regulation.
- improve data sharing across EU Health Agencies, supporting initiatives such as: 'one substance, one assessment'; Joint antimicrobial resistance reporting, and Environmental impact reporting.
- support consumers of Electronic Product Information, who will be able to develop consumer- and patient-friendly services whilst AI-powered data pipelines facilitate the transformation from paper-based product information to electronic formats.

With this platform the Agency aims to build on the historical knowledge and data insights, to guide consistent regulatory decision-making. By safely making available its critical data sets and providing a common set of analytical tools to data scientists of the Network, we will move from collecting insights to process impact.

1.3.5. Strengthening methodology and decision-making

The Agency invests in providing training to its scientific committees, their working parties and the EU network to grow expertise and build capacity on methodological aspects of study design, conduct, analysis, reporting and result interpretation, and on robustness of evidence based on interventional or non-interventional data sources. This results in higher quality and clearer regulatory assessment outputs and more robust decision-making by EMA scientific committees and working parties, including the Methodology Working Party (MWP), which uses the available cross-disciplinary expertise in the EMRN to support methodological innovation, such as modelling and use of artificial intelligence, and provide advice on complex methodologies in medicine development. Through the Methodology European Specialised Expert Community (ESEC), the Agency harnesses methodological expertise available across Europe and fosters knowledge transfer, information sharing and effective communication. This collaborative framework contributes to capability building and strengthens methodological support to core regulatory activities. By leveraging the expertise within ESEC, MWP supports the development of guidance to applicants, considering the most recent scientific and methodological advancements, as applicable to regulatory decision-making.
EMA places emphasis on international collaboration to advance global knowledge sharing and collaboration on methodological topics. This includes continued engagement with global partners such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
The Agency promotes dialogue with stakeholders, including medicine developers and academic researchers, by organising scientific workshops and participating in joint research initiatives and publicly funded consortia on key methodological topics.

1.3.6. Clinical trials

This area of work focuses on strengthening the environment for the design, authorisation, conduct and monitoring of clinical trials in the EU, to support more robust, timely, and patient-relevant regulatory decisions.

Clinical Trials Coordination Group (CTCG). EMA supports the operations of the secretariat for the CTCG, including the organisation and operation of regular plenary meetings and weekly meetings of assessors. These activities contribute to the harmonisation and optimisation of the regulatory environment while safeguarding the rights, safety and wellbeing of clinical trial participants and ensuring the generation of robust data.

Clinical Trials Information System (CTIS). The Agency is responsible for the maintenance and development of the CTIS, including the delivery of new system functionalities. The Agency remains committed to simplifying CTIS business rules to enhance user experience and improve efficiency for sponsors, researchers and regulators. CTIS maintenance and improvement remain top priorities, in line with the deliverables of the Simplification Task Force and modernisation planning. New development and delivery of the system will follow the Agile methodology. A multi-year CTIS modernisation plan is in place to deliver a dependable and responsive system that can adapt to evolving user needs, emerging technologies and new legislation. More details are available in Section B.2 of this document, under 'Network Portfolio'.

Accelerating Clinical Trials in the EU (ACT EU). EMA continues its collaboration with the European Commission and Heads of Medicines Agencies (HMA) under the ACT EU initiative to make Europe a more attractive location for clinical trials. ACT EU engages with clinical trial stakeholders through the Multi-stakeholder Platform, which provides strategic and operational input that is reflected in the programme's multi-annual workplan. EMA remains fully committed to the work of ACT EU, understanding its strategic importance to drive improvements in the EU clinical trials environment. Collaboration between stakeholders and the network remains central to the programme delivery.

Support to HERA's clinical trial coordination mechanism. EMA continues to provide the necessary contributions to the HERA Board Sub-Group on the prioritisation of clinical trials and their funding for public health emergencies.

1.3.7. Real-world evidence (RWE)

The Agency in collaboration with the European medicines regulatory network works to establish a sustainable framework for integrating real-world data (RWD) and real-world evidence (RWE) into regulatory decision-making, complementing evidence from clinical trials. During the 2026–28 period the Agency will take steps to determine an RWD/RWE framework for the veterinary domain.

European Health Data Space (EHDS). The implementation of the EHDS will further expand access to RWD, offering broader data for secondary use. Through these initiatives, EMA ensures that regulatory decisions are increasingly supported by high-quality, timely, and reliable evidence from real-world data throughout the lifecycle of medicines complementing clinical trial findings.

Data Analytics and Real World Interrogation Network (DARWIN EU®). This is a key mechanism which provides timely and reliable evidence on the use, safety, and effectiveness of medicines, including vaccines, using healthcare data from across Europe. EMA also generates RWE through in-house studies conducted by its team of pharmacoepidemiologists and data scientists, as well as through studies commissioned via EMA's research framework contracts. In line with the EMA and the European Centre for Disease Prevention and Control (ECDC) extended mandates, the Agency collaborates with ECDC to deliver the Vaccine Monitoring Platform. This jointly generates RWE on the

uptake, effectiveness and safety of vaccines via independent RWD non-interventional studies using ECDC and EMA's scientific and operational infrastructure and procurement, including the use of DARWIN EU®.

HMA-EMA Real-World Data Catalogues. To support transparency and access to data, EMA maintains the HMA-EMA Real-World Data Catalogues which contains metadata from RWD sources and studies. These catalogues help researchers, regulators, and pharmaceutical companies identify and assess suitable data sources for generating real-world evidence, and also to identify RWD studies already performed or ongoing for regulatory use. The Agency will continue to provide methodological advice on the relevance of RWD sources to answer specific research questions, on non-interventional (RWD) study designs, and on analytical methods leveraging RWD within regulatory submissions.

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP). The Agency coordinates the ENCePP, which promotes collaboration, transparency and high-quality non-interventional research including development and maintenance of methodological standards and governance principles.

Advancing the use of RWD and RWE. To advance the use of RWD and RWE the Agency fosters international collaboration to support knowledge sharing, guideline development and collaboration on studies. This includes ongoing engagement with global partners such as International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

1.3.8. Small and medium sized enterprises (SMEs)

The Agency provides targeted support to small and medium-sized enterprises (SMEs) to facilitate the development and authorisation of new human and veterinary medicines. Recognising the unique challenges SMEs face — such as limited regulatory expertise and financial resources — EMA offers, via the SME office, dedicated assistance to provide guidance, fee incentives, and administrative assistance throughout the lifecycle of a medicine. SMEs benefit from scientific advice, early dialogue opportunities and access to initiatives like the PRIME scheme for promising medicines. The Agency also supports SMEs through training programmes and engagement with stakeholders, and EU organisations that promote innovation. For example, by working closely with the European Innovation Council (EIC) to provide tailored guidance to EIC-funded SMEs developing advanced therapies and breakthrough technologies. By offering this structured support, EMA plays a key role in fostering a vibrant biopharmaceutical innovation ecosystem across Europe, helping SMEs bring novel therapies to patients.

1.3.9. International cooperation

The Agency develops and implements a long-term international strategy, runs different international activities, like regular exchanges of information on products, guidelines, policies, and other activities that take place across the product lifecycle across all therapeutic and product areas. In addition to this, it supports the evaluation of medicines intended for use in low- and middle-income countries and capacity building and training of non-EU regulators.

1.3.10. Communication activities

The Agency's communication activities aim to support its mission of protecting public and animal health, and the achievement of its strategic priorities. The Agency uses the most appropriate communication channels to provide and maintain timely, accurate, trustworthy and high-quality

information on EMA's activities and their benefits to its stakeholders, partners, and European citizens. The Agency produces a wide variety of communication materials including news announcements, web pages, infographics and videos. It disseminates these via a range of channels, with its corporate website, ema.europa.eu, being the main channel with over a million visits every month. The Agency fosters productive relationships with the media, both general and specialist, through the provision of press materials, the organisation of press briefings and media interviews, and timely response to journalists' queries. To maximise the public health impact of its work, the Agency plans, executes and coordinates communication campaigns to reach out with specific goals targeted to relevant audiences.

It maintains and manages specific communication and information exchange platforms, and provides up-to-date information to its stakeholders, partners and the general public on its work and outputs, as well as on important subject matters and developments. This includes lay-language summaries on medicines approvals and other regulatory outcomes. EMA shares its information also within the European medicines regulatory network in advance of publication to ensure that consistent messages on medicines are available to citizens across the EU.

EMA develops high-quality product-related information and keeps this up to date, including information on emerging issues. Efforts are made to ensure that patients, healthcare professionals and the wider public recognise EMA as a trusted source of information. It responds to external enquiries from stakeholders and partners in an efficient manner with consistent, high quality, timely and targeted information. A special and dedicated service is available to patients and healthcare professionals who seek clarification from EMA on specific topics of interest. The Agency is also collaborating with other EU institutions and enhanced its social media monitoring to become aware, at an early stage, of dis- and misinformation and to take appropriate action proactively.

To do so the Agency maintains its corporate website's content, features and functionalities, as well as overseeing and guiding the design, development and content of other websites that it maintains for the benefit of their users and the European public at large.

Lastly, through its Information Centre, the Agency also provides the knowledge resources needed to support the work of its scientific staff and experts. It also makes available communication-related services, oversees EMA's branding, corporate identity and online visibility, and organises media and communication training for EMA staff.

1.3.11. Public and stakeholder engagement

EMA maintains an EU wide network of stakeholder organisations. It is continuously expanding this network, to allow enhanced interaction and dialogue with patients, consumers, healthcare professional organisations and industry associations. The goal is to optimise the Agency's public service role in improving human and animal health. To achieve this, the Agency aims to systematically consider the perspectives of all relevant stakeholders from early stages, ensuring that its outputs address stakeholders' needs and concerns, while also raising awareness of EMA's work and fostering trust and confidence in the EU regulatory system.

Interactions involving patients and healthcare professionals (HCPs) range from information provision and consultation to participation in the scientific activities of the Agency and its committees, as well as the review of information intended for publication. The Agency will engage stakeholders also to support the implementation of EMANS 2028, as well as for the implementation of the new EU pharmaceutical legislation once the text is finalised.

A number of tools and mechanisms for interaction are available. These include the identification of appropriate experts (patients and HCPs) and their involvement in cross-Agency assessment procedures

for medicines. For non-product related issues, the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) provide a useful platform for dialogue and exchange. For industry associations, EMA has established an Industry Standing Group.

1.3.12. Transparency

The Agency places high importance on the transparency, openness, and efficiency of its interactions with partners and stakeholders. In addition to the activities described above, public access to documents and information is provided in accordance with Regulation (EC) No 1049/2001, Policy 0043 and the Code of Good Administrative Behaviour. The number of requests for access to documents and information is continuously increasing.

The proactive publication of clinical data continues for COVID-19 products and therapies, with increased transparency resulting from the phased restart of Clinical Data Publication under Policy 0070 for centrally authorised medicinal products since September 2023, and from the proactive publication of Risk Management Plans (RMPs), and PRAC Assessment Reports and Periodic Safety Update Reports (PSURs) for COVID-19 vaccines. Specialised assessment of proposals for redaction of commercially confidential information (CCI) and protected personal data (PPD) and for anonymisation in clinical documents, post-authorisation assessments reports, RMPs, assessment reports and other documents for publication, ensures the protection of personal data and commercial confidentiality while at the same time increasing transparency on EMA decisions on centrally authorised products.

2. Horizontal public and animal health activities

2.1. Innovation and development

Through innovation in regulatory science and the implementation of the European medicines regulatory network strategy (EMANS), the Agency actively promotes the integration of scientific and technological advances—such as personalised medicines, biomarkers, advanced therapy medicinal products (ATMPs), and novel manufacturing methods—into the regulatory framework. It provides early scientific advice, supports horizon scanning, and facilitates collaboration with innovators through initiatives like the Innovation Task Force (ITF) and the PRIME scheme. EMA also works closely with EU and international partners to align regulatory approaches and promote research investment. EMA co-leads the EU-Innovation Network to foster early regulatory support and collaboration for innovative medicines and emerging health technologies across Europe. Through this engagement with the European innovation offices, EMA helps streamline innovation from research to clinical application. These efforts ensure that regulatory pathways remain agile and capable of accommodating breakthroughs in science and technology, thereby accelerating the development and availability of innovative, high-quality medicines for patients across the EU.

2.2. Regulatory science and academia

EMA collaborates actively through a dedicated academia support function with the broader research community to advance regulatory science and ensure that the regulatory system keeps pace with scientific innovation. Through its ongoing partnerships with academic and not-for-profit organisations, EMA fosters the development of new methodologies, tools, and evidence frameworks that support the evaluation of increasingly complex medicines. The Agency engages in joint research initiatives, contributes to publicly funded consortia, and supports knowledge exchange through scientific workshops and training programmes. Together with HMA, EMA convenes the European Platform for Regulatory Science Research that supports scientists advancing their work and increasing its impact. These efforts are aimed at addressing regulatory science gaps, promoting methodological innovation (e.g. in modelling, simulation, and real-world data), and strengthening the evidence base for decision-making. EMA also works to incorporate academic insights into regulatory policy, ensuring that new scientific approaches are rigorously evaluated and translated into practical regulatory tools. This close cooperation with academia reinforces EMA's role as a forward-looking, evidence-based authority that supports innovation while safeguarding public and animal health.

2.3. Supply and availability of medicines and medical devices

EMA plays an increasingly critical role in safeguarding the supply and availability of medicines and medical devices across the EU. Under its extended mandate, Regulation (EU) 2022/123, EMA coordinates EU-level actions to monitor, prevent, and mitigate shortages, in preparation for and during crises. The Agency leads initiatives such as the European Shortages Monitoring Platform (ESMP) and works closely with EMA's Medicines Shortages Steering Group (MSSG) to ensure availability of medicines and strengthen the resilience of their supply chains. EMA helps monitor the supply of antibiotics across the EU/EEA as part of MSSG-led preparedness. Ahead of autumn and winter, it works with key marketing authorisation holders to assess current and future availability and prevent shortages. The Agency also engages with international counterparts, including through the Drug Shortages Global Regulatory Working Group, to share and gather information and identify potential opportunities for harmonisation of approaches.

The Agency's role, as well as the role of the MSSG and its operational Medicine Shortages Single Point of Contact (SPOC) Working Party, will be further extended with the proposed pharmaceutical legislation. In line with the European Commission Communication Addressing medicine shortages in the EU (2023), the Agency continues to prepare for the implementation of that legislation, including advancing work to update the Union list of critical medicines annually and further supporting MSSG in critical shortage management, preparedness activities and measures to support the secure and continued supply of critical medicines. By way of example, this includes extensive engagement with stakeholders to mitigate and manage shortages at EU level and coordinated development of a methodology to identify vulnerabilities in the supply chains of medicines on the Union list, to inform regulatory and industrial policy measures set out in proposed legislation. To support that work, the Agency has already engaged with industry stakeholders to optimise data sharing approaches, using Shortage Prevention Plans and Shortage Mitigation Plans. In parallel, the Agency is also progressing the expansion of the European Shortages Monitoring Platform (ESMP) and work to facilitate data interoperability with Member State, marketing authorisation holders and other relevant systems is ongoing. The Agency will also develop capacity for the use of AI technology and provide frameworks for the use of AI tools, as necessary, in accordance with the Network Data Steering Group's workplan for 2025–2028.

EMA continues to provide scientific and regulatory input to support the European Commission's efforts, including to inform negotiations on the proposed pharmaceutical legislation and the proposed Critical Medicines Act.

In the medical devices' domain, EMA manages expert panels and provides scientific opinions on high-risk devices, including those integrating medicinal substances. The Medical Devices Shortages Steering Group (MDSSG) and Medical Device Single Point of Contact Working Party have been established, as per Regulation (EU) 2022/123 to ensure preparedness for future public health emergencies.

By way of follow-up to the ECA audit 19/2025 on Critical shortages of medicines, EMA is committed to comply with the recommendations that are directed towards the Agency, specifically with respect to operation of a single medicines database and a single reporting platform and improved communication with the public by providing information on possible alternative medicines.

Through these efforts, the Agency contributes to a coordinated, proactive response to supply challenges, ensuring continuity of care and timely access to essential healthcare products for patients across the EU.

2.4. Public health threats

This area of work relates to managing scientific activities related to preparedness and response to public health emergencies, operation and management of the Emergency Task Force (ETF), an advisory and support body that coordinates regulatory activities in preparation for and during public-health emergencies, as per Regulation (EU) 2022/123. In this context, the Agency could run specific studies to support its response to public health emergencies. In addition, this includes coordinating and leading the vaccine strategies and the AMR strategy, conducting intelligence activities on countermeasures for emerging health threats and collecting information across the Agency and outside on products and their statuses shared with EU institutions (SANTE, HERA or the cabinet). Following the European Court of Auditors' Special Report 12/2024, 'The EU's Response to the COVID-19 Pandemic', EMA has taken the necessary steps to implement the recommendations outlined in the report, including updating its health threats plan, currently under consultation with relevant parties before its publication. Through this area of work the Agency also supports the joint HERA/ECHO/EMA pilot exercise on a shelf-life extension programme. Lastly, through this area of work the Agency supports

the World Health Organization (WHO) in the work of the Collaborative Open Research Consortium (CORC), focusing on the prioritisation and assessment of viral families.

2.5. One Health

EMA, in collaboration with the other EU agencies that have a technical and scientific mandate on topics falling under the One Health umbrella, comprising the ECDC, ECHA, EEA and EFSA, will aim to facilitate strategic coordination in the implementation of the One Health approach, promote a One Health-driven research agenda, enhance capacity building on One Health, strengthen One Health stakeholders' engagement and support the development of partnerships through joint One Health activities, as part of the strategics objectives included in the 'Cross-agency One Health task force framework for action'. To progress towards this objective EMA is working on a strategy encompassing a workplan to operationalise the necessary steps in future Single programming documents.

2.6. EMRN capacity and capability building

In order to enhance scientific and regulatory expertise, the Agency runs the EU Network training Centre (EU NTC), which provides a learning and knowledge sharing ecosystem for the European medicines regulatory network (EMRN). The EU NTC aims to strengthen capacity and capability building on core regulatory and scientific areas within the Network and relevant external audiences through the provision of up-to-date training and ensure that the network of assessors and inspectors (both new and existing) acquire and maintain the necessary knowledge and competencies to meet new regulatory challenges brought about by emerging scientific and technical innovation. This area of work serves as a key component of the Agency's wider effort to ensure the sustainability of the EMRN model. To this extent EMA coordinates related training initiatives in the area of capacity building (e.g. EU4Health) whilst working to incentivise development of training as well as evaluate new ways of working. This area of work increases collaboration with stakeholders, including the extension of service to target audiences to meet the needs of new stakeholders (in close alignment with activities identified within the strategic priorities of the network) and increases the availability of EU NTC content on regulatory, scientific, data and digital topics available to wider audiences to support regulatory work. Capitalising on the experience of the EU NTC, the Agency has also launched a Digital Academy, which aims to build digital literacy, capability, and capacity at EMA and EMRN through the development of a digital knowledge-sharing academy. The objective is to increase digital literacy and stimulate development of digital skills to support digital capability and capacity building at EMA and in the Network.

2.7. Crisis management

These activities relate to management and coordination of Agency-wide activities for preparedness and response to crisis events, both product and non-product related, including major issues with policy, political, and reputational consequences for the Agency, or important public-health related events.

The Agency maintains its activities to support the streamlining, harmonisation and rationalisation of processes in response to crises and incidents. This includes organising necessary training and coordinating the implementation of EMA's Overarching Crisis Preparedness and Response Framework across the Agency. The Framework, which is underpinned by specific crisis and incident management plans, ensures the Agency's overall response to crises are carried out in an efficient and coordinated manner.

With a view to ensuring effective crisis communication within EMA and the Network, the Agency implements specific crisis communication processes in close cooperation with the Network, building on the lessons learnt from COVID-19 and other past crises.

2.8. Competitiveness

Competitiveness within EMA's mandate lies in the Agency's ability as regulators to efficiently and effectively support the translation of innovation into medicines that reach patients. This not only ensures that the European regulatory environment remains attractive to innovators, developers, and investors, but also reinforces our commitment to safeguarding patient safety and public health.

In addition to the Agency's existing tools — such as the SME Office, the Innovation Task Force (ITF), and the PRIME scheme — EMA aims to further strengthen its role by proactively engaging with innovation clusters such as technology transfer offices (TTOs), incubators, or biotech hubs.

By bringing regulators closer to where innovation takes place, the Agency can both deepen its understanding of the evolving innovation ecosystem and identify emerging trends and potential regulatory gaps. At the same time, this proximity enables the Agency to provide innovators with timely, relevant regulatory insight — helping accelerate the journey from scientific discovery to safe and effective medicines.

Recent surveys conducted among key European Technology Transfer Offices and biotech hubs have highlighted a clear need — and mutual benefit — in bridging the regulatory knowledge gap. This gap is increasingly recognised as a critical factor in accelerating innovation.

In parallel, enhancing understanding of private investment strategies in the healthcare sector — particularly those of venture capital firms — can offer valuable insights into mid- to long-term scientific and technological trends. These insights would enable the European medicines regulatory network to anticipate developments and adapt more proactively to innovator's need, ultimately helping to accelerate translation and development timelines.

Strategic engagement with investors also presents a unique opportunity to raise early awareness of the regulatory support tools available to innovators. To support this, the Agency will undertake a mapping exercise and actively engage with key private investors across Europe to identify areas of common interest and seek to co-develop a sustainable engagement framework.

Finally, the Agency will seek to leverage opportunities arising from new legislation — such as the revision of the EU pharmaceutical legislation, the Critical Medicines Act, and the Biotech Act — to strengthen its impact and that of the regulatory network on EU competitiveness.

2.9. Implementation of the Common Data Platform on Chemicals under the 'one substance, one assessment' legislation

Over the next three years, EMA will continue its preparatory work for the implementation of the Regulation establishing a Common Data Platform on Chemicals, which was adopted in late 2025 as part of the 'one substance, one assessment' legislative package. The Regulation requires five EU Agencies (ECHA, EFSA, EEA, EMA, EU-OSHA) and the European Commission to submit chemicals-related data to ECHA for inclusion in the platform, which is expected to be operational by the end of 2028. EMA will contribute with data related to chemical active substances approved by EMA that are in scope of the Regulation, including environmental risk assessment (ERA) data for human and veterinary medicinal products, non-clinical study data for human medicines, and maximum residue limits for veterinary medicines. EMA will also provide predicted no effect concentration (PNEC) values to support the development of a repository of environmental reference values within the platform and will also provide relevant available data on 'early warning signals' from its medicine evaluation activities to the European Environment Agency (EEA). EMA will work in close collaboration with ECHA, the European Commission and other relevant EU agencies to ensure a ensure smooth implementation of this new piece of chemicals legislation. With respect to the implementation of the new tasks under the 'one

substance, one assessment' legislation, to support the development of the Common Data Platform on Chemicals, in 2026 EMA will launch a procurement procedure to outsource selected tasks such as the activities for the integration of data from past evaluation procedures and other preparatory activities needed to ensure timely and structured data submission to ECHA.

3. Corporate activities

3.1. Corporate governance

The Agency provides the secretariat for the organisation of EMA's Management Board plenary meetings and its subgroups and ensures that key statutory and strategic documents are duly considered and adopted by the Board. EMA also interacts with the MB Secretariats of other EU Agencies to share best practices and streamline processes. The Agency works very closely with the Heads of national human and veterinary Medicines Agencies (HMA) under a joint European medicines agencies network strategy (EMANS – see 'B.1 EMANS Implementation' in this document), including via joint implementation activities (e.g. see A 1.3.3; 1.3.4; 1.3.5 in this document) and meetings.

Moreover, the Agency ensures operational performance through the delivery of fit-for-purpose governance and management services, which collectively support its strategic and operational objectives. Key components are:

- implementation and supervision of quality- and risk-management and internal-control processes, which include integrated quality-management practices and comprehensive risk assessments conducted annually at the residual level, factoring in existing controls and mitigations, the EU Agencies benchmarking programme, annual reviews of sensitive functions, ex post controls, and the maintenance of a register of exceptions, all of which contribute to a robust internal control environment;
- development and maintenance of corporate policies under regular review, in line with its quality management system and, as required, to implement audit findings, European Ombudsman recommendations or relevant Court rulings. Each policy is a statement of the Agency's strategic orientation, overall intentions and directions related to a specific subject. Key policies, endorsed by the Agency's Management Board, concern the handling of competing interests, records management and archiving, access to documents, publication of clinical data, multilingualism on the EMA website, identify and access management to EMA IT systems. The Agency also monitors new developments that may require the creation of new policies, e.g. on the use of AI in the Agency.
- planning, monitoring, and reporting activities, which encompass the full corporate planning cycle— from strategic planning and the development of annual work programmes and budgets to the subsequent monitoring and reporting activities that track progress and outcomes. This component also includes the operational and strategic management of IT services and enterprise IT architecture, supporting strategic planning, road mapping, and application portfolio optimisation. To this purpose the Agency supports the work of the Network ICT Advisory Committee (NICTAC) and of the Network Portfolio Advisory Group (NPAG) in delivering its workplan across key themes.
- data protection activities, through which EMA prioritises the safeguarding of personal data across its operations. Under the guidance of EMA's Data Protection Officer (DPO), the Agency drives a comprehensive data protection programme aligned with the European Union Data Protection Regulation (Regulation (EU) 2018/1725). This includes proactive compliance facilitation, expert advice, and targeted training efforts. Guided by the principles and recommendations of the European Data Protection Supervisor (EDPS) and the European Data Protection Board (EDPB), EMA continuously strengthens its internal data protection culture and extends support to the EU Network through structured training offerings and advisory engagement on all data protection matters.
- auditing activities, which are implemented in compliance with the Financial Regulation and the Global Internal Audit Standards issued by the Institute of Internal Auditors, through an independent internal audit capability that provides the Executive Director and Management Board with

independent, objective, risk-based assurance, advice, insight and foresight on the Agency's governance, risk management, and internal control processes.

- coordination of the environmental management system (EMS) in accordance with the EMAS management standard, with activities such as maintaining a system manual, an Environmental Policy, preparation of a roadmap for environmental management, managing planning and reporting of environmental management information, and calculation of the Agency's greenhouse gas emissions among other things. The environmental management impacts operational activities throughout the Agency such as including green criteria in the Agency procurements where applicable, embedding environmental considerations into our processes and procedures, and maintaining a sustainable lifecycle approach with an aim of continuous improvements. In December 2024 the EMA EMS was successfully validated towards the EMAS management standard and EMA received EMAS registration on 17 January 2025. The Agency further aims to support continuous improvements towards the target of a 55% reduction of its carbon emissions by 2030, in line with the Regulation (EU) 2021/1119, establishing the framework for achieving climate neutrality (the European Climate Law), and of leading by example (see also Annex VI of this document).
- management of premises and office accommodation, security, business continuity, health and safety, reception and switchboard, mail management, reprographics, and off-site archives, as well as catering.

3.2. Legal affairs

This area of work covers the provision of legal advice on matters related to pharmaceutical law, contracts and procurement, staff and financial matters, data protection, corporate governance, and anti-fraud issues. It also involves handling complaints submitted to the European Ombudsman and representing the Agency before the Court of Justice of the European Union. The Agency cooperates closely with the European Commission and provides advice and support on, among other things, the implementation of new legislation, the drafting and implementation of internal guidance and policies, the establishment of working arrangements with other regulatory bodies, EU institutions and agencies. The work further includes assessing potential conflicts of interest of scientific experts, Management Board members and EMA staff, deciding on access to documents and preparing replies to requests for information. In addition, this area of work encompasses the legal scrutiny of scientific opinions for both human and veterinary medicinal products, interactions with OLAF and EPPO, and the preparation and implementation of the Agency's anti-fraud strategy and the related action plan.

3.3. Institutional affairs

This area of work covers the Agency's interactions with the EU institutions, in particular the European Commission, the European Parliament, the Council, and other EU agencies. This includes contributions to general requests from the EU institutions for technical input and information, as relevant for EU policy-making and legislative initiatives; acting as a general contact point for the EU institutions on matters concerning pharmaceuticals and the work of EMA; supporting the participation of EMA's Executive Director and other senior EMA representatives in high-level institutional meetings, and hosting ad hoc visits of representatives of the EU institutions to the Agency.

EMA interacts with other EU agencies, such as ECDC, EFSA, ECHA and EUDA, under the existing Working Arrangements between EMA and these agencies. Building upon the work initiated in 2024 under the 'one substance, one assessment' initiative, the Agency will further strengthen its collaboration with EFSA and ECHA. This enhanced cooperation will focus on the monitoring of scientific assessments of chemical substances that may also be utilised in medicinal products. Key activities will

include systematic information exchanges regarding EFSA and ECHA workplans, joint training sessions on respective regulatory frameworks, and staff exchange programmes. EMA experts will continue to review the work programmes of other agencies to identify substances of cross-cutting relevance. For such substances, they will closely observe the scientific evaluations conducted by EFSA and ECHA. These efforts aim to ensure that EMA experts gain a comprehensive understanding of assessments conducted under other legislative frameworks, which could have implications for the availability of medicinal products within the European Union.

3.4. Information management

IT operations at EMA are strategically evolving to support a fully digital, data-driven regulatory network across Europe. Central to this transformation is the shift to a cloud-native architecture, enabling scalable, secure, and cost-efficient digital services. EMA is enhancing network interoperability to meet legislative demands and foster seamless data exchange across the EMRN. A strong focus on platform standardisation and integration is eliminating silos and improving operational cohesion. AI is being embedded at scale to automate processes, boost decision-making, and increase regulatory efficiency. Robust data security frameworks are being reinforced to protect sensitive health data and ensure compliance. EMA is also reducing vendor lock-in by adopting open, interoperable solutions that support long-term sustainability. A product-oriented delivery model is replacing traditional service structures, aligning IT outputs more closely with stakeholder needs. These efforts are underpinned by a modernisation mindset and a commitment to operational efficiency. Collectively, they position EMA to respond with agility to emerging challenges and opportunities in the regulatory landscape.

3.5. Information security

The Agency develops and implements an information security strategy and security policy and oversees the implementation of the administrative and technical controls to ensure that the information assets are appropriately and consistently protected in order to reduce the Agency's risks to an acceptable level. This includes the performance of security and risk assessments, audits and compliance procedures, as well as security awareness initiatives and training. The Agency is also responsible for ensuring compliance with the Cybersecurity Regulation (Regulation (EU, Euratom) 2023/2841 of the European Parliament and of the Council of 13 December 2023).

3.6. Administrative activities

3.6.1. Human resources

The Agency develops and implements staff policies and guidelines related to the management of human resources. The Agency is implementing its Human Resources Strategy in the domains of strategic resource planning, talent management, staff wellbeing and workplace. The implementation of this strategy considers the evolution of external and internal factors that impact the Agency's workforce, allowing prompt and agile responses to challenges and opportunities, through the development of specific initiatives to address them.

Other activities covered within this area of work include talent acquisition and talent management, including management of staff performance and development, managing personnel administration and payments, running the traineeship programme, providing health and wellbeing support, management of ethics and compliance, including managing staff declarations of interests, managing HR related procurements, all of which support the achievement of the Agency's strategic objectives, in compliance with the Staff and the Financial Regulations.

3.6.2. Finance

In order to ensure the fulfilment of its mission while ensuring full compliance with the obligations set out in the EMA Financial Regulation and adherence to the highest international standards, the Agency implements a wide range of financial activities, including budget execution, financial support, establishment of accounts, payment and revenue management, cash resource oversight, ex ante verification of transactions, and procurement, contract and grants management support. Through these functions, the Agency enables operational excellence and ensures the responsible use of resources in pursuit of its mission.

B) Strategic transformation initiatives

1. EMANS implementation

In March 2025 the EMA MB and the HMA Management group adopted the updated EMAN Strategy to 2028. The approach taken for the updated strategy (EMANS 2028) recognises the urgent need to adapt to a number of developments — notably the enactment of new legislations to handle health threats, the establishment of the Directorate-General Health Emergency Preparedness and Response (DG HERA) to improve the EU's preparedness, technological advance in particular in the area of artificial intelligence (AI) — while it ensures that the strategy helps the network to take the necessary preparatory steps to be in the best position to smoothly implement the legislative changes that will be introduced with the revision of the EU pharmaceutical legislation. The Network strategy to 2028 focuses on six priority areas. The themes have been chosen with the view of supporting the core work of evaluating human and veterinary medicines, while promoting the development of new medicines and ensure that they reach patients (for the complete overview of the cascading of the multi-annual planning, see the tables at the end of this section):

1. Accessibility.
2. Leveraging data, digitalisation and artificial intelligence.
3. Regulatory science, innovation and competitiveness.
4. Antimicrobial resistance and other health threats.
5. Availability and supply of medicines.
6. Sustainability of the network.

The overarching theme of EMANS 2028 is that of rapid change. This drives many of the consideration in the six focus areas. For most part the theme applies to both innovative medicines and off-patent medicine, such as generics and biosimilar. The whole strategy is underpinned by the 'One Health' approach to protecting public health. This is an integrated approach that aims to sustainably balance and optimise the health of humans, animals and ecosystems. This is essential for dealing with global threats as the health of humans, domestic and wild animals, plants and the wider environment are closely entwined. The implementation of this strategy will take into account important legislative and policy developments in areas such as environmental sustainability, the European Green Deal and the single assessment of substances.

As a vision for the near future, the strategy paints a vision for 2028 and beyond of an EU where:

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

Themes

The following tables describe in detail the medium-term strategic objectives, the actions needed to achieve them and the relevant expected results. The table represents a complete overview of all the elements which constitute the cascading of the multi-annual planning (namely, theme, strategic goals, objectives, multi-annual activities). The implementation of all the objectives mentioned below will span the multi-annual strategy timeframe (2026–2028) and will be implemented via the multi-annual activities. These are prioritised on an annual basis and included in Section 3 – Annual work programme.

