EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Final Programming Document 2025-2027

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Foreword

I am pleased to introduce the European Medicines Agency's Single programming document (SPD) for 2025 to 2027. The document outlines the challenges and goals for the upcoming three years, and presents the final work programme for 2025, along with medium- and long-term objectives.

2025 is a very special year for EMA: our Agency will celebrate its 30th Anniversary since its creation in 1995. At a time of rapid change, EMA and its Regulatory Network need to adapt and seize opportunities that both the technological and regulatory landscape bring.

2025 marks the transition year between the current European Medicines Agency Network Strategy (EMANS) to 2025 and the revised and updated Strategy to 2028. During 2024 the Agency has worked in close collaboration within the EU Medicines Regulatory Network to take account of recent regulatory and technological developments and to lay the groundwork for the upcoming revision of the EU pharmaceutical legislation. The EMANS to 2028 reflects this work, and it is expected to be adopted by the EMA Management Board in the course of 2025 and to be fully reflected in the 2026-28 Single Programming Document.

Looking ahead to the coming year, 2025 will also bring important milestones: the end of the transition period for the Clinical Trials Regulation, the entering into force of the Health Technology Assessment (HTA) Regulation and of the New Fee Regulation (NFR), and the launch of the European Shortages Monitoring Platform (ESMP). This SPD takes into account the activities related to all these important milestones, as well as the preparatory initiatives EMA is undertaking to improve its readiness in view of the European Commission's proposal to revise the existing general pharmaceutical legislation.

In 2025 the Agency will place particular emphasis on the following three key areas.

Firstly, we will continue to concentrate on accelerating and optimising the assessment of key medicines by enabling high-quality, robust and rapid assessments based on scientific and clinical evidence. Building on the experience from our focus on using cancer medicines as a pathfinder, EMA will additionally seek to apply learnings to key medicines in other therapeutic areas. Through various initiatives, EMA will work on streamlining and simplifying the assessments, on obtaining better clinical evidence from trials and generating real-word evidence towards better evidence-based decisions, and on harnessing the potential of AI to optimise medicines assessments.

Secondly, we will focus on facilitating the path to accessibility and strengthening the availability of medicines. EMA will support the successful application of the HTA Regulation and will implement the regulatory/HTA interface. We will monitor the availability of medicines, as well as preventing and mitigating their effects, and we will strengthen the supply chains of critical medicines.

Thirdly, we will pay particular attention on seizing the opportunities to future-proof medicines regulation in the EU and design innovative ways of working. As we prepare for the new pharmaceutical legislation, we need to enhance our efforts to maintain the sustainability of the Network. In 2025, in anticipation to the new legislation, we will start engaging with our scientific committees to explore the potential of new ways of working to optimise the centralised and other procedures. Simplicity of processes, streamlined templates and enabling increased work-sharing will ensure that Network resources are used in a sustainable manner. We will boost capacity and capability in the Network by investing in developing training curricula and better training content

Finally, managing the Agency's London premises continues to require us to divert resources and to deviate some of our core business activities, and could impact some of the work described in this 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
ACDC	Agile capabilities delivery contract
ACE	Analytics Centre of Excellence
ACPC	Advisory Committee on Procurement and Contracts
ACT	Accelerating Clinical Trials in the EU
AD	administrator category post
ADR	Adverse drug reaction
AE	Adverse event
AF	Advisory function
AF-HT	Advisory function Public Health Threats
AF-INS	Advisory function Information Security
Agency	European Medicines Agency
AI	Artificial intelligence
AM	Antimicrobial
AMA	African Medicines Agency
AMEG	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
ASEAN	Association of South East Asian Nations
AST	Assistant category post
AST/SC	Secretarial and clerical category post
ASU	Antimicrobial sales and use
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
AUDA	African Union Development Agency
BDSG	Big data steering group
BI	Business Intelligence
CA	Contract agent
CAP	Centrally authorised product
CAT	Committee for Advanced Therapies
CBRN	Chemical, biological, radiological and nuclear
CCI	Commercially confidential information
CDP	Clinical Data Publication
CDPC	EU Common Data Platform for Chemicals
CHMP	Committee for Medicinal Products for Human Use
CIO	Chief information officer
CMA	European Commission Critical Medicines Alliance