Theme 1: Accessibility

Strategic goal	Objective	Activities	Expected results
1.1 Optimise the path to accessibility by working with other decision makers (HTA bodies and payers)	1.1.1 Contribute to the successful implementation of the HTA Regulation whilst preserving the remits of regulators and HTA bodies, respectively	1.1.1.1 Provide the Joint Clinical Assessment Subgroup (JCASG) with all the relevant information from the centralised procedure and measure effectiveness together with JCASG	Timely provision of information in line with legal requirements for all medicinal products subject to JCAs JCASG is informed about issues in the regulatory review that might impact the JCA assessment scope
		1.1.1.2 Collaborate with the HTA Coordination Group in parallel joint scientific consultations (JSCs) giving scientific advice to technology developers	Requests for advice from developers on how to adjust their programmes to ensure they generate evidence relevant for both regulators and HTA bodies are addressed Cooperation established between regulators and HTA bodies on the selection of

Strategic goal	Objective	Activities	Expected results
			development programmes that would benefit from parallel JSC
		1.1.1.3 Exchange information on upcoming applications and future health technologies for planning purposes and for horizon scanning	Information on future applications and technologies shared regularly for planning purposes
	1.1.2 Foster the generation of robust scientific evidence to serve different decision makers (regulators, HTA bodies and payers)	1.1.2.1 Continue dialogue between regulators and HTA bodies on principal evidence requirements and how to identify evidence gaps early and provide guidance on how to address such gaps efficiently	Greater clarity on key principles from regulatory and HTA perspectives that help guide innovative development programmes and address overarching non-product issues. New methodologies/frameworks developed for generating evidence for understudied/ underserved populations
		1.1.2.2 Establish a dialogue between regulators, HTA bodies and payers on evidence generation for well-established use medicines (including evidence for repurposing such medicines) and medicines for special populations	Greater understanding of challenges and possible models/solutions for specific types of developments (such as off-patent innovation, repurposing of medicines and the generation of evidence for understudied populations)
		1.1.2.3 Involve patients and carers in discussions about evidence planning in collaboration with the JSCSG	Patients and carers are involved in all parallel JSC procedures Greater sharing of experiences and practices with patients and carers
	1.1.3 Enhance communication with other decision makers about the scientific considerations leading to regulatory outcomes	1.1.3.1 Implement new template changes for EPARs which aim to improve transparency regarding evidence supporting marketing authorisations	Greater transparency regarding the evidence leading to regulatory decisions as a result of the new EPAR template changes
		1.1.3.3 Provide targeted communications on the methodologies, evidence needs and assessment of studies for demonstrating biosimilarity in general and for specific products	Better uptake and availability of biosimilars
1.2 Deepen engagement with healthcare policy makers on initiatives and research relevant	1.2.1 Contribute to initiatives exploring the perspective different stakeholders have about unmet medical needs and how they inform considerations about clinical	1.2.1.1 Continue multi-stakeholder engagement (involving regulators, HTA bodies, payers, patients, healthcare professionals and industry) on the concept of unmet medical needs	Better understanding of the commonalities and differences in the decision-making by different bodies

Strategic goal	Objective	Activities	Expected results
to sustain health technology accessibility	significance, significant benefit and major contributions to patient care	1.2.1.2 Develop guidance for sponsors on obtaining robust, meaningful and interpretable input from patients, including paediatric patients, to understand their experiences with their disease and treatment	Enhanced insights into patients' experiences and the impact on societal health of medicines for unmet medical needs
	1.2.2 Conduct research to better understand accessibility for medicines addressing unmet needs and how evidence requirements affect decision outcomes	1.2.2.1 Explore a methodology for reviewing and monitoring decisions and underlying evidence from the regulatory evaluation of a medicine through to the health technology assessment and, if feasible, decisions on pricing and reimbursement	Greater clarity on the evidentiary parameters affecting accessibility, including the impact of early access schemes Better insights into obstacles to timely access to medicines for understudied/ underserved populations (e.g. children)
		1.2.2.2 Follow-up review of the impact of parallel advice on regulatory, HTA and access, in collaboration with HTA bodies	Greater understanding of the value of parallel JSC
	1.2.3 Continue collaborative work on methodologies for the generation of evidence that is also relevant for health technology assessments	1.2.3.1 Ensure regular touchpoints between MWP, MPGSG and CTCG to identify common interests in methodology development	Greater oversight of and collaboration on methodology guidance developments
		1.2.3.2 Engage with collaborative platforms for regulators, HTA bodies, NCAPR and other payer organisations, academia and developers on generation of evidence, particularly RWE	Projects and initiatives, e.g. on RWE, consider needs of different decision makers. More data sources available to support the needs of HTA bodies and payers. More clarity about specific challenges of gathering evidence for ATMPs as well as access decisions.
		1.2.3.3 Prepare a joint output paper on evidence requirements at the indication/disease level with HTA bodies and payers	An output paper on evidence requirements for three conditions

Theme 2: Leveraging data, digitalisation and artificial intelligence

Strategic goal	Objective	Activities	Expected results
2.1 Maximise the generation, interoperability, use and exchange of data to support EU decision-making in the context of key EU legislative initiatives (notably the European Health Data Space and new pharmaceutical legislation)	2.1.1 Embed the use of healthcare data from diverse populations in the network's processes, including in support of the EHDS implementation, and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, e.g. genomic data)	2.1.1.1 Foster adoption of advanced/innovative methodologies and integration into regulatory decision-making of evidence generated from data that can complement clinical trial data (with greater access to data, pilot, smart business processes and a programme of change management)	Greater use by decision-makers of advanced/innovative methodologies and evidence from data that complement clinical trial data for a wide range of regulatory use cases Learnings and experience are shared from pilot studies on novel types of data. When relevant, healthcare data and novel types of data are routinely used to support regulatory decision making
		2.1.1.2 Foster analysis of clinical trial data (including process, methodological, technical, training and organisational aspects) while working on implementing relevant provisions of the new pharmaceutical legislation	Greater use of evidence generated from clinical study data analysis to strengthen and support acceleration of regulatory decision-making in preparation for the new pharmaceutical legislation
		2.1.1.3 Establish and implement an EMRN data analytics framework to maximise benefits from the EMRN key data assets for public and animal health	Greater investment in data and analytics and support methods and skills in line with the EMRN data analytics framework.
	2.1.2 Ensure a high level of interoperability (including through the use of master data), standardisation and quality of data addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed	2.1.2.1 Establish and implement an EMRN data strategy to ensure appropriate data governance is in place for managing EMRN data assets in compliance with data protection and data security	Greater management of the EMRN data assets in line with the EMRN data strategy, to meet high quality standards, standardisation, sharing and usability
		2.1.2.2 Deliver a programme of uptake of data standards and of interoperability, in line with the revised EMRN data standardisation strategy Strengthen interoperability of the network data	Improved interoperability and leveraging of data, based on master data and related data standards, leading to greater regulatory efficiency and better decision-making

Strategic goal	Objective	Activities	Expected results
		Progress with and harmonise the implementation of master data and related data standards within the network	
		2.1.2.3 Agree and implement an approach to strengthen cataloguing of the network data assets and to improve their quality	An established common approach for data cataloguing and quality of the network data assets
2.2. Leverage digitalisation, experimentation and innovation to deliver optimised regulatory processes	2.2.1 Reinforce the network's digital infrastructure in line with the Network Portfolio Vision to drive the digital transformation of the network's scientific and regulatory processes	2.2.1.1 Optimise, prioritise and deliver the Network Portfolio in support of the EMANS strategic objectives	Network Portfolio that anticipates, effectively responds to and manages digitalisation for the development of the Network's digital infrastructure
		2.2.1.2 Build a digital infrastructure that places end-users at the centre to support the transformation of scientific and regulatory processes and strengthen engagement with industry via the Regulatory Optimisation Group (ROG)	Improved operational efficiency and overall sustainability of the network supported by end-to-end data driven digitally connected regulatory processes
		2.2.1.3 Improve capabilities to engage stakeholders and customers, to manage change adaptation and adoption, and to manage synergies and dependencies across the Network	Greater preparedness among end users for changing their ways of working
	2.2.2 Foster a culture of continuous experimentation and innovation across the network	2.2.2.1 Deliver learning and knowledge sharing experiences across the EMRN, including AI learning in line with EU AI Act	Workforce is equipped for a fundamental shift in ways of working and are continuously evolving through learnings
		2.2.2.2 Integrate innovation and experimentation with emerging technologies within the Network Portfolio	Accelerated delivery of the Network Portfolio and modernisation of technology
		2.2.2.3 Create an experimentation framework that builds on the	The transformation of critical business operations across the Network's services and tools

Strategic goal	Objective	Activities	Expected results
		experimentation efforts with emerging technologies across the Network	
2.3 Realise the Network vision on AI across all EMANS focus areas	2.3.1 Leverage experimentation and technological advances in AI to support the digital business transformation of the EU network	2.3.1.1 Develop an AI tools framework to support collaborative development and sharing of AI tools across the Network and ensure AI use is compliant with the AI Act	Greater development, use and sharing of AI tools across the network, in full compliance with the AI Act
		2.3.1.2 Develop a system to collect knowledge mining and AI ideas/use cases and develop AI tools for the Network	Tools for knowledge mining and efficiency in decision-making across the network are made available, based on a collection and prioritisation of proposals from across the network
		2.3.1.3 Develop AI network research priorities	A published document on AI research priorities
	2.3.2 Harness the potential of AI throughout the medicines' lifecycle	2.3.2.1 Strengthen the support given to various fora such as ITF, QIG, PTM and SAWP related to the evaluation of AI in the medicines' lifecycle	A strengthened process for supporting innovation fora and functions, such as ITF, QIG (quality innovation group), PTM (portfolio and technology meetings) and SAWP
		2.3.2.2 Publish principles for responsible AI, map AI terminology and ensure AI guidance is available and up to date to support medicines lifecycle	Updated AI guidance available for the whole life cycle of medicines The publication of global regulators' principles for responsible AI and an AI terminology map comparing global medicines regulatory terms in AI
		2.3.2.3 Roll out a training programme to ensure AI literacy and the development of an expert workforce	Increased AI literacy among all staff to enable safe and effective use of AI Greater expertise among key staff involved in guiding and regulating industry and using AI to improve medicines regulation

Theme 3: Regulatory science, innovation and competitiveness

Strategic goal	Objective	Activities	Expected results
3.1 Promote the future proofing of the EU innovation ecosystem by monitoring and integrating advancing science and technology in medicines development and manufacturing	3.1.1 Continue to support innovation and enable rapid integration and adaptation of scientific and technological advancements in the development of human and veterinary medicines in a timely manner	3.1.1.1 Consider how to support scientific and technological progress in practice to better prepare for the new EU pharmaceutical legislation and related acts (e.g. CMA, Biotech Act) and Life-Science Strategy	Practical solutions to effectively prepare for the new EU pharmaceutical legislation and related acts are identified and implemented
		3.1.1.2 Share best practices on integrating advanced science and technology in medicines development and implement recommendations identified through a stakeholder survey and other fora	Advanced science and technology is better integrated in medicines development and manufacturing
		3.1.1.3 Engage with TTOs, biotech hubs, investors and funding organisations to raise awareness of support to innovation and EU competitiveness in the pharmaceutical field	Increased awareness of regulatory support tools and incentives
	3.1.2 In collaboration with other EU bodies, implement a model for efficient, timely and coordinated EU horizon scanning for human and veterinary medicines to inform the development of regulatory tools and approaches and identify areas where additional expertise is needed	3.1.2.1 Further develop and pilot an optimised horizon scanning methodology involving the EU-Innovation Network and other relevant stakeholders	Relevant stakeholders are fully integrated in the EMA horizon scanning process based on an optimised methodology
		3.1.2.2 Identify and triage new and emerging platform technologies to understand their impact on existing regulatory approaches and expertise	EMRN is ready to handle the regulatory impact of new and emerging therapeutic platforms and technologies
		3.1.2.3 Discuss best HzS practices and explore opportunities for collaboration with other initiatives and stakeholders (e.g. ICMRA, medical devices network, HTA horizon scanning, WHO, JRC, EIC, IncreaseNET)	Identify HzS topics of common interest which should be discussed among different stakeholders

Strategic goal	Objective	Activities	Expected results
	3.1.3 Facilitate the development and implementation of novel manufacturing technologies and analytical techniques, including with a view to facilitating the adoption of more sustainable practices with a reduced carbon footprint	3.1.3.1 Identify the most promising developments and define priority areas in pharmaceutical manufacturing (green, analytical technologies, delivery systems, materials, devices and facility design concepts)	Better understanding of priority areas in pharmaceutical manufacturing
		3.1.3.2 Engage with industry, academia, vendors, learned societies and international partners aiming to identify challenges and propose solutions (including through agile guidance development) Use knowledge sharing and training initiatives involving QIG and EU NTC to develop Network capabilities in novel technologies	Network has identified challenges and proposed solutions for developers by collaborating with different stakeholders
		3.1.3.3 Provide end-to-end product specific support on novel manufacturing technologies from early development throughout the product lifecycle through QIG one-on-one meetings, SAs, and expert input in assessment teams	Improved development and implementation of novel manufacturing technologies and analytical techniques. Product specific support is provided from early development throughout the product lifecycle
3.2 Foster generation of high quality and impactful evidence with particular focus on clinical trials	3.2.1 Support the generation of high-quality evidence in quality, non-clinical (including non-animal methods) and clinical domains by researchers and sponsors from early development stages and provide timely and more accessible scientific and/or regulatory advice	3.2.1.1 Develop, and provide a streamlined support framework enabling optimised regulatory support for the development of innovative medicines (including training and educational materials)	Developers and manufacturers of innovative medicines have access to clear, lean and efficient regulatory support tools
		3.2.1.2 Optimise efficient mechanisms for dialogue between sponsors/applicants and assessors of the Member States, with the aim of addressing scientific and regulatory issues	Dialogue between sponsors/applicants and assessors on scientific and regulatory issues is optimised

Strategic goal	Objective	Activities	Expected results
		3.2.1.3 Explore support mechanisms involving other stakeholders, such as the pre-grant advice which involve the funding bodies	Better understanding of the value of potential additional support mechanisms e.g. the pre-grant advice
	3.2.2. Foster innovation and the improved planning and conduct of clinical trials and emerging clinical data generation (including the integration of real-world data) in conjunction with activities related to theme 2	3.2.2.1 Support the effective implementation of the ACT EU objectives and workplan to modernise clinical trials and make EU attractive for conducting clinical trials	EU is more attractive for clinical trials sponsors
		3.2.2.2 Coordinate and enhance activities focused on methodological aspects of clinical trials, promoting innovative well-structured study designs and generation of high-quality evidence for human and veterinary medicines	Improved stakeholder experience benefiting from EU clinical trial guidance landscape, enabling innovative well-structured study designs
		3.2.2.3 Support the implementation of ICH E6(R3)	Innovative trial design is possible in Europe
	3.2.3 Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation in collaboration with other EU initiatives and institutions (e.g. the Joint Research Centre) and align approaches internationally (e.g. with ICMRA)	3.2.3.1 Establish new pathways for sharing of data generated with 3Rs testing methods (including NAMs) through expansion of the voluntary data submission procedure Elaborate targeted training activities on 3Rs testing methods (including NAMs) and best practices to foster their acceptance by EMA and the EU regulatory network	More evidence is generated though the implementation of non-clinical and 3Rs methods, and NAMs
	3.2.3 Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation in collaboration with other EU initiatives and institutions (e.g. the Joint Research	3.2.3.2. Draft, revise and update guidance related to 3Rs testing approaches and NAMs, non-clinical evidence generation, modelling, simulation and extrapolation, regulatory acceptance and ICH guidelines	Updated guidelines and reflection papers related to 3Rs testing approaches and NAMs, non-clinical methods, regulatory acceptance criteria, ICH guidelines are available to sponsors

Strategic goal	Objective	Activities	Expected results
	Centre) and align approaches internationally (e.g. with ICMRA)		
	3.2.3 Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation in collaboration with other EU initiatives and institutions (e.g. the Joint Research Centre) and align approaches internationally (e.g. with ICMRA)	3.2.3.3. Promote international convergence on 3Rs testing approaches and NAMs in collaboration with the EU-Network, EC and other EU public bodies involved	Network is actively engaged in international cooperation to foster 3R Qualification and regulatory acceptance of 3Rs testing methods including NAMs through the active follow-up of relevant EU projects.
3.3 Promote stakeholder cooperation to accelerate the translation of innovation into therapies, facilitate the repurposing of existing therapies and increase EU competitiveness	3.3.1 Develop network-led partnerships with key stakeholders (e.g. academia, and industry and funding bodies) to deliver impactful progress in regulatory science and research and provide training	3.3.1.1 Continue and expand the involvement of EU network regulatory scientists in externally funded projects while strengthening the coordination and involvement among regulators in different funded programs such as Horizon Europe, the Innovative Health Initiative, and EU4Health	Competent authorities are regularly involved in relevant EU and national projects funded by e.g. Horizon Europe, Innovative Health initiative and EU4Health
		3.3.1.2 Seek opportunities to collaborate with key stakeholders on research topics of common interest and bidirectional training	Researchers and regulators benefit of bidirectional training and expanded collaboration
		3.3.1.3 Address identified regulatory-science research needs via the European Platform for Regulatory Science	Regulatory-science research needs are addressed enabling better evidence generation and medicine development
	3.3.2 Enhance the regulatory competence of researchers and developers from academia, hospitals and small and medium-sized enterprises (SMEs) to facilitate the translation of research into innovative medicines through direct support and pre-competitive research collaborations	3.3.2.1 Implement recommendations from the repurposing pilot	EU is attractive region for repurposing medicines and related projects and business
		3.3.2.2 Review and refine existing support to ensure that it meets the specific needs of SMEs and academic researchers	SMEs and academic research needs are addressed
		3.3.2.3 Engage with stakeholders in professional education and research	SMEs and academic researcher needs are addressed

Strategic goal	Objective	Activities	Expected results
		environments (e.g. research-conducting learned societies, research organisations, university organisations, transfer organisations, funding organisations) in both human and veterinary related domains	
	3.3.3 Increase collaboration with medical device experts, notified bodies, ethics committees and patient communities, HTA bodies and the Substances of Human Origin (SoHO) network in conjunction with the European Commission to support development and authorisation of combination products	3.3.3.1 Support the COMBINE project and consider how lessons learned from the project can be applied to other areas	Network has learnt key lessons from the COMBINE project and assessed their applicability across other interface areas to streamline and harmonise regulatory processes
		3.3.3.2 Promote increased collaboration among medicinal product competent authorities and between different regulatory frameworks on the regulatory status of borderline products	More EU wide consistent and transparent approaches to the classification and regulatory status of borderline products is achieved

Theme 4: Antimicrobial resistance and other health threats

Strategic goal	Objective	Activities	Expected results
4.1 Contribute to responsible use of antimicrobials and effective antimicrobial stewardship using a One Health approach	4.1.1 Continue to implement the requirements for the mandatory collection and reporting of sales and use data for antimicrobials in animals and for improving access to information and data and communicating the findings	4.1.1.1 Report on sales of veterinary antimicrobials and on the use of antimicrobials in animals in ESUAvet annual reports Prepare the 5th Joint inter-agency report on integrated analysis of antimicrobial consumption and antimicrobial resistance in bacteria from humans and food-producing animals (JIACRA)	Detailed statistics (including trend analyses) available on the number of antimicrobials sold and used in animals across the EU/EEA Integrated analysis available with identification of associations of antimicrobial consumption and antimicrobial resistance in bacteria from both human and veterinary sectors, providing a One Health perspective
		4.1.1.1 Report on sales of veterinary antimicrobials and on the use of antimicrobials in animals in ESUAvet annual reports Prepare the 5th Joint inter-agency report on integrated analysis of antimicrobial consumption and antimicrobial resistance in bacteria from humans and food-producing animals (JIACRA)	Detailed statistics (including trend analyses) available on the number of antimicrobials sold and used in animals across the EU/EEA Integrated analysis available with identification of associations of antimicrobial consumption and antimicrobial resistance in bacteria from both human and veterinary sectors, providing a One Health perspective
		4.1.1.2 Update guidance and further development of methodology, indicators and tools for analysis, reporting and dissemination of data on the volume of sales and on the use of antimicrobials in animals	Improved quality, consistency and comparability of data on antimicrobial sales and use across EU/EEA countries and animal sectors
		4.1.1.3 Continue to collect data on use of antimicrobials in animals and facilitate exchange of experiences between Member States	Improved access to sales and use data for antimicrobials
	4.1.2 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, while incorporating	4.1.2.1 Develop guidance for the product information of existing antibiotics and prescribing practices	Revision of the CVMP's guideline on the SPCs of antimicrobials to reflect restrictions on use e.g. for products authorised for prophylactic use Reduction in inappropriate or unnecessary use of antimicrobials as a result of improved clarity in the PI and better prescribing practices

Strategic goal	Objective	Activities	Expected results
	relevant new provisions in the new pharmaceutical legislation	4.1.2.2 Preserve existing therapeutic options by continuously raising awareness through education, best practices sharing and training Raise awareness of resistance to antiparasitic and antifungal agents	Strengthening NTC training as an instrument for implementing education and best practice
		4.1.2.3 Contribute to the CVMP's dosage review and adjustment of selected veterinary antibiotics (ADRA) project, which aims to update dosage recommendations for selected veterinary antibiotics	Updated and scientifically justified dosage recommendations for selected veterinary antibiotics, based on a comprehensive review of existing data
	4.1.3 In collaboration with relevant EU bodies, define a roadmap for point-of-care diagnostics to support the development of improved diagnostic tests	4.1.3.1 Complete reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals	A comprehensive overview of the current landscape of diagnostic tests used to guide antibiotic use in veterinary medicine
	4.1.4 Develop, update, and promote regulatory guidance on antimicrobial use in animals to guarantee therapeutic options and minimise the impact of antimicrobial resistance while also supporting the development, implementation and uptake of guidance for human medicines	4.1.4.1 Promote guidance on antimicrobial use by adapting existing guidelines and creating new ones Finalise EMA's approach to antimicrobial resistance in the environment	Updated set of guidelines on the responsible use of antimicrobials in animals reflecting latest scientific evidence, evolving resistance patterns, and the requirements of Regulation (EU) 2019/6
		4.1.4.3 Adjust current approach for addressing rational use besides the update of SmPCs, e.g. publications and papers drafted in collaboration with learned societies for infectious diseases and experts	Availability of up-to-date information on best practices for antibiotics use
4.2 Support development of new antimicrobial agents and alternatives to the use of antimicrobials in collaboration with international partners	4.2.1 Provide guidance on regulatory pathways for phages and other innovative products in human and veterinary medicine, engaging with relevant stakeholders	4.2.1.1 Define regulatory requirements and develop a framework for innovative non-traditional medicinal products	Easy access to support for rapid development of products that can assist in the reduction of the use of antimicrobials
		4.2.1.2 Work on harmonising requirements for new antibacterial/antifungal agents for human use through the quadrilateral	Several virtual quadrilateral meetings held in Q1 2025 to discuss antifungals, pneumonia endpoints, paediatric development and bacteriophages

Strategic goal	Objective	Activities	Expected results
		activities with FDA, PMDA and HC and expand collaboration to include work with ICMRA	
	4.2.2 Engage stakeholders in pipeline discussions with a view to facilitating the development and eventual authorisation of relevant products	4.2.2.1 Advance informal dialogue through the ETF and formal scientific advice in areas of unmet need related to AMR, including for vaccines for bacterial pathogens	Support for SMEs and academics developing new agents
		4.2.2.2 Include OPEN partners and other international regulators as needed in the discussion on approval of new products addressing AMR	Faster approval in EU and in other parts of the world
		4.2.2.3 Reflect on the uptake by MAHs of VAMFs and vPTMFs with a view to determining if they are delivering benefits in terms of easier management of products and/or facilitating product development/ authorisation	Clarity on the benefits of VAMFs and vPTMFs in terms of easier management
	4.2.3 Support the European Commission and Member States in the implementation of new business models for antimicrobials (particularly antibiotics), including eligibility assessment	4.2.3.1 Provide technical support with respect to the implementation of the new pharmaceutical legislation and provide support with defining criteria for eligible products Support G7/20 in developing incentives for new antibiotics and ensure EU initiatives are progressing	Successful implementation of the legislation on incentives and other ancillary initiatives on new business models
		4.2.3.2 Support interactions with HTA bodies around value of new antimicrobials Interact via workshops and meetings with HTA bodies/payers/governments on setting up appropriate incentives for new medicines with impact on AMR	More clarity about the value of new products based on scientific evidence available Ranking of key attributes for new medicines to be rewarded

Strategic goal	Objective	Activities	Expected results
4.3 Strengthen regulatory preparedness for health threats	4.3.1 Refine regulatory activities to increase preparedness and harmonise approaches for investigating medicinal products during emergencies, including for conducting timely clinical trials during emergencies	4.3.1.1 Complete guidance for medical countermeasures for CBRN threats, including on use of non-clinical efficacy data with radionuclear chapter to be drafted by the ETF Organise workshop on non-clinical evidence to support approval of CBRN MCMs	Clear criteria for approval of MCMs for CBRN threats and availability of guidance documents Incentives in place to foster the regulatory submission
		4.3.1.2 Document lessons learned following emergency use by Member States under Article 110 and generate advice/guidance on data gathering/generation during emergencies that could support subsequent authorisation	Lessons learned and possible guidance Implementation of new legislation on TEMA
		4.3.1.3 Agree internationally on approaches for approval before emergencies and on conducting clinical trials during crises Engage with WHO via the CORC framework with respect to viral families Engage with academia, industry and NGOs on clinical study design via ETF Conclude work on ACT EU PA11 deliverables on clinical trials in public health emergencies	Progress in international collaboration with WHO, CEPI, CORCs and other players
	4.3.2 Respond to health threats that could be related to climate and environmental changes, using the One Health approach, as defined by OHHLEP, when applicable and in close collaboration with other Union agencies	4.3.2.1 Map health threats and pipeline of medical countermeasures while engaging with HERA, ECDC and NATO	Complete mapping health threats and pipeline of medical countermeasures

Strategic goal	Objective	Activities	Expected results
	4.3.3 Expand the international alignment on regulatory requirements from Quadrilateral (US FDA Health Canada-PMDA-EMA) agreements to achieve more global consensus	4.3.3.1 Promote global convergence on regulatory requirements through ICMRA, WHO, RAGNA and other international mechanisms	Expanded regulatory interactions through WHO/CEPI and CORC and greater international convergence
	4.3.4 Adopt necessary regulatory flexibilities to support the development and authorisation of countermeasures for use in emergencies, including those caused by chemical, biological, radiation and nuclear threats	4.3.4.1 Support implementation of incentives for CBRN MCMs to be stockpiled	Incentives in place to foster the regulatory submission
	4.3.5 Explore ways to better inform the public about medicines for health threats to engender trust in the medicines and the regulatory system	4.3.5.1 Respond to queries from the public and the media and publish papers to outline scientific positions on vaccines and medicines to be used in emergencies	Progress in combating misinformation about vaccines and medicines used in emergencies
		4.3.5.2 Fund additional studies to answer specific questions about vaccinations not covered by the obligations in marketing authorisations Define with ECDC the scope of vaccine efficacy and post-approval safety studies to be conducted under the auspices of the Vaccine Monitoring Platform	The availability of more robust scientific data on which to base communication for the public Progress in establishment of the VMP
		4.3.5.3 Engage with learned societies and citizens to ensure a good understanding of the value of vaccines while implementing the vaccine outreach strategy, publishing scientific papers and contributing to conferences	Greater effectiveness in the way regulators communicate with the public and healthcare providers

Theme 5: Availability and supply of medicines

Strategic goal	Objective	Activities	Expected results
5.1 Strengthen the availability of medicines to protect public and animal health	5.1.1 Identify specific root causes of shortages for human and veterinary medicines and develop harmonised strategies to improve the prevention and management of shortages, particularly for critical medicines	5.1.1.1 Expand on work completed in 2019 to develop a common EU template with predefined root causes that can be incorporated into national shortage notification systems	More consistency in reporting of root causes across the EU network to inform better management and prevention strategies and interoperability of national IT systems with ESMP
		5.1.1.2 Quantify shortages of veterinary medicines and identify root causes	More clarity on the extent of shortages concerning veterinary medicines
		5.1.1.3 Work with the newly established MSSG Working Group on the Vulnerability Assessment Methodology to identify and evaluate vulnerabilities in the supply chains of critical medicines, ultimately for the application by Member States, in preparation for the proposed pharmaceutical legislation and the Critical Medicines Act	Agreement on at-risk products requiring coordinated actions at the European level, including regulatory support where applicable and in preparation for the proposed pharmaceutical legislation (e.g. MSSG recommendation)
	5.1.2 Improve coordination of activities related to improving availability of human medicines and implement best practices in conjunction with stakeholders and international partners	5.1.2.1 Review outcomes of the pilot phase for the implementation of shortage prevention and mitigation plans and develop proposals for how any identified challenges are to be addressed	Greater oversight of supply chains of critical medicines to manage and prevent shortages and strengthen supply chains
		5.1.2.2 Promote harmonisation of reporting on availability of medicines across the Network Promote the use of machine-to-machine interfacing to facilitate automated data exchange between ESMP and Member States' and Industry systems, based on application programming interfaces (API) developed by the Agency	Greater oversight to manage and prevent shortages and strengthen supply chain of critical medicines
	5.1.3 Work with the European Commission to coordinate national	5.1.3.1 Contribute to EU-level discussions and best practices on	Better coordination and more informed national policies and appropriately weighted

Strategic goal	Objective	Activities	Expected results
	and EU strategies for human medicines, including stockpiling, to reduce the possible impact of national measures on availability of medicines in other countries	national and EU-level approaches to stockpiling and contingency stock requirements, including potential impact on the Voluntary Solidarity Mechanism	measures being introduced, which are effective for shortage prevention as well as management of shortages Promotion of best practices and make available quantitative data that can underpin any recommendations
		5.1.3.2 Develop guidance for MAHs and Member States to ensure effective utilisation of surplus reallocated stocks and best practices at Member State level to support the efficient movement of stocks	Rapid reallocation of stocks across Member States and more timely responses to MS experiencing a critical shortage of a medicine
	5.1.4 Improve transparency and communication on both the launch of medicinal products and shortages with relevant stakeholders, including patients, healthcare professionals and HTA bodies	5.1.4.1 Introduce specific tools and processes for MAHs to maintain up-to-date and correct product-related information and information on marketing status of centrally and nationally authorised products with support from NCAs where required	NCAs can make available to the public and public bodies accurate and up-to-date information related to medicine availability of centrally authorised products, including through applications such as national e-prescribing systems
		5.1.4.2 Make improvements to EMA and NCA public catalogues of shortages making use of developments in related systems and platforms	Comprehensive, improved and timely shortage related information that is publicly available
		5.1.4.3 Promote public awareness and understanding of the role of medicines regulators, and other stakeholders, in relation to shortages	Increased public awareness of intricacies and nuances of the medicines supply chain, as well as the roles and responsibilities of the various stakeholders involved
5.2 Reinforce the oversight and protection of the supply chain and increase inspector capacity	5.2.2 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	5.2.2.1 Develop third country inspection planning cooperation and coordination for all products (CAPs and NAPs)	Use of EudraGMDP 3rd country inspection planning module
		5.2.2.2 Update the CoUP to improve current risk-based approach to inspection planning, including with	Update the CoUP to facilitate use of reliance, hybrid inspections and distant assessment as tools in inspection programmes and to

Strategic goal	Objective	Activities	Expected results
		respect to the use of reliance, hybrid inspection and distant assessment for verification of GMP compliance	improve risk-based approach to inspection planning
	5.2.3 Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines in the supply chain	5.2.3.1 Implement a workplan for the GMDP IWG Working Group on GDP	New/Revised CoUP procedures on GDP aspects. New guidance for wholesalers performing risk assessment on the verification of authenticity of medicinal products at risk of falsification
		5.2.3.2 Implement a joint audit programme for GDP (EU4H11)	A joint audit programme for GDP inspectorates
		5.2.3.3 Coordinate communication actions to raise awareness of the dangers of falsifications to patients	Greater public awareness of the dangers posed by falsified medicines
	5.2.4 Keep good manufacturing practice (GMP) requirements updated in light of technological progress in manufacturing (e.g. with respect to digital, AI and other technological systems)	5.2.4.1 Implement the GMDP IWG work programme with a focus on modernising GMP	Updated guidance such as Chapter 1, Annex 11, Chapter 4 and Annex 15 and new Annex 22
		5.2.4.2 Develop with involvement of QIG and GMDP IWG interim guidance to facilitate implementation of advanced manufacturing technologies where needed	New Q&As published, e.g. for 3D printing
	5.2.5 Improve and inter-link information in current databases (e.g. EudraGMDP)	5.2.5.1 Redevelop EudraGMDP and ensure all Member States enter data in EudraGMDP (e.g. for human and veterinary products for GDP) as required by legislation	Better functioning database (less downtime, user complaints etc) All Member States entering relevant data in EudraGMDP database

Theme 6: Sustainability of the network

Strategic goal	Objective	Activities	Expected results
6.1 Reinforce the scientific and regulatory capacity and capability of the network.	6.1.1 Ensure the network has the capacity and capability to support innovation and the use of new methodologies, AI and data analytics and to be equipped for the new pharmaceutical legislation	6.1.1.1 Conduct surveys and analyses of the network capacity and capabilities to better align with upcoming regulatory work and further develop a model for predicting incoming work in collaboration with stakeholders	Better predictability of incoming work and optimised resource allocation through enhanced oversight and monitoring of the capacity to NCAs to undertake assessment work of upcoming submissions
		6.1.1.2 Increase network capacity through a structured onboarding and training programme for new assessors and strengthen the collaboration on talent management among NCAs	Increased capacity of the network and long-term sustainability
		6.1.1.3 Build capabilities in the network in priority areas through a structured training programme	Increased capabilities in identified areas (e.g. methodology, inspectorate)
	6.1.2 Explore ways to improve efficiency by creating centres of excellence and allocating NCA resources more strategically	6.1.2.1 Complement assessment teams by facilitating the identification and incorporation of external experts in assessment teams	A more flexible and robust model of assessment teams
		6.1.2.2 Develop the clusters of excellence as areas of specialised expertise in the network	More optimal use of resources in areas of need
	6.1.3 Build the network's capability to carry out the digital transformation of its scientific and regulatory processes, knowledge management, ways of working and tools[1]	6.1.3.1 Further streamline the centralised procedure and related documentation and implement new ways of working benefiting from collaborative tools	Increased capacity as a result of improved process efficiency, and use of collaborative tools
		6.1.3.2 Develop and implement a structured, competency-based training architecture that ensures network experts acquire the skills and knowledge required	See activities under goals 2.2 and 2.3

[1] This objective is pursued also through activities under goals 2.2 and 2.3.

Strategic goal	Objective	Activities	Expected results
		to support the digital transformation of scientific and regulatory processes	
6.2 Establish a shared operating model to support network activities and collaboration	6.2.1 For human medicines, prepare for the implementation of new legislation combined with the modernisation and consolidation of IT systems[2]	6.2.1.1 Support the transformation of scientific and regulatory processes by building a digital infrastructure that places end-users at the centre	See activities under goals 2.2 and 2.3
		6.2.1.2 Implement the variations regulation framework and the new classification guidelines	A more streamlined and simplified framework for post-authorisation medicines
		6.2.1.3 Carry out an impact analysis and plan for the implementation of the pharmaceutical legislation	Timely implementation of the new legislative framework
	6.2.2 For veterinary medicines, continue to build on the progress achieved in implementing the veterinary regulation and align IT solutions across sectors	6.2.2.1 Activate the outcome of the implementing and delegated acts derived from the regulation on veterinary medicinal products, especially on the area of GMP and AMR	Full implementation of the veterinary regulation framework, including implementing and delegated acts for GMP, essential substances for horses and aquaculture and, upon request, review of other relevant areas like variations (update of list of VNRAs as needed).
		6.2.2.2 Continuous enhancement of UPD functionality based on EMA product owner, Network product owner and expert stakeholder requirements, including improvements to the VNRA process, bulk data submission process and OPAD processes	Increased data quality and enhanced functionality of the UPD that streamlines operational processes Ability of UPD to supports six times peak daily volume of users seen in 2024. Increased user satisfaction scores in the annual user survey
	6.2.3 Explore opportunities for shared data, process and technology initiatives including AI	6.2.3.1 Enhance the network's engagement in strategic level initiatives/joint actions addressing the	See activities under objective 2.2

[2] This objective is pursued also through activities under goals 2.2 and 2.3.

Strategic goal	Objective	Activities	Expected results
	and establish a model for joint EMA/HMA sponsorship for such initiatives	challenges in the field of network's digitalisation	
		6.2.3.2 Leverage EU and national experience with AI initiatives for the benefit of the network through a coordinated programme (AI workplan)	More AI initiatives solutions developed by the network (EMA, NCAs) made available to the whole network
	6.2.4 Contribute to the implementation of the new EMA fee regulation and regularly monitor and adjust the cost-based system for fees and NCA remuneration	6.2.4.1 Implement the new fee regulation through the timely adaptation of systems, regulatory and financial processes	Maintenance of a high-quality service to MAHs/MAAs and the financial sustainability of the Agency and the network
		6.2.4.2 Implement a mechanism for establishment of fees for new activities and for the revision of existing fees, charges and remunerations	Long-term sustainability of the network
6.3 Strengthen public and stakeholder engagement and global convergence with international partners	6.3.1 Enhance capacity of the network through international convergence, information and work sharing and multilateral cooperation	6.3.1.1 Lead and contribute to guidance development activities in the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)	International harmonisation for the development and assessment of medicines.
		6.3.1.2 Lead and contribute to global harmonisation of requirements for 3Rs and new approach methodologies (NAMs) as part of International Medicines Regulators' Working Group	Global position statement on 3Rs and enhanced global harmonisation of requirements including agreement on acceptance criteria for 'New Approach Methodologies' (NAMs) within specific contexts of use
	6.3.2 Together with the European Commission, strengthen international collaboration to perform legal duties relating to inspections and to face global challenges related to new methodologies and continuous manufacturing	6.3.2.1 Pilot collaborative assessments for post-approval CMC (chemistry, manufacturing, and controls) and hybrid inspections	International convergence and better harmonised outcomes without additional regulatory burden for the industry

Strategic goal	Objective	Activities	Expected results
	6.3.3 Strengthen cooperation between European and international partners and support regulatory systems in EU candidate countries and the African Medicines Agency	6.3.3.1 Leverage EU experience and expertise for the creation of the African Medicines Agency Support the piloting of a joint African assessment Support the roll-out of a training curriculum for assessors and projects to strengthen regulatory systems at the national level in Africa	Strengthened medicines regulation in Africa at the continental and national levels.
		6.3.3.2 Assist beneficiary national competent authorities in aligning their standards and practices with those established in the EU (IPA programme)	Enhanced regulation of medicinal products for human and veterinary use in the region through revised and aligned standards and practices with those of the European Union.
		6.3.3.3 Support WHO reliance pathways, promoting the EU regulatory system and documents that can be used as reliance tools for other national regulatory authorities	Greater use of EU evaluations in WHO reliance
	6.3.4 Develop and implement a framework for communication and stakeholder engagement to address information needs of the public and counter mis/disinformation	6.3.4.1 Revise the joint EMA/HMA communication action plan to further strengthen stakeholder engagement in the network and leverage social media and new tools	Strengthened stakeholder engagement and greater use of social media tools
		6.3.4.2 Strengthen engagement with key stakeholders to support the use of patient experience data in EU medicines development and regulatory decision-making, while also increasing overall transparency	Better decision making of regulatory procedures enriched with valuable supportive data of clinical use of medicines
		6.3.4.3 Develop a communication approach to promptly identify and proactively address false narratives	More proactive engagement with misinformation

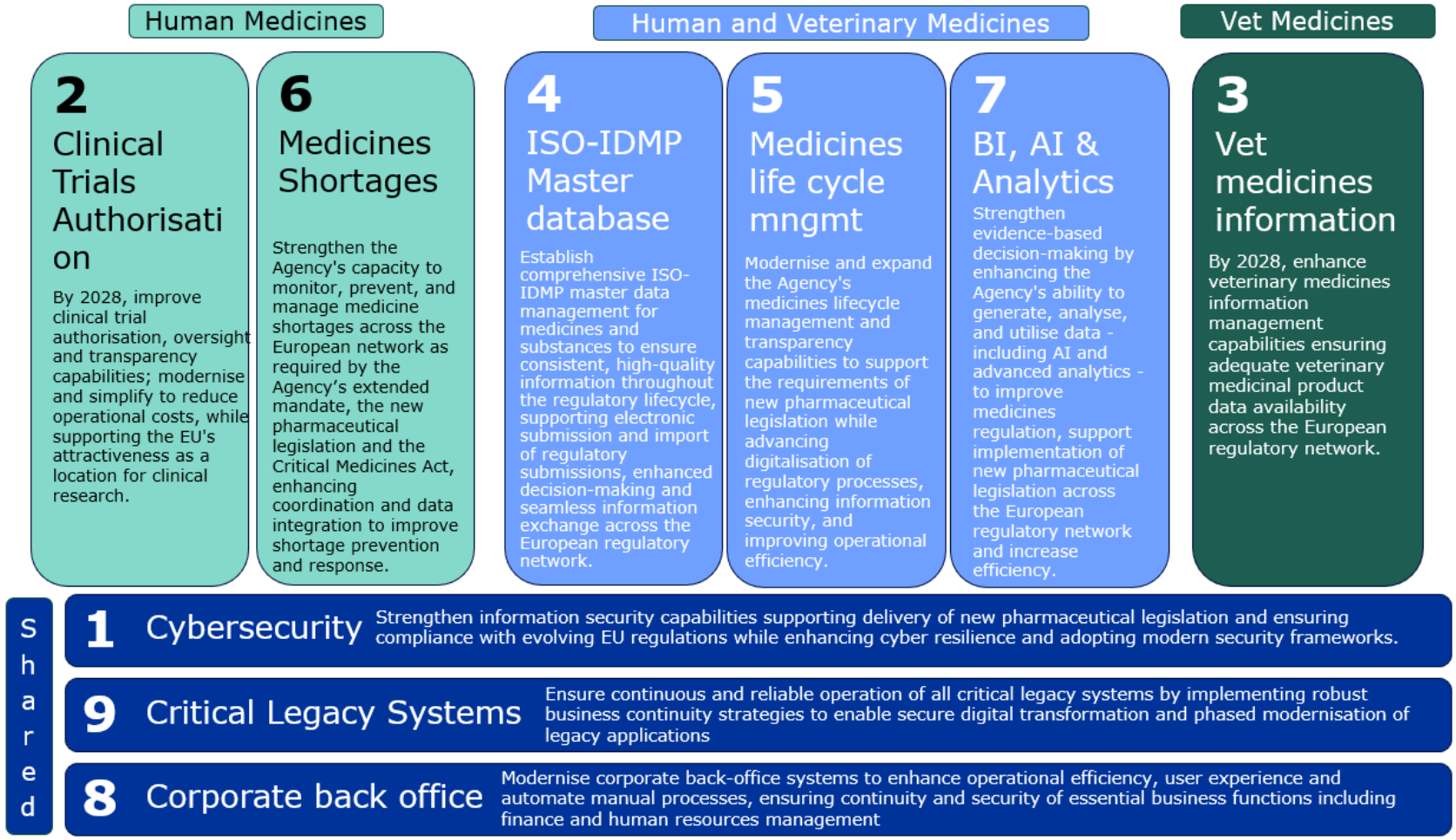
2. Digitalisation initiatives and Network Portfolio

2.1. Digitalisation

The Agency is driving an extensive digitalisation effort to transform into a data-driven, digitally enabled regulator, with the core aim of enhancing regulatory effectiveness, and strengthening the resilience and sustainability of the entire regulatory network. This ambition is guided by a technology vision centred on providing modern digital services through an IT platform strategy, enabling seamless operations and collaboration across the European medicines regulatory network (EMRN). The transformation involves critical activities such as the modernisation of IT systems, adopting a cloud-native enterprise architecture, and developing advanced analytics capabilities to support medicines evaluation. The Agency operates a digital innovation framework (Digilab methodology) to generate hypotheses, redesign processes, and conduct cross-organisational experimentation with new technologies like AI, machine learning and leverage opportunities of citizen development. Furthermore, the Agency is committed to maturing its Agile Transformation, implementing the Scaled Agile Framework (SAFe) methodology to deliver value faster and with higher quality, especially within the Network Portfolio governance. Implementation at scale focuses on maximising customer success through multidisciplinary teams, fostering a modernisation mindset by transitioning legacy systems to secure, cost-efficient cloud platforms, and ensuring operational excellence by strengthening information security and data protection compliance, while also advancing network interoperability in line with legislative requirements. Overall, the Agency utilises a Lean-Agile approach to govern and coordinate all digitalisation efforts, ensuring strategic alignment across the entire regulatory network. A major strategic focus is leveraging artificial intelligence (AI), with multi-annual workplan (overseen by the Network Data Steering Group). The AI workplan will help the EMRN to embrace opportunities of AI personal productivity, automating processes and systems, increasing insights into data and supporting more robust decision-making to benefit public and animal health. These efforts are designed to streamline regulatory workflows, increase transparency, and ensure more robust evidence generation, all while aligning with evolving EU legislation, including preparing for the European Health Data Space and the AI Act. This complex, disruptive change is managed through driving initiatives that profoundly impact the Agency's strategy and operational structure.

2.2. Network Portfolio

The Agency's Network Portfolio focuses on delivering nine multi-annual objectives. These reflect the fundamental purpose of the organisation, align to the overall value it provides (e.g. safe and effective medicines for the public, discovery of innovative medicines that address unmet medical needs, etc.) and support the achievement of the long-term strategic goals set out in the EMANS 2028 Strategy, as well as Agency's corporate enhancement.



EMA contribution to the implementation of EU priorities and policies

The Agency, in compliance with Article 32 (2) of the Framework Financial Regulation, contributes to the implementation of the EU political priorities. For the period 2024–2029, the European Commission has identified the following priorities:

1. A new plan for Europe's sustainable prosperity and competitiveness.
2. A new era for European Defence and Security.
3. Supporting people, strengthening our societies and our social model.
4. Sustaining our quality of life: food security, water and nature.
5. Protecting our democracy, upholding our values.
6. A global Europe: leveraging our power and partnerships.

In line with its mandate, EMA supports the implementation of a selection of EU policies by executing its multi-annual strategy and by pursuing its strategic goals (for the exhaustive list and details of the strategic goals, please refer to the table in the previous section *EMANS Implementation Themes)*. Specifically, the contribution of the Agency focuses on the following priorities:

EC Priority (ECP)	EC Policy/Action	EMA MAWP area	EMA MAWP reference
1. A new plan for Europe's sustainable prosperity and competitiveness.	*A clean industrial deal*	B.1 EMANS 2028	Theme 3 Regulatory science, innovation and competitiveness Theme 4 Antimicrobial resistance and other health threat Theme 6 Sustainability of the network
	A more circular and resilient economy	B.1 EMANS 2028 A.2 Horizontal public and animal health activities	Theme 1 Accessibility Theme 2 Leveraging data, digitalisation and artificial intelligence Theme 5 Availability and supply of medicines 2.7 Competitiveness
	EU strategy for data — Boosting productivity with digital tech diffusion	B.1 EMANS 2028	Theme 2 Leveraging data, digitalisation and artificial intelligence

EC Priority (ECP)	EC Policy/Action	EMA MAWP area	EMA MAWP reference
2. A new era for European Defence and Security.	*A preparedness Union*	B.1 EMANS 2028 A.2 Horizontal public and animal health activities	Theme 4 Antimicrobial resistance and other health threats 2.4 Public health threats
5. Protecting our democracy, upholding our values.	*Protecting our democracy*	A.1 Product related activities	1.3.7 International cooperation 1.3.8 Communication activities
	Protecting citizens at the heart of our democracy	A.1 Product related activities	1.3.7 International cooperation 1.3.8 Communication activities
6. A global Europe: leveraging our power and partnership	*Enlargement as a geopolitical imperative*	A.1 Product related activities	1.3.7 International cooperation
	A new economic foreign policy	A.1 Product related activities	1.3.7 International cooperation

Human and financial resources – outlook for the years 2026–2028

Overview of the past and current situation

Overview

In 2025, the total budget (revenue and expenditure), as adopted by the EMA Management Board on 12 December 2024, amounted to €600,230,000. On the revenue side, this included €549,320,000 in fee revenues and contributions from the EU budget totalling €48,914,000 and miscellaneous revenues for €1,996,000. On the expenditure side, this included €183,127,000 in Title I: staff expenditure; €92,067,000 in Title II infrastructure and operating/IT expenditure; in Title III: operational expenditure a total of €325,036,000.

The staffing ceilings in 2025 were 704 temporary agents (TA), 203 contract agents (CA) and 45 national experts on secondment (SNE). This staffing level is determined by additional 23 new pharmaceutical legislation related TA posts and a reduction of an additional 10 out of 40 time-bound TA posts. The remaining 20 time-bound posts will be reduced during 2026. Throughout the year, the Agency operated an occupancy rate close to 100%.

Outlook for the years 2026-2028

New tasks

On 26 April 2023, the European Commission presented a draft legal proposal for the revision of the pharmaceutical legislation. The draft texts include a number of very significant changes to the authorisation framework, along with a set of potential new tasks for the Agency. At the time of drafting of this document the legislative procedure is still ongoing, therefore the Agency will elaborate more specifically on additional new tasks in future Single programming documents once the final text is adopted. During 2026 the Agency will continue to look into preparation for the implementation of the legislative proposal and use this opportunity to future proof medicines regulation in the EU and the work of EMA within the EU medicines regulatory network. As for financial resources the draft proposal includes €1.172 million of EU contribution for 2026. With regard to additional human resources, the draft proposal includes 19 TA posts as for 2024, 18 TA posts as from 2025 and 15 TA posts as from 2026.

During 2026 the Agency expects the entry into force also of the 'one substance one assessment' legislative package and of the Critical Medicines Act proposal. Both initiatives include additional human resources for EMA, namely: 4 time-bound CA posts for a period of three years for 1S1A and 3 TA posts for the Critical Medicines Act.

Growth of existing tasks

EMA's fee-funded workload continues to grow every year due to the increasing number of authorised Centrally Authorised Products (hence, more fee-funded post-authorisation monitoring and maintenance activities) and new or expanding activities. On average, each newly authorised product generates 27 subsequent post-authorisation applications, and numerous associated activities in the areas of pharmacovigilance, access to documents, requests for information, legal aspects, requests for international cooperation and information exchange. The product portfolio increases by around 100 new products each year. In addition to application-related workload, significant new tasks, both legislative and non-legislative, have been assigned to the Agency over the last years (e.g. significant growth in demand linked to access to documents legislation,

implementation of GDPR/EUDPR, Medical Device Regulation, Clinical Trials Regulation, early support to innovation, regulatory science research and competitiveness). The impact of these tasks on EMA was either not foreseen in the original Financial Statements of the European Commission, or concerned additional activities which were added by co-legislators during the legislative process, or were tasks requested by the Commission within EMA's mandate but requiring significant EMA resources (e.g. ad-hoc requests for scientific opinions, input for Commission evaluations and impact assessments, contributions to initiatives under new EU strategies).

In the short term, EMA has managed to absorb some of the above-mentioned activities, both fee-related and new legislation-related, through efficiency gains and effective staff reallocation. This has led to an increased reliance on short-term staffing contracts, as Contract Agents or, of even more concern, short-term 'interim' contracts and contractors. Following the EC decision to grant 12 additional TAs for workload related activities in 2026, the Agency has identified that for 2027 a minimum of an additional 43 TA posts is required for the Agency to remain sustainable and deliver on our public health responsibilities. These posts could be funded from the increasing level of fee-generating activities, at no additional cost to the EU budget.

Resource programming for the years 2026-2028

Financial resources

In 2026, the total revenue from fees is expected to reach €563.2 million based on the new Fee Regulation (EU) 2024/568 on fees and charges payable to EMA, which became applicable in 2025. For 2026 the EU/EEA contribution is set at €50.8 million, out of which a portion relates to London premises, and the rest is in line with the Multiannual Financial Framework. The orphan medicinal products contribution in the draft budget 2026 and preliminary draft budget 2027 reflects the amount proposed in the EU budget. Staff expenditures include the salary increase proposed by the European Commission for 2025 and 2026. The 2026 and 2027 budgets include EU funding for EMA premises in London. IT project development is expected to remain stable compared to 2025 budget delivering the portfolio of projects described in this document and maintaining the IT operations infrastructure supporting both pan-European databases and Agency-specific applications.

Human resources

The draft budget 2026 includes 10 permanent TA posts to cover business as usual activities, 10 additional TA posts linked to the preparatory activities of the new pharmaceutical legislation, and 12 additional fees financed TA posts granted to cope with additional workload increase driven by the growing products portfolio and by the additional obligations put on the Agency by various legislative proposals. Moreover, it includes 3 additional TA posts linked to the Critical Medicines Act, published by the European Commission in March 2025. Lastly, the draft budget 2026 reflects the termination of the remaining 20 TA posts that were awarded in 2021 to cope with the extra workload linked to the response to the COVID-19 pandemic.

Following the implementation of the NPL related staffing plan, the Agency is deemed to receive 8 additional TA posts in 2027.

In addition, the Agency will request for 2027 43 TA posts to cater for the growth of existing tasks, as follows:

For the 2027 preliminary draft budget, the Agency will request an additional 43 TA posts to cater for the growth of existing tasks, as follows.

- 14 additional TA posts for workload linked to the growing product portfolio. Detailed justification for this request is provided above under *Growth of existing tasks*. This request becomes even more significant in view of the entry into force of the Regulation (EU) 2024/568 on fees and charges payable to EMA and the consequences this will have on stakeholders' expectations for the level of services to be provided by the Agency.
- 12 posts for additional tasks in anticipation of the new pharmaceutical legislation (NPL), including increased management of Centrally Authorised Products (CAPs) and Nationally Authorised Products (NAPs) critical shortages and European Shortages Monitoring Platform (ESMP) extension of functionalities, as well as additional task related to the Critical Medicine Act e.g. the Methodology for and conduct of Vulnerability analyses of the supply chain of Critical medicines.
- 5 additional TA posts linked to the implementation of Regulation (EU) 536/2014 (Clinical Trials Regulation – not including changes from the Biotech Act). The Agency is running all support IT infrastructure and coordinating operations and user and stakeholder support heavily relying on unstable resource including interims and seconded national experts. Therefore, there is a critical need to stabilise the teams implementing legislative requirements for which EMA never received any compensation posts. Moreover, these resources would also contribute to the expedition of the integration between the EU HTA IT platform and internal EMA systems (IRIS) as well as to the IT support, development and use of electronic Product Information (ePI) for human medicines.
- 5 posts for activities linked to support the implementation of the EC Life Science Strategy, including the operational support to early innovation competitiveness, forecasting and Horizon scanning activities and regulatory science research. Additional investment is needed in the management of partnerships toward regulatory preparedness. Overall support to EU competitiveness strategies, with significant increase of direct engagement with EU Technology and scientific clusters.
- 2 additional posts for the implementation and operation of Regulation EU 2024/1689 (the AI Act). The Agency has never received any compensation posts for the implementation of this legislation which places important requirements for AI risk management and reporting and support to stakeholders including guidance (not including provisions in the Biotech Act).
- 1 additional TA post to enhanced cooperation with regulatory authorities in the Latin America and Caribbean Region and contribute to supporting the development of the regulatory agency for medicines in Latin America and the Caribbean (AMLAC).
- 3 additional TAs to support communication, stakeholder engagement and transparency related activities including work to address the rising tide of mis-/dis- information on medicines, as well as in the remit of the right of access to EU documents as established by Regulation (EC) No. 1049/2001 (Articles 7 and 8).
- 1 additional TA post due to higher operational demands with increased security responsibility and complexity, as well as increased risk exposure levels for the Agency over the past years, following the relocation of EMA offices.

As explained under '*Growth of existing tasks*, the granting of these additional posts request would alleviate the Agency's reliance on short term staffing contract, de facto making a more efficient and effective use of the Agency's fee income budget.

Lastly, the Agency invites the EC to consider the resourcing impact that upcoming legislative proposals will have on EMA. EMA is aware that at least two imminent pieces of legislation may possibly have significant resource implications for the work of the Agency depending on the final tasks proposed by the EC and the subsequent agreement in Council. However, proposals for

staffing requirements prior to finalisation of any legislative text would be premature at the time of drafting of this document. The Agency therefore invites the EC to consider the resourcing impact that upcoming legislative proposals will have on EMA so that these estimates can be adapted if necessary. This is particularly relevant for proposals such as the Biotech act, revision of the Medical Devices Regulation, EC Life Science Strategy, New Cybersecurity Regulation, AI Act, EHDS, EUDPS, and various cross-sectoral regulations.

Strategy for achieving efficiency gains

The Agency's product portfolio increases by around 100 new products each year. In addition, over the course of the same period, the Agency has been given responsibility for significant new legal tasks, such as developing and managing of a pan-European clinical trials database. Throughout this period, the Agency has clearly demonstrated significant productivity gains and more efficient ways of working.

Considering the changes for the upcoming years, EMA will keep further developing its efficiency gains strategy mainly following two dimensions: a) process improvement; b) digitalisation.

Process improvement: The Agency keeps focusing on process review to complete the integration of the Human Medicines Division activities, as a result of the future proofing project drivers. The exercise has two goals: the first is to revise the operations to increase efficiency and support a time and capacity model, and the second is to prepare optimised processes for transfer to the IRIS Platform. In the long run, the same structure will be used for all Agency processes.

Furthermore, the new pharmaceutical legislation will introduce further novelties in the way that medicines regulation operates in Europe. In this context, the review of the existing processes will be required. Such processes will be reviewed with the possibility to optimise them as much as it is possible while addressing the new legal framework in the future. Lastly, while resourcing constraints will not allow to deliver the full scope at the necessary pace, the Agency will strive to address in 2026 also the requirements of the HTA Regulation for exchange of information through the HTA IT platform.

Agile governance: One of the flagship projects of the Agency is the introduction of a Lean-Agile (SAFe) methodology in the context of the implementation of the new Network Portfolio governance at EMA. The Scaled Agile Framework (SAFe) is a methodology that helps organisations to scale agile practices to deliver value to customers faster and with higher quality. It provides a set of principles, best practices, and tools for developing and delivering large-scale, complex software systems. The objective is to cope with longer planning horizons, ensuring the necessary level of accountability in the deliverables and be driven by business value. This approach is expected to improve the synchronisation of deliverables, granting sufficient space for the introduction of innovation and best practices in the operations of the Agency. In 2023, the Agency decided to further support its journey to implement the Lean-Agile (SAFe) way of working in the Network Portfolio across its value streams by establishing a Lean-Agile Centre of Excellence (LACE) team. LACE's vision is to implement the Lean-Agile (SAFe) way of working in the Network Portfolio across its value streams within 3 years and explore how it can be applied across EMA's operations within 5 years. In 2026, the Agency will continue working to strengthen the Network Portfolio maturity to supports the innovation, digitalisation and automation of its activities, while allowing for rapid process adaptation to enhance agility and efficiency. The implementation of Agile practices and principles will continue in key business areas, such as HR, and will be explored further in emerging business areas. This approach aims to foster the cultural shift necessary to anticipate and address the future challenges faced by the Agency.

Digitalisation: In a constantly evolving environment, the Agency is embracing digital transformation to ensure a proper response. In 2020, to develop and execute a digitalisation strategy, the Agency equipped itself with a Digital Business Transformation Task Force. In 2026, it continues to develop digitalisation activities by:

- accelerating the development of Digital and Analytics Solutions through the creation of the Analytics Centre of Excellence (ACE) and the Digital Innovation Lab (DigiLab):
    - ACE is a digital toolbox experimentation hub where the Agency tests and expands its capacity to experiment with new analytics technologies such as artificial intelligence (AI) and machine learning in relation to business-process design, automation, information, and knowledge management. Automated recognition of personal data in documents, reengineering the procurement process, and utilising AI to find anomalies between submission data in documents and databases are just a few examples of initiatives.
    - DigiLab is a framework designed to deliver services to support experimentation with digital innovation, including novel technologies. The goal is to find solutions to existing and emerging business needs where digital technologies can improve or radically change the way the Agency work.
- establishing the Digital Change Workstream to manage digital transformation programme and oversight, digital change management and digital capability and capacity building. The workstream drives complex digital change initiatives that impact on the strategy of EMA, its structure and operations in relation to the Network, its partners and stakeholders. Its objective is to adapt EMA operations to fundamental changes brought by legislative initiatives, digital technologies and global trends, to meet stakeholders' needs and expectations.
- continuation of EMA core business process digitalisation via IRIS – a modern and secure online platform to handle knowledge and regulatory and scientific procedures. The platform integrates data and information from other EMA systems to provide an efficient and user-friendly portal for applicants and tools to increase efficiency in managing regulatory procedures for EMA staff, Committees and experts of the EU medicines regulatory network.
- improving the electronic submissions process by replacing electronic application forms with a modern and adaptable digital interface that better supports data integration and process efficiencies across the product lifecycle.

Complementing the work done by the Digital Business Transformation Task Force, the Administration Division runs specific programme targeting the revamping and streamlining of the HR processes and IT tools and, in parallel, the enhancement of the financial and reporting systems. The objective over the years is to increase the efficiency of the processes, freeing staff capacity to deal with added value tasks.

Negative priorities

In line with European Commission guideline for drafting the Single Programming Document, section identifies activities where the scope and speed of implementation are currently calibrated to existing staff levels, noting that additional posts investment would enable a more ambitious scope and accelerated delivery.

As described in sections 2.2 and 2.3 above, EMA's fee-funded workload continues to grow every year due to the increasing number of authorised Centrally Authorised Products which have implications across EMA activities, from scientific advice, assessment and post authorisation work, to access to documents, communication, stakeholder engagement, legal and regulatory matters, data management and international collaboration. These activities have not received corresponding increase in staffing. Even though, some of the new tasks that have been assigned to the Agency over the last years received increase in EMA's staff establishment plan, a significant number of new tasks entrusted to the Agency in the past have not. Thus far, this situation has been managed through efficiency gains and effective staff reallocation, as described under section 2.4 above. It has, however, also required increased reliance on Contract Agents and on short-term 'interim' contracts and contractors. The high costs and lack of long-term stability associated with using these types of resources is not sustainable and is restricting the Agency's ability to optimise its contribution to a robust and sustainable European Health Union.
More specifically, the following areas have marked an increase in workload and despite being supported through the above-mentioned alternative resourcing streams, the investment of additional TAs would greatly enhance the Agency's capacity to adequately deliver on some important activities, notably:

- The proactive technology lifecycle management to replace/upgrade obsolete hardware and software, ensuring that all critical systems are maintained with up-to-date and supported technologies. As the Agency cannot maintain a sustained pace, the reliance on obsolete hardware and software increases the risk of operational disruptions impacting the entire EMRN. Furthermore, this reliance on ageing systems undermines the Agency's ability to respond effectively to new requirements likely to arise from forthcoming legislation such as the Bio Tech Act and the new pharma legislation.
- The strategic assessment of the opportunities that the development and integration of AI functionalities could offer for the EMRN.
- The management of the workload with regard to various transparency related activities, including in the remit of the right of access to EU documents as established by Regulation (EC) No. 1049/2001 (Articles 7 and 8).
- International regulatory cooperative activities, in particular enhancing cooperation with Latin American countries.

Part III: Work programme 2026

Executive summary

For the 2026 planning cycle the Agency has revised the structure of its Single programming document. The structure of the 2026 Annual work programme now mirrors the 2026–28 Multi-annual programming document structure, which is organised around two blocks:

A. Statutory activities, which encompass **1)** product-related activities supporting the development, evaluation, and monitoring of medicines to ensure their safety, efficacy, and quality, **2)** horizontal public health activities **3)** corporate activities and *B. Strategic transformation initiatives* which include **1)** specific time-bound multi-annual goals and objectives included in the overall Network strategy to 2028. **2)** Digitalisation and Network Portfolio activities, aiming at enhancing efficiency and effectiveness of the current operations.

The 2026 Annual work programme includes, where relevant, detailed workload and performance indicators to measure the implementation of each of these areas of work. For ease of reference, the areas of work under each of the two blocks have been reproduced in the following table:

Block	Level 1	Level 2	Level 3
A. Statutory activities	1. Product related activities	1.1 Evaluation and supervision of human medicines	1.1.1 Pre-authorisation activities
			1.1.2 Initial evaluation
			1.1.3 Post-authorisation
			1.1.4 Referrals
			1.1.5 Pharmacovigilance activities
			1.1.6 Cooperation with the HTA Coordination Group
		1.2 Evaluation and supervision of veterinary medicines	1.2.1 Pre-authorisation activities
			1.2.2 Initial evaluation
			1.2.3 Post-authorisation activities
			1.2.4 Arbitrations and referrals
			1.2.5 Pharmacovigilance activities
		1.3 Horizontal and other product related activities	1.3.1 Inspections and compliance
			1.3.2 Committees, working parties, and expert management

Block	Level 1	Level 2	Level 3
			1.3.3 Medical devices
			1.3.4 Data governance and data management
			1.3.5 Strengthening methodology and decision making
			1.3.6 Clinical trials
			1.3.7 Real world evidence
			1.3.8 Small and medium sized enterprises
			1.3.9 International cooperation
			1.3.10 Communication activities
			1.3.11 Public and stakeholders engagement
			1.3.12 Transparency
	2. Horizontal public and animal health activities	2.1 Innovation and development	
		2.2 Regulatory science and academia	
		2.3 Supply and availability of medicines and medical devices	
		2.4 Public health threats	
		2.5 One Health	
		2.6 EMRN capacity and capability building	
		2.7 Crisis management	
		2.8 Competitiveness	
		2.9 Implementation of the Common Data Platform on Chemicals under the 'one substance, one assessment' legislation	
	3. Corporate activities	3.1 Corporate governance	
		3.2 Legal affairs	
		3.3 Institutional affairs	
		3.4 Information management	
		3.5 Information security	
		3.6 Administration activities	3.6.1 Human resources
			3.6.2 Finance

Block	Level 1	Level 2	Level 3
B. Strategic Transformation initiatives	1. EMANS 2028 implementation		
	2. Digitalisation initiatives and Network Portfolio	2.1 Digitalisation	
		2.2 Network Portfolio	

With several significant legislative initiatives on the horizon, 2026 is likely to be one of the most transformative years for the European Union's regulatory pharmaceutical landscape. To address the challenges of these rapid and unprecedented changes, the Agency will place particular focus on three areas: leveraging the changes introduced by the new pharmaceutical legislation to *reimagine EMA* so that it can pursue its new vision of *a fast path from innovation to safe and effective medicines, supporting innovation for public and animal health* and *investing in its staff and the network of tomorrow* to ensure that the EU regulatory network is equipped with the necessary capacities and capabilities to deliver the forthcoming transformation.

The Agency will not only work on modernising regulatory processes but also on establishing the foundation for a more agile and data-driven regulatory system. This work aims at simplifying regulatory pathways and fostering collaboration across the EU network, creating an environment where innovation can translate more efficiently into benefits for patients and animals. EMA will also step up its early engagement activities following a strategic revision and optimisation of its operating model for development support, complemented by an expanded outreach effort to biotech hubs, academia, and investors. This will strengthen the embedment of regulatory science in Europe's innovation ecosystem. The Agency will maintain a significant focus on strengthening evidence planning and generation including through DARWIN EU®, enabling real-world data to inform regulatory decisions, and modernising clinical trial methodologies to deliver more impactful outcomes.

Ultimately, people are at the heart of our regulatory system, and it is only through the work and commitment of our staff and experts that we can deliver on all these ambitions. Resourcing of our network remains a significant challenge, and this has been the focus of work of the joint EMA/HMA Strategic Resource Oversight Group (SROG) since 2022. In 2026, we foresee investments in expanding capacity and capabilities through clusters of excellence and expert pools, while equipping the EMRN workforce with new skills in AI, agile methodologies, and change management.

Lastly, at a time when reinforcing trust in science and institutions is more critical than ever, during 2026 the Agency will continue to strengthen visibility and actively counter misinformation and disinformation, addressing anti-scientific narratives by working closely with partners and stakeholders and by adopting innovative communication strategies that reach diverse audiences. We will do this together with the Network as we remain committed to the principles of transparency, scientific excellence, and trust that underpin the European medicines regulatory system.

With these investments the Agency aims at ensuring that the network remains resilient, adaptive, and ready to meet future challenges.

A) Statutory activities

1. Product related activities

1.1. Evaluation and supervision of human medicines

1.1.1. Pre-authorisation activities

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Scientific advice and protocol assistance (non-exhaustive list)	Total scientific-advice and protocol-assistance requests	766	720	785	785	801
	Requests for parallel scientific advice and protocol assistance with international regulators	1	4	4	4	4
	Requests for parallel scientific advice and protocol assistance with HTA	3	8	10	10	10
	Scientific advice for PRIME products	42	40	44	44	44
	Protocol-assistance and follow-up requests	131	128	140	140	143
	Requests for qualification of novel methodologies	14	16	17	17	17
	Scientific advice by ETF	24	28	30	28	28
Supporting the development of PRIority MEdicines	PRIME eligibility requests received	58	60	60	60	60
Orphan medicinal product designation and related maintenance procedures	Applications for orphan designation received	193	210	210	210	210
Development of medicines for children	Total paediatric-procedure applications received	771	799	807	835	844
Classification and certification of advanced therapy medicinal products (ATMPs)	Submitted requests for ATMP classification	40	40	40	40	40

1.1.2. Initial evaluation

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Scientific assessment of medicines submitted for centralised marketing authorisation	Non-orphan medicinal products	33	50	50	52	53
	Orphan medicinal products	21	28	28	24	24
	Similar biological products	41	24	24	27	27
	Generics, hybrid, informed-consent applications, etc.	15	17	16	14	14
	Scientific opinions for non-EU markets (Art 58)	1	1	1	1	1
	Paediatric-use marketing authorisations	3	3	1	1	1
	Requests for accelerated assessment accepted	4	5	6	6	6
	ATMP marketing authorisation application requests received	7	5	5	5	5
	Reviews on the maintenance of the orphan designation criteria at MAA stage	30	40	30	30	30

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Scientific assessment of medicines submitted for centralised marketing authorisation	% of initial marketing authorisation applications that had received centralised scientific advice	-	70%	65%	65%	65%
	Average assessment time for new active substances and biosimilars	198.45	205	205	205	205
	Average clock-stop for new active substances and biosimilars	169.80	180	150	140	140
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	75.00%	50%	50%	50%	50%

1.1.3. Post-authorisation activities

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Variations to marketing authorisations	Type IA variations	3,931	4,000	4,000	4,000	4,000
	Type IB variations	3,323	3,750	3,750	3,750	3,750
	Type II variations	1,333	1,411	1,204	1,214	1,226
Line extensions of marketing authorisations	Extensions of marketing authorisations	33	35	35	39	39

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Maintenance activities	Average assessment time for variations that include extension of indication	184.92	180	180	180	180

1.1.4. Referrals

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Referrals	Pharmacovigilance-related referrals	2	4	4	4	4
	Other referral procedures	3	7	7	7	7

1.1.5. Pharmacovigilance activities

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Pharmacovigilance	Signals peer-reviewed by EMA	1,254	1,200	1,100	1,100	1,100
	Number of ICSRs for CAPs (reports received)	1,230,390	1,500,000	1,500,000	1,500,000	1,500,000
	Signals assessed by PRAC (validated by EMA)	39	40	40	40	40
	PSURs (standalone CAPs only) started	627	556	580	604	607
	PSURs single assessment (CAPs with NAPs) started	49	54	46	53	53
	PSURs single assessment (NAPs only) started	234	308	320	341	343

1.1.6. Cooperation with the HTA Coordination Group

Workload indicator for this area of work is covered in 1.1.1.

1.2. Evaluation and supervision of veterinary medicines

1.2.1. Pre-authorisation activities

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Scientific advice	Scientific advice requests received and validated	27	20	20	20	20
Limited markets	Requests for classification as limited market under Article 4(29) and eligibility under Article 23	14	12	10	10	10

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Scientific advice	Scientific advice procedures completed within set timeframes	100.00%	100%	100%	100%	100%

1.2.2. Initial evaluation

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Initial evaluation	Initial marketing authorisation applications	27	29	23	23	23
Establishment of MRLs	New MRL applications	0	0	0	0	0
	MRL extension/modification applications	4	2	2	2	2
	MRL extrapolations	0	1	1	0	0
Other MRLs activities	Review of draft Codex MRLs	9	5	5	5	5

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Initial evaluation	Initial procedures completed within legal timeframes	100.00%	100%	100%	100%	100%

1.2.3. Post-authorisation activities

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Variations requiring assessment	Total variations	268	320	320	320	336
	Variations level 1	3	2	2	2	2
	Variations level 2	63	91	91	91	96
	Variations level 3	77	97	97	97	102
	Variations level 4	125	110	110	110	116
Maintenance activities	Transfers of marketing authorisations	3	0	1	1	1

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Maintenance activities	Post-authorisation applications evaluated within the legal timeframes	99.00%	100%	100%	100%	100%

1.2.4. Arbitrations and referrals

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Arbitration procedures	Total arbitrations and referrals	1	3	3	3	3

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Referrals	Referral procedures managed within the legal timelines	100%	100%	100%	100%	100%

1.2.5. Pharmacovigilance activities

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Pharmacovigilance activities	Annual statements submitted by MAHs	100%	100%	100%	100%	100%
	G.I.19 submitted by MAHs further to regulator's signal management recommendation	100%	100%	100%	100%	100%
	Unrecorded AEs out of the total number of AEs reported[3]	-	-	4%	4%	4%

[3] New indicator introduced in 2026 work programme.