Term/abbreviation	Definition
CMO	Chief Medical Officer
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
CO_2	Carbon dioxide
COA	Clinical Outcome Assessments
Commission	European Commission
committee(s)	Scientific committee(s) of the Agency
COSO	Committee of Sponsoring Organizations of the Treadway Commission
Council	European Council
CR	Common Repository
CRM	Customer Relationship Management
CRP	Collaborative registration procedure
CT	Clinical trial
CTCG	Clinical Trials Coordination Group
CTIS	Clinical trials information system
CTR	Clinical Trials Regulation
CVMP	Committee for Medicinal Products for Veterinary Use
DAP	Data Analytics Platform
DARWIN	Data Analytics and Real World Interrogation Network
DG DIGIT	European Commission Directorate-General for Digital Services
DG GROW	European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG INTPA	European Commission Directorate-General for International Partnerships
DG NEAR	European Commission Directorate-General for Neighbourhood and Enlargement Negotiations
DG SANTE	European Commission Directorate-General for Health and Food Safety
DGT RTD	European Commission Directorate-General for Research and Innovation
DIA	Drug Information Association
DigiLab	EMA Digital Innovation Lab
DQ	Data Quality
EAB	EMA Architecture Board
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
ECP	European Commission Priority
eCTD	Electronic Common Technical Document
EDPB	European Data Protection Board
EDPS	European Data Protection Supervisor
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EIB	European Investment Bank
EIC	European Innovation Council

Term/abbreviation	Definition
EIT	European Institute of Innovation and Technology
EMA	European Medicines Agency
EMANS	European Medicines Agency Network Strategy
EMAS	EU Eco-Management and Audit Scheme
EMP-TC	Evaluation of Medicinal Products Technical Committee
EMRN	European medicines regulatory network
EMWP	European Medicines Web Portal
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
END	Seconded national expert (Experts nationaux détachés)
EPAR	European public assessment report
EPPO	European Public Prosecutors Office
ERA	Environmental risk assessment
ERA4Health	Partnership Fostering a European Research Area for Health
eRMR	Electronic Reaction Monitoring Reports
ESEC	European Specialised Expert Community
ESMP	European Shortages Monitoring Platform
ESPAS	European Strategy and Policy Analysis System
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
ETF	Emergency Task Force
ETL	Extract, transform, and load
EU	European Union
EU DPR	European Union Data Protection Regulation
EU NTC	EU Network Training Centre
EU4Health	Programme for the Union’s action in the field of health
EUAN	European Agencies Network
EU-ANSA	EU Agencies Network on Scientific Advice
EUDA	European Union Drugs Agency
EUDPR	Data protection Regulation for EU institutions and bodies
EUDPS	European Data Protection Supervisor
EUI	European University Institute
EU-IN	EU Innovation Network
OH AMR	One Health AMR
EUNTC	EU Network Training Centre
EUR	Euro
EURD	European Union reference dates
EURS	European Review System for eCTDs
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVIP	European Vaccination Information Portal
EVVet	EudraVigilance Veterinary
EXB	EMA Executive Board
FAIR	Findable, accessible, interoperable and reusable
FA	Focus Area

Term/abbreviation	Definition
FDA	United States Food and Drug Administration
FG (I, II, III, IV)	Function group (for contract agent staff)
FTE	Full-time equivalent
GCP	Good clinical practice
GDP	Gross domestic product
GDPR	General Data Protection Regulation
GLP	Good laboratory practice
GMDP IWG	Good Manufacturing and Distribution Practice Inspectors Working Group
GMP	Good manufacturing practice
GxP	Good practice (e.g. laboratory, clinical, manufacturing etc)
GVP	Good pharmacovigilance practice
HC	Healthcare
HCIN	Heads of Communication and Information Network
HCP	Healthcare professional
HCPWP	Healthcare professionals' working party
HL7	Health Level 7
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HMA/EMA TF AAM	HMA/EMA Task Force on Availability of Authorised Medicines for Human and Veterinary Use
HQ	Headquarters
HMPC	Committee on Herbal Medicinal Products
HR	Human resources
HS	Horizon Scanning
HTA	Health technology assessment
HTACG	Member State Coordination Group on HTA
HTAR	Regulation (EU) 2021/2282 on health technology assessment
HTV	Heath Threats and Vaccines Strategy
IA	International Affairs
ICF	Internal control framework
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	Individual case-safety report
ICT	Information and communication technologies
IDMP	International Organisation for Standardisation (ISO), Identification of Medicinal Products (IDMP) standards
IHD	Instant Health Data
IHI	Innovation Health Initiative
IHSI	International Horizon Scanning Initiative
IM	Information management
IMI2	Innovative Medicines Initiative
IPA	Instrument for Pre-accession Assistance
IPRP	International Pharmaceutical Regulators Programme

Term/abbreviation	Definition
IQM	integrated quality management
IRIS	Platform facilitating the exchange of regulatory and scientific information between EMA and organisations developing medicinal research products for potential use in the European Union
ISO	International Organisation for Standardisation
IT	Information technology
ITF	Innovation Task Force
IVD	In-vitro diagnostics
IVDR	In-Vitro Diagnostic Regulation
JAP	Joint Audit Programme
JCA	Joint Clinical Assessment
JIACRA	Joint inter-agency antimicrobial consumption and resistance analysis
JRC	European Commission's Joint Research Centre
JSC	Joint Scientific Consultation
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
MAWP	EMA multiannual work programme
MB	Management Board
MD	Medical devices
MDR	Medical Devices Regulation
MLM	Medical literature monitoring
MLT	Medicines Leadership Team
MON	Monitoring
MP	Medicinal Products
MRA	Mutual recognition agreement
MRL	Maximum residue limit
MS	Member State of the European Union
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products
MTA	Managing the Agency
MUMS	Minor use, minor species
MVP	Minimum viable product
MWP	Methodology Working Party
NAP	Nationally authorised product
NCA	National competent authority
NDSG	Network Data Steering Group
NEPAD	New Partnership for Africa's Development
Network	European medicines regulatory network
NFR	New Fee Regulation
NGO	Non-governmental organisation
NICTAC	Network ICT Advisory Committee

Term/abbreviation	Definition
NIS	Non-Interventional Study
NLP	Natural Language Processing
NITAG	National immunization technical advisory groups of WHO
NPL	New pharmaceutical legislation
NPAG	Network Portfolio Advisory Group
NRA	National Regulatory Agencies
NTWP	Novel Therapies and Technologies Working Party
NVR	New veterinary regulation
OLAF	European Anti-Fraud Office
OMCL	Official Medicines Control Laboratories
OPEN	Opening our Procedures at EMA to Non-EU authorities
P1	Priority 1 Incidents
Parliament	European Parliament
PB	EMA Portfolio Board
PCWP	Patient and consumer working party
PDCO	Paediatric Committee
PGx SIA	Pharmacogenomics specialised interest area
PHE	Public Health Emergency
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PhVWP	Pharmacovigilance working party
PIP	Paediatric investigation plan
PLM	Product Lifecycle Management Value Stream
PMF	Plasma master file
PMO	Office for administration and payment of individual entitlements
PMS	Product Management Services
PO	Product Owner
PoC	Proof of concept
POC	Point of Contact
PPD	Protected personal data
PQ	WHO Prequalification
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	Pharmacovigilance Risk Assessment Committee
PRE	Procedures Revenue and Expenditure
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PSUR	Periodic safety-update report
PUI	Product User Interface
PUMA	Paediatric-use marketing authorisation
Q	Quarter
QAT	Quality Assurance Test
QoNM	Qualification of Novel Methodologies
QIG	Quality Innovation Group
RCT	Randomised controlled trials
RFI	Request for information