1.3. Horizontal and other product related activities

1.3.1. Inspections and compliance

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Coordination of inspections	GMP (excluding PMF)	134	405	396	370	377
	GLP	1	0	1	1	1
	GCP	93	108	111	114	116
	Pharmacovigilance	18	11	12	12	12
	PMF	76	60	60	60	60
Quality defects	Notifications of suspected quality defects	395	450	450	450	450
Sampling and testing programme	Medicinal products included in the sampling and testing programme	83	70	94	90	90
Certificates	Standard certificate requests	4,845	9,850	9,998	10,148	10,249
	Urgent certificate requests	985	2,488	2,525	2,563	2,589
Parallel distribution	Parallel distribution initial notifications	2,656	2,800	2,860	2,930	2,959
	Parallel distribution annual updates	5,691	5,500	5,900	6,200	6,262

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Certificates	Standard certificates issued within the established timelines (30 working days)	100.00%	90%	90%	90%	90%
	Average days to issue standard certificate	6.00	15	15	15	15
	Urgent certificates issued within established timelines (2 working days)	99.00%	98%	98%	98%	98%
Parallel distribution	Parallel distribution initial notifications checked for compliance within the established timeline	98.00%	98%	98%	98%	98%

1.3.2. Committees, working parties, and expert management

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Meeting management	Number of reimbursed meetings	257	334	334	334	334
	Committee meetings	76	76	76	76	76
	Working Parties	60	29	29	29	29
	Workshops, Forum, Seminars, Infoday	46	39	39	39	39
	Other meetings	104	190	190	190	190
	Number of virtual meetings (audio-, video- and web conferences)	1,609	6,500	6,500	6,500	6,500
	Number of reimbursed delegates	3,759	5,000	5,000	5,000	5,000
	Number of non-reimbursed delegates	1,347	1,500	1,500	1,500	1,500
Herbal medicinal products	New herbal monographs	1	1	1	1	1
	Reviewed herbal monographs	15	20	20	20	20
	Revised herbal monographs	10	5	5	5	5
	List entries	2	1	1	1	1

1.3.3. Medical devices

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Medical devices	Medical Devices with an ancillary medicinal substance	1	1	1	1	1
	Companion diagnostics opinions	10	15	15	15	15
	Number of CECPs and PECPs	77	103	85	85	70
	Number of advices to manufactures	17	2	5	5	5

1.3.4. Data governance and data management

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Data governance and analytics	Number of data board activities supported[4]	-	-	20	20	20

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Healthcare data	RFI and Service Desk requests related to EudraVigilance and to Art.57/PhV Fees data analyses addressed according to set timelines	94.00%	90%	90%	90%	90%
	Percentage of monthly updates of the ADR report website performed according to the timelines	100.00%	90%	90%	90%	90%
	Percentage of EV QAT Service Desk requests addressed according to set timelines	-	-	90%	90%	90%
Data governance and analytics[5]	Percentage of Data Asset entry completion in the EMA Data Catalogue	-	-	90%	90%	90%
	Percentage of completion of mandatory metadata fields of entered Data Assets in the EMA Data Catalogue	-	-	100%	100%	100%

[4] New indicator added in the 2026 work programme. NDSG Meetings, Data Board Meetings, Data Strategy Area Leads Meetings, Data Community Meetings
[5] New indicators added in the 2026 work programme.

1.3.5. Strengthening methodology and decision making

Workload Indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Methodology	Number of methodological advice provided on product procedures	71	80	90	100	150
	Number of active methodology guideline drafting groups led by MWP	12	15	15	15	15
	Number of methodological contributions to guidelines led by other committees and working parties	11	15	15	15	15

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Methodology	Product procedure requests for methodological support completed as per timelines	100.00%	90%	90%	90%	90%
	Planned MWP contribution to guidelines led by other committees and working parties	100.00%	75%	75%	75%	75%

1.3.6. Clinical trials

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Clinical trials systems	Number of business validation for CTIS releases	20	18	18	18	18
	Number of KPIs reports published[6]	11	4	4	4	4
	Number of EudraCT reports and number of CTIS data analyses and reporting[7]	144	110	110	110	110

[6] Under ACT EU, EMRN publishes statistics on the authorisation of clinical trials in the EU/EEA. This information provides an insight into how the CTR is transforming the clinical trial environment in the EU/EEA. The reports are based on data retrieved from CTIS Implementation progress reports.
[7] Including ad-hoc and regular reporting (weekly dashboards for bi-weekly newsflash, MB monthly reports, ACT EU KPI reports, CTCG).

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Clinical trials transformation	Number of regular CTIS/CTR events[8]	76	86	86	86	86
	Number of CT highlights newsletters	-	-	11	11	11
	Number of ACT EU multi-stakeholder workshops[9]	10	12	12	12	12

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Clinical trials systems	RFI and Service Desk requests related to CTIS and EudraCT Business addressed within set timelines	73.00%	90%	90%	75%	75%
	WHO XML upload for CTIS (monthly) and EudraCT (weekly) with the expected scope of records	100.00%	90%	90%	90%	90%
Clinical trials transformation	ACT EU multi-stakeholder workshops organised according to workplan	83.00%	80%	80%	80%	80%
	Support to the secretariat for CTCG and physical hosting 4 times per year	100.00%	100%	100%	100%	100%
	Provide secretariat for CTCG weekly assessors round table	100.00%	100%	100%	100%	100%

1.3.7. Real-world evidence (RWE)

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Real-world evidence	Number of non-interventional studies performed (ongoing or completed)	59	60	60	60	60

[8] CTIS Walk-in Clinics, Bitesize talks, Quarterly CTIS Forum with Stakeholders, CTIS Info event, CTCG Plenary, Assessors Roundtables, CTIS Sponsor End-user training, CTIS POEG.
[9] Led and co-organised events; including multi-stakeholder platform (MSP) advisory group.

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Real-world evidence	Studies performed within less than 26 weeks[10]	66.00%	60%	60%	60%	60%
	Non-Interventional Study (NIS) protocols and summary results registered in HMA/EMA Catalogue of RWD studies within a month after finalisation	100%	90%	90%	90%	90%

1.3.8. Small and medium sized enterprises

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
SME support	Regulatory assistance delivered	246	205	255	266	266
	SME briefing meetings	3	5	7	9	9
	Requests for SME qualification	374	410	418	437	437
	Requests for SME status renewal	1,412	1,389	1,436	1,456	1,456
	Workshops organised (SME support)	0	1	1	1	1

[10] Excluding framework contract studies.

1.3.9. International cooperation

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
International affairs	Number of product-related interactions with international stakeholders – including requests for information and requests for documents	269	250	250	250	250
	Number of participations in external forums	30	40	40	40	40
	Number of external participants in training organised by International Affairs	679	750	500	500	500
	Number of visits to EMA / fellowships organised by International Affairs	12	12	15	15	15

1.3.10. Communication activities

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Communication activities	Number of documents published on EMA website	7,490	7,500	7,500	7,500	7,500
	Number of pages published and updated on EMA website	3,340	3,500	3,500	3,500	3,500
	Number of press releases and news items published	115	120	120	100	100
	Numbers of press and other external briefings conducted	8	2	2	2	2
	Numbers of social media posts published	501	450	450	450	450
	Number of completed interviews	26	20	20	20	20
	Number of media queries responded	781	900	1,000	1,000	1,000
	Number of reports, brochures, leaflets laid out or printed, social media visuals	914	900	1,200	1,200	1,200

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Communication activities	Average rating of pages on corporate website during the year	n/a	3.8	3.9	3.9	3.9
	Satisfaction level of partners/stakeholders with EMA communications as per 'EMA perception survey for communication'	70.00%	n/a	80%	n/a	80%

1.3.11. Public and stakeholder engagement

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Public and stakeholder engagement	Number of medicines overview and medicines overview updates published	214	170	180	180	180
	Number of professional membership organisation events attended by participating Agency staff	29	25	25	25	25
	Number of sessions with Agency representatives	204	150	150	150	150
	Number of patients and consumers eligible organisations	41	42	46	46	46
	Number of healthcare professionals' eligible organisations	41	44	44	44	44
	Active patients' expert nominated by EMA	186	180	180	180	180
	Active healthcare professionals' experts nominated by EMA	84	80	80	100	100
	Number of messages circulated via 'Early Notification System'	539	500	500	500	500
	Number of EMA communications pro-actively sent to stakeholders	246	200	200	200	200
	Requests for information received	7,285	8,000	8,000	8,000	8,000

Performance indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Public and stakeholder engagement	Satisfaction level of patient and consumer organisations	n/a	80%	80%	n/a	80%
	Satisfaction level of Healthcare Professionals organisations	n/a	80%	80%	n/a	80%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	77.00%	75%	75%	75%	75%
	Triage of incoming requests received via AskEMA within set timelines	100.00%	100%	100%	100%	100%
	Responses to RFI within set timelines (for EMA)	84.00%	95%	95%	95%	95%

1.3.12. Transparency

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Transparency	Access to documents, requests received	520	750	750	750	750
	Access to documents, documents released	1,175	2,000	2,000	2,000	2,000
	Clinical Data Publication (CDP), Procedures published	73	120	120	120	120
	Clinical Data Publication (CDP), Documents published	5,817	8,000	10,000	10,000	10,000
	Exceptional Transparency Measures (EXTM) publication of documents related to the COVID-19 mRNA vaccines[11]	-	300	1,500	1,200	-

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Transparency	Responses to ATD within set timelines[12]	95.00%	90%	90%	90%	90%

[11] New activity, anticipated to be completed by 2027.

[12] Calculated according to the legal timeline stated in Regulation (EC) No 1049/2001 and from the date on which the requester is informed of the start of the procedure.

2. Horizontal public and animal health activities

2.1. Innovation and development

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Innovation and emerging therapies	Number of Innovation Task Force briefing meeting requests received	-	80	90	95	100
	Innovation Task Force briefing meetings conducted	30	40	35	35	35
	Portfolio and Technology meetings conducted	19	20	20	20	20
	Number of items screened (estimate) for Horizon Scanning	9,470	8,000	20,000	20,000	20,000
	Number of Horizon Scanning signals identified	8	15	15	15	15
	External collaboration meetings on Horizon Scanning	4	8	8	8	8
	Number of reports produced (including deep dive, short reports)	7	5	5	5	5
	Number of European Union Innovation Network plenary and subgroup meetings	40	25	25	25	25
	Workshops organised (Innovation and emerging therapies)	3	1	3	3	3

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Innovation and emerging therapies	Percentage of Innovation Task Force briefing meeting requests triaged	-	100%	100%	100%	100%
	Number of presentations to Committees, Working Parties, lunch talks to disseminate business intelligence compiled via the Innovation Task Force, the Business Analysis Forecasting function	-	40	60	65	70

2.2. Regulatory science and academia

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Regulatory science research and academia	Academia briefing meetings conducted	16	16	20	30	30
	New involvements in externally funded regulatory science projects managed	18	10	15	15	15
	Collaborating experts: onboarded or deliverables managed	17	16	20	20	20
	Workshops organised (Regulatory science and academia)	0	2	3	3	3

2.3. Supply and availability of medicines and medical devices

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Supply and availability of medicines and devices	Number of MSSG meetings	11	8	12	12	12
	Number of Vulnerability Analysis and MSSG recommendations	-	-	10	15	15
	Management of shortages of CAPs	1,224	750	2,000	2,000	2,000
	Number of notifications of critical shortages (CAPs and NAPs, human + vet) circulated via SPOC Working Party	69	75	100	100	100
	Number of requests for information received from the SPOC Working Party and international partners	26	30	50	50	50
	Number of SPOC Working Party meetings (including subgroups and meetings with MAHs)	-	-	120	120	120
	Number of Solidarity Mechanism cases	7	10	15	20	20
	Workshops organised (Supply and availability of medicines)	5	7	1	1	1

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Supply and Availability of Medicines and Devices	Percentage of CAP shortages processed	-	100%	100%	100%	100%
	Percentage of notifications of critical shortages (CAPs and NAPs, human + vet) managed	-	100%	100%	100%	100%

2.4. Public health threats

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
ETF	Number of ETF meetings	32	30	30	30	30
	Informal advice by ETF to developers of medicines	52	32	40	40	40
	Informal advice by ETF on Clinical Trials	5	13	13	10	10

2.6. EMRN capacity and capability building

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
EU Network Training Centre (EU NTC)	New or updated EU NTC training curricula related to scientific, regulatory and digital topics	1	2	2	2	2
	Number of training events advertised to the Network	158	75	75	75	75
	Number of in-person delegates registered for face-to-face training events sponsored by EU NTC	-	350	350	350	350
	Number of NCAs who received remuneration for priority training services	-	6	6	6	6
	Number of NCAs that have contributed to training the Network	-	7	7	7	7

2.8. Competitiveness

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Competitiveness	Number of biotech hubs/TTOs engaged through collaboration programme	-	-	20	20	20
	Workshops organised (competitiveness)	-	-	2	2	2

3. Corporate activities

3.4. Information management

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Information management	Volume of tickets processed	117,000	132,000	138,000	138,000	138,000
	EMA Community: Total number of users	-	75,500	79,275	83,239	87,401
	N of IT external contractors managed	-	712	748	785	824

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Information management	Satisfaction of EMA internal and external users	95.80%	80%	80%	80%	80%
	Service Level Agreement (SLA) Compliance Rate	89.70%	91%	85%	85%	85%
	Availability of IT systems (Systems Uptime and Reliability)	99.97%	100%	98%	98%	98%
	Average time to detect and respond to security incident (hours)	-	-	4	4	4
	Security Operation Centre monitoring capabilities: Events processed per second (% increase)	-	-	20%	20%	20%

3.6. Administrative activities

3.6.1. Human resources

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Human resources	Total TA staff recruited against vacant posts	47	40	50	40	40
	Staff turnover rate (staff leaving against total no. of staff TA & CA)	3.50%	4%	5%	4%	4%
	Total TA, CA, END at the Agency	969	988	967	1,010	1,010
	Number of new contracts TA, CA, SNE including contract changes (excluding renewals)	96	109	120	100	100

Performance indicators

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Human resources	Posts on the Agency establishment plan filled	100.00%	99%	99%	99%	99%
	Average time to run selection procedures from the publication of the vacancy notice to establishment of reserve list	2.95 months	3 months	3 months	3 months	3 months

3.6.2. Finance

Workload indicators

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Finance	Procurement procedures (including reopening of procedures) finalised	42	46	42	42	42
	Financial commitments initiated	1,666	1,200	1,200	1,200	1,200
	Payment transactions initiated	40,638	41,116	42,000	42,000	42,000

	Number of sales orders (excl. Pre-payments)	36,504	15,000	14,000	14,000	14,000
	Number of submissions (i.e. cases) registered	14,083	14,000	13,000	13,000	13,000
	Financial queries and disputes on fees invoices	4,196	7,200	6,000	6,000	6,000
	Receivable overdue for more than 30 days (including provision for bad debts)	4.88%	<10%	<10%	<10%	<10%

Performance indicators

		Results	**Expected results**	**Targets**		
		2024	**2025**	**2026**	**2027**	**2028**
Finance	Revenue appropriations implemented	100.05%	97%	97%	97%	97%
	Expenditure appropriations implemented	99.72%	95%	95%	95%	95%
	Payments against appropriations carried over from year N-1	97.08%	95%	95%	95%	95%
	The maximum rate of carryover to year N+1 vs. total budget N	16.10%	15%	15%	15%	15%
	The maximum rate of carryover to year N+1 Title 1	3.07%	10%	10%	10%	10%
	The maximum rate of carryover to year N+1 Title 2	13.31%	20%	20%	20%	20%
	The maximum rate of carryover to year N+1 Title 3	26.00%	30%	30%	30%	30%
	Payment transactions within the Financial Regulation's time limits	97.18%	97%	97%	97%	97%

B) Strategic transformation initiatives

1. EMANS implementation

Theme 1: Accessibility

Activities	Expected results	2026 deliverables/outputs
1.1.1.1 Provide the Joint Clinical Assessment Subgroup (JCASG) with all the relevant information from the centralised procedure and measure effectiveness together with JCASG	Timely provision of information in line with legal requirements for all medicinal products subject to JCAs JCASG is informed about issues in the regulatory review that might impact the JCA assessment scope	Review of experience with information sharing between EMA and the HTA secretariat in the context of JCAs Provision of information for all concerned central marketing authorisation applications
1.1.1.2 Collaborate with the HTA Coordination Group in parallel joint scientific consultations (JSCs) giving scientific advice to technology developers	Requests for advice from developers on how to adjust their programmes to ensure they generate evidence relevant for both regulators and HTA bodies are addressed Cooperation established between regulators and HTA bodies on the selection of development programmes that would benefit from parallel JSC	Review of operations for provision of parallel JSCs Parallel JSCs for developments selected by the JSCSG
1.1.1.3 Exchange information on upcoming applications and future health technologies for planning purposes and for horizon scanning	Information on future applications and technologies shared regularly for planning purposes	A report about the sharing of information related to the planning and forecast of the joint clinical assessments and joint scientific consultations in accordance with Article 2 of Commission Implementing Regulation (EU) 2024/2699 Update report for planning and forecasting joint clinical assessments for medicinal products
1.1.2.1 Continue dialogue between regulators and HTA bodies on principal evidence requirements and how to identify evidence gaps early and	Greater clarity on key principles from regulatory and HTA perspectives that help guide innovative	Identification of follow-up topics and initiation of content exchange based on the published document *Joint HTAb-Regulatory Perspectives on*

Activities	Expected results	2026 deliverables/outputs
provide guidance on how to address such gaps efficiently	development programmes and address overarching non-product issues. New methodologies/frameworks developed for generating evidence for understudied/ underserved populations	*Understanding Evidence Challenges, Managing Uncertainties and Exploring Potential Solutions* Presentation of joint perspectives at stakeholder events (e.g. ISPOR)
1.1.2.2 Establish a dialogue between regulators, HTA bodies and payers on evidence generation for well-established use medicines (including evidence for repurposing such medicines) and medicines for special populations	Greater understanding of challenges and possible models/solutions for specific types of developments (such as off-patent innovation, repurposing of medicines and the generation of evidence for understudied populations)	Initiation of dedicated dialogue to increase understanding of the legal mandates and networking activities across the different stakeholder groups
1.1.2.3 Involve patients and carers in discussions about evidence planning in collaboration with the JSCSG	Patients and carers are involved in all parallel JSC procedures Greater sharing of experiences and practices with patients and carers	Review of operations to support identification and involvement of patient and carer experts in parallel JSC Contributions to related activities of the HTA Stakeholder Network
1.1.3.1 Implement new template changes for EPARs which aim to improve transparency regarding evidence supporting marketing authorisations	Greater transparency regarding the evidence leading to regulatory decisions as a result of the new EPAR template changes	A review of experience following implementation of the revised EPAR template for new marketing authorisation application procedures, focusing on elements relevant for HTA work
1.1.3.3 Provide targeted communications on the methodologies, evidence needs and assessment of studies for demonstrating bio similarity in general and for specific products	Better uptake and availability of biosimilars	Facilitation of multi-stakeholder discussions (including with healthcare professionals) at meetings and conferences, and publication of a joint EMA/HMA statement on the methodologies, evidence needs and assessment results for demonstration of bio similarity
1.2.1.1 Continue multi-stakeholder engagement (involving regulators, HTA bodies, payers, patients, healthcare professionals and industry) on the concept of unmet medical needs	Better understanding of the commonalities and differences in the decision-making by different bodies	Facilitation of multi-stakeholder discussions at conferences

Activities	Expected results	2026 deliverables/outputs
1.2.1.2 Develop guidance for sponsors on obtaining robust, meaningful and interpretable input from patients, including paediatric patients, to understand their experiences with their disease and treatment	Enhanced insights into patients' experiences and the impact on societal health of medicines for unmet medical needs	Consultation of HTA bodies in the finalisation of the reflection paper on patient experience data and follow-up actions
1.2.2.1 Explore a methodology for reviewing and monitoring decisions and underlying evidence from the regulatory evaluation of a medicine through to the health technology assessment and, if feasible, decisions on pricing and reimbursement	Greater clarity on the evidentiary parameters affecting accessibility, including the impact of early access schemes Better insights into obstacles to timely access to medicines for understudied/ underserved populations (e.g. children)	Completion and promotion of the outcome of an analysis of evidence requirements for decisions on products addressing unmet medical needs
1.2.2.2 Follow-up review of the impact of parallel advice on regulatory, HTA and access, in collaboration with HTA bodies	Greater understanding of the value of parallel JSC	Finalisation of an analysis of the access decisions for medicinal product developments that underwent parallel consultation (as a follow-up to Tafuri et al, Br J Clin Pharmacol (2016) 82 965–973)
1.2.3.1 Ensure regular touchpoints between MWP, MPGSG and CTCG to identify common interests in methodology development	Greater oversight of and collaboration on methodology guidance developments	Establishment of regular exchanges between the chairs of MWP, MPGSG and CTFG on guidelines and workplans
1.2.3.2 Engage with collaborative platforms for regulators, HTA bodies, NCAPR and other payer organisations, academia and developers on generation of evidence, particularly RWE	Projects and initiatives, e.g. on RWE, consider needs of different decision makers. More data sources available to support the needs of HTA bodies and payers. More clarity about specific challenges of gathering evidence for ATMPs as well as access decisions.	Completion of DARWIN EU studies providing RWE analysis for HTAs Follow-up of studies as requested by HTA bodies Establishment of an RWE community Identification of follow-up topics in relation to the RWE recommendations in the *Joint HTAb-Regulatory Perspectives on Understanding Evidence Challenges, Managing Uncertainties and Exploring Potential Solutions*

Activities	Expected results	2026 deliverables/outputs
1.2.3.3 Prepare a joint output paper on evidence requirements at the indication/disease level with HTA bodies and payers	An output paper on evidence requirements for three conditions	Identification of the first condition for the joint paper, also as follow-up to the joint HTAb-regulatory perspectives on understanding evidence challenges, managing uncertainties and exploring potential solutions

Theme 2: Leveraging data, digitalisation and artificial intelligence

Activities	Expected results	2026 deliverables/outputs
2.1.1.1 Foster adoption of advanced/innovative methodologies and integration into regulatory decision-making of evidence generated from data that can complement clinical trial data (with greater access to data, pilot, smart business processes and a programme of change management)	Greater use by decision-makers of advanced/innovative methodologies and evidence from data that complement clinical trial data for a wide range of regulatory use cases Learnings and experience are shared from pilot studies on novel types of data. When relevant, healthcare data and novel types of data are routinely used to support regulatory decision making	Approximately 100 RWE studies initiated by the network Procurement launched for service provider for DARWIN EU® 2 Rollout of new minimum viable product (MVP) for NCAs for EudraVigilance data Collaboration with EC on implementing acts for European Health Data Space
2.1.1.2 Foster analysis of clinical trial data (including process, methodological, technical, training and organisational aspects) while working on implementing relevant provisions of the new pharmaceutical legislation	Greater use of evidence generated from clinical study data analysis to strengthen and support acceleration of regulatory decision-making in preparation for the new pharmaceutical legislation	Rollout of clinical study data analysis change management (training and engagement) and follow-up pilot report Collaboration with EC on the implementation of the new pharmaceutical legislation
2.1.1.3 Establish and implement an EMRN data analytics framework to maximise benefits from the EMRN key data assets for public and animal health	Greater investment in data and analytics and support methods and skills in line with the EMRN data analytics framework	Consultation on the EMRN data analytics framework
2.1.2.1 Establish and implement an EMRN data strategy to ensure appropriate data governance is in place for managing EMRN	Greater management of the EMRN data assets in line with the EMRN data strategy, to meet high	Implementation of EMRN data strategy

Activities	Expected results	2026 deliverables/outputs
data assets in compliance with data protection and data security	quality standards, standardisation, sharing and usability	
2.1.2.2 Deliver a programme of uptake of data standards and of interoperability, in line with the revised EMRN data standardisation strategy Strengthen interoperability of the network data Progress with and harmonise the implementation of master data and related data standards within the network	Improved interoperability and leveraging of data, based on master data and related data standards, leading to greater regulatory efficiency and better decision-making	Agreement on model for EMRN working arrangements for PMS data management (joint NDSG/ROG) Provision of support to the ROG PMS data qualification feasibility study Recommendation for EHDS on PMS for cross border healthcare NDSG recommendations for SMS substance master data Consultation on EMRN data standardisation strategy
2.1.2.3 Agree and implement an approach to strengthen cataloguing of the network data assets and to improve their quality	An established common approach for data cataloguing and quality of the network data assets	Rollout of EMRN critical data assets catalogue, in preparation of EHDS and EMRN use cases Agreement on data quality approach (including quality indicators) for EMRN critical data assets
2.2.1.1 Optimise, prioritise and deliver the Network Portfolio in support of the EMANS strategic objectives	Network Portfolio that anticipates, effectively responds to and manages digitalisation for the development of the Network's digital infrastructure	Network Portfolio objectives aligned with EMANS objectives
2.2.1.2 Build a digital infrastructure that places end-users at the centre to support the transformation of scientific and regulatory processes and strengthen engagement with industry via the Regulatory Optimisation Group (ROG)	Improved operational efficiency and overall sustainability of the network supported by end-to-end data driven digitally connected regulatory processes	Deliverables/outputs in the ROG workplan as adopted and endorsed by HMA and EMA's Management Board Digital Infrastructure related deliverables, subject to prioritisation for 2026 as per the Network Portfolio Roadmap A UX hub that will ensure the standardisation of UX practices, methodology and deliverables across the design of digital products delivered under the Network Portfolio and ensure user centricity

Activities	Expected results	2026 deliverables/outputs
2.2.1.3 Improve capabilities to engage stakeholders and customers, to manage change adaptation and adoption, and to manage synergies and dependencies across the Network	Greater preparedness among end users for changing their ways of working	Mature EMA's Change Management Centre of Expertise (CoE) to build and grow change management capabilities of staff across the Agency and disseminate practices to the Network in support of the Network Portfolio
2.2.2.1 Deliver learning and knowledge sharing experiences across the EMRN, including AI learning in line with EU AI Act	Workforce is equipped for a fundamental shift in ways of working and are continuously evolving through learnings	Launch of new training courses and modules on AI, data and digitalisation for the EMRN in EU NTC Learning Management System and Digital Academy
2.2.2.2 Integrate innovation and experimentation with emerging technologies within the Network Portfolio	Accelerated delivery of the Network Portfolio and modernisation of technology	Develop and run a framework for experimentation in support of the Network Portfolio for digitalisation and data experimentation and integrate it to SAFe Agile methodology
2.2.2.3 Create an experimentation framework that builds on the experimentation efforts with emerging technologies across the Network	The transformation of critical business operations across the Network's services and tools	Centralised portfolio of innovation ideas prioritised and aligned with strategic objectives Optimally transformed business processes as a result of emerging technologies, data analytics, AI implemented solutions Innovative solutions and PoCs leveraging AI capabilities under Knowledge Mining and AI Use cases initiative
2.3.1.1 Develop an AI tools framework to support collaborative development and sharing of AI tools across the Network and ensure AI use is compliant with the AI Act	Greater development, use and sharing of AI tools across the network, in full compliance with the AI Act	Publication of AI Tools framework to support sharing of/collaboration on AI tools in the EMRN
2.3.1.2 Develop a system to collect knowledge mining and AI ideas/use cases and develop AI tools for the Network	Tools for knowledge mining and efficiency in decision-making across the network are made available, based on a collection and prioritisation of proposals from across the network	Roadmap on AI to the network, including on use of generative AI
2.3.1.3 Develop AI network research priorities	A published document on AI research priorities	Publication of AI research priorities

Activities	Expected results	2026 deliverables/outputs
2.3.2.1 Strengthen the support given to various fora such as ITF, QIG, PTM and SAWP related to the evaluation of AI in the medicines' lifecycle	A strengthened process for supporting innovation fora and functions, such as ITF, QIG (quality innovation group), PTM (portfolio and technology meetings) and SAWP	Continued support in the evaluation of AI in medicines lifecycle
2.3.2.2 Publish principles for responsible AI, map AI terminology and ensure AI guidance is available and up to date to support medicines lifecycle	Updated AI guidance available for the whole life cycle of medicines The publication of global regulators' principles for responsible AI and an AI terminology map comparing global medicines regulatory terms in AI	Consultation on guidance on AI in Pharmacovigilance, with PRAC (MWP) Consultation on Principles for Responsible AI and AI terminology
2.3.2.3 Roll out a training programme to ensure AI literacy and the development of an expert workforce	Increased AI literacy among all staff to enable safe and effective use of AI Greater expertise among key staff involved in guiding and regulating industry and using AI to improve medicines regulation	Digital Academy training including for AI literacy, through EU NTC framework Annual AI public workshop Continued knowledge sharing and support from the European Specialised Expert Community (ESEC) AI Specialised Interest Area (SIA) in the evaluation of AI in medicines lifecycle EMRN Masterclass on AI with ESEC

Theme 3: Regulatory science, innovation and competitiveness

Activities	Expected results	2026 deliverables/outputs
3.1.1.1 Consider how to support scientific and technological progress in practice to better prepare for the new EU pharmaceutical legislation and related acts (e.g. CMA, Biotech Act) and Life-Science Strategy	Practical solutions to effectively prepare for the new EU pharmaceutical legislation and related acts are identified and implemented	Identification of practical activities to carry out in the coming years to implement the EU pharmaceutical legislation and related acts

Activities	Expected results	2026 deliverables/outputs
3.1.1.2 Share best practices on integrating advanced science and technology in medicines development and implement recommendations identified through a stakeholder survey and other fora	Advanced science and technology is better integrated in medicines development and manufacturing	Exchanges and engagement with all stakeholders including researchers, patients, industry and healthcare professionals working on the development of innovative medicinal products, technologies and methodologies on innovation: Surveys, consultations and webinars Agreement on best practices, recommendations and activities for integration and adaptation of scientific and technological advances in the development of human and veterinary medicines
3.1.1.3 Engage with TTOs, biotech hubs, investors and funding organisations to raise awareness of support to innovation and EU competitiveness in the pharmaceutical field	Increased awareness of regulatory support tools and incentives	Development of information tool kits. Organisation of engagement and increase outreach activities Identification of relevant TTOs and Biotech hubs for engagement
3.1.2.1 Further develop and pilot an optimised horizon scanning methodology involving the EU-Innovation Network and other relevant stakeholders	Relevant stakeholders are fully integrated in the EMA horizon scanning process based on an optimised methodology	Publication of horizon scanning reports on radiopharmaceuticals, ELMs and progress on reports on healthy ageing and phages (in collaboration with ETF and Veterinary colleagues Horizon scanning meetings with companies organised on an ad-hoc basis for veterinary medicines
3.1.2.2 Identify and triage new and emerging platform technologies to understand their impact on existing regulatory approaches and expertise	EMRN is ready to handle the regulatory impact of new and emerging therapeutic platforms and technologies	Engagement platform/process for developers to discuss to receive feedback on platform technologies following provisions in the NPL
3.1.2.3 Discuss best HzS practices and explore opportunities for collaboration with other initiatives and stakeholders (e.g. ICMRA, medical devices network, HTA horizon scanning, WHO, JRC, EIC, IncreaseNET)	Identify HzS topics of common interest which should be discussed among different stakeholders	Collaboration with other relevant HzS initiatives e.g. JRC, EFSA, WHO, NIH

Activities	Expected results	2026 deliverables/outputs
3.1.3.1 Identify the most promising developments and define priority areas in pharmaceutical manufacturing (green, analytical technologies, delivery systems, materials, devices and facility design concepts)	Better understanding of priority areas in pharmaceutical manufacturing	HzS and stakeholder meetings identifying priority areas in pharmaceutical manufacturing Manufacturing site visits Analysis of relevant outcome from QIG workplan on green, analytical technologies, delivery systems, materials, devices and facility design concepts
3.1.3.2 Engage with industry, academia, vendors, learned societies and international partners aiming to identify challenges and propose solutions (including through agile guidance development) Use knowledge sharing and training initiatives involving QIG and EU NTC to develop Network capabilities in novel technologies	Network has identified challenges and proposed solutions for developers by collaborating with different stakeholders	Listen-and-learn focus group meetings to identify challenges and discuss solutions for novel manufacturing technologies and analytical techniques with stakeholder Provision of training on topics within the remit of the QIG through the EU NTC and dedicated sessions at WPs/IWGs
3.1.3.3 Provide end-to-end product specific support on novel manufacturing technologies from early development throughout the product lifecycle through QIG one-on-one meetings, SAs, and expert input in assessment teams	Improved development and implementation of novel manufacturing technologies and analytical techniques. Product specific support is provided from early development throughout the product lifecycle	One-on-one meetings with stakeholders on novel manufacturing technologies and manufacturing site visits
3.2.1.1 Develop, and provide a streamlined support framework enabling optimised regulatory support for the development of innovative medicines (including training and educational materials)	Developers and manufacturers of innovative medicines have access to clear, lean and efficient regulatory support tools	Publication and dissemination of training and educational material also in connection/collaboration with IncreaseNET
3.2.1.2 Optimise efficient mechanisms for dialogue between sponsors/applicants and assessors of the Member States, with the aim of addressing scientific and regulatory issues	Dialogue between sponsors/applicants and assessors on scientific and regulatory issues is optimised	Agreement on SNSA process and logistics optimising stakeholder experience and feed-back
3.2.1.3 Explore support mechanisms involving other stakeholders, such as the pre-grant advice which involve the funding bodies	Better understanding of the value of potential additional support mechanisms e.g. the pre-grant advice	Conclude pilot on pre-grant advice and agree on FU actions

Activities	Expected results	2026 deliverables/outputs
3.2.2.1 Support the effective implementation of the ACT EU objectives and workplan to modernise clinical trials and make EU attractive for conducting clinical trials	EU is more attractive for clinical trials sponsors	Publication of regular reports to monitor the European clinical trials environment Continued engagement with stakeholders to identify CTR implementation and other challenges, driving delivery of solutions in collaboration with network groups Action plan to support non-commercial sponsors with a regulatory helpdesk, interactive map of national support, dedicated webinars and training
3.2.2.2 Coordinate and enhance activities focused on methodological aspects of clinical trials, promoting innovative well-structured study designs and generation of high-quality evidence for human and veterinary medicines	Improved stakeholder experience benefiting from EU clinical trial guidance landscape, enabling innovative well-structured study designs	Workshop on platform trials Regular cooperation between relevant parties (MWP/CTCG/HTA) involved in clinical trials guidance development Roadmap of methodology guidance development (including RWE) and signposting delivered Provision of consolidated advice of scientific and regulatory nature Generation and delivery of valid and reliable RWE via DARWIN EU and the FWC (≈100 research questions addressed per year) Maintenance of the Pharmaco-Epidemiology and RWE curriculum to ensure up-to-date knowledge available to the network International collaboration on methods for RWD/RWE (e.g. ICH E23) and collaborative studies (via ICMRA WG on PHE)
3.2.2.3 Support the implementation of ICH E6(R3)	Innovative trial design is possible in Europe	Implementation of ICH E6 (R3) supported by change management activities, including training activities focused on fitness for purpose and risk-based approaches

Activities	Expected results	2026 deliverables/outputs
		Multi-stakeholder workshop on risk-based approaches
3.2.3.1 Establish new pathways for sharing of data generated with 3Rs testing methods (including NAMs) through expansion of the voluntary data submission procedure Elaborate targeted training activities on 3Rs testing methods (including NAMs) and best practices to foster their acceptance by EMA and the EU regulatory network	More evidence is generated though the implementation of non-clinical and 3Rs methods, and NAMs	Support for the development, qualification and regulatory acceptance of 3Rs testing methods (including new approach methodologies or NAMs) through: Training activities including the elaboration of a specific 3Rs curriculum for assessors via the EU NTC platform and dedicated webinars via non-clinical and NAMs ESEC Compilation of data shared by pharmaceutical industry and CROs on 3Rs testing methods (including NAMs) for building evidence on these test methods to support regulatory acceptance Compilation of and sharing specifically with academia the advice mechanisms available for early dialogue with regulators: national innovation offices, ITF, SA
3.2.3.2. Draft, revise and update guidance related to 3Rs testing approaches and NAMs, non-clinical evidence generation, modelling, simulation and extrapolation, regulatory acceptance and ICH guidelines	Updated guidelines and reflection papers related to 3Rs testing approaches and NAMs, non-clinical methods, regulatory acceptance criteria, ICH guidelines are available to sponsors	Publication of new and revised guidelines and concept papers related to non-clinical development and 3Rs testing approaches including acceptance criteria for new approach methodologies (NAMs)
3.2.3.3. Promote international convergence on 3Rs testing approaches and NAMs in collaboration with the EU-Network, EC and other EU public bodies involved	Network is actively engaged in international cooperation to foster 3R Qualification and regulatory acceptance of 3Rs testing methods including NAMs through the active follow-up of relevant EU projects.	Organisation of and attendance at workshops and conference on 3Rs with different stakeholders to promote international harmonisation and cooperation in fostering 3Rs testing including NAMs Participation at the International Medicines Regulators' Working Group on 3Rs (IMRWG3Rs) Participation in EC activities (e.g. development of roadmap towards phasing out of animal testing for chemical safety assessment) and collaboration with