Term/abbreviation	Definition
ROG	Regulatory Optimisation Group
RMP	Risk Mitigation Plan
RPM	Regulatory Procedure Management
RSS	Regulatory science strategy
RWD	Real World Data
RWE	Real World Evidence
SAFe	Scaled Agile Framework
saMS	Safety assessing Member State
SAWP	Scientific Advice Working Party
SC	Scientific committee
SCG	Scientific Coordination Group
SISAQOL	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints in Cancer Clinical Trials
SLA	Service level agreements
SME	Small and medium-sized enterprise
SmPC	Summary of Product Characteristics
SNE	Seconded national expert
SNSA	Simultaneous national scientific advice
SoHO	Substances of human origin
SPMP	Shortages Prevention and Management plans
SPOC	Single point of contact system on availability/shortages in human and veterinary agencies in the EU
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TB	Tuberculosis
TBC	To be confirmed
TBD	To be decided
TC	Teleconference
TCIP	Technology Capability Implementation Plan
TDA	EMA Data Analytics and Methods task force
TDT	EMA Digital Business Transformation task force
TF	Task force
TFAAM	EMA/HMA joint task force on availability of authorised medicines for human and veterinary use
TIG	Technical Implementation Guide
TLM	Technology Lifecycle Management and Information Security Value Stream
TRS	EMA Regulatory Science and Innovation Task Force
TWG1	Thematic working group 1
UPD	Union product database
UPhD	Union pharmacovigilance database
UC	Use cases
US	United States of America
UX	User experience
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

Term/abbreviation	Definition
VMP	EU Vaccines Monitoring Platform
VS	Value Stream
WGCP	Work with Working Group of Communication Professionals
WHO	World Health Organization
WLA	WHO-Listed Authority
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.

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, 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 in the assessment of certain categories of medical device.

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 2022, the Regulation on Health Technology Assessment (Regulation (EU) 2021/2282) came into force, with a 3-year implementation period before application as of January 2025. 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 technologies.

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;

- Collaborates with the Health Technology Assessment 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 technologies.

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

In the 2025-2028 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 continues 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 Agency's operating landscape. The 2025 work programme reflects the initiatives the Agency will take to address these changes. Considering the evolving context, the following points are noteworthy:

Network Resourcing and Committees workload As highlighted throughout this document, the Agency's products portfolio has been steadily growing over the past ten years. This growth translates not only into additional workload for the Agency but also for its Scientific Committees. In fact, this growth has significantly intensified the demands on scientific committees, which are under increasing pressure to evaluate submissions and provide scientific opinions. The network faces resource and expertise constraints which are likely to be further exacerbated in the future in view of e.g., the growing number of advanced therapy medicinal products, combination products, as well as by the shift of political priorities away from public health to other urgent issues. There were some important lessons learned during the COVID-19 pandemic, some of which have been implemented as part of EMA's extended mandate, and others which will be reviewed as part of the revisions to the pharmaceutical legislation. While the Agency remains committed to keep prioritising process improvement, digitalisation, resource optimisation and capacity building in its forthcoming planning cycles, it must be recognized 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.

Reform of the EU pharmaceutical legislation On 26 April 2023, the European Commission published its proposal for reforming the Pharmaceutical Legislation, including revisions to Directive 2001/83/EC, Regulation (EC) No 726/2004 (general pharmaceutical legislation), Regulation (EC) No 1901/2006 on medicines for children (Paediatric Regulation), and Regulation (EC) No 141/2000 on medicines for rare diseases (Orphan Regulation). The European Medicines Agency (EMA) will continue to support the institutions, in particular the European Commission, during the legislative process on the revision of the EU pharmaceutical legislation. In addition, the Agency will continue analysing the implications of the legislative proposals and reflecting on how the new proposed approaches, once agreed by the co- legislators, might be implemented in the most efficient manner.

Digitalisation and AI The influence of digitalisation and artificial intelligence (AI) in medicines regulation continues to grow. AI systems are becoming an important tool supporting evaluation of medicines and powering automation across business processes. EMA will continue the implementation of the BDSG multi-annual AI workplan as endorsed by EMA Management Board in December 2023. Throughout the execution of the workplan, stakeholders will be consulted, engaged and informed. Moreover, EMA will work to deliver the European Medicines Regulatory

Network's (EMRN) vision on AI which aims to build a regulatory system that harnesses the capabilities of AI for personal productivity, process automation and systems efficiency, increased insights into data and strengthened decision-support for the benefit of public and animal health.

International Environment EMA is involved in two main international areas: supporting the EU's political priorities, particularly in response to changes resulting from the war in Ukraine and contributing to the establishment of the African Medicines Agency (AMA) in collaboration with the European Commission, WHO, and the African Union. The Agency will continue to monitor political developments and engage in enlargement-related activities as well as investing in global health initiatives.

Legislative Revisions Several pieces of EU legislation, such as the Fee Regulation, the Artificial Intelligence Act, the European Health Data Space, and the new HTA Regulation, will be adopted or become applicable in the coming years. These changes may create new tasks for EMA and necessitate interaction with new entities at both EU and Member State levels. These developments offer an unprecedented opportunity to simplify and modernize 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.

Access to Affordable Medicines Healthcare systems face growing challenges in providing access to affordable medicines, leading to inequalities across EU Member States and increasing political and public pressure. New initiatives, such as European HTA cooperation and WHO efforts on affordable innovation, may require further engagement from EMA in its role in facilitating access to medicines.

Medical Devices The Agency's scope of action in the medical devices area was significantly increased by Regulation (EU) 2017/745, and now by Regulation (EU) 2022/123 on EMA's extended mandate. Following continuous cooperation with the European Commission and exchanges with partners and stakeholders, the Agency realises that it may be more and more involved in the medical devices area, an industry which is at the forefront of innovation (e.g. use of software, nanotechnology, sensor technologies, robotics, 3D printing, and materials science) and with a significant influence on healthcare delivery. In the context of the medical devices and in vitro diagnostics regulations and its newly extended mandate, specifically through issuing of scientific opinions related to consultation procedures initiated by notified bodies on specific categories of medical devices and the management of medical devices expert panels, the Agency, in close cooperation with the European Commission, monitors the evolution of the medical devices' sector, to better understand required capabilities in this area.

Collaboration on Patient Access The new Health Technology Assessment Regulation formalizes EMA's collaboration with the HTA Coordination Group, building on previous voluntary work. This legal mandate ensures a more structured and sustainable framework for cross-decision-maker collaboration, recognizing its value in improving patient access to medicines.

Data Governance, Management and Analysis The importance of data in medicines regulation is rapidly increasing. EMA will continue to invest in data governance to align with EU policy initiatives, including in preparation for the European Health Data Space Regulation. In addition, work on the governance, management and analysis of data will deliver more efficient regulatory processes and greater insights for decision making. In this work, EMA ensures data are managed in a safe and ethical environment. This work will be delivered in close collaboration with the European Medicines Regulatory Network.

Public Health Emergencies Following the official end of the COVID-19 pandemic, EMA remains focused on preparedness for future public health emergencies, including zoonotic threats, in line

with its extended mandate. The Agency collaborates with the European Commission, HERA, and the European Centre for Disease Prevention and Control (ECDC) to ensure ongoing readiness for public health threats, including the Mpox Public Health Emergency of International Concern or potential outbreaks. Arrangements between EMA and HERA, established in 2023, will continue to evolve with specific working methods and contact points being developed. The EMA's Emergency Task Force (ETF) is contributing to the HERA Board subgroup with presentations and clinical trial insights, while the ETF chair also serves as an observer in both the HERA subgroup and the prioritization group.

Supply and availability of medicines In line with the expectations of the extended EMA mandate under Regulation (EU) 2022/123 and the European Commission's communication on addressing medicine shortages in the EU and pre-empting the development of the Critical Medicine Act, the agency's role in the coordination of EU level actions on the management of medicines shortages continues to develop and strengthen. In close collaboration with its partners within the Regulatory network and under the strategic guidance of Medicine's shortage Steering Group (MSSG), the agency is leading the development of tools and the implementations of key recommendations for actions toward mitigation and prevention of medicine's shortage in Europe. As a member of the Critical Medicines Alliance, the agency provides regulatory insight and expertise on the Management of medicine's shortage to support the identification of key areas and priorities for industrial policy actions with the aim to strengthen the supply of critical medicines in the EU and ultimately enhance efforts to prevent and address shortages effectively.