Activities	Expected results	2026 deliverables/outputs
		EU sister agencies (one substance one assessment, environmental risk assessment) Collaboration with relevant partners: WHO, UK NC3Rs, HESI Global, EPAA, ICMRA, etc Regular 3RsWP meetings with stakeholders to promote 3R. Publication of a paper on past and future 3Rs activities at the Agency
3.3.1.1 Continue and expand the involvement of EU network regulatory scientists in externally funded projects while strengthening the coordination and involvement among regulators in different funded programs such as Horizon Europe, the Innovative Health Initiative, and EU4Health	Competent authorities are regularly involved in relevant EU and national projects funded by e.g. Horizon Europe, Innovative Health initiative and EU4Health	Regular presentation and dissemination of relevant funding calls to HMA and EMA fora: HMA plenary meetings, SCG, EU-IN. Active commenting on and influencing relevant national and EU projects, programmes and funding calls including Horizon Europe, Innovative Health Initiative (IHI) and EU4Health and share experiences between EMA/CAs in participating in regulatory science projects
3.3.1.2 Seek opportunities to collaborate with key stakeholders on research topics of common interest and bidirectional training	Researchers and regulators benefit of bidirectional training and expanded collaboration	Organisation of bidirectional training sessions with researchers and regulators
3.3.1.3 Address identified regulatory-science research needs via the European Platform for Regulatory Science	Regulatory-science research needs are addressed enabling better evidence generation and medicine development	Organisation of meetings of the European Platform for Regulatory Science and delivery of selected Regulatory Science Research Needs (RSRN) with academic researchers Complete the 1-year platform pilot phase: assessment of working procedures, sharing achievements, experiences and conclusions of the pilot phase
3.3.2.1 Implement recommendations from the repurposing pilot	EU is attractive region for repurposing medicines and related projects and business	Identification of follow-up actions based on the learnings and recommendations provided in the repurposing pilot report

Activities	Expected results	2026 deliverables/outputs
3.3.2.2 Review and refine existing support to ensure that it meets the specific needs of SMEs and academic researchers	SMEs and academic research needs are addressed	Engagement with stakeholders to explore the suitability of available regulatory support from their perspective and identify ways to further optimise them Addressing the recommendations from SME survey
3.3.2.3 Engage with stakeholders in professional education and research environments (e.g. research-conducting learned societies, research organisations, university organisations, transfer organisations, funding organisations) in both human and veterinary related domains	SMEs and academic researcher needs are addressed	Regulatory tools disseminated and training delivered to researchers and developers using the EU NTC
3.3.3.1 Support the COMBINE project and consider how lessons learned from the project can be applied to other areas	Network has learnt key lessons from the COMBINE project and assessed their applicability across other interface areas to streamline and harmonise regulatory processes	'All-in-one' pilot follow-up activities
3.3.3.2 Promote increased collaboration among medicinal product competent authorities and between different regulatory frameworks on the regulatory status of borderline products	More EU wide consistent and transparent approaches to the classification and regulatory status of borderline products is achieved	A platform for competent authorities from different networks to discuss the classification of innovative borderline products

Theme 4: Antimicrobial resistance and other health threats

Activities	Expected results	2026 deliverables/outputs
4.1.1.1 Report on sales of veterinary antimicrobials and on the use of antimicrobials in animals in ESUAvet annual reports Prepare the 5th Joint inter-agency report on integrated analysis of antimicrobial consumption and antimicrobial resistance in	Detailed statistics (including trend analyses) available on the number of antimicrobials sold and used in animals across the EU/EEA Integrated analysis available with identification of associations of antimicrobial consumption and antimicrobial resistance in bacteria from both human and veterinary sectors, providing a One Health perspective	Publication of the annual ESUAvet report Publication of the 5th JIACRA report

Activities	Expected results	2026 deliverables/outputs
bacteria from humans and food-producing animals (JIACRA)		
4.1.1.1 Report on sales of veterinary antimicrobials and on the use of antimicrobials in animals in ESUAvet annual reports Prepare the 5th Joint inter-agency report on integrated analysis of antimicrobial consumption and antimicrobial resistance in bacteria from humans and food-producing animals (JIACRA)	Detailed statistics (including trend analyses) available on the number of antimicrobials sold and used in animals across the EU/EEA Integrated analysis available with identification of associations of antimicrobial consumption and antimicrobial resistance in bacteria from both human and veterinary sectors, providing a One Health perspective	Publication of the annual ESUAvet report Publication of the 5th JIACRA report
4.1.1.2 Update guidance and further development of methodology, indicators and tools for analysis, reporting and dissemination of data on the volume of sales and on the use of antimicrobials in animals	Improved quality, consistency and comparability of data on antimicrobial sales and use across EU/EEA countries and animal sectors	Development of public dashboards with ESUAvet data for improving access to information and data and communicating the findings
4.1.1.3 Continue to collect data on use of antimicrobials in animals and facilitate exchange of experiences between Member States	Improved access to sales and use data for antimicrobials	Annual submission of updated dataset on antimicrobial use in animals, disaggregated by animal species, production types, and routes of administration by EU/EEA Member States
4.1.2.1 Develop guidance for the product information of existing antibiotics and prescribing practices	Revision of the CVMP's guideline on the SPCs of antimicrobials to reflect restrictions on use e.g. for products authorised for prophylactic use Reduction in inappropriate or unnecessary use of antimicrobials as a result of improved clarity in the PI and better prescribing practices	Concept paper for revision of the CVMP's SPC guideline on antimicrobials
4.1.2.2 Preserve existing therapeutic options by continuously raising awareness through education, best practices sharing and training Raise awareness of resistance to antiparasitic and antifungal agents	Strengthening NTC training as an instrument for implementing education and best practice	Investigation into the feasibility of opening of NTC training to (public) stakeholders

Activities	Expected results	2026 deliverables/outputs
4.1.2.3 Contribute to the CVMP's dosage review and adjustment of selected veterinary antibiotics (ADRA) project, which aims to update dosage recommendations for selected veterinary antibiotics	Updated and scientifically justified dosage recommendations for selected veterinary antibiotics, based on a comprehensive review of existing data	Initiate a pilot for scientific advice of selected active substance/route of administration/target species combination (based on survey results) under Article 141(1) of Regulation
4.1.3.1 Complete reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals	A comprehensive overview of the current landscape of diagnostic tests used to guide antibiotic use in veterinary medicine	Publication of the reflection paper in 2026
4.1.4.1 Promote guidance on antimicrobial use by adapting existing guidelines and creating new ones Finalise EMA's approach to antimicrobial resistance in the environment	Updated set of guidelines on the responsible use of antimicrobials in animals reflecting latest scientific evidence, evolving resistance patterns, and the requirements of Regulation (EU) 2019/6	Publication of a reflection paper on the assessment of public health risks related to antimicrobial resistance acquired via the environment and resulting from the use of veterinary medicines Support provided to the European Commission, as necessary, in relation to revisions of the AMEG categorisation, and revisions of the lists of substances reserved for human use (in accordance with Commission Delegated Regulation (EU) 2021/1760) and substances not to be used under the cascade or with certain conditions
4.1.4.3 Adjust current approach for addressing rational use besides the update of SmPCs, e.g. publications and papers drafted in collaboration with learned societies for infectious diseases and experts	Availability of up-to-date information on best practices for antibiotics use	Review of the priority list of antibacterial agents requiring updates in the product information Pilot alternative approaches to inform prescribers on how to use old antibiotics
4.2.1.1 Define regulatory requirements and develop a framework for innovative non-traditional medicinal products	Easy access to support for rapid development of products that can assist in the reduction of the use of antimicrobials	Publication of a concept paper on quality and safety requirements for RNA interference and RNA antisense therapies for veterinary use
4.2.1.2 Work on harmonising requirements for new antibacterial/antifungal agents for human use through the quadrilateral activities with FDA, PMDA and HC and expand collaboration to include work with ICMRA	Several virtual quadrilateral meetings held in Q1 2025 to discuss antifungals, pneumonia endpoints, paediatric development and bacteriophages	Alignment in the area of antifungals and paediatrics Discussions with other regulators via ICMRA and OPEN

Activities	Expected results	2026 deliverables/outputs
4.2.2.1 Advance informal dialogue through the ETF and formal scientific advice in areas of unmet need related to AMR, including for vaccines for bacterial pathogens	Support for SMEs and academics developing new agents	Following a pilot, broad support for SMEs developing new antibacterial, TB and antifungal agents including vaccines
4.2.2.2 Include OPEN partners and other international regulators as needed in the discussion on approval of new products addressing AMR	Faster approval in EU and in other parts of the world	A platform for international dialogue on AMR medicines beyond the quadrilateral framework
4.2.2.3 Reflect on the uptake by MAHs of VAMFs and vPTMFs with a view to determining if they are delivering benefits in terms of easier management of products and/or facilitating product development/ authorisation	Clarity on the benefits of VAMFs and vPTMFs in terms of easier management	Update on the reflection process
4.2.3.1 Provide technical support with respect to the implementation of the new pharmaceutical legislation and provide support with defining criteria for eligible products Support G7/20 in developing incentives for new antibiotics and ensure EU initiatives are progressing	Successful implementation of the legislation on incentives and other ancillary initiatives on new business models	Defined criteria for eligibility of new antibacterial agents for incentives and role of EMA ETF
4.2.3.2 Support interactions with HTA bodies around value of new antimicrobials Interact via workshops and meetings with HTA bodies/payers/governments on setting up appropriate incentives for new medicines with impact on AMR	More clarity about the value of new products based on scientific evidence available Ranking of key attributes for new medicines to be rewarded	Enable fit-for-purpose new incentives.
4.3.1.1 Complete guidance for medical countermeasures for CBRN threats, including on use of non-clinical efficacy data with radionuclear chapter to be drafted by the ETF	Clear criteria for approval of MCMs for CBRN threats and availability of guidance documents Incentives in place to foster the regulatory submission	A pipeline of MCMs approved in the EU to support stockpiling Dialogue with NATO and military on CBRN development and data generation

Activities	Expected results	2026 deliverables/outputs
Organise workshop on non-clinical evidence to support approval of CBRN MCMs		
4.3.1.2 Document lessons learned following emergency use by Member States under Article 110 and generate advice/guidance on data gathering/generation during emergencies that could support subsequent authorisation	Lessons learned and possible guidance Implementation of new legislation on TEMA	Initiation of a lessons learned process Preparations for TEMA implementation
4.3.1.3 Agree internationally on approaches for approval before emergencies and on conducting clinical trials during crises Engage with WHO via the CORC framework with respect to viral families Engage with academia, industry and NGOs on clinical study design via ETF Conclude work on ACT EU PA11 deliverables on clinical trials in public health emergencies	Progress in international collaboration with WHO, CEPI, CORCs and other players	Core protocols for key syndromes and diseases Complete ACT EU programme on Clinical trials in public health emergencies
4.3.2.1 Map health threats and pipeline of medical countermeasures while engaging with HERA, ECDC and NATO	Complete mapping health threats and pipeline of medical countermeasures	Up-to-date map and list of health threats and medical countermeasures
4.3.3.1 Promote global convergence on regulatory requirements through ICMRA, WHO, RAGNA and other international mechanisms	Expanded regulatory interactions through WHO/CEPI and CORC and greater international convergence	Contribution to key CORCs, e.g. flaviviruses. Promotion of ICMRA workshop on development of new antibacterial agents
4.3.4.1 Support implementation of incentives for CBRN MCMs to be stockpiled	Incentives in place to foster the regulatory submission	Defined criteria for eligibility and role of ETF
4.3.5.1 Respond to queries from the public and the media and publish papers to outline scientific positions on vaccines and medicines to be used in emergencies	Progress in combating misinformation about vaccines and medicines used in emergencies	Replies to queries from public/media in accordance with EMA/NCA practices

Activities	Expected results	2026 deliverables/outputs
		Publication of scientific papers by EMA/NCA staff and experts on emerging issues
4.3.5.2 Fund additional studies to answer specific questions about vaccinations not covered by the obligations in marketing authorisations Define with ECDC the scope of vaccine efficacy and post-approval safety studies to be conducted under the auspices of the Vaccine Monitoring Platform	The availability of more robust scientific data on which to base communication for the public Progress in establishment of the VMP	Publications and presentations at international conferences on the scientific data supporting vaccines and therapeutics for tackling emergencies
4.3.5.3 Engage with learned societies and citizens to ensure a good understanding of the value of vaccines while implementing the vaccine outreach strategy, publishing scientific papers and contributing to conferences	Greater effectiveness in the way regulators communicate with the public and healthcare providers	Implement vaccine outreach strategy Establish a vaccine core expert group to complement consultation via existing stakeholder groups. Finalise 'vaccine essentials' and publish articles in scientific journals

Theme 5: Availability and supply of medicines

Activities	Expected results	2026 deliverables/outputs
5.1.1.1 Expand on work completed in 2019 to develop a common EU template with predefined root causes that can be incorporated into national shortage notification systems	More consistency in reporting of root causes across the EU network to inform better management and prevention strategies and interoperability of national IT systems with ESMP	Review of root cause classification/categories, taking into consideration previous work to reflect current practices
5.1.1.2 Quantify shortages of veterinary medicines and identify root causes	More clarity on the extent of shortages concerning veterinary medicines	Mapping of shortages of veterinary medicines
5.1.1.3 Work with the newly established MSSG Working Group on the Vulnerability Assessment Methodology to identify and evaluate vulnerabilities in the supply chains	Agreement on at-risk products requiring coordinated actions at the European level, including regulatory support where applicable and	Delivery of a draft Vulnerability Assessment Methodology

Activities	Expected results	2026 deliverables/outputs
of critical medicines, ultimately for the application by Member States, in preparation for the proposed pharmaceutical legislation and the Critical Medicines Act	in preparation for the proposed pharmaceutical legislation (e.g. MSSG recommendation)	
5.1.2.1 Review outcomes of the pilot phase for the implementation of shortage prevention and mitigation plans and develop proposals for how any identified challenges are to be addressed	Greater oversight of supply chains of critical medicines to manage and prevent shortages and strengthen supply chains	Finalisation of Shortage Prevention and Mitigation Plan Pilot and review of the templates Publication of a report outlining the Shortage Prevention and Mitigation Plan Pilot
5.1.2.2 Promote harmonisation of reporting on availability of medicines across the Network Promote the use of machine-to-machine interfacing to facilitate automated data exchange between ESMP and Member States' and Industry systems, based on application programming interfaces (API) developed by the Agency	Greater oversight to manage and prevent shortages and strengthen supply chain of critical medicines	Identify elements that need to be harmonised to facilitate machine-to-machine interoperability
5.1.3.1 Contribute to EU-level discussions and best practices on national and EU-level approaches to stockpiling and contingency stock requirements, including potential impact on the Voluntary Solidarity Mechanism	Better coordination and more informed national policies and appropriately weighted measures being introduced, which are effective for shortage prevention as well as management of shortages Promotion of best practices and make available quantitative data that can underpin any recommendations	Identification of barriers to the transfer of stocks between countries in the context of the VSM
5.1.3.2 Develop guidance for MAHs and Member States to ensure effective utilisation of surplus reallocated stocks and best practices at Member State level to support the efficient movement of stocks	Rapid reallocation of stocks across Member States and more timely responses to MS experiencing a critical shortage of a medicine	Development of best-practice guidance documents
5.1.4.1 Introduce specific tools and processes for MAHs to maintain up-to-date and correct product-related information and information	NCAs can make available to the public and public bodies accurate and up-to-date information related to medicine availability of centrally	A survey within the network to assess current approaches by NCAs to interacting with MAHs to ensure marketing status information that is

Activities	Expected results	2026 deliverables/outputs
on marketing status of centrally and nationally authorised products with support from NCAs where required	authorised products, including through applications such as national e-prescribing systems	maintained for nationally authorised products is accurate For CAPs, a comprehensive assessment of the marketing status system, including available data, to identify and understand challenges with regard to marketing status information. Identification and implementation of technical solutions and communication activities to address these challenges based on results of the survey and comprehensive assessment of the marketing status system
5.1.4.2 Make improvements to EMA and NCA public catalogues of shortages making use of developments in related systems and platforms	Comprehensive, improved and timely shortage related information that is publicly available	A survey within the network to assess level of compliance with Good Practice Guidance on public information on shortages. Based on the results, development of follow-up actions to improve EU information practice (consider interdependence with ESMP and EMWP development).
5.1.4.3 Promote public awareness and understanding of the role of medicines regulators, and other stakeholders, in relation to shortages	Increased public awareness of intricacies and nuances of the medicines supply chain, as well as the roles and responsibilities of the various stakeholders involved.	Information and engagement on shortages activities including development and facilitation of a public webinar on shortages, creation of factsheet, and selected campaigns
5.2.2.1 Develop third country inspection planning cooperation and coordination for all products (CAPs and NAPs).	Use of EudraGMDP 3rd country inspection planning module	Shared 3rd country inspection plan for NAPs and CAPs
5.2.2.2 Update the CoUP to improve current risk-based approach to inspection planning, including with respect to the use of reliance, hybrid inspection and distant assessment for verification of GMP compliance	Update the CoUP to facilitate use of reliance, hybrid inspections and distant assessment as tools in inspection programmes and to improve risk-based approach to inspection planning	CoUP updated with reference to reliance, hybrid inspection and distant assessment
5.2.3.1 Implement a workplan for the GMDP IWG Working Group on GDP	New/Revised CoUP procedures on GDP aspects.	New GDP inspection procedures available in CoUP New Q&A for wholesalers

Activities	Expected results	2026 deliverables/outputs
	New guidance for wholesalers performing risk assessment on the verification of authenticity of medicinal products at risk of falsification	
5.2.3.2 Implement a joint audit programme for GDP (EU4H11)	A joint audit programme for GDP inspectorates	NA
5.2.3.3 Coordinate communication actions to raise awareness of the dangers of falsifications to patients	Greater public awareness of the dangers posed by falsified medicines	If any need is identified, notification by EMA or NCAs of launch of any communication/ media campaigns or other actions
5.2.4.1 Implement the GMDP IWG work programme with a focus on modernising GMP	Updated guidance such as Chapter 1, Annex 11, Chapter 4 and Annex 15 and new Annex 22	Publication of updated guidance as available
5.2.4.2 Develop with involvement of QIG and GMDP IWG interim guidance to facilitate implementation of advanced manufacturing technologies where needed	New Q&As published, e.g. for 3D printing	Publication of Q&A on 3D printing
5.2.5.1 Redevelop EudraGMDP and ensure all Member States enter data in EudraGMDP (e.g. for human and veterinary products for GDP) as required by legislation	Better functioning database (less downtime, user complaints etc) All Member States entering relevant data in EudraGMDP database	Approval of budget to start modernisation Ongoing maintenance activities

Theme 6: Sustainability of the network

Activities	Expected results	2026 deliverables/outputs
6.1.1.1 Conduct surveys and analyses of the network capacity and capabilities to better align with upcoming regulatory work and further develop a model for predicting incoming work in collaboration with stakeholders	Better predictability of incoming work and optimised resource allocation through enhanced oversight and monitoring of the capacity to NCAs to undertake assessment work of upcoming submissions	Annual report and quarterly updates of forecast submissions based on surveys and pipeline interactions with applicants Annual NCA survey to forecast rapporteur capacity. Network capacity analysis and quarterly monitoring reports.

Activities	Expected results	2026 deliverables/outputs
6.1.1.2 Increase network capacity through a structured onboarding and training programme for new assessors and strengthen the collaboration on talent management among NCAs	Increased capacity of the network and long-term sustainability	Launch of onboarding programme for Committee members Establishment of a joint NCA forum on HR/recruitment IncreaseNET deliverables: Specialty training packages for regulatory assessors and case studies Final report on on-the-job training programs Recommendations sent to CMDh and EMA on possibilities for optimisation of work and work sharing Different outcomes supporting NCAs at innovation
6.1.1.3 Build capabilities in the network in priority areas through a structured training programme	Increased capabilities in identified areas (e.g. methodology, inspectorate)	EU NTC training Specialty training packages for regulatory assessors and case studies (Increase NET) Organisation of face-to-face assessors' day at EMA
6.1.2.1 Complement assessment teams by facilitating the identification and incorporation of external experts in assessment teams	A more flexible and robust model of assessment teams	A pilot to incorporate external experts in assessment teams coordinated by EMA Creation of pools of external experts that can undertake assessment work or other related activities (e.g. training)
6.1.2.2 Develop the clusters of excellence as areas of specialised expertise in the network	More optimal use of resources in areas of need	Identification of areas of specialised expertise requiring a cluster of excellence and establishment of a plan for piloting and implementation.
6.1.3.1 Further streamline the centralised procedure and related documentation and implement new ways of working benefiting from collaborative tools	Increased capacity as a result of improved process efficiency, and use of collaborative tools	Implementation of new systems for procedure and documents management (IRIS, SharePoint) enabling collaborative ways of working

Activities	Expected results	2026 deliverables/outputs
		Streamlined assessment reports facilitating rapporteur and experts collaboration, integrating input from relevant committees and WPs Streamlining of centralised procedure through the development of AI tools supporting
6.1.3.2 Develop and implement a structured, competency-based training architecture that ensures network experts acquire the skills and knowledge required to support the digital transformation of scientific and regulatory processes	See activities under goals 2.2 and 2.3	See activities under goals 2.2 and 2.3
6.2.1.1 Support the transformation of scientific and regulatory processes by building a digital infrastructure that places end-users at the centre	See activities under goals 2.2 and 2.3	See activities under goals 2.2 and 2.3
6.2.1.2 Implement the variations regulation framework and the new classification guidelines	A more streamlined and simplified framework for post-authorisation medicines	Data and Systems adaptation (SPOR, eAF) for the implementation of new variations classification guidelines Publication of new and updated EMA/CMDh regulatory and scientific guidance
6.2.1.3 Carry out an impact analysis and plan for the implementation of the pharmaceutical legislation	Timely implementation of the new legislative framework	Establishment of a plan for implementation of the new legislation
6.2.2.1 Activate the outcome of the implementing and delegated acts derived from the regulation on veterinary medicinal products, especially on the area of GMP and AMR	Full implementation of the veterinary regulation framework, including implementing and delegated acts for GMP, essential substances for horses and aquaculture and, upon request, review of other relevant areas like variations (update of list of VNRAs as needed).	Replies to EC questions on the aquaculture and horse list addressed The 'cascade list' advice will be further revised to take into account the two above mentioned lists
6.2.2.2 Continuous enhancement of UPD functionality based on EMA product owner, Network product owner and expert	Increased data quality and enhanced functionality of the UPD that streamlines operational processes	Two-way information exchange with authorised users via API

Activities	Expected results	2026 deliverables/outputs
stakeholder requirements, including improvements to the VNRA process, bulk data submission process and OPAD processes	Ability of UPD to supports six times peak daily volume of users seen in 2024. Increased user satisfaction scores in the annual user survey	VNRA related improvements implemented Improved UX in data search OPAD process enhancements Weekly check of all critical data for data owners to take action if needed
6.2.3.1 Enhance the network's engagement in strategic level initiatives/joint actions addressing the challenges in the field of network's digitalisation	See activities under objective 2.2	See activities under goal 2.2
6.2.3.2 Leverage EU and national experience with AI initiatives for the benefit of the network through a coordinated programme (AI workplan)	More AI initiatives solutions developed by the network (EMA, NCAs) made available to the whole network	Centralised portfolio of innovation ideas prioritised and aligned with strategic objectives
6.2.4.1 Implement the new fee regulation through the timely adaptation of systems, regulatory and financial processes	Maintenance of a high-quality service to MAHs/MAAs and the financial sustainability of the Agency and the network	Activity finalised in 2025 (i.e. system adaptations, launch of prepayment systems)
6.2.4.2 Implement a mechanism for establishment of fees for new activities and for the revision of existing fees, charges and remunerations	Long-term sustainability of the network	Publication of annual report on revenue, granted reductions and waivers Regular fee monitoring and — if applicable — reporting to EC on recommendations for fee, charge or remuneration adjustments.
6.3.1.1 Lead and contribute to guidance development activities in the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)	International harmonisation for the development and assessment of medicines.	Regular participation in ICH biannual assembly meetings To lead as rapporteur and/or contribute to the development of guidance
6.3.1.2 Lead and contribute to global harmonisation of requirements for 3Rs and new approach methodologies (NAMs) as part	Global position statement on 3Rs and enhanced global harmonisation of requirements including agreement on acceptance criteria for 'New	Delivery of 3-year rolling work plan for the non-clinical domain

Activities	Expected results	2026 deliverables/outputs
of International Medicines Regulators' Working Group	Approach Methodologies' (NAMs) within specific contexts of use	
6.3.2.1 Pilot collaborative assessments for post-approval CMC (chemistry, manufacturing, and controls) and hybrid inspections	International convergence and better harmonised outcomes without additional regulatory burden for the industry	Finalisation of ongoing pilots
6.3.3.1 Leverage EU experience and expertise for the creation of the African Medicines Agency Support the piloting of a joint African assessment Support the roll-out of a training curriculum for assessors and projects to strengthen regulatory systems at the national level in Africa	Strengthened medicines regulation in Africa at the continental and national levels.	Implementation of 11 grants to EU NCAs and 1 grant to EDQM leveraging their expertise to foster regulatory, scientific and administrative capacity and foster mutual reliance e-learning curriculum for African junior inspectors Open LMS to African regulators
6.3.3.2 Assist beneficiary national competent authorities in aligning their standards and practices with those established in the EU (IPA programme)	Enhanced regulation of medicinal products for human and veterinary use in the region through revised and aligned standards and practices with those of the European Union.	Publication of annual report on IPA programme activities Provision of training activities (of which one is face to face) to EU (potential) candidate countries Regular participation of EU (potential) candidate representatives as observers to selected EMA working groups and parties
6.3.3.3 Support WHO reliance pathways, promoting the EU regulatory system and documents that can be used as reliance tools for other national regulatory authorities	Greater use of EU evaluations in WHO reliance	Engagement with industry and relevant stakeholders (e.g. WHO) to promote reliance on the EU system. (Any more specific task) Participation in international regulatory fora of regulators to promote the EU systems and the tools that can be used in reliance Report on the experience with international collaborative assessment programmes Support the development of international cooperation agreement that can support reliance

Activities	Expected results	2026 deliverables/outputs
6.3.4.1 Revise the joint EMA/HMA communication action plan to further strengthen stakeholder engagement in the network and leverage social media and new tools	Strengthened stakeholder engagement and greater use of social media tools	A framework strategy for external communication and stakeholder engagement aligned with EMANS and implemented through annual communication plans New tools for stakeholder engagement developed and tested (e.g. enhanced CHMP early dialogue, dedicated industry newsletter launched, etc)
6.3.4.2 Strengthen engagement with key stakeholders to support the use of patient experience data in EU medicines development and regulatory decision-making, while also increasing overall transparency	Better decision making of regulatory procedures enriched with valuable supportive data of clinical use of medicines	Development of guidance on the use of patient experience data in regulatory procedures and released for public consultation Increased transparency and promoted relevance of PED in decision making through inclusion of a dedicated section in CHMP assessment reports
6.3.4.3 Develop a communication approach to promptly identify and proactively address false narratives	More proactive engagement with misinformation	An operational infodemic insights framework following a pilot Streamlined trust-building measures incorporated into all communication activities

2. Digitalisation initiatives and Network Portfolio

2.1. Digitalisation

To support the delivery of the following cross cutting digitalisation initiatives in 2026 the Agency will allocate €1.7 m.

MAWP	Initiative	Expected result	Start	End	Performance indicators
B.3	Regulatory simplification & optimisation for digitalisation	• Drive network-wide process transformation: Empower the Regulatory Optimisation Group (ROG) to lead and coordinate engagement across the network for harmonised EU network regulatory process transformation. • Strengthen the ROG business community: Enhance the role and participation of the ROG national competent authorities (NCA) business community to ensure strong business and regulatory input in Network IT developments and digital initiatives. • Establish business architecture practice: Build a business architecture capability integrated with enterprise architecture practice and portfolio management to ensure strategic alignment between EMA/EMRN objectives, organisational structures, processes, and data models, providing an enterprise-wide view of transformation.	2026	2026	Results achieved
	High quality data	• Harmonise PMS data management: Establish a joint NDSG/ROG agreement on EMRN working arrangements for PMS data management to ensure coherence, data quality, and shared responsibility. • Support PMS data qualification: Provide technical and analytical support to the ROG PMS data qualification feasibility study, ensuring informed decision-making and readiness for operationalisation.	2026	2026	Results achieved
	Digitalisation and AI	• Shape an innovation portfolio: Maintain a centralised portfolio of innovation ideas prioritised and aligned with EMA strategic objectives, ensuring transparent governance and measurable value creation via introducing the experimentation runway approach adjacent to Network Portfolio. • Leverage AI through experimentation: Experiment to develop tools through the Knowledge mining and AI use cases initiative, that connect and analyse information	2026	2026	Results achieved

MAWP	Initiative	Expected result	Start	End	Performance indicators
		across documents and databases, using AI to enhance decision-making across the medicines lifecycle. • Coordinate AI change management: Design and implement a change management approach for digital transformation and AI adoption, addressing cultural, organisational, and capability aspects—both within EMA and across the network (NDSG workplan). • Leverage citizen development frameworks for digital transformation, starting by socialising the use of the power platform to business users and develop and maintain a citizen developers' framework and set and operate a user's community on Microsoft power platform to boost digital acceleration. • Integrate further customer centricity and user experience in product design process by adopting and integrating UX-design mindset and of UX-design principles and practices across the organisation, especially during the development of new online products.			
B.3	Strengthen collaboration and change implementation	• Optimise Network Portfolio management processes to enable clear agreements on implementation efforts, providing stakeholders with improved predictability on workload and impact at team level. • Enhance Agile collaboration mechanisms and governance structures across the Network to facilitate coordinated implementation of change initiatives, ensuring consistent communication, shared ownership, and efficient delivery. • Organise staff engagement workshops on the adoption of digital products and on agile ways of working, to gather insights on challenges faced, ensuring feedback informs future improvement and support measures. • Develop internal team capabilities on Agile and change management and toolkits to support teams at EMA through change and transitions	2026	2026	Results achieved
B.3	New pharma legislation readiness	• Experiment and Innovate: Design and test new regulatory and operational processes through targeted experimentation and Proofs of Concept (PoCs) supporting the implementation of the new pharma legislation (NPL), Leveraging emerging technologies, data analytics, and AI to transform regulatory and business processes for improved efficiency and effectiveness.	2026	2026	Results achieved

Workload indicators[13]

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Digitalisation	Number of Use Cases worked in Innovation portfolio pipeline	-	-	15	18	20
	Number of new digital tools delivered from Innovation portfolio	-	-	5	7	9

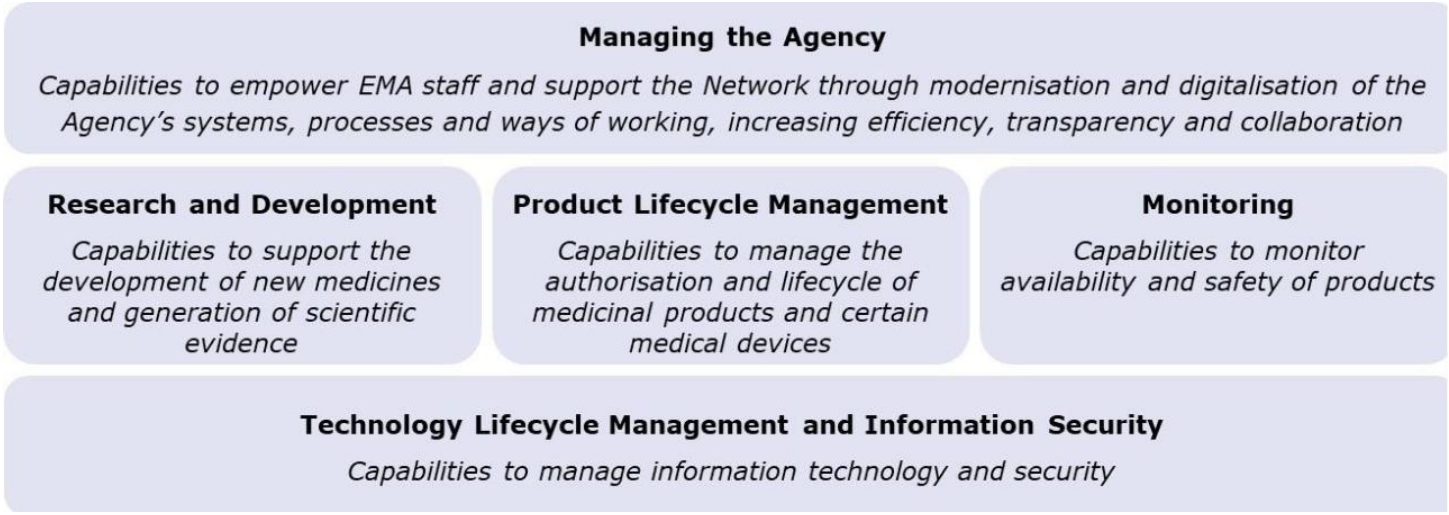
Performance indicators[14]

		Results	Expected results	Targets		
		2024	2025	2026	2027	2028
Digitalisation	Number of business processes redesigned as a result of Innovation Portfolio	-	-	3	5	7

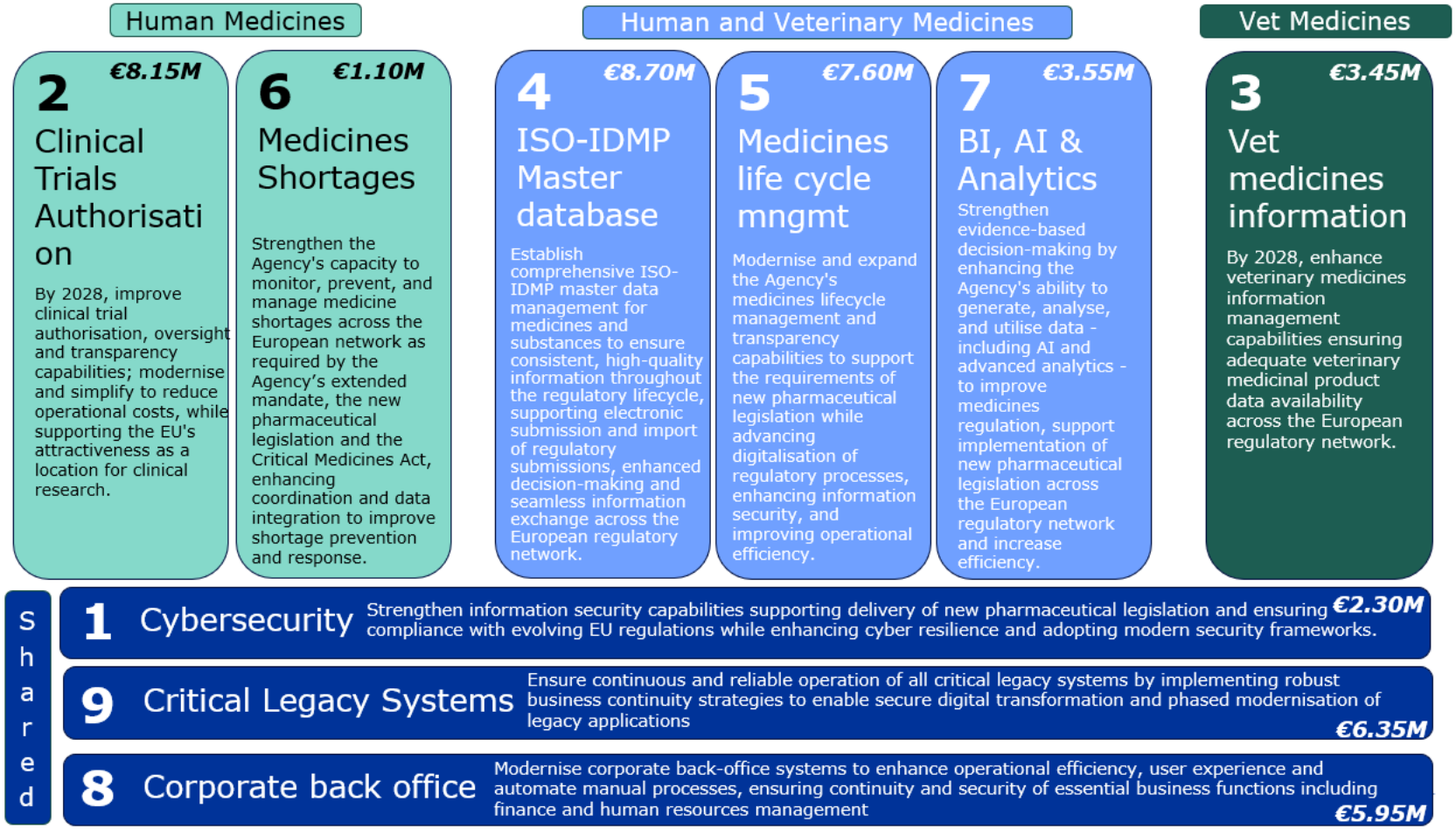
[13] New indicators introduced in the 2026 work programme.
[14] New indicators introduced in the 2026 work programme.