Competitiveness The outcome of the report on "The future of European competitiveness" (Report by Mario Draghi), clearly suggest that the European Union runs the risk of sliding behind in the global competitiveness of its pharmaceutical sector. Improving Europe's competitiveness is already one of the drivers for the revision of the pharmaceutical legislation. Other legislative initiatives are being discussed, such as the Biotech act, the Critical Medicine Act, to further shape and improve the European Union as a competitive environment for innovators, developers and investors. In this context the Agency should seek to operate with a clear view on its contributions to EU competitiveness and therefore should work on articulating an aligned strategic ambition and an operational plan to enhance EU competitiveness.

London Premises Following Brexit and the Agency's relocation to the Netherlands in 2019, the management of the situation(s) in connection to EMA's former premises in London remains a major focal point, continuing to divert resources. Recent developments, achieved through intense negotiations, although mitigating present risks, cannot exclude future risks to the Agency's ability to meet its objectives.

In conclusion, the 2025-2028 period presents EMA with both challenges and opportunities as it adapts to regulatory reforms, technological advancements, and an evolving global context. Through strategic planning and collaboration, the Agency remains committed to navigating this dynamic landscape to safeguard public health in the EU.

Part II: Multi-annual programming 2025–2027

1 Multi-annual work programme

The EMA Multi-annual work programme 2025-2027 has been developed by clustering the activities around 3 main pillars:

1. **Product-related activities**: this block encompasses objectives concerning medicines lifecycle, working parties and guidelines.
2. **Strategies (EMANS and RSS)[1] and public health activities**: this block includes objectives taken onboard by EMA to contribute to the implementation of the overall Network strategy. This section is based on the six EMANS focus areas and also covers non-product related public health tasks (e.g. communication, international cooperation, etc.).
3. **Network Portfolio**: this block covers IT development activities, aiming at enhancing efficiency and effectiveness of the current operations.

The achievement of the multi-annual objectives is derived from the execution of the actions detailed in the Annual work programme and their implementation is supported by the business services.

PILLAR 1:

Human medicines: The Division oversees and manages human medicines throughout their lifecycle, from evidence-generation planning, through evaluation and monitoring of medicines, to interfacing with stakeholders and health care systems, to facilitate access and optimal use of medicines. The division also manages the exchange of information with health technology assessment (HTA) bodies under the HTA Regulation, with new legal responsibilities from January 2025 at the regulatory / HTA interface. The Division collaborates with international regulators and within the EU medicines regulatory network to produce patient-centred high-quality outputs to ensure patient trust.

The Division supports a pilot programme (ICMRA-PQKMS), where International Regulators collaborate in the assessment step of quality variations submitted under regional procedures and a reliance programme together with WHO on post approval quality changes, where low- and middle-income countries rely on the EMA outcomes. Both pilot programmes aim to facilitate the faster implementation of important manufacturing changes that enable manufacturers to increase their manufacturing capacity faster and thus, medicines supply globally. The Division is actively engaging with International Regulators to better leverage on existing resources and ensure the verification of GxP compliance through Mutual Recognition Agreements (MRAs), international collaboration (ICMRA hybrid inspections) or pilots for reliance for GMP reinspections.

With the publication of the proposal for a new pharmaceutical legislation for human medicines, the Agency will explore ways to implement 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. The increased number of periodic safety update reports (PSURs) that had a data lock date set to 2025 when the Pharmacovigilance Regulation came into force in 2012 will also impact the work of the Division, PRAC add National Competent Authorities. Additional tasks entrusted to the Agency in the area of combination products with medical devices and companion diagnostics will continue to become increasingly prominent. Moreover, new responsibilities in the clinical

[1] At the time of drafting this SPD, the revised/updated Strategy to 2028 is being drafted.

evaluation and advice of high-risk medical devices will further increase in support of a timely access of innovative devices in the EU.

The investment in information management programmes continues to be pivotal to handle the anticipated increase in applications over the coming years and to enable the use of advanced digital tools for a more integrated knowledge management of the lifecycle of medicines. Increasing efficiency and attention to prioritisation of activities will be necessary in making progress in regulatory science by implementing the strategy, with particular focus on supporting the development of innovative medicines, including anti-cancer medicines as a pathfinder, as well as strengthened development support for PRIME products, facilitating the use of innovative approaches (incl. AI and digitalisation) in the manufacture and control of medicines, and improving the sustainability of the EU medicines regulatory network.

Veterinary medicines: The Veterinary Medicines Division has nearly fully implemented the implementation of Regulation (EU) 2019/6 (Veterinary Regulation), which had a significant impact on business processes, scientific procedures, and IT systems. The Division managed a seamless transition to the new set of rules, effective as of 28 January 2022. The Division will continue to face a growth in workload related to CAPs procedures, new methodologies for pharmacovigilance surveillance, and the need to keep reviewing and updating the necessary guidance and processes based on real life experience of the implementation. The Veterinary Regulation also entails new responsibilities for Committee for Medicinal Products for Veterinary Use (CVMP), Pharmacovigilance working party (PhVWP) and Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary (CMDv), together with Stakeholders communication, which is more than ever a central aspect of the implementation. Another key objective is represented by the deployment, enhancement, management, and maintenance of the new or updated IT systems necessary for implementing Regulation (EU) 2019/6: Union Product Database (UPD), Union pharmacovigilance database (UPhD), Collection of Antimicrobial Sales and Use (ASU), Union Manufacturers and Wholesale Distributors Database as well as the gradual integration of veterinary procedures in IRIS.

The measurement of the activities under Pillar 1 is carried out through the annual workload and performance indicators.

PILLAR 2:

Following the publication of the mid-term report, the European Medicines Regulatory Network (EMRN) started work on reviewing the scope of the strategy to cover the network's goals and objectives up to 2028. At the time of drafting of this document the Strategy to 2028 is under development and undergoing a public consultation period. The current timeline foresees the adoption of the revised/updated Strategy by the EMA Management Board during its meeting in March 2025. While the twelve months of 2025 will mark the transition year between the EMAN Strategy to 2025 and the reviewed and updated EMAN Strategy to 2028, it is possible to anticipate that the updated strategy will recognise the need to implement the learnings from the COVID-19 pandemic (e.g. new legislation to handle health threats), and adapt to recent scientific and technological advances including in the area of artificial intelligence. In addition, we expect an increased focus on competitiveness, brought to the fore by the Draghi report, and operationalised by the European Commission through the revision of the General Pharmaceutical Legislation and the development of a Biotech Act.

During 2025 the EMANS 2025 priority areas remain the key drivers for the Agency activities linked to non-product related public health activities. Since EMA is a significant contributor to the realisation of network objectives, the network multi-annual goals constitute the framework of EMA's new planning cycle. This principle is corroborated by the integration of strategic goals and

the execution of the EMA Regulatory Science to 2025 Strategy with the Network Strategy.

The network strategy to 2025 focuses on six priority areas (for the complete overview of the cascading of the multi-annual planning, see the tables at the end of this section):

1. Availability and accessibility of medicines.
2. Data analytics, digital tools and digital transformation.
3. Regulatory science, innovation and competitiveness.
4. Antimicrobial resistance and other emerging health threats.
5. Supply-chain challenges.
6. Sustainability of the network and operational excellence.

These areas cover a wide range of topics which are interlinked to multiple themes. Among these, it is essential to mention the need for pandemic preparedness; the increasingly insidious effects of antimicrobial resistance; the impacts of innovation, digitalisation and big data, and the need to ensure competences and capacity for the Network to deal with them. Increased collaboration and engagement with stakeholders, international partners, and downstream decision-makers, as well as the need to prepare adequately for the implementation of new legislation also represents pivotal topics for EMANS implementation. Finally, as emphasised by the COVID-19 crisis, the strategy will have an increased focus on the supply chain at global level, particularly to minimise shortages, and on environmental issues, and a recognition of the importance of good communication and transparency. The annual actions contributing to Pillar 2 activities have been distributed over the timeframe of the strategies (2020-2025).