2.2. Network Portfolio

To support the Agency's work and achievement of set objectives, the Agency organises the Network Portfolio under five value streams. Value streams help organise the Portfolio into sub-portfolios that do not have to compete with each other, and that support the achievement of the long-term strategic objectives. Value streams are stable, with dedicated leadership, resources and capacity:



The following table illustrates the 2026 budget allocation for each of the Network Portfolio objectives:



The table below details the main products and deliverables (epics) currently planned for 2026, to be reviewed during quarterly Planning Interval ceremonies. The planned deliverables for 2027 will continue to progress in achieving the strategic goals of each value stream, and specific products and deliverables per value stream will be further defined during the preparation of the final work programme 2027, based on the progress made in 2026.

Note: Necessary maintenance and improvements to newly developed systems are foreseen, even when not specifically listed as a deliverable

Value stream/products	Legal basis (if applicable)	Start date	End date	Deliverables 2026	Portfolio objective
Product Lifecycle Management value stream (PLM VS) *Capabilities to authorise and manage lifecycle of medicines and medical devices*					
Medicinal Product Management System (PMS)	Regulation 726/2004, art.57(2) Regulation (EC) 520/2012, art.25 and 26 Regulation (EC) 536/2014, art.81-93) (Clinical Trials Regulation) Pharmacovig. fees reg. 658/2014, art.7 Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	2017	2028	Provide the public with a PMS application programming interface (API) so that the public can read medicinal product data from PMS through an API. Connect PMS and IRIS with an API, and ensure PMS API data validation is in place to enable the decommissioning of SIAMED (enabler epic) Complete analysis for a roadmap to decommission the Art. 57/XEVMPD	4
Product data management user interface *(part of the Product Lifecycle Management Portal)*		2023	2026	Develop write capabilities in the product user interface (PUI) for Industry, EMA and NCA to either enter or edit medicinal product data in PMS	4
Electronic application form (eAF) *(part of the Product Lifecycle Management Portal)*		2021	2028	Maintenance of the eAF for human variations for CAPs and non-CAPs	4
Electronic product information (ePI) *(part of the Product Lifecycle Management Portal)*		2022	2026	Develop functionalities that are essential for go-live Go-live of minimum viable product	5
Union Product Database (UPD)	Regulation (EU) 2019/6; associated implementing act	2021		Continue implementation of new capabilities and improve existing features, e.g. build API for uploading volume of sales (VoS) data by MAH, improve UPD data quality	3

Value stream/products	Legal basis (if applicable)	Start date	End date	Deliverables 2026	Portfolio objective
				Implement Northern Ireland access policy changes	
Regulatory Procedure Management (RPM) for PLM *(part of the IRIS portal)*		2022	2027	Develop and roll out the capability to manage initial marketing authorisation applications (H & V) (+ Medicines for All & ancillary substances) in IRIS Build regulatory procedure management capabilities in IRIS in readiness for the new pharma legislation	5
eCTD4 (eSubmissions incl. EURSnext/Central Repository)		2021	2027	Roll out optional use of eCTD v4 for dossier submissions for Centrally Authorised Products (CAPs) Pilot eCTD v4 dossier submissions for non-CAPs Analysis on a Central EU Repository for dossiers for CAPs and non-CAPs	5
European Medicines Web Portal (EMWP)	Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, art. 26(1)	2024	2027	Perform user research and initial UX design to support the design and future development of EMWP	5
Research and Development Management value stream (R&D VS) *Capabilities to foster the development of medicines and generate scientific evidence*					
Regulatory Procedure Management (RPM) for R&D *(part of the IRIS portal)*		2023	2026	Roll out of the pre-authorisation processes to go along with the initial marketing authorisation application (H & V) in IRIS	5
Clinical Trials Information System (CTIS)	Regulation (EC) 536/2014, art.80-82	2014	2028	CTIS maintenance and continuous improvements to further improve stability, usability and user satisfaction CTIS Public Portal maintenance and improvements Building on the CTIS modernisation foundation epic started in 2025, initiate new epic to progress the modernisation roadmap; integrate relevant changes required by the Biotechnology Act, when possible.	2

Value stream/products	Legal basis (if applicable)	Start date	End date	Deliverables 2026	Portfolio objective
				Continue the simplification principles of CTIS functionalities to support CTIS modernisation in 2026 and beyond Modernisation of CTIS Business Intelligence (CTIS BI) capabilities with transition to a new business intelligence platform and alignment with CTIS modernisation	
Knowledge Mining and artificial intelligence (AI)		2025	2028	Develop knowledge mining and AI capabilities for EMA and the Network (custom products) to drive digital transformation and to improve efficiency in the evaluation of human and veterinary medicines Expand Scientific Explorer's capabilities to bridge evidence generation and evaluation support	7
Monitoring value stream (MON VS) *Capabilities to monitor availability and safety of products*					
European Shortages Monitoring Platform (ESMP)	Regulation (EU) 2022/123	2022	2027	Maintenance and improvements to ESMP Implement voluntary solidarity mechanism Implement vulnerability assessment methodology to support the secure and continue supply of critical medicines for EU patients and health systems Implement critical shortage management, shortage prevention plan and shortages mitigation plan to minimise the impact on patients and health systems Management of the Union list of critical medicines (ULCM)	6
Regulatory Procedure Management (RPM) for Monitoring *(part of the IRIS portal)*		2023	2026	Maintenance and improvements on inspections and parallel distribution, including New Fee Regulation (NFR) Eliminate use of Excel for inspections planning of Good Pharmacovigilance Practices (GVP) and Good Manufacturing Practices (GMP)	5

Value stream/products	Legal basis (if applicable)	Start date	End date	Deliverables 2026	Portfolio objective
EudraGMDP	Directive 2001/83/EC, art. 111(6) Regulation (EU) 2019/6, art. 91	2026	2027	Modernise the EudraGMDP platform by refactoring obsolete components to ensure scalability and enable new pharma legislation implementation in 2027	9
Union Pharmacovigilance Database (UPhV)	Regulation (EC) 726/2004, art.57(d) Regulation (EU) 2019/6; associated implementing acts	2017	2026	UPhV product development completed in 2024, maintenance to continue in 2026 Simplify NCA signal management by eliminating the reliance on Excel Implement Northern Ireland access policy changes	3
EudraVigilance (EV) Human		2026	2026	Ensure routine maintenance, including bug fixes and improvements of EV platform in 2026 Conduct an analysis and propose a roadmap for the simplification of the EV platform, including the consumption of PMS data instead of xEVMPD Propose technological simplification plan for the EV platform	4
Signal and Safety Analytics (SSA)		2025	2026	Roll-out of the SSA minimum viable product (MVP) and post-MVP enhancements Provide managed services to support Members States' users during the roll-out Include additional electronic Reaction Monitoring Report (eRMR) metrics	7
Early Notification System (ENS)		2025	2026	Go-live, hypercare, and routine maintenance	5
Antimicrobial Sales & Use (ASU)	Regulation (EU) 2019/6, art 57 Commission Delegated Act 2021/578 Commission Implementing Act 2022/209	2021	2026	ASU product development completed in 2024, maintenance to continue in 2026 Bug fixing and small updates to support data growth for current species and new species in 2026 Implement Northern Ireland access policy changes	3

Value stream/products	Legal basis (if applicable)	Start date	End date	Deliverables 2026	Portfolio objective
Managing the Agency value stream (MTA VS) *Capabilities to empower EMA staff and support the Network through modernisation and digitalisation of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration*					
SAP Finance replacement		2023	2027	Finalise analysis, definition of business requirements, and technology selection	8
SAP HR replacement		2023	2027	Replace SAP HR Core module and continue HR processes modernisation	8
SAP Business Technology Platform (BTP) (New Fee Regulation)	Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency	2023	2028	Implement the management of the remaining manual fee processes	8
AskEMA replacement		2024	2027	Complete technology selection and contracting	8
Anonymisation@EMA		2025	2026	Automate anonymisation of personal/clinical data in large sets of documents	8
Customer Relationship Management (CRM) tool		2025	2026	Start analysis and technology selection	8
Workplace Experience		2024	2027	Finalise analysis and technology selection	8
Technology Lifecycle Management and Information Security value stream (TLM VS) *Capabilities to manage information technology and security*					
Information Security and Cyber Security enhancements		2022		Cyber & Information Security enhancements Operational Security enhancements Application Security enhancements Security awareness programme	1
Legacy application modernisation		2023		FileMaker application and Java application modernisation pilot Evaluation of investment	1

Workload indicators[15]

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Change management	Number of boot camps delivered	3	2	4	4	4
	Number of staff/managers attending change management learning activities per year	37	34	56	56	56
	Number of portfolio epics and other initiative supported	-	22	20	20	20
Network Portfolio	Number of epics completed or ongoing	44	33	33	35	37
	Number of members in the Agile Hive Community	431	466	470	481	490
	Number of people trained in Agile methodology	98	54	70	86	91
	Number of Agile training sessions	24	7	10	12	15
	Number of public system demo	13	12	13	13	13
	Number of viewers per public system demo	>19,000	>19,000	>19,000	>19,000	>19,000

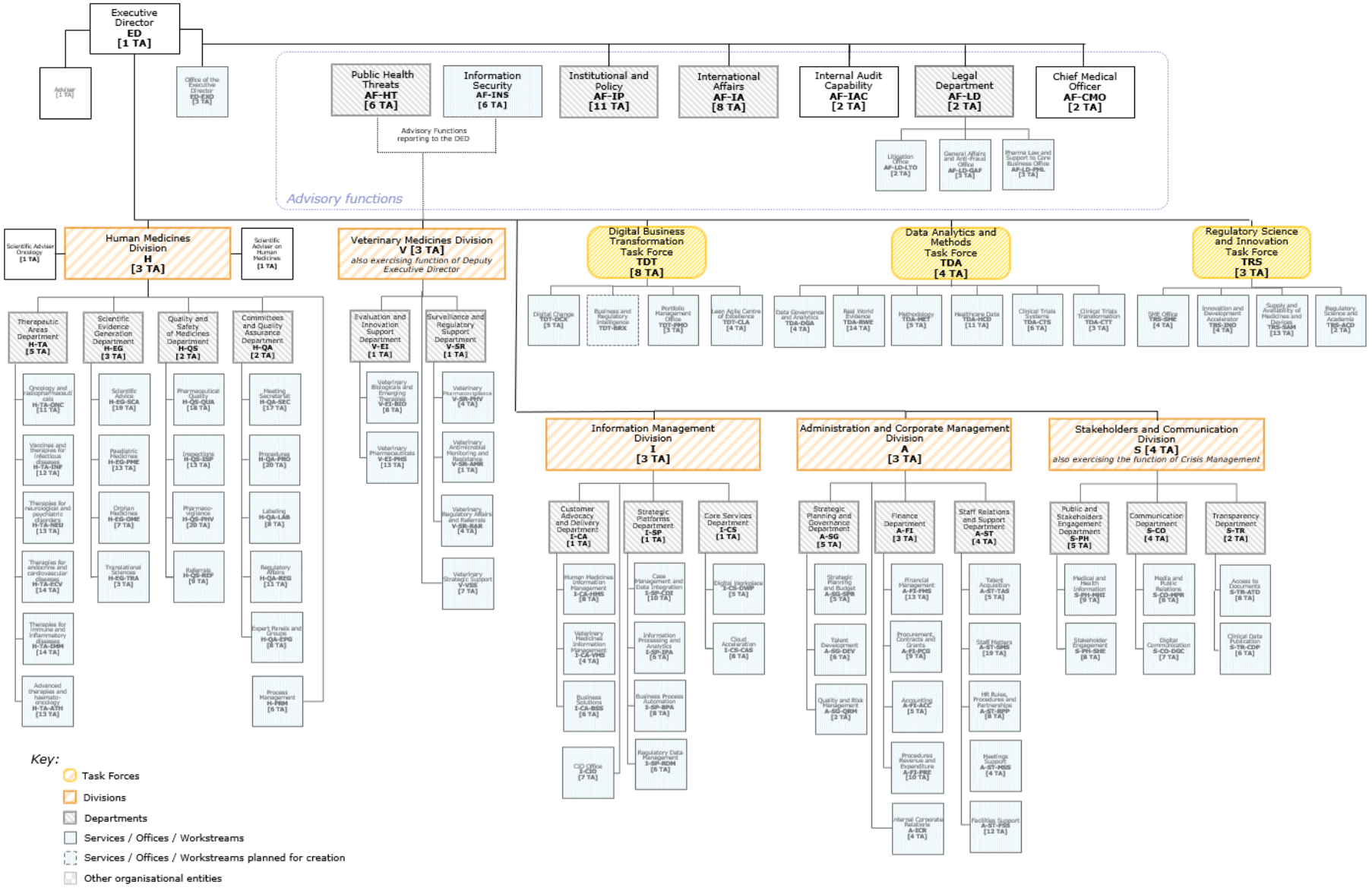
Performance indicators[16]

		Results	Expected results	Forecasts		
		2024	2025	2026	2027	2028
Change management	Overall stakeholder satisfaction with change management support[17]	-	NP 33% / NN 28%	SES: N/A	SES: NP 50% / NN 20%	SES: N/A
Network Portfolio	Network Portfolio predictability[18]:	85.00%	86%	87%	88%	88%
	Number of features demonstrated in public system demos	111	115	115	112	110
	Number of products involved in the demos	24	24	23	22	22

[15] New indicators introduced in the 2026 work programme.
[16] New indicators introduced in the 2026 work programme.
[17] The percentage indicated refers to positive replies to the EMA Staff engagement survey question "I feel that, at EMA, changes (organisational, regulatory...) are managed effectively."
[18] It indicates the accuracy of the Agile teams quarterly planning linked to the business committed objectives.

Annexes

Annex I Organisational chart


Executive Director
ED
[1 TA]
Adviser
[1 TA]
Office of the Executive Director
ED-EXD
[3 TA]
Public Health Threats
AF-HT
[6 TA]
Information Security
AF-INS
[6 TA]
Institutional and Policy
AF-IP
[11 TA]
International Affairs
AF-IA
[8 TA]
Internal Audit Capability
AF-IAC
[2 TA]
Legal Department
AF-LD
[2 TA]
Chief Medical Officer
AF-CMO
[2 TA]
Advisory Functions reporting to the DED
Litigation Office
AF-LD-LTO
[2 TA]
General Affairs and Anti-Fraud Office
AF-LD-GAF
[3 TA]
Pharma Law and Support to Core Business Office
AF-LD-PHL
[3 TA]
Advisory functions
Scientific Adviser Oncology
[1 TA]
Human Medicines Division
H
[3 TA]
Scientific Adviser on Human Medicines
[1 TA]
Veterinary Medicines Division
V [3 TA]
also exercising function of Deputy Executive Director
Digital Business Transformation Task Force
TDT
[8 TA]
Data Analytics and Methods Task Force
TDA
[4 TA]
Regulatory Science and Innovation Task Force
TRS
[3 TA]
Therapeutic Areas Department
H-TA
[5 TA]
Scientific Evidence Generation Department
H-EG
[3 TA]
Quality and Safety of Medicines Department
H-QS
[2 TA]
Committees and Quality Assurance Department
H-QA
[2 TA]
Evaluation and Innovation Support Department
V-EI
[1 TA]
Surveillance and Regulatory Support Department
V-SR
[1 TA]
Digital Change
TDT-DCK
[5 TA]
Business and Regulatory Intelligence
TDT-BRX
Portfolio Management Office
TDT-PMO
[5 TA]
Lean Agile Centre of Excellence
TDT-CLA
[4 TA]
Data Governance and Analytics
TDA-DGA
[4 TA]
Real World Evidence
TDA-RWE
[14 TA]
Methodology
TDA-MET
[5 TA]
Healthcare Data
TDA-HCD
[11 TA]
Clinical Trials Systems
TDA-CTS
[6 TA]
Clinical Trials Transformation
TDA-CTT
[3 TA]
SME Office
TRS-SME
[4 TA]
Innovation and Development Accelerator
TRS-IND
[4 TA]
Supply and Availability of Medicines and Devices
TRS-SAM
[13 TA]
Regulatory Science and Academia
TRS-ACD
[2 TA]
Information Management Division
I
[3 TA]
Administration and Corporate Management Division
A
[3 TA]
Stakeholders and Communication Division
S [4 TA]
also exercising the function of Crisis Management
Key:
Task Forces
Divisions
Departments
Services / Offices / Workstreams
Services / Offices / Workstreams planned for creation
Other organisational entities

Annex II Resources allocation per activity 2026

Work programme activities	STAFF		Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	Total expenditure	
			€'000	€'000	€'000	€'000	€'000	€'000	%
	Temporary Agent	Contract Agent & Seconded National Experts	Title 1	Title 2 & Budget Item 3105	Budget item 3000 & 3003	Article 301 & item 3033	Articles 302 & 303		
1 Evaluation activities for human medicines	**267**	**94**	**73,389**	**40,127**	**4,814**	**205,172**	**13,603**	**337,105**	**56%**
1.1 Pre-authorisation activities	72	23	20,006	9,946	2,334	37,200	1,012	70,497	12%
1.2 Initial evaluation activities	54	13	14,868	4,263	19	49,058	1,419	69,626	12%
1.3 Post-authorisation activities	70	24	18,417	13,668	-	101,517	3,138	136,741	23%
1.4 Referrals	7	1	1,684	480	-	212	246	2,621	0%
1.5 Pharmacovigilance activities	48	24	13,252	10,073	1,231	16,927	7,058	48,541	8%
1.6 Other specialized areas and activities	8	7	3,807	1,005	729	-	2	5,543	1%
1.7 Medical Devices	6	2	1,355	691	501	259	729	3,535	1%
2 Evaluation activities for veterinary medicines	**29**	**11**	**7,160**	**4,631**	**240**	**18,115**	**818**	**30,963**	**5%**
2.1 Pre-authorisation activities	2	0	323	380	35	2,229	55	3,022	1%
2.2 Initial evaluation activities	10	4	2,237	705	33	931	205	4,110	1%
2.3 Post-authorisation activities	9	3	1,860	2,781	-	2,432	496	7,569	1%
2.4 Arbitrations and Referrals	1	0	196	86	-	98	62	441	0%
2.5 Pharmacovigilance activities	4	2	1,412	376	153	12,425	-	14,367	2%
2.6 Other specialized areas and activities	5	1	1,132	303	19	-	-	1,454	0%
3 Horizontal activities and other areas	**256**	**109**	**77,122**	**56,045**	**11,272**	**18,428**	**18,865**	**181,731**	**30%**
3.1 Committee coordination	68	28	19,203	6,371	6,504	-	1,260	33,337	6%
3.2 Inspection and Compliance	24	18	8,118	7,940	108	18,428	998	35,592	6%
3.3 Partners and Stakeholders	50	12	14,898	3,365	2,529	-	1,035	21,828	4%
3.3a Transparency and access to documents	13	8	4,012	1,571	-	-	1,075	6,658	1%
3.3b Information	48	25	14,824	14,941	1,619	-	181	31,565	5%
3.4 International activities	20	9	6,456	1,374	93	-	-	7,923	1%
3.5 Information Management (incl. data and scientific studies)	33	8	9,612	20,482	419	-	14,316	44,828	7%
4 Corporate Governance and Support activities	**159**	**34**	**38,740**	**12,188**	**1,119**	**-**	**9**	**52,056**	**9%**
4.1 Governance, quality management and internal audit	22	4	6,611	2,528	1,025	-	2	10,166	2%
4.2 Finance	29	11	6,911	2,494	-	-	7	9,412	2%
4.3 Information technology	48	12	12,444	3,219	94	-	-	15,757	3%
4.4 Human resources	48	7	10,095	3,270	-	-	-	13,365	2%
4.5 Infrastructure services	12	0	2,679	677	-	-	-	3,356	1%
Total	**712**	**248**	**196,411**	**112,990**	**17,444**	**241,715**	**33,294**	**601,854**	**100%**

FTEs are calculated as follows:	FTEs
Temporary Agents	719
Vacancies	7
Total Temp	712
Contract Agents	203
Seconded National Experts	45
Total Staff	**960**

Rent London premises (funded by EU contribution)	**13,686**
Budget 2026	**615,540**

Annex III Financial resources 2026–2028

Table 1 – Revenue

General revenues

Revenues	2025	2026	2027	2028
	Revenue estimated by the agency	Budget forecast	Budget forecast	Budget forecast
EU contribution	€ 48,921,331	€ 50,856,000	€ 52,329,000	€ 51,320,000
Other revenue	€ 541,568,550	€ 564,684,000	€ 578,772,000	€ 590,347,000
PROVISIONAL REVENUE				
Total revenue	**€ 590,489,881**	**€ 615,540,000**	**€ 631,101,000**	**€ 641,667,000**

REVENUES	General Revenues					General Revenues			
	Executed 2024[1]	Estimated by the agency 2025[2]	2026		VAR 2026/2025 (%)	2027		VAR 2027/2026 (%)	forecast 2028
			agency request	budget forecast		agency request	budget forecast		
1 Revenue from services rendered	€ 441,834,527	€ 539,896,175	€ 563,195,000	€ 563,195,000	4.32%	€ 577,280,000	€ 577,280,000	2.50%	€ 588,825,000
2 EU and EFTA contribution	€ 46,283,191	€ 48,921,331	€ 50,856,000	€ 50,856,000	3.95%	€ 52,329,000	€ 52,329,000	2.90%	€ 51,320,000
- of which special contribution for orphan medicinal products	*€ 9,298,575*	*€ 20,958,625*	*€ 15,172,000*	*€ 15,172,000*	*-27.61%*	*€ 17,650,000*	*€ 17,650,000*	*16.33%*	*€ 14,370,000*
- of which EEA/EFTA contribution	*€ 842,766*	*€ 1,327,290*	*€ 1,190,000*	*€ 1,190,000*	*-10.34%*	*p.m.*	*p.m.*	*p.m.*	*p.m.*
- of which assigned revenues deriving from previous years' surpluses	*€ 10,459,043*	*€ 20,939*	*€ 4,595,000*	*€ 4,595,000*	*p.m.*	*p.m.*	*p.m.*	*p.m.*	*p.m.*
3 Third countries contribution	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'
- of which EEA/EFTA (excluding Switzerland)	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
- of which Candidate Countries	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
4 Other contributions	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
- of which delegation agreement, ad hoc grants	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
5 Administrative operations	€ 1,825,870	€ 1,412,599	€ 1,290,000	€ 1,290,000	-8.68%	€ 1,290,000	€ 1,290,000	0.00%	€ 1,316,000
- Of which interest generated by funds paid by the Commission by way of the EU contribution (FFR Art. 58)	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
6 Revenues from services rendered against payment	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
7 Correction of budgetary imbalances	€ 0	€ 0	€ 0	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.
9 Miscellaneous revenue	€ 2,184,195	€ 259,776	€ 199,000	€ 199,000	n/a	€ 202,000	€ 202,000	p.m.	€ 206,000
TOTAL REVENUES	**€ 492,127,784**	**€ 590,489,881**	**€ 615,540,000**	**€ 615,540,000**	4.24%	**€ 631,101,000**	**€ 631,101,000**	2.53%	**€ 641,667,000**

1) Data as per final 2024 accounts
2) Updated in accordance with the provisional outturn.

Additional EU funding: grant, contribution and service level-agreements

REVENUES	2025	2026	2027	2028
	Budget forecast	Budget forecast	Budget forecast	Budget forecast
TOTAL REVENUES	€ 4,731,500	€ 2,484,000	€ 6,770,500	€ 3,170,237

REVENUES	General Revenues						
	Executed 2024	Estimated by the agency 2025	2026		VAR 2026/2025 (%)	Forecast 2027	Forecast 2028
			Agency request	Budget forecast			
ADDITIONAL EU FUNDING STEMMING FROM GRANTS (FFR Art.7)	€ 18,997	€ 131,500	€ 184,000	€ 184,000	39.92%	€ 170,500	€ 170,237
ADDITIONAL EU FUNDING STEMMING FROM CONTRIBUTION AGREEMENTS (FFR Art.7)	€ 2,053,472	€ 4,600,000	€ 2,300,000	€ 2,300,000	-50.00%	€ 6,600,000	€ 3,000,000
ADDITIONAL EU FUNDING STEMMING FROM SERVICE LEVEL AGREEMENTS (FFR Art. 43.2)	n/a	n/a	n/a	n/a	n/a	n/a	n/a
TOTAL	€ 2,072,469	€ 4,731,500	€ 2,484,000	€ 2,484,000	-48%	€ 6,770,500	€ 3,170,237

Table 2 – Expenditure

Expenditure	2024 [1]		2025		2026		2027		2028	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1 - Staff expenditure	€ 165,632,413	€ 165,632,413	€ 188,482,011	€ 188,482,011	€ 196,411,000	€ 196,411,000	€ 203,758,000	€ 203,758,000	€ 208,172,000	€ 208,172,000
Title 2 - Infrastracture and operating expenditure	€ 81,835,616	€ 81,835,616	€ 91,885,508	€ 91,885,508	€ 95,380,000	€ 95,380,000	€ 95,088,000	€ 95,088,000	€ 96,990,000	€ 96,990,000
Title 3 - Operational expenditure	€ 243,017,321	€ 243,017,321	€ 310,211,911	€ 310,211,911	€ 323,749,000	€ 323,749,000	€ 332,255,000	€ 332,255,000	€ 338,899,000	€ 338,899,000
Title 9 - Provisional appropriations			€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 490,485,351**	**€ 490,485,351**	**€ 590,579,430**	**€ 590,579,430**	**€ 615,540,000**	**€ 615,540,000**	**€ 631,101,000**	**€ 631,101,000**	**€ 644,061,000**	**€ 644,061,000**

1) Data as per final 2024 accounts

Expenditure	2024			2025			2026 [1]			2027			2028		
	Fee related activities	Non-fee related activities	Total	Fee related activities	Non-fee related activities	Total	Fee related activities	Non-fee related activities	Total	Fee related activities	Non-fee related activities	Total	Fee related activities	Non-fee related activities	Total
Title 1 - Staff expenditure	€ 102,193,599	€ 63,438,814	€ 165,632,413	€ 112,610,245	€ 75,871,767	€ 188,482,011	€ 120,934,896	€ 75,476,104	€ 196,411,000	€ 156,104,893	€ 47,653,107	€ 203,758,000	€ 159,486,586	€ 48,685,414	€ 208,172,000
Title 2 - Infrastructure and operating expenditure	€ 38,202,698	€ 30,507,918	€ 68,710,616	€ 44,761,418	€ 32,976,569	€ 77,737,987	€ 46,174,963	€ 35,519,037	€ 81,694,000	€ 59,347,665	€ 22,238,335	€ 81,586,000	€ 61,575,842	€ 22,683,158	€ 84,259,000
Title 3 - Operational expenditure	€ 223,669,425	€ 19,347,896	€ 243,017,321	€ 281,896,917	€ 28,314,995	€ 310,211,911	€ 293,987,885	€ 29,761,115	€ 323,749,000	€ 254,550,158	€ 77,704,842	€ 332,255,000	€ 259,640,319	€ 79,258,681	€ 338,899,000
Title 9 - Provisional appropriations	€ 0		€ 0	€ 0		€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 364,065,722**	**€ 113,294,628**	**€ 477,360,351**	**€ 439,268,579**	**€ 137,163,330**	**€ 576,431,909**	**€ 461,097,744**	**€ 140,756,256**	**€ 601,854,000**	**€ 470,002,716**	**€ 147,596,284**	**€ 617,599,000**	**€ 480,702,747**	**€ 150,627,253**	**€ 631,330,000**
% of total expenditure	**76%**	**24%**	**100%**	**76%**	**24%**	**100%**	**77%**	**23%**	**100%**	**76%**	**24%**	**100%**	**76%**	**24%**	**100%**
Expenditure related to London premises (30 Churchill Place)						€ 14,147,521			€ 13,686,000			€ 13,502,000			€ 12,731,000
Total expenditure			**€ 477,360,351**			**€ 590,579,430**			**€ 615,540,000**			**€ 631,101,000**			**€ 644,061,000**
* Full-time Equivalent	498	411	**909**	582	370	**952**	609	351	**960**	646	372	**1018**	646	372	**1018**
% of total FTEs	55%	45%	**100%**	61%	39%	**100%**	63%	37%	**100%**	63%	37%	**100%**	63%	37%	**100%**

1) On this table staff are shown in FTEs and might differ from the number of staff in Annex IV.

EXPENDITURE	Commitment appropriations								
	Executed budget 2024[1]	Estimated by the Agency, 2025[2]	Draft budget 2026		VAR 2026/2025 (%)	Forecast 2027		VAR 2027/2026	Forecast 2028
			Agency request	Budget forecast		Agency request	Budget forecast		
Title 1 - Staff Expenditure									
11 Staff holding a post provided for in the list of posts	€ 140,476,516	€ 159,263,580	€ 166,099,000	€ 166,099,000	4.29%	€ 174,371,000	€ 174,371,000	4.98%	€ 178,198,000
- of which establishment plan posts	*€ 117,868,604*	*€ 134,603,260*	*€ 140,001,000*	*€ 140,001,000*	*4.01%*	*€ 147,335,000*	*€ 147,335,000*	*5.24%*	*€ 150,568,629*
- of which external personnel	*€ 22,607,911*	*€ 24,660,320*	*€ 26,098,000*	*€ 26,098,000*	*5.83%*	*€ 27,036,000*	*€ 27,036,000*	*3.59%*	*€ 27,629,371*
12 Expenditure relating to staff recruitment	€ 95,928	€ 201,814	€ 280,000	€ 280,000	38.74%	€ 262,000	€ 262,000	-6.43%	€ 267,000
13 Duty travel expenses and incidental expenditure	€ 784,546	€ 881,370	€ 1,500,000	€ 1,500,000	70.19%	€ 1,850,000	€ 1,850,000	23.33%	€ 1,887,000
14 Socio-medical infrastructure	€ 3,494,147	€ 3,799,146	€ 4,202,000	€ 4,202,000	10.60%	€ 4,401,000	€ 4,401,000	4.74%	€ 4,489,000
15 Staff training	€ 1,059,830	€ 1,047,425	€ 1,458,000	€ 1,458,000	39.20%	€ 1,501,000	€ 1,501,000	2.95%	€ 1,531,000
16 External services	€ 19,579,447	€ 23,034,955	€ 22,663,000	€ 22,663,000	-1.61%	€ 21,159,000	€ 21,159,000	-6.64%	€ 21,582,000
17 Receptions and events	€ 142,000	€ 253,721	€ 209,000	€ 209,000	-17.63%	€ 214,000	€ 214,000	2.39%	€ 218,000
Total Title 1	**€ 165,632,413**	**€ 188,482,011**	**€ 196,411,000**	**€ 196,411,000**	4.21%	**€ 203,758,000**	**€ 203,758,000**	**3.74%**	**€ 208,172,000**
Title 2 - Infrastructure and operating expenditure									
20 Investment in immovable property, renting of buildings and associated costs	€ 30,522,832	€ 31,653,540	€ 33,620,000	€ 33,620,000	6.21%	€ 32,809,000	€ 32,809,000	-2.41%	€ 33,465,000
21 Corporate information and communication technology	€ 43,591,156	€ 50,272,539	€ 50,350,000	€ 50,350,000	0.15%	€ 50,763,000	€ 50,763,000	0.82%	€ 51,778,000
22 Movable property and associated costs	€ 626,236	€ 660,014	€ 1,087,000	€ 1,087,000	64.69%	€ 889,000	€ 889,000	-18.22%	€ 907,000
23 Current administrative expenditure	€ 1,642,998	€ 1,113,144	€ 1,491,000	€ 1,491,000	33.94%	€ 1,519,000	€ 1,519,000	1.88%	€ 1,549,000
24 Postal and delivery services	€ 19,800	€ 25,500	€ 35,000	€ 35,000	37.25%	€ 35,000	€ 35,000	0.00%	€ 36,000
25 Other meetings	€ 102,841	€ 124,319	€ 129,000	€ 129,000	3.77%	€ 133,000	€ 133,000	3.10%	€ 136,000
26 Restaurant and catering	€ 963,425	€ 2,314,000	€ 2,389,000	€ 2,389,000	3.24%	€ 2,426,000	€ 2,426,000	1.55%	€ 2,475,000
27 Information and publishing	€ 1,458,011	€ 1,964,351	€ 2,664,000	€ 2,664,000	35.62%	€ 2,746,000	€ 2,746,000	3.08%	€ 2,801,000
28 Business consultancy and audit services	€ 2,908,317	€ 3,758,100	€ 3,615,000	€ 3,615,000	-3.81%	€ 3,768,000	€ 3,768,000	4.23%	€ 3,843,000
Total Title 2	**€ 81,835,616**	**€ 91,885,508**	**€ 95,380,000**	**€ 95,380,000**	**3.80%**	**€ 95,088,000**	**€ 95,088,000**	**-0.31%**	**€ 96,990,000**
Title 3 - Operational expenditure									
300 Meetings	€ 4,952,182	€ 5,809,448	€ 6,640,000	€ 6,640,000	14.30%	€ 6,673,000	€ 6,673,000	0.50%	€ 6,806,000
301 Evaluation of medicinal products	€ 177,099,498	€ 234,673,401	€ 240,410,000	€ 240,410,000	2.44%	€ 247,193,000	€ 247,193,000	2.82%	€ 252,137,000
302 Translations	€ 4,957,129	€ 5,348,780	€ 4,908,000	€ 4,908,000	-8.24%	€ 5,174,000	€ 5,174,000	5.42%	€ 5,277,000
303 Scientific studies and services	€ 16,812,889	€ 23,913,964	€ 29,691,000	€ 29,691,000	24.16%	€ 30,355,000	€ 30,355,000	2.24%	€ 30,962,000
31 Expenditure on business related IT projects	€ 39,195,624	€ 40,466,318	€ 42,100,000	€ 42,100,000	4.04%	€ 42,860,000	€ 42,860,000	1.81%	€ 43,717,000
Total Title 3	**€ 243,017,321**	**€ 310,211,911**	**€ 323,749,000**	**€ 323,749,000**	**4.36%**	**€ 332,255,000**	**€ 332,255,000**	**2.63%**	**€ 338,899,000**
900 Provisional appropriations	€ 0	€ 0	€ 0	€ 0	0.00%	€ 0	€ 0	0.00%	€ 0
Total Title 9	**€ 0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**	**0%**	**€ 0**
TOTAL EXPENDITURE	**€ 490,485,351**	**€ 590,579,430**	**€ 615,540,000**	**€ 615,540,000**	**4.23%**	**€ 631,101,000**	**€ 631,101,000**	**2.53%**	**€ 644,061,000**

1) Data as per final 2024 accounts
2) Updated in accordance with the provisional outturn .

Table 3 – Budget outturn and cancellation of appropriations 2022–2024 (C1, C11, C2, R0 and CL)

Budget outturn	2022	2023	2024 [1]	2025 [2]
Revenue actually received (+)	€ 435,940,241.40	€ 461,524,567.24	€ 502,584,563.56	€ 607,558,882.40
Payments made (-)	-€ 323,521,935.71	-€ 372,652,447.84	-€ 421,656,091.85	-€ 530,606,505.99
Carry-over of appropriations (-)	-€ 111,229,771.50	-€ 98,509,524.66	-€ 81,568,907.54	-€ 81,893,106.30
Cancellation of appropriations carried over (+)	€ 4,455,177.77	€ 5,174,935.87	€ 2,782,128.67	€ 2,727,862.17
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 5,349,241.90	€ 4,401,553.29	€ 2,282,868.97	€ 2,401,180.40
Exchange rate differences (+/-)	-€ 533,910.72	€ 81,854.69	€ 170,422.56	-€ 168,727.45
Adjustment for negative balance from previous year (-)	€ 0.00	€ 0.00		€ 0.00
Total	**€ 10,459,043.14**	**€ 20,938.59**	**€ 4,594,984.37**	**€ 19,585.23**

1) Data as per final 2024 accounts.
2) Data updated in accordance with the provisional outturn.

The financial outturn for 2025, a surplus of EUR 19 585, representing 0.003% of the approved budget (including Amending budgets), i.e. EUR 600.2 million, cf. the draft budget outturn for fund sources (C1, C11 & C2).

The Agency's adopted budget consists of non-differentiated appropriations only, so no distinction is made between commitment and payment appropriations.

Budget implementation 2025 is as follows:

- Title I -Staff expenditure: cancellation of commitment appropriation was 0.4%, resulting in a final implementation of 99.6%, which is considered a good result;
- Title II - infrastructure and operating expenditure: cancellation of commitment appropriation (including non-automatic carry forward) was 0.8%, resulting in a final implementation of 99.2%, which is considered a good result;
- Title III - operational expenditure: cancellation of commitment appropriation was 1.8%, resulting in a final implementation of 98.2%, which is considered a good result.

The agency complied with the KPIs on the ceiling of the amounts carried forward to 2026 (from C1 to C8):

- Overall carry forward (indicative ceiling of 15%), where 12.7% of total committed appropriations were carried forward to 2026
- Title I (indicative ceiling of 10%), where 3.05% of committed appropriations were carried forward to 2026.
- Title II (indicative ceiling of 20%), 18.42% of committed appropriations were carried forward to 2026.
- Title III (indicative ceiling of 30%), 16.78% of committed appropriations were carried forward to 2026.

Annex IV Human resources – quantitative

Table 1 – Staff population and its evolution; overview of all categories of staff

A. Statutory staff and SNEs

Staff	2025			2026	2027	2028
ESTABLISHMENT PLAN POSTS	**Authorised Budget**	**Actually filled as of 31/12/2025**	**Occupancy rate %**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**
Administrators (AD)	505	502	99%	516	566	566
Assistants (AST)	199	199	100%	203	204	204
Assistants/Secretaries (AST/SC)	0	0	0%	0	0	0
TOTAL ESTABLISHMENT PLAN POSTS	**704**	**701**	**100%**	**719**	**770**	**770**
EXTERNAL STAFF	**Envisaged FTE**	**Executed FTE as of 31/12/2025**	**Execution Rate %**	**Envisaged FTE**	**Envisaged FTE**	**Envisaged FTE**
Contract Agents (CA)	203	214	105%	203	203	203
Seconded National Experts (SNE)	45	45	100%	45	45	45
TOTAL EXTERNAL STAFF	248	259	104%	248	248	248
TOTAL STAFF	**952**	**960**	**101%**	**967**	**1018**	**1018**

B. Additional external staff expected to be financed from grants, contributions or service level agreements

Human Resources	2025	2026	2027	2028
	Envisaged FTEs	Envisaged FTEs	Envisaged FTEs	Envisaged FTEs
Contract Agents (CA)	9.6	10.0	8.5	8.5
Seconded National Experts (SNE)	0	0	0	0
TOTAL	9.6	10.0	8.5	8.5

C. Other human resources

Structural Service providers

	Actually in place as of 31/12/2023	Actually in place as of 31/12/2024
Security	23	23
IT service desk	29	29
IT maintenance and support 'time & means' contracts only	4	0
Reception	10	8
Building maintenance[1]	n/a	n/a
Cleaning	26	26
Catering	27	27
Reprographics and mail services	7	7

Interim workers

	Total FTEs in year 2023	Total FTEs in year 2024	Total FTEs in year 2025
Number	110	123	120

Table 2 – Multi-annual staff policy plan 2024, 2025, 2026, 2027, 2028

Function group and grade	2023				2024				2025				2026		2027		2028	
	Authorised budget		Actually filled as of 31/12/2023		Authorised budget		Actually filled as of 31/12/2024*		Authorised budget		Actually filled as of 31/12/2025*		Envisaged		Envisaged		Envisaged	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16		0		0		0		0		0		0		0		0		0
AD 15		3		0		3		3		3		1		3		2		2
AD 14		12		3		12		12		12		11		13		15		15
AD 13		12		11		12		12		15		15		18		17		17
AD 12		57		52		61		61		64		64		64		68		68
AD 11		49		49		50		50		49		49		51		45		45
AD 10		53		53		57		57		59		59		60		64		64
AD 9		66		66		82		82		94		94		109		95		95
AD 8		87		87		78		78		81		81		76		86		86
AD 7		89		89		90		90		85		85		93		95		95
AD 6		67		67		55		55		43		43		29		79		79
AD 5		0		0		0		0		0		0		0		0		0
AD TOTAL	**0**	**495**		**477**	**0**	**500**		**500**	**0**	**505**		**502**		**516**		**566**		**566**
AST 11		2		2		3		3		3		3		3		3		3
AST 10		7		7		7		7		7		7		7		7		7
AST 9		10		10		10		10		13		13		15		15		15
AST 8		14		14		15		15		19		19		23		20		20
AST 7		25		25		29		29		38		38		41		33		33
AST 6		31		31		35		35		26		26		40		48		48
AST 5		43		43		49		49		56		56		42		48		48
AST 4		43		43		32		32		22		22		16		12		12
AST 3		12		12		11		11		15		15		16		18		18
AST 2		0		0		0		0		0		0		0		0		0
AST 1		0		0		0		0		0		0		0		0		0
AST TOTAL	**0**	**187**		**187**	**0**	**191**		**191**	**0**	**199**		**199**		**203**		**204**		**204**
AST/SC1																		
AST/SC2																		
AST/SC3																		
AST/SC4																		
AST/SC5																		
AST/SC6																		
AST/SC TOTAL	**0**	**0**			**0**	**0**			**0**	**0**		**0**	**0**	**0**		**0**		**0**
GRAND TOTAL	**0**	**682**		**664**	**0**	**691**		**691**	**0**	**704**		**701**	**0**	**719**		**770**		**770**

*) EMA makes use of Article 38(2) FR to offset workforce loss through part-time work undertaken by TA staff. In 2024, the average part time loss was 13.1 FTE, allowing for the appointment of 4 additional staff not included above.

External personnel

Contract Agents

Contract agents	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	Headcount as of 31/12/2024	FTE corresponding to the authorised budget 2025	Executed FTE as of 31/12/2025	Headcount as of 31/12/2025	Envisaged FTE 2026	Envisaged FTE 2027	Envisaged FTE 2028
Function Group IV	125	111	119	128	118	130	131	134	137
Function Group III	78	100	99	75	96	100	72	69	66
Function Group II	0	0	0	0	0	0	0	0	0
Function Group I	0	0	0	0	0	0	0	0	0
Additional CA	0	0	0	0	0	0	0	0	0
TOTAL	**203**	**211**	**218**	**203**	**214**	**230**	**203**	**203**	**203**

Seconded National Experts

Seconded National Experts	FTE corresponding to the authorised budget 2025	Executed FTE as of 31/12/2025	Headcount as of 31/12/2025	Envisaged FTE 2026	Envisaged FTE 2027	Envisaged FTE 2028
Total	45	45	52	45	45	45

Table 3- Recruitment forecasts N+1 following retirement/mobility or new requested posts

Job title in the Agency	**Type of contract (TA or CA)**		**TA**		**CA**
			Function group/grade of recruitment internal (Brackets) and external (single grade) foreseen for publication		**Recruitment Function Group (I, II, III and IV)**
	Due to foreseen retirement/ mobility	**New post requested due to additional tasks**	**Internal (brackets)**	**External (brackets)**	
Communication Senior Specialist		Requirement for AD8 exists in the service, but currently no vacant position. Therefore selection is planned for constituting a RL.	AD08 and above	AD08	
Customer Portfolio Lead		Refresh of RLs	AD06 and above	AD06	
Customer Portfolio Analyst		Refresh of RLs			FGIV
Data Science Specialist		Refresh of RLs	AD06 and above	AD06	
Biostatistician Specialist		Refresh of RLs	AD06 and above	AD06	
ATD Officer		Refresh of RLs			FGIV
Senior Scientific Specialist ERA			AD08 and above	AD08	

Financial Officer	Resignation of incumbent				FGIV
Pharmacovigilance Specialist		Refresh of RLs	AD06 and above	AD06	
Regulatory Affairs Specialist		Refresh of RLs	AD06 and above	AD06	
Quality and Manufacturing Specialist		Refresh of RLs	AD06 and above	AD06	
Scientific Specialist (Procedures)		Refresh of RLs	AD06 and above	AD06	

Annex V Human resources – qualitative

A. Recruitment policy
Implementing rules in place:

		Yes	No	If no, which other implementing rules are in place
Engagement of CA	Model Decision C(2019)3016	X		
Engagement of TA	Model Decision C(2015)1509	X		
Middle management	Model Decision C(2018)2542	X		
Type of posts	Model Decision C(2018)8800	X		
Function of adviser	Model decision C(2018)2209	X		

B. Appraisal and reclassification/promotions
Implementing rules in place:

		Yes	No	If no, which other implementing rules are in place
Appraisal TA	Model Decision C(2015)1513	X		
Appraisal CA	Model Decision C(2015)1456	X		
Reclassification of TA	Model Decision C(2015)9560	X		
Reclassification of CA	Model Decision C(2015)9561	X		

Table 1 – Reclassification of TAs/Promotion of officials

Grades	Average seniority in the grade among reclassified staff						
	2021	2022	2023	2024	2025	Actual average over 5 years	Average over 5 years (According to decision C(2015)9563)
AD05	2.21	2.00				2.11	2.8
AD06	2.81	3.13	3.6	3.37	3.32	3.31	2.8
AD07	4.81	3.29	3.75	3.48	2.87	3.72	2.8
AD08	3.25	3.88	5.1	3.57	3.58	3.95	3
AD09	4.62	3.33	6.12	3.4	3.57	4.08	4
AD10	5.2	4.95	3.54	6.67	4.75	5.16	4
AD11	8	2.92	5	6.25	5.8	5.88	4
AD12	2.84		7	8.38	6	7.04	6.7
AD13	9.5			3	7	7.2	6.7
AST1			8.58			8.58	3
AST2	4.28	3.12	4			3.6	3
AST3	3.89	3.57	3.69	3.4	3.26	3.56	3
AST4	4.91	3.73	3.5	3.63	3.02	3.7	3
AST5	5.2	3.75	3.8	3.58	4	3.97	4
AST6	5.14	3.50	3.67	4.22	3.67	4.13	4
AST7	11	3.00	5.25	5	4	4.92	4
AST8		3.00		4.5	5	4.5	4
AST10 (Senior assistant)							5
AST/SC1	N/A	N/A	N/A	N/A	N/A	N/A	4
AST/SC2	N/A	N/A	N/A	N/A	N/A	N/A	5
AST/SC3	N/A	N/A	N/A	N/A	N/A	N/A	5.9
AST/SC4	N/A	N/A	N/A	N/A	N/A	N/A	6.7
AST/SC5	N/A	N/A	N/A	N/A	N/A	N/A	8.3

Table 2 – Reclassification of contract staff

Function Group	Grade	Staff in activity at 1.01.2023	How many staff members were reclassified in 2024	Average number of years in grade of reclassified staff members 2024	How many staff members were reclassified in 2025	Average number of years in grade of reclassified staff members 2025	Average number of years in grade of reclassified staff members according to Decision C(2015)9561
CA IV	17	5			2	4.67	Between 6 and 10 years
	16	13	1	4.67	1	4.84	Between 5 and 7 years
	15	20	2	3.25			Between 4 and 6 years
	14	56	11	3.06	10	3.88	Between 3 and 5 years
	13	10	1	4.21	2	3.38	Between 3 and 5 years
CA III	11	9	1	3			Between 6 and 10 years
	10	43	2	3	3	3.9	Between 5 and 7 years
	9	41	4	3.11	7	3.49	Between 4 and 6 years
	8	4	3	3.36	1	3.21	Between 3 and 5 years
CA II	6						Between 6 and 10 years
	5	1					Between 5 and 7 years
	4						Between 3 and 5 years
CA I	2						Between 6 and 10 years
	1						Between 3 and 5 years

C. Gender representation

Table 1 – Data on 31/12/Year N-1 /statutory staff (only officials, TA and CA)

		2025							
		Official		Temporary		Contract agents		Grand total	
		Staff	%	Staff	%	Staff	%	Staff	%
Female	Administrator level	0		242	35%	93	40%	335	36%
	Assistant level (AST & AST/SC)	0		194	28%	85	37%	279	30%
	Total	**0**	**0**	**436**	**62%**	**178**	**77%**	**614**	**66%**
Male	Administrator level	0		229	33%	37	16%	266	29%
	Assistant level (AST & AST/SC)	0		36	5%	15	7%	51	5%
	Total	**0**	**0**	**265**	**38%**	**52**	**23%**	**317**	**34%**
Grand total		**0**	**0**	**701**	**100%**	**230**	**100%**	**931**	**100%**

Table 2 – Data regarding gender evolution over 5 years of the Middle and Senior management[19]

	2020		2025	
	Number	%	Number	%
Female managers	**10**	**38%**	**12**	**43%**
Male managers	**16**	**62%**	**16**	**57%**

[19] Staff who is defined as middle manager by the applicable General implementing provisions on middle management.

D. Geographical balance

Explanatory figures to highlight nationalities of staff (split per Administrator/CA FG IV and Assistant /CA FG I, II, III)

Table 1 – Data on 31/12/year N-1 – statutory staff only (officials, TA and CA)

Nationality	2025					
	AD + CA FG IV		AST/SC- AST + CA FGI/CA FGII/CA FGIII		TOTAL	
	Number	% of total staff members in AD and FG IV categories	Number	% of total staff members in AST SC/AST and FG I, II and III categories	Number	% of total staff
Austria	7	1%	1	0%	8	1%
Belgium	22	4%	2	1%	24	3%
Bulgaria	10	2%	9	3%	19	2%
Croatia	10	2%	3	1%	13	1%
Cyprus	0	0%	2	1%	2	0%
Czechia	3	0%	13	4%	16	2%
Denmark	3	0%	5	2%	8	1%
Estonia	0	0%	7	2%	7	1%
Finland	7	1%	5	2%	12	1%
France	82	14%	26	8%	108	12%
Germany	41	7%	17	5%	58	6%
Greece	53	9%	29	9%	82	9%
Hungary	10	2%	17	5%	27	3%
Ireland	17	3%	3	1%	20	2%
Italy	80	13%	44	13%	124	13%
Latvia	3	0%	8	2%	11	1%
Lithuania	7	1%	12	4%	19	2%
Luxembourg	0	0%	0	0%	0	0%
Malta	0	0%	0	0%	0	0%
Netherlands	27	4%	7	2%	34	4%
Norway	3	0%	0	0%	3	0%
Poland	15	2%	32	10%	47	5%
Portugal	47	8%	12	4%	59	6%
Romania	29	5%	11	3%	40	4%
Slovakia	9	1%	17	5%	26	3%
Slovenia	2	0%	2	1%	4	0%
Spain	90	15%	30	9%	120	13%
Sweden	5	1%	4	1%	9	1%
United Kingdom	19	3%	12	4%	31	3%
Other	0	0%	0	0%	0	0%
TOTAL	601	100%	330	100%	931	100%

Table 2 - Evolution over 5 years of the most represented nationality in the Agency*

Most represented nationality	2020		2025	
	Number	%	Number	%
Italian	**103**	**13%**	**124**	**13%**

E. Schooling

Agreement in place with the European School(s) of The Hague and Bergen				
Contribution agreements signed with the EC on type I European schools	**Yes**	**Yes with European School Bergen**	~~No~~	
Contribution agreements signed with the EC on type II European schools	**Yes**	**Yes with European School The Hague**	~~No~~	
Number of service contracts in place with international schools	None			
Description of any other solutions or actions in place: Statutory education allowance is in place				

Annex VI Environmental management

Following the EMAS audit in September 2024 and implementation of corrections towards non-conformities before the end of 2024, EMA received its confirmed registration to EMAS on 17 January 2025. The validated Environmental Statement 2023 was published on the EMA external website by 17 February 2025.

During the first half of 2025 a new environmental roadmap for the period 2025 to 2028 was prepared and endorsed by the Agency EXB in August 2025.

An internal environmental audit was performed in May 2025 and identified no non-conformities and seven observations for improvements and confirmed the EMA EMS to be effectively managed.

The Environmental Statement 2024 underwent validation by an external EMAS verifier in October 2025 and will be published on the EMA external website.

EMA recognises the European Climate Law, Regulation (EU) 2021/1119, for Europe's economy and society to become climate neutral by 2050, and the intermediate of reducing net greenhouse gas emissions by at least 55% by 2030. Whilst the EU Climate Law compares to 1990 levels, when the Agency did not exist, the Agency compares to 2015 levels.

In compliance with EMAS Regulation Annex 1, paragraph 4 the Agency has identified all direct and indirect aspects with an impact on the environment in an aspect register to determine which of those aspects are significant. The Agency has adopted a life cycle perspective to identify the stages that it can control or influence. Based on the environmental aspects, environmental objectives have been determined with targets, key performance indicators to monitor and actions to achieve the objectives in line with EMAS Annex II part A.6.2.1, Annex 4, paragraph C2, and Annex 2, part A.6.2.2.

To support reaching the long-term targets, the following objectives are identified:

Aspect	**Environmental objectives**	**Key performance indicator**	**Target 2026–2028**	**Actions to achieve environmental objectives**
Direct	Energy efficiency: 'EMA drives energy efficiency in line with good practices'	Total annual consumption of energy (heating, cooling, electricity) per FTE Total share of energy from sustainable sources	To establish a reduction trend over the programming period. Continue to use 100% renewable electricity	Investment in upgrading the building management system, allowing for adjustments of temperature set-point to optimise efficiency

Aspect	Environmental objectives	Key performance indicator	Target 2026–2028	Actions to achieve environmental objectives
				Replacement scheme of electronic equipment such as laptops[20] and other small electrical devices, products and appliances for further energy efficiency, when technically and financially justifiable
	Material efficiency: 'EMA drives material efficiency in line with good practices'	Consumption of sheets of office paper per FTE per working day	Monitor consumption	Promote reduced use of single-use materials along 'circularity approach' Promote paper-less workflows and digitalisation
	Material sustainability: 'EMA implements green criteria in its procurements for conscious selection of sustainable materials'	Choice of materials used, for the environmental impact and reduction of hazards	Green criteria to be used in all procurements where applicable, in line with green public procurement guidelines	Promote choice of sustainable materials with eco-labels or equivalent products, and sustainable/fair-trade and seasonal produce
	Water – 'EMA drives water efficiency in line with good practices'	Total annual consumption of water per FTE	Monitor consumption	
	Waste: 'EMA drives waste reduction in line with good practices'	Total annual generation of waste, per FTE	To monitor all waste streams generation	Monitor total waste per FTE and year, monitor WEEE waste generation and disposal by volume, and manage waste along a 'circularity approach'
	Land contamination – not relevant (no further land to be used)	N/A	N/A	N/A
	Emissions: 'EMA drives emission reduction, targeting climate neutrality by 2050'	Emissions of greenhouse gases [t] from meetings with external participants reimbursed by the Agency,	Target to reduce emissions from delegates travel, within the planning period, with **45%**	Monitor and report travel by staff and delegates towards the agreed targets on a regular basis, with consideration and for alignment to rules in place, for a balanced approach between face-to-face

[20] IT hardware procurements are concluded under DIGIT-run FWCs accessible to all participating EUI's. These FWCs include the requirement that all tenderers comply with the applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions. When selecting Hardware to add to the Catalogues (for example under MEQ IV Lot 1) the energy rating of the devices (for laptops, desktops & monitors) is one of the criteria used to evaluate the various devices proposed by the tenderers for inclusion in the relevant catalogues.

Aspect	Environmental objectives	Key performance indicator	Target 2026–2028	Actions to achieve environmental objectives
		Emissions from staff duty travel, and Emissions from staff commuting and teleworking	compared with 2015[21] i.e. carbon budget of 1469 TCO2e. Target of **5%** annual reduction of emissions from staff travel, during the programming period[22] Emissions from staff commuting and teleworking will be monitored over the programming period	and virtual participation in meetings and other events Staff survey regarding commuting and teleworking on an annual basis for data gathering. Awareness campaigns about emissions from different means of commuting and from different energy solutions
Indirect	Environmental effects of medicines for human and veterinary use (ERA)	As included in the single programming document (SPD) 2026–2028	n/a	Actions as included in the SPD 2026–2028

In July to September 2025, the staff survey to capture carbon emissions from commuting and teleworking was performed. The results from this survey will be included in the Annex for environmental management reporting in the Agency's 2025 Annual Activity Report, and in the 2025 Environmental Statement. The statement will be published once it has been validated by an external EMAS verifier.

As part of the Agency's induction training new starters receive information of the environmentally friendly credentials of the EMA building, how to work at the EMA offices by consideration to sustainable behaviour, the objectives and targets for improvements and the focus towards reaching EMAS registration.

Through the EMA Green Group, several awareness and communication campaigns are planned for 2026 to support the monitored areas above.

In 2026, further environmental performance indicators are monitored for calculation of the Agency's CO^2 emissions. For preparation of the Environmental Statement EMA voluntarily uses the Sectoral Reference Document on best environmental management practices, sector environmental performance indicators, and benchmarks of excellence for the public administration sector reflected in Commission Decision (EU) 2019/61 (SRD) with further guidance from the JRC publication on Best Environmental Management Practice for the Public Administration Sector (BEMP), since that is the Management Practice

[21] 2015 used as reference it being the last year of 'normal' EMA activities prior to the UK referendum in 2016, and the Covid-19 pandemic, each affecting the Agency's activities in 2016 to 2019 and 2020 to 2023 respectively due to Business Continuity Plans. In 2015, the carbon calculations included emissions from building consumption (energy, water, waste) and business travel, without information separating delegate's travel from staff missions. Target is set on the total emissions.
[22] Carbon budget for staff travel: outcome in 2024 of 278,2 TCO2e, adjusted carbon budget for 2025 to 264 TCO2e, 251 TCO2e in 2026, 238 TCO2e in 2027, and 227 TCO2e in 2028.

closest to the Agency's activities. Following the SRD and BEMP the environmental management reporting in the Environmental Statement will include total consumption, and environmental performance indicators with reporting on total consumption per Sqm of office per year, and total consumption per FTE per year further broken down for each aspect.

It can also be noted that the EMA building has a BREEAM rating of Excellent and Energy Rating A++.

Annex VII Building Policy

#	Building Name and type	Location	Surface area (in m²)			Rental contract					Host country (grant or support)
			Office space	non-office	Total	Rent (€/year)	Duration of the contract	Type	Breakout clause Y/N	Conditions attached to the breakout clause (if applicable)	
1	EMA premises Amsterdam	Domenico Scarlattilaan, 6 Amsterdam, 1083 HS	22,574	10,837	33,411	11,385,790	20 years 1.5 months from commencement date of 15/11/2019 to 31/12/2039	Lease agreement with CGREA (Central Government Real Estate Agency)	Y (condition to terminate)	The Lease can be terminated - At any time by mutual consent of the parties - At any moment by the Lessee/EMA with a notice period of 6 months if a decision is made to transfer EMA headquarters to another EU location - By either party after a consecutive period of 6 months of force majeure events which make the performance of the aggrieved Party impossible.	EUR 18 million inducement of which EUR 15 million were for enhancements to fitting out the premises and EUR 3 million are for rent reductions over the term of the lease.
2	Previous EMA premises, London – **sub-let**	30 Churchill Place, Canary Wharf, London E14 5EU	26,213	4,127	30,340	Funding through sub-lease and specific EU contribution	25 years from 1 July 2014 to 30 June 2039	Lease agreement with Canary Wharf Limited	N	No break-clause	None

#	Building Name and type	Location	Surface area (in m²)			Rental contract					Host country (grant or support)
			Office space	non-office	Total	Rent (€/year)	Duration of the contract	Type	Breakout clause Y/N	Conditions attached to the breakout clause (if applicable)	
TOTAL			40,520	23,231	63,751	11,385,790 (rent for EMA building in NL) *plus* specific EU contribution for previous premises in London					

Building projects in planning phase

None.

Building projects submitted to the European Parliament and the Council

No new building dossiers were submitted in 2025.

The most recent submission remains the March 2024 building dossier (EMA/122997/2024), which was submitted to the Budgetary Authority on 27 March 2024 and sought authorisation to amend the sub-underlease of the Agency's pre-Brexit office premises in London. This was approved by the European Parliament on 8 April 2024 and by the Council on 24 April 2024.

The amended sub-underlease documentation was signed in October 2024, valid as of January 2024. The sub-undertenant has since honoured the agreed new terms.

As of November 2025, the Agency continues to monitor the financial stability of its sub-undertenant at 30 Churchill Place and the sub-undertenant continues to honour the revised terms. No further instabilities have occurred since the amended sub-underlease agreement, and the Agency remains contractually protected under the amended lease. These developments align with the strategic objectives outlined in the Agency's Final programming document 2025–2027.

Following the EU decision to relocate the Agency post-Brexit, the matter of EMA's London premises was not made part of the negotiation package. This resulted in the lease remaining in force and the Agency having to maintain its contract for its former headquarters in London. The Agency continues to urge resolution of the London building matter at the political level.

Annex VIII Privileges and immunities

Agency privileges	Privileges granted to staff Protocol of privileges and immunities/diplomatic status
Agency has the most extensive legal capacity accorded to legal persons under the laws of the Host State (the Netherlands).	Staff (including Dutch nationals) do not pay national taxes on their EU salary.
Agency's premises, property and assets are inviolable, as well as Agency's archives and correspondence.	The Head of the Agency and the members of his/her household are accorded the same privileges and immunities as accorded by the Netherlands to heads of diplomatic missions in accordance with the Vienna Convention.
In case of interruption or threatened interruption of public services in the Agency's premises, the Agency is accorded the priority given to essential agencies and organs of the Host State (the Netherlands).	Certain EMA staff members are conferred with a status which equates to the same privileges and immunities as members of the diplomatic staff under the Vienna Convention on diplomatic relations of 1961.
Absence of restriction for Agency's financial assets (funds, currency, cash, or securities), and immunity from legal proceedings in the Host State (the Netherlands) – including immunity from search, seizure, requisition, confiscation, expropriation, and any other form of interference.	All other EMA staff are conferred with a status which equates to the same privileges and immunities as member of the administrative and technical staff of the diplomatic missions under the Vienna Convention on diplomatic relations of 1961.
The Agency, its assets, income, and other property are exempt from all direct taxes, within the scope of its official activities. Within the scope of its official activities, the Agency is also exempt from some indirect taxes listed in Article 13 of the Seat Agreement.	
For official uses, the Agency is exempted from import and export restrictions and duties.	
The Agency is exempt from the following indirect taxes: import and export taxes and duties; motor vehicle tax; tax on passenger motor vehicles and motorcycles; value added tax paid on goods and services supplied on a recurring basis or involving expenditure totalling €225 or more; excise duties included in the price of alcoholic beverages and hydrocarbons such as fuel oils and motor fuels; real property transfer tax; insurance tax; energy tax; and tax on water mains. The Agency is also exempt from any other indirect taxes or duties of a substantially similar character as the ones mentioned above, enacted by the Netherlands after the signature of the seat agreement.	
The Agency is exempt from all custom duties, prohibitions and restrictions on import and export in respect of goods and publications intended for its official use.	

Annex IX Evaluations

Article 86 of Regulation (EC) 726/2004 report on the experience of the operation of EU marketing authorisation procedures

The latest evaluation of the Agency's operation pursuant to Article 86 of the Regulation (EC) No 726/2004 was published on 31 August 2021 and is available in the form of a Report from the Commission to the European Parliament and the Council on the experience acquired with the procedures for authorising and supervising medicinal products for human use, in accordance with the requirements set out in the EU legislation on medicinal products for human use (COM/2021/497 final). The study assessed the extent to which the current marketing authorisation system for medicines met its objectives in the period 2010–2017. This report links to the pharmaceutical strategy for Europe and will inform its implementation, with regard to possible legislative and non-legislative measures. It also complements the ongoing revision of the EU pharmaceutical legislation including the regulations on medicines for rare diseases and on medicines for children. The implementation of the report's recommendations is being planned and will depend on the changes in the EU pharmaceutical legislation, as proposed by the European Commission in April 2023 and as ultimately agreed by the European Parliament and Council of the EU following conclusion of the legislative process. Further details on this evaluation report, including the supporting studies commissioned for it, are available at: https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu_en#related-information

The previous evaluation of the Agency took place in 2009, and resulted in a European Commission report that was published in January 2010. The Agency's follow-up to the recommendations from this report has been described in detail in the Programming Document 2018–2020.

Revision of rules on fees payable to the European Medicines Agency

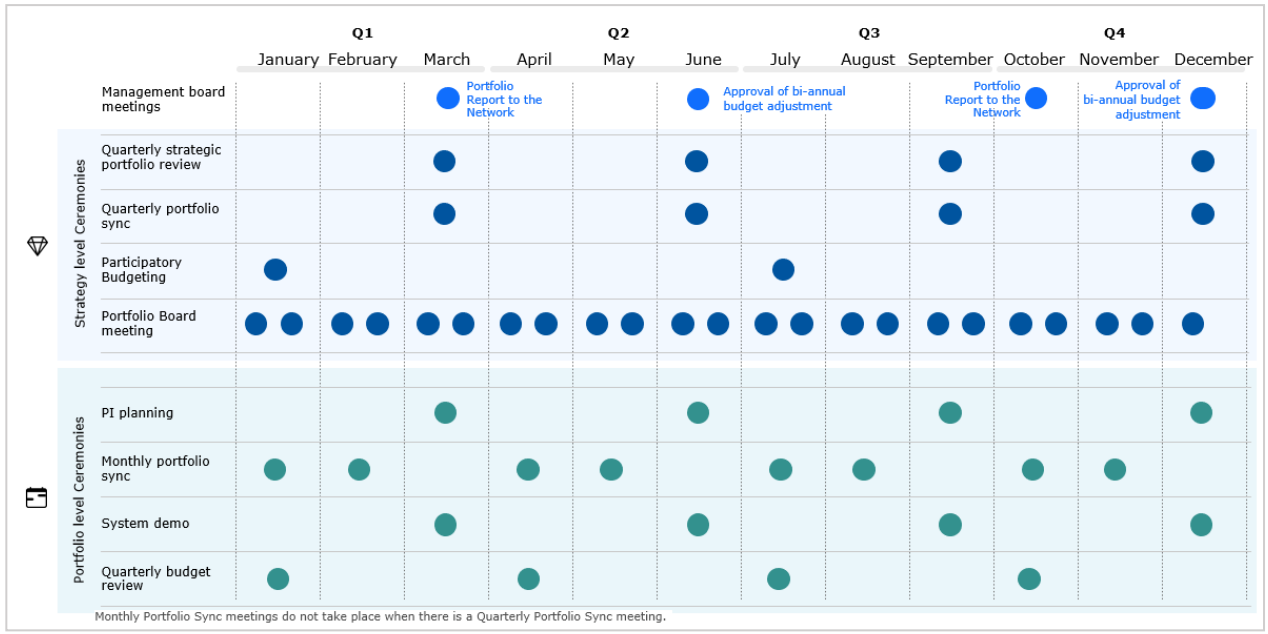
Based on the outcome of the evaluation of the EMA fee system finalised in 2019, the European Commission launched a legal proposal in December 2022 to update the legal framework on EMA fees. Following adoption by the European Parliament and the Council, the revised framework set-out in Regulation (EU) 2024/568 entered into force on 1 January 2025.

Reform of the EU pharmaceutical legislation, including the Orphan and Paediatric Regulations

On 26 April 2023, the Commission adopted a proposal for a new Directive and a new Regulation, which revises and replaces the existing general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on medicines for children and for rare diseases (Regulation 1901/2006 and Regulation 141/2000/EC, respectively). Several consultation activities related to the revision of the general pharmaceutical legislation have been published at the same time. To support the revision of the Orphan and Paediatric Regulations, the Commission had performed an evaluation of the experience with the operation of these 2 regulations, the results of which were published by the European Commission on 11 August 2020 (more details **here**). The non-legislative recommendations included in the paediatric report of 2017 are being implemented by EMA, in coordination with the European Commission, in the context of the EMA-HMA Action plan for supporting development of medicines for children.

Evaluation of Agile epics

The EMA Financial Regulation establishes the requirement for ex ante and retrospective evaluations for programmes and activities and used to be applied to the programmes and projects of the EMA portfolio. During 2021–2022, EMA transitioned from a programme and project approach into a new Agile way of working, where projects were replaced by Agile epics (an 'epic' means a container for a solution initiative, aligned with Portfolio objectives). The framework defining the new EMA Agile way of working has been implemented and is currently being refined. As a consequence, instead of evaluation of projects, EMA now performs evaluation of Agile epics. Similarly to the original projects gated procedure, under the Agile approach EMA retains a proportionate approach to evaluations and avoids burdening the system with unnecessary levels of evaluation, control and reporting, and epics oversight is responsibility of the Portfolio Board (PB), and ultimately of the Executive Board (EXB). The PB is responsible for approving the start of epics and monitoring their progress throughout the stages in their lifecycle, via monthly and quarterly reports. In exceptional circumstances, the PB may escalate certain epic issues to the EXB for resolution. The epic lifecycle foresees approval of a solution idea at a first stage, called epic hypothesis. The following stage aims for the approval of an epic lean business case. Oversight of progress and steering of the epic development is provided by the PB via reporting through Agile Ceremonies, with escalation to the Executive Board when necessary. Ex ante evaluations are conducted at the time of epic approval (when the epic presents its lean business case, including cost estimates, for the proposed solution) before the work and budget expenditure are formally initiated. When the total estimated epic cost exceeds EUR 1 million, the evaluation is conducted by the PB against pre-defined criteria, aiming to ensure a remaining sound business case. As follow-up actions, monthly and quarterly reporting ceremonies take place until the epic is finalised. Retrospective evaluations are conducted when an epic is formally concluded. When actual costs at epic closure exceed EUR 3 million, the retroactive evaluation is conducted by the PB against pre-defined criteria. Interim evaluations are conducted by the PB when the status of an ongoing epic is reviewed due to relevant modifications to scope, timeline and/or budget, and consequently its costs move from under the EUR 1 million threshold to above that mark. The results of ex ante and retrospective evaluations are reported twice a year as part of the 'Ex ante and retrospective evaluations report to the Management Board'. In addition, epic progress tracking is presented on every Quarterly Portfolio Review ceremony, in which Management Board representatives participate as part of the NPAG. The NPAG is the Network Portfolio Advisory Group, representing the Management Board and HMA within IT portfolio management; the NPAG attends relevant ceremonies jointly with the Portfolio Board, ensuring oversight of progress and providing input on strategic decisions. Given this new Agile approach is being consolidated and formally documented in detail, some of the terms and definitions mentioned above may change. The picture below illustrates the flow after an epic is approved by the Portfolio Board at a Portfolio Board meeting, then prioritised as part of a Participatory Budgeting Ceremony and finally included in the scope of a Programme Planning Increment (planning of work to be undertaken in the next quarter). Afterwards, the epic is continuously reported and monitored through ceremonies, which include monthly and quarterly reviews and also quarterly system demos, to ensure timely transparency of progress.


Q1
Q2
Q3
Q4
January
February
March
April
May
June
July
August
September
October
November
December
Management board meetings
Portfolio Report to the Network
Approval of bi-annual budget adjustment
Portfolio Report to the Network
Approval of bi-annual budget adjustment
Strategy level Ceremonies
Quarterly strategic portfolio review
Quarterly portfolio sync
Participatory Budgeting
Portfolio Board meeting
Portfolio level Ceremonies
PI planning
Monthly portfolio sync
System demo
Quarterly budget review
Monthly Portfolio Sync meetings do not take place when there is a Quarterly Portfolio Sync meeting.

Annex X Strategy for organisational management and internal control system

The purpose of the EMA internal control and organisational management strategy is to support and enable achievement of the Agency's strategic priorities and objectives, by ensuring that adequate and well-designed organisational structures, systems, and processes are implemented, appropriate controls are in place, improvements are identified and introduced in a timely and continuous manner, and flexible and performance-based governance is exercised.

The following guiding principles form the basis of the internal control strategy in the Agency:

• *Focus on performance and efficiency*, while maintaining simplicity of processes and compliance with legal, financial and regulatory requirements.

• *A quality focus and mind-set*. The Agency is committed to quality and excellence, both in terms of delivering high quality results and outputs in its work and cultivating a quality mind-set.

• *Continuous improvement of* systems, structures, processes and procedures, in line with recognised quality standards.

• *Transparency, fairness and independence*. The systems and processes are built to be fair, objective and independent, and so as to produce reliable outcomes and results. Transparency is key to building the trust in the systems and the results. Transparency also underpins communications with both internal and external stakeholders as well as the systems and processes themselves.

• *Evidence and fact-based approach and timely action.* Actions are taken and decisions made, based on sound evidence and reliable, relevant and timely information from trusted sources.

• *Fostering efficiency and effectiveness through integrated working methods*. The system and activities are devised to encourage collaboration and to ensure optimal efficiency and effectiveness through coherent, cohesive, integrated ways of working.

• *Firm commitment to high standards and levels of integrity*. Consistently, from top leadership down to every level, managers set the tone by showing through their attitudes, words, and actions a strong commitment to quality, objectivity, and integrity in all aspects of Agency work.

Internal controls are aimed toward achievement of several objectives:

- **Operational** objectives — related to the effectiveness and efficiency of operations, including operational and financial performance goals, and safeguarding any assets and information against loss.
- **Reporting** objectives — related to internal and external financial and non-financial reporting and its reliability, timeliness, transparency, or meeting of other requirements that may be established by EMA.
- **Compliance** objectives — related to the EMA's adherence to applicable policies, rules, and regulations.

- **Risk management** objectives — related to prevention, detection, correction and follow-up of fraud and irregularities, and adequate management of the risks relating to the legality and regularity of the underlying transactions.

EMA internal control framework is based on the COSO[23] model of internal control, and consists of five integrated internal control components, supported by seventeen principles.

Organisational management

Internal control governance, roles, and responsibilities

The Executive Director is ultimately responsible for effective implementation of the internal control strategy and framework and puts in place the necessary structures and systems to ensure attaining of the Agency's goals and objectives in the most efficient and effective way. In implementing internal controls, the Executive Director is supported by the EMA Executive Board, through its strategic planning and implementation monitoring activities, as well as periodic review of internal control system; managers at all levels of the Agency, through their day-to-day running, monitoring and continuously improving the Agency's operations; Internal Control Coordinator and IQM and planning coordinators across the Agency, that help to coordinate internal control activities throughout the organisation; and EMA internal audit function, that provides an independent oversight and opinion of the internal control system, its efficiency and improvement opportunities.

EMA management structures and bodies

The key Agency's management bodies that ensure delivery of the Agency's responsibilities, and by extension – implement internal controls, include the Management Board (MB), which has a supervisory role, with general responsibility for budgetary and planning matters; the Executive Board (EXB), which considers both the strategic issues and high-level cross-Agency operational issues; Medicines Leadership Team (MLT) – a governance and decision-making body of the Agency's scientific operations divisions; Portfolio Board (PB) – the body responsible for the oversight and review of the Agency projects throughout all the phases; Scientific Coordination Board (SciCoBo) – a high-profile management body, created to ensure the strategic coordination between the scientific committees of the Agency, and the EMA Architecture Board (EAB) – the IT architecture governance body of the Agency.

Delegation of powers and responsibilities

To enact the most effective management of the Agency and ensure proportionality and effective decision-making at the lowest possible level corresponding to the associated risks, financial, operational and staff-related delegations have been put in place at the Agency without prejudice to the Executive Director's power, cascading throughout the managerial structures decision-making powers on specific acts, to ensure uninterrupted and effective business operations. The delegations in place are updated as required, to reflect any relevant organisational or staff changes.

[23] Committee of Sponsoring Organizations of the Treadway Commission (COSO) Internal Control — Integrated Framework, June 2017.

Internal control system

Purpose of internal control system

Internal control system at the Agency is aimed at helping the organisation achieve its objectives and sustain operational and financial performance, respecting rules, and regulations. It supports sound decision making, considering risks to the achievement of objectives and reducing them to acceptable levels through cost-effective controls.

Components

Internal control system at the Agency is comprised of several components, each serving a specific function, and each individually and all collectively providing assurance to the Executive Director that the organisation and its processes are run effectively:

- **Internal control framework** (ICF) is the umbrella for all internal control elements and is based on the COSO model of internal control, covering a wide range of topics and aspects of the Agency's operations and ways of functioning. Internal control framework is reviewed annually.
- **Ex-ante controls** are carried out daily, in line with Article 45 (5) of the Financial Regulation, to prevent errors and irregularities before the authorisation of operations, to mitigate risks of non-achievement of objectives, and to assure the Authorising Officer that the budget implementation does respect the budgetary principles of sound financial management and transparency.
- **Ex-post controls** are conducted annually in line with Article 45 (8) of the Financial Regulation, to ascertain that the processes and procedures are correctly implemented and followed, and that they comply with the applicable provisions, and to help detect and correct potential errors and irregularities of operations.
- **Exception** reporting procedure is in place to ensure that all instances of overriding of controls or deviations from established processes and procedures are documented, justified, and duly approved before action is taken. Data from the exceptions register is analysed at least twice a year.
- **Sensitive function review** aims to identify and manage the posts where there is a risk of the jobholders deliberately misusing their decision-making power or influence for personal gain (financial or otherwise), and to ensure that adequate internal control systems are in place to mitigate the risks of these sensitive posts. The risk assessment is conducted annually, and all functions considered sensitive are recorded in the Sensitive functions' register.
- **Quality management system** at EMA is based on ISO 9001 and Internal Control Framework requirements and helps to coordinate and direct the Agency's activities to meet regulatory requirements and improve its effectiveness and efficiency on a continuous basis.
- **Risk management** aims to ensure that potential issues and critical risks to delivery of the Agency's activities and objectives are properly identified, managed, and reduced to an acceptable level of risk-tolerance. An encompassing cross-Agency risk identification and management exercise is conducted at least once a year.

- **Anti-fraud strategy** covers a 3-year period and is accompanied by a corresponding action plan, outlining both specific focus areas and actions for the next years, and several continuous actions that are carried out every year, such as a specific standalone fraud risk assessment, with the identified fraud risks included in the overall Agency risk register. Anti-fraud training is organised as part of the induction training and via mandatory anti-fraud e-learning training for new staff members. Staff are made aware of how to report any suspects of wrongdoings, and disciplinary procedures are in place as per the rules of the Staff Regulations.
- **Whistleblowing** is an anonymous and confidential process that allows employees and external parties to disclose information about a wrongdoing or misbehaviour of an organisation, such as mismanagement, corruption, or fraud, without jeopardising their safety and position with the organisation. Whistleblowing procedure for EMA staff has been in place since 2014, and a new policy on how EMA handles allegations of improprieties received from external parties was reviewed by EMA in April 2022.
- **Conflict of interest**: To preserve impartiality and objectivity in every aspect of the Agency's work, a number of policies and rules on management of competing interests have been put in place and are regularly updated, describing specific arrangements, requirements and processes applying to the EMA Management Board, scientific committee members and experts, EMA staff and candidates, as well as consultants and contractors.
- **Data protection**: To fulfil its tasks and mission, the Agency handles daily a significant amount of commercially confidential information (e.g. information that pharmaceutical companies submit to the Agency in the context of EMA's authorisation and supervision activities), as well as personally sensitive data, such as staff data or meeting participant names and data. To ensure careful, transparent, and correct handling of private data and confidential information, EMA processes personal data in accordance with the rules laid down in Regulation (EU) 2018/1725 – data protection rules for EU institutions (EU DPR, in force since 11 December 2018) and is subject to the supervision of the European Data Protection Supervisor (EDPS).
- **Management supervision** provides for an oversight of the Agency's performance on a more encompassing and broader-view level. Managers at all levels monitor and measure on a daily or periodic basis the Agency's performance on several dimensions, maintaining oversight, tracking progress, and enabling flexible and timely adjustments where needed.
- **Project management controls**, The Agency has been implementing a new governance structure and ways of working, based on agile principles and the Scaled Agile Framework (SAFe) methodology, to better meet the IT software development needs of the EU's regulatory network for medicines. Ex-ante and retrospective evaluations are also part of the new Agile way of working.
- **Procurement management**: To ensure that any services or goods procured to support the Agency's work are obtained in a transparent and efficient way, ensuring objective and equal treatment of all tenderers, and eliminating any possibility of misconduct and corruption, the Agency follows the rules and processes laid out in the Public Procurement Directive 2014/24/EU and Financial Regulation in purchasing services, works or supplies. **Advisory Committee on Procurement and Contracts** (ACPC) is also set up to further ensure compliance, fairness and legality of the procurement procedures done at the Agency.

- **Risk-based assessments, audits, and evaluations** are conducted as part of the internal control system to identify gaps, assess performance, benefits, impact, and added value of the Agency's processes and activities, as well as to support continuous improvement of the operations of the Agency.

Review and continuous improvement of the internal control system

The Agency periodically monitors performance of the internal control system to identify internal control deficiencies, register and assess the results of controls, control deviations and exceptions.

In line with the Agency's commitment to excellence in governance and accountability, the internal control system will continue to evolve, the focus for the coming years is on: embedding continuous monitoring and assessment into daily operations, complemented by periodic self-assessments and targeted evaluations when organisational or process changes occur; an annual risk assessment will ensure that controls remain proportionate to identified risks, avoiding duplication and unnecessary administrative burden, while regular updates to the control framework will maintain alignment with evolving strategic objectives and legal requirements.

Assurance will be strengthened through close collaboration with both internal and external auditors, ensuring timely follow-up of audit recommendations and fostering a culture of transparency and learning.

The Agency will also continue to invest in effective communication, awareness, and training to reinforce accountability and ethical behaviour across all levels.

Annex XI Plan for grant, contribution and service-level agreements

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2025**	**2026**	**2027**	**2028**
Grants received										
PREMIER	29/06/2020	EUR 47,000	6 years from 01/09/2020	Innovative Medicines Initiative 2 Joint Undertaking	Prioritisation and risk evaluation of medicines in the environment	Amount	3,500	3,500	p.m.	p.m.
						Number of CA/FTE				
						Number of SNEs/FTE				
SISAQOL	30/10/2020	EUR 76,800	5 years from 01/01/2021	Innovative Medicines Initiative 2 Joint Undertaking	Setting international standards in analysing patient-reported outcomes and quality of life endpoints	Amount	10,000	10,000	p.m.	p.m.
						Number of CA/FTE				
						Number of SNEs/FTE				
RealiseD	12/02/2024	EUR 554,459	5 years from 01/01/2025	Innovative Health Initiative	Comprehensive methodological and operational approach to clinical trials in rare and ultra-rare diseases	Amount	108,000	108,000	108,000	108,000
						Number of CA/FTE				
						Number of SNEs/FTE				
Bridge	Est. Q4-2025	EUR 197,237	3 years from 01/11/2025	Innovative Health Initiative	Breakthrough regulatory innovation and development through sandbox environments	Amount	10,000	62,500	62,500	62,237
						Number of CA/FTE				
						Number of SNEs/FTE				
						Amount	**131,500**	**184,000**	**170,500**	**170,237**
						Number of CA/FTE	**0.0**	**0.0**	**0.0**	**0.0**
Total grants received						**Number of SNEs/FTE**	**0**	**0**	**0**	**0**
Contribution agreements										

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2025**	**2026**	**2027**	**2028**
IPA 2024–2026	11/12/2023	EUR 600,000	3 years from 01/01/2024	European Commission DG ENEST	Participation of candidate countries and potential candidates in EMA training and activities	Amount	200,000	200,000	p.m.	p.m.
						Number of CA/FTE				
						Number of SNEs/FTE				
ePi II (as amended)	31/05/2024	est. EUR 3.9 million	5 years from 01/01/2024	European Commission, DG SANTE/ EU4Health	Implementation of the action 'electronic Product Information (ePI) for medicinal products'	Amount	2,400,000	p.m.	p.m.	p.m.
						Number of CA/FTE				
						Number of SNEs/FTE				
NDICI AFRICA	20/12/2023	EUR 10 million	4.6 years (55 months) from 01/05/2023	European Commission, DG INTPA	Local Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa	Amount	2,000,000	2,000,000	2,000,000	2,000,000
						Number of CA/FTE	6	6	6	6
						Number of SNEs/FTE				
OSOA	Est. 2025	Est. EUR 8.2 million	Est. 5 years from 01/01/2026	European Commission, DG ENV	Establishment of a Common Data Platform. The work will include development and operation of infrastructure and the governance and provision of data into the platform.	Amount		100,000	4,600,000	1,000,000
						Number of CA/FTE		4	4	4
						Number of SNEs/FTE				
Total contribution agreements						**Amount**	**4,600,000**	**2,300,000**	**6,600,000**	**3,000,000**
						Number of CA/FTE	**6**	**10**	**10**	**10**
						Number of SNEs/FTE	**0**	**0**	**0**	**0**
Service-level agreements										

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2025**	**2026**	**2027**	**2028**
EMA does not provide services to other EU entities, hence has no corresponding service level agreements						Amount				
						Number of CA/FTE				
						Number of SNEs/FTE				
Total service-level agreements:						**Amount**				
						Number of CA/FTE				
						Number of SNEs/FTE				
Grants provided										
1. AMA AUDA-NEPAD Grant	17/07/2024	EUR 450,000	15 months from 17/07/2024	AUDA-NEPAD	Pilot to establishing Evaluation of Medicinal Products Technical Committee (EMP-TC) AND Good Manufacturing Practices Technical Committee (GMP TC) continental processes	Amount	225,000			p.m.
						Number of CA/FTE	0	0	0	0
						Number of SNEs/FTE	0	0	0	0
2. AMA EMRN Grant	Q4 2024 – Exact date depends on grant (total of 11 grants signed under this call)	EUR 984,300	36 months from signature in 2024	Call for proposal, open to European medicines regulatory network members	Strengthening of the African regional and / or national scientific and regulatory capacity	Amount	172,270	404,240	404,240	p.m.
						Number of CA/FTE	0	0	0	0
						Number of SNEs/FTE	0	0	0	0
3 AMA EDQM Grant	02/09/2025	EUR 899,247	26 months from signature in 2025	Direct award to EDQM/Council of Europe	Strengthening quality control of medicines in Africa	Amount	224,812	337,500	336,035	p.m.
						Number of CA/FTE	0	0	0	0
						Number of SNEs/FTE	0	0	0	0
Total grants provided						**Amount**	**622,082**	**741,740**	**740,275**	**p.m.**
						Number of CA/FTE	**0**	**0**	**0**	**0**
						Number of SNEs/FTE	**0**	**0**	**0**	**0**

Annex XII Strategy for cooperation with third countries and international organisations

Introduction: Legislative background, main drivers

This strategy outlines the EMA's mission and objectives regarding bilateral and multilateral international activities. It entails sub-strategies on specific topics and partners which will guide activities in the coming years.

External drivers

Legislative changes

Since its creation in 1995 from Regulation 2309/93/EEC, the European Medicines Agency has played an active role in international activities with responsibility to provide technical and scientific support to international organisations on issues related to the evaluation of medicinal products such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), as well as an obligation to collaborate with the World Health Organization (WHO) on international pharmacovigilance. This cooperation is implemented in collaboration with the European Commission.

The EU harmonisation for pharmaceuticals, ongoing since 1965, had allowed the extension of its approach into the international arena, which was developed from the 1990s in the form of international harmonisation activities, ICH and VICH, and successfully reformed and enlarged in 2015.

EU enlargement in 2004, 2007 and 2013 were supported by preparatory activities in the framework of the Pan-European Regulatory Forum (1999–2004) and continue with the Instrument for Pre-Accession (IPA) support to candidate countries and potential candidates. The 2004 revision of the Agency's founding through Regulation (EC) No 726/2004 introduced a more comprehensive recognition of the Agency's international role, in particular through the introduction of the EU-M4all pathway to address public health needs in non-EU countries in cooperation with WHO. This pathway combines EMA's scientific review capabilities with the local epidemiology and disease expertise of WHO and national regulators in the target countries. In addition, it builds on the principle of reliance, aimed mostly at low and middle-income countries especially in Africa, and allows the CHMP to issue scientific opinions on medicines not intended to be marketed in the EU.

This period has also seen increased use of EMA assessments in the WHO Collaborative Reliance Procedure (CRP) and industry engagement using EMA as a regulatory reliance partner. In 2022, the Agency's legal mandate was extended by Regulation (EU) 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness. Public health crises such as the COVID-19 pandemic challenged medicines regulators worldwide and demonstrated once again the necessity of international cooperation, collaboration and information exchange. EMA, together with EU national competent authorities and European Commission members, played a key role in regulatory approval of the COVID-19 vaccines and therapeutics, working through the International Coalition of Medicines Regulatory Authorities (ICMRA) and other international forums.

The EU Global Health Strategy adopted in 2022 further highlighted the EMA's contribution to promoting reliance on the scientific outputs of the EU health/science-based agencies and the Agency's commitment to supporting partnerships in Africa, Latin America and the Caribbean, and the Asia-Pacific regions.

Emerging public health threats

Many partners, including WHO, have highlighted that COVID-19 will not be the last pandemic. Ongoing efforts to deliver the WHO Pandemic Treaty emphasise the importance of regulatory cooperation and systems strengthening as part of efforts to prevent, detect and mitigate health emergencies.

The 2023 joint EMA and Heads of Medicines Agencies 'COVID-19 Lessons Learned: Joint report on the response to the Public Health Emergency' stressed the importance of global collaboration as one of the key pillars in the successful EMA and network response.

Recent public health emergencies such as the COVID-19 pandemic and outbreaks of mpox and Ebola in Sub-Saharan Africa and incidences of shortages of medicines have further demonstrated the importance and benefits of international collaboration.

A changing political environment

The war in Ukraine prompted major changes in the EU landscape, notably with the discussion on EU enlargement as Georgia, Moldova and Ukraine have been granted candidate status – raising the total number of EU candidate countries and potential candidates to 10. In line with EU political priorities, the Agency will collaborate to support candidate countries and potential candidates and this activity will remain a priority in coming years.

EMA also contributes to the EU Global Gateway through the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies ('MAV+') to support the operationalisation of the African Medicines Agency and regulatory systems capacity.

China and India are major producers of APIs and finished products imported into the EU and cooperation with these countries are priorities for EMA in terms of supply chain integrity and medicines availability, GMP compliant manufacturing, GCP clinical trial data integrity, and training.

New developments in the pharmaceutical sector

The globalisation in the pharmaceutical sector has pointed to a need to develop synergies through collaboration, cooperation and communication with international regulatory partners with the main objective of supporting convergence on the approach to authorisation and supervision of medicines, as well as capacity building.

Supply chain integrity in a global environment for manufacturing creates challenges and justifies international collaboration to ensure quality, decrease duplication of activities and focus resources on risk areas.

Support to training and capacity building activities should decrease the risk of quality defects and poor quality-management and consequently contribute to the prevention of shortages and ensure the quality of the medicine reaching the patient. This is also critical to reduce substandard and falsified medicines.

International collaboration in challenging areas such as real-world data and emerging and novel therapies allows to discuss common challenges, to leverage data, network and expertise resources, fosters regulatory and scientific convergence/alignment.

Support research, innovation and early development to stimulate development of better medicines.

Support international harmonisation, reliance and regulatory convergence

The promotion of reliance and convergence of regulatory approaches for pharmaceutical approvals and monitoring is crucial to reducing the regulatory burden on both regulators and manufacturers.

One major issue faced by regulators is a lack of resources or specific competencies required to perform their duties effectively specially with increasingly complex technologies and novel evidence generation techniques.

By promoting reliance, regulators can rely on data and evaluations from trusted sources, such as other regulatory agencies, to facilitate efficient and effective reviews. This helps to avoid duplication of work, reduces the need for resources that may not be readily available and promotes capacity building.

EMA has actively promoted informed regulatory reliance on its scientific outputs both for initial marketing authorisations and post-approval changes. This includes a joint EMA-WHO pilot for reliance on post-approval changes and the Agency's participation in the ICMRA Product Quality Knowledge Management (PQKM) initiative.

Additionally, convergence of regulatory approaches can help standardise requirements across different regions, making it easier for manufacturers to develop products that meet the necessary standards. Ultimately, this can lead to more timely access to innovative medical products for patients in need.

Risk-based approaches — including collaborative reviews, work-sharing and reliance — are now considered an important part of any regulators' toolkit.

Vision

EMA pursues the mission to **establish strong, effective and purposeful partnerships with non-EU regulators to protect public and animal health in the EU and around the globe** through communication, scientific and regulatory convergence, as well as information exchange. More specifically, four objectives guide the EMA's international activities:

- Objective 1: Strengthen partnerships with international counterparts.
- Objective 2: Enhance international regulatory cooperation, convergence and reliance.

- Objective 3: Strengthening regulatory science expertise and capacity building.
- Objective 4: Contribute to international preparedness and response to health emergencies.

Current collaborative activities

Bilateral activities

Confidentiality arrangements (CA)

A number of formalised confidentiality arrangements have been signed between the European Commission, European Medicines Agency and counterpart authorities in Australia, Brazil, Canada, Japan, the Republic of Korea, Switzerland and USA, as well as with the European Department for the Quality of Medicines (EDQM) and WHO. Full details of these are available on the EMA website[24]. Most relate to medicines for human use only, but some also include veterinary medicines.

Confidentiality arrangements are essential tools of collaboration, allowing exchange of meaningful and useful information; they allow better use of resources and contribute to the EMA role in protecting and promoting public and animal health in the EU. Increasing requests for relationships with the European Commission and/or the European Medicines Agency mean that alternative for more agile arrangements will be explored.

Mutual recognition agreements

The European Union has operational mutual recognition agreements (MRAs) in place since 2002, allowing EU Member States and the MRA partner to mutually recognise outcomes of inspections of manufacturers carried out by the respective inspection services. These MRAs cover the exchange of GMP inspection information with Australia, Canada, Japan, New Zealand, Switzerland and the USA.

The Agency is responsible for implementation and operational aspects of these MRAs. MRAs with Australia, Canada, Japan, New Zealand, Switzerland and the USA are currently operational, but with slightly different provisions as to scope and applicability. There is a different type of agreement between EU and Israel (ACAA), which allows mutual recognition of products, not limited to pharmaceuticals. The EU-UK Trade and Cooperation Agreement include provisions that permit mutual recognition of GMP inspections between the two jurisdictions.

Parallel scientific advice

Parallel scientific advice procedures provide a mechanism for EMA and FDA assessors and sponsors to exchange their views on scientific issues on new medicinal products to optimise product development and avoid unnecessary differences in methodology, endpoints, comparators, statistical analysis, etc.

[24] https://www.ema.europa.eu/en/partners-networks/international-activities/international-agreements

After a hiatus in use of the procedure during the COVID-19 pandemic, there is a growing number of requests from sponsors. The possibility of parallel scientific advice is available to all sponsors, including small and medium-sized enterprises. EMA will continue to promote parallel scientific advice with a special focus in medicinal products intended for conditions with unmet medical needs, indications lacking development guidelines, rare diseases, ATMPs and products using novel technologies (e.g. advance manufacturing).

International collaboration under the OPEN framework

EMA collaborates with medicine regulators outside the European Union EU in the scientific evaluation of certain priority medicines, within a framework called OPEN (Opening Procedures at EMA to Non-EU authorities). OPEN provides a framework for near-concurrent review by one or multiple additional regulatory authorities, each conducting their own assessment in parallel to the EMA evaluation while sharing scientific expertise and maintaining their scientific and regulatory independence.

Following consultation with partner regulators and industry, the scope of the OPEN Framework was expanded by the Agency's Management Board in October 2025, leading the way to increased use.

Participation in EMA Committees work - Access to EMA data

Nominated experts from confidentiality arrangement partners may observe EMA committee and working party meetings to follow discussions on specific topics. These authorities do not have access to EMA's repositories or databases, with the exception of the paediatric database of PIPs which is accessible to FDA.

Fellowships and liaison placements

EMA and FDA initially, then WHO, PMDA and Health Canada, have organised fellowships, where a staff member is seconded to the other Agency for a number of weeks with the aim to work on a specific priority topic and increase the interactions between the relevant teams.

Additionally, since 2009, EMA and FDA have seconded staff members (Liaison Officials) to each other's Agency, and Japan MHLW/PMDA has a Liaison Official at EMA also since 2009.

Multilateral activities

Clusters

Focused thematic 'clusters' have existed since 2004 initially involving EMA and US FDA experts and cover a wide range of therapeutic areas and disciplines; these now include other partners with whom mutual confidentiality arrangements are in place. Clusters have different objectives and compositions. Some are

more a forum for exchange of information and experience (e.g. patient engagement), others involve scientific discussions of specific medicines (e.g. paediatric, vaccines). The framework for the operation of the current clusters and their operation was recently reviewed and will be implemented in 2025-26.

Early notification system

The Agency shares advance notice of upcoming safety issues relating to medicinal products within the scope of its activities with international regulatory agencies with whom confidentiality arrangements are in place, with a view to alerting them in advance to upcoming concerns that may affect products on their markets.

Exchange of information – communication

International Affairs directly responds to questions, queries and providing access to documents and reports, either redacted, or unredacted for commercially confidential information (where there is a CA). In all cases, documents are redacted to protect personal data where there is no data protection equivalency decision by the European Commission.

Publication of EMA Clinical Data (policy 70): The implementation of the publication of clinical data policy has been the occasion for intense collaboration with Health Canada, which has adopted a similar policy with similar application of personal data redaction. The plan is to reduce workload and duplication by relying on the publication by the other Agency of the same report.

ICMRA

The International Coalition of Medicines Regulatory Authorities (ICMRA) is an informal group of leaders of medicines regulatory authorities that provides strategic directions for enhanced collaboration, improved communication and approaches to jointly address common challenges. ICMRA's mission is to safeguard public health by facilitating strategic leadership and greater cooperation of international medicines authorities on shared regulatory issues and challenges.

The European Commission and EMA collaborate in this forum alongside a number of EU national competent authorities. The EMA Executive Director was chair of ICMRA until October 2025 and the Agency, working alongside the Directorate-General for Health and Food Safety (DG SANTE) and the EU national authority members, will continue to play a leading role.

ICH and VICH

The Agency is required by its founding Regulation to provide technical and scientific support in the context of discussions organised in the framework of international conferences on harmonisation (Article 57j, Regulation (EC) No 726/2004). EMA supports the EU delegations in ICH and VICH through support to the management, setting of priorities and provision of technical and scientific expertise to the expert groups through its scientific committees, EU expert network and working parties.

It also supports EU involvement in the International Pharmaceutical Regulators Programme (IPRP) and its working groups.

PIC/S

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive cooperation in the field of GMP. PIC/S mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products." EMA is an associated partner organisation, not a member of PIC/S, and supports its activities and participates in PIC/S meetings.

Others

There are other initiatives with international partners, which may be bilateral or multilateral, such as the Specific Transatlantic Initiatives, those on Antimicrobial Resistance, the Trans-Atlantic Task force on Antimicrobial Resistance (TATFAR), the tri-partite activities with Japan, the OECD (on GCP), etc.

International priorities for 2026

Objective 1: Strengthen partnerships with international stakeholders.

To meet the challenges of the evolving pharmaceutical sector, EMA builds on its partnerships with international organisations and regulators worldwide. EMA will strengthen its cooperation and communication with international regulatory partners, both in bi- and multilateral settings. Beyond that, EMA will support research, innovation and early development to stimulate global development of better medicine. Activities to achieve objective 1 are:

- EMA's leading role in International Coalition of Medicines Regulatory Authorities (ICMRA) and participation in priority projects.
- Cooperate on activities of mutual interest within the ICH and VICH framework and WOAH:
    - Development and adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance through ICH
    - Participation in the IPRP program
    - Continue to support development of the ICH E21 guideline on inclusion of pregnant and breastfeeding individuals in clinical trials
- Continue support to clusters, parallel scientific advice and other scientific and regulatory interactions, including the review of the operation of the clusters
- Promote internships, fellowships and exchanges with other international regulators

- Support ongoing collaboration on big data initiatives and real-world evidence
- Support ongoing collaboration on innovative areas, such as advanced manufacturing, application of AI throughout lifecycle of medicinal products
- Improve the exchange of information between MRA and PIC/s partners through international programmes, such as the API International Programme
- Proactively publish clinical data supporting marketing authorisations
- International Cooperation Platform (IntCoP): Strengthen exchange of information and coordination, fostering a harmonised EU approach to international cooperation on medicines between national competent authorities, the European Commission Directorate-General for Health and Food Safety (DG SANTE) and EMA, through a dedicated communication and discussion channel
- Increase the awareness of the EU system through dedicated sessions, including awareness sessions for international regulators
- Continue providing answers to queries and requests for exchange of information.
- Develop IT tools (e.g. SharePoint or other technical solution) for information and document sharing with international partners

Objective 2: Enhance international regulatory cooperation, convergence and reliance.

Considering the globalisation of pharmaceutical development and manufacturing and advances in technologies and evidence generation techniques, regulatory agencies are facing new challenges that require them to adapt their processes. To achieve this, risk-based strategies such as collaborative reviews, work sharing, and reliance are increasingly seen as crucial tools in the regulatory toolkit. By adopting these approaches, regulators can ensure timely patient access to medicines, while optimising their use of resources.

The Agency will focus on supporting global collaborative assessment, convergence of regulatory approaches and reliance. Priority activities include:

- Foster collaborative engagement with regulatory counterparts, including through the OPEN Framework, and explore engagement through projects such as Project Orbis.
- Explore the capabilities for global collaborative submission reviews for anti-cancer and other classes of medicines and technologies by fostering cooperation between international regulators.
- Support the maintenance and development of MRAs alongside the European Commission
- Continue collaborative activities with WHO to:

- Promote awareness and use of EU-M4all regulatory pathway, in particular for medicines, including vaccines and generics, intended to prevent or treat diseases of major public health interest
- Promote awareness and use of the EMA role in the WHO Collaborative Registration Procedures, and development of the procedures
- Contribute to global and regional efforts to promote understanding of and use of reliance pathways, in particular the joint EMA-WHO Post-Approval Changes Reliance Pilots
- Support the WHO paediatric network and initiatives
- Cooperate with marketing authorisation holders and international regulators in pilots to demonstrate feasibility and public health benefit of regulatory reliance

Objective 3: Strengthening regulatory science expertise and capacity building.

In light of the developments in the pharmaceutical industry, EMA will collaborate with regulators to advance regulatory science accordingly. At the same time, the Agency recognises its own existing expertise and invests into capacity building to support less mature regulatory systems. To this end, priority activities are:

- Contribute to international forums and the European approach to scientific excellence through workshops, training activities, and awareness sessions, participation in international conferences such as ICDRA, DIA, etc., and national initiatives in priority countries (resources and priorities permitting).
- Working under the European Commission Directorate-General for International Partnerships (DG INTPA) grant, support the operationalisation of the African Medicines Agency and regulatory system strengthening at continental, regional and national levels in Africa.
- Working under the European Commission Directorate-General for Enlargement and the Eastern Neighbourhood (DG ENEST) grant through the Instrument for Pre-Accession Assistance (IPA), provide assistance to candidate countries and potential candidates, to align their standards and practices with those established in the European Union, and to further foster their integration process.
- Explore and foster opportunities for the EU medicines regulatory network to contribute to scientific and regulatory training events organised outside the EU (EU NTC)
- Provide and support training on priority areas (GMP, GCP) for priority countries.
    - Support activities in China and India, including bilateral meetings in the context of the Commission's agreements on pharmaceuticals with these countries, with focus on GCP and GMP.

- Enhance inspector capacity building at EU and international level to harmonise approaches to regulatory inspections procedures to address requirements and challenges of APIs, medicinal products, excipients, new technologies and continuous manufacturing)
- Maintain EMA webpage collecting training opportunities for non-EU partners.

Objective 4: Contribute to international preparedness and response to health emergencies.

Bearing in mind health emergencies like the COVID-19 pandemic, mpox and the nitrosamines crisis, EMA prepares for future emergencies both in the European and the global health context. Priority activities in this regard include:

- EMA's leadership role (chair) in International Coalition of Medicines Regulatory Authorities (ICMRA) and continued support to the ICMRA secretariat, and participation in priority projects:
    - Promote increased international cooperation in the area of supply chain, data integrity and shortages: Improve coordination of information and actions on shortages, including implementation of best practices for international partners. International collaboration on shortages-related strategic topics and shortages case-management at the level of the Global Regulatory Shortage Network
    - Promote the responsible use of antimicrobials and their alternatives and establish an ERA framework
    - Support to the management of health crises
    - Public Health Emergency Clinical Trials Working Group

Annex XIII Global budgetary envelope reserved for financing decisions

Introduction

In accordance with Article 72 of the Agency's Financial Regulation[25]

1. A budgetary commitment shall be preceded by a financing decision. Administrative appropriations may be implemented without a prior financing decision.
2. The annual and multi-annual work programmes of the Union body included in the single programming document referred to in Article 32 shall be equivalent to a financing decision for the activities it covers, provided that the elements set out in Article 32(2) and (3) are clearly identified. A multiannual financing decision shall specify that the implementation of the decision is subject to the availability of budget appropriations for the respective financial years after the adoption of the budget or as provided for in the system of provisional twelfths.
3. The financing decision shall also set out the following:
    a. for grants: the type of applicants targeted by the call for proposals or direct award and the global budgetary envelope reserved for the grants;
    b. for procurement: the global budgetary envelope reserved for procurements;
    c. for prizes: the type of participants targeted by the contest, the global budgetary envelope reserved for the contest, and a specific reference for prizes with a unit value of EUR 1,000,000 or more.

As the Agency does not award prizes, the tables below set out the global budgetary envelope reserved grants as per 3a) and for procurement for operational expenditure as per 3.b) above.

Basic act and financing source

See in this document *Mission Statement* and *Legal Mandate.*

Grants to be awarded in the context of the EMA-AMA Contribution Agreement

N/A

[25] EMA/MB/911312/2019.

Operational procurement

A Statutory activities	Indicative budget
This block encompasses different areas of work: **1)** product-related activities supporting the development, evaluation, and monitoring of medicines to ensure their safety, efficacy, and quality. This includes pre-authorisation guidance, scientific advice, regulatory assessments, and collaboration with stakeholders to facilitate timely access to safe, effective treatments for patients. **2)** horizontal public health activities **3)** corporate activities.	EUR 108,235,000
Budget line 3003, current budget C1	
Budget line 3030, current budget C1 and assigned revenue R0	
Budget line 2114	

B Strategic change	Indicative budget
This block includes: **1)** specific time-bound multi-annual goals and objectives included in the overall Network strategy to 2028. The EMANS to 2028 strategy supports the core work of evaluating human and veterinary medicines, while promoting the development of new medicines and ensure that they reach patients. **2)** Network Portfolio activities, aiming at enhancing efficiency and effectiveness of the current operations. These developments are also key enabler for the implementation of the EMAN Strategy.	Up to EUR 150,000,000
Budget line 3031, current budget C1	
Budget line 3105, current budget C1	
Budget line 2113 (tbc)* planned procurement procedure for IT related activities includes operational expenditures under A Statutory activity	