An overview of the activities potentially affected by resources constraints is available in section 2.5 of this document. The output and timing of the actions included in the overview is dependent on available capacity.

The performance of the activities under Pillar 2 follows the structure of EMANS and RSS, therefore is measured through the achievement of the specific annual actions.

International activities

International activities can be bilateral or multilateral, including ongoing collaborations with existing confidentiality arrangement partners, allowing product-specific discussions and exchange of documents. EMA international activities support the role of the European Commission and wider EU public and animal health interests, including the 2022 EU Global Health Strategy.

Development of new confidentiality arrangements will be temporarily put on hold as well as the expansion of the mutual recognition agreement with the US FDA for vaccines and plasma-derived products (awaiting US FDA's decision on the inclusion of these products into the scope of the MRA). Along with promoting EMA-US FDA parallel scientific advice and fellowships, the Agency will foster collaborative engagement with regulatory counterparts, including through the OPEN initiative, and will actively promote reliance on EMA scientific output by other regulators, in particular through WHO facilitated pathways. EMA will continue to engage actively in the WHO Coalition of Interested Parties.

EMA will continue to actively participate in various international platforms (e.g. ICMRA, ICH, PIC/S, VICH, WHO, etc). Health crises (COVID-19, mpox, nitrosamines), supply chain issues, Article 58 'EU-Medicines4all' pathway, support to priority countries, capacity building (including IPA training for EU candidate countries and potential candidates, and support for the creation of African

Medicines Agency) and scientific training are among the Agency's priorities. Enhancing current levels of engagement with Latin American and Caribbean regulatory counterparts is subject to resource constraints. Activities to raise awareness of the Agency's global health and international engagement will be carried out.

Communication, engagement, and transparency

EMA is committed to providing timely, accurate, trustworthy, and high-quality information on medicines evaluated by EMA through the most appropriate communication channels, as well as information on other activities of interest to stakeholders, partners, and European citizens. It recognises that transparency is key to reinforcing trust in regulatory decisions and is committed to further increasing transparency.

The Agency is strengthening its outreach via different media channels and the production of more graphic and audio-visual content tailored for specific audiences. EMA aims to carry out more communication campaigns on relevant public health topics together with Member States and other partners. The Agency's corporate website, which was relaunched on an updated, more secure platform in collaboration with the European Commission's Directorate-General for Digital Services (DIGIT) in late 2023, will undergo a series of further incremental improvements, with new features to further improve the user experience.

The Agency will continue to tackle vaccine hesitancy by supporting extensive proactive public communication, webinars and meetings in close cooperation with EU partners and Member States (via the Working Group of Communication Professionals). It will continue to interact on a regular basis with ECDC and NITAGs, keep information on vaccines updated on its corporate website and continue to refine the European Vaccination Information Portal (EVIP) – an EU website on vaccination that it maintains jointly with ECDC and the European Commission. EMA will also continue to provide high-quality responses to public requests for information. Communication, engagement and transparency activities will focus on supporting the Agency's strategic priorities in the years ahead, in line with the European medicines agencies network strategy (EMANS) and the Agency's MAWPs.

Requests for access to documents (ATD) have increased in number and complexity. As the Agency moved out of its business continuity setting in 2023, work is ongoing to introduce process improvements, additional tools, and outsource some elements of the work, to build efficiency and address the backlog of requests that built up whilst resources were redeployed to work on COVID-19 related activities. Clinical Data Publication (CDP) for COVID-19 related medicines will continue with other exceptional transparency activities, such as the publication of RMPs and PRAC Assessment Reports and Periodic Safety Update Reports (PSURs) for COVID-19 medicines. Clinical Data Publication was relaunched in September 2023 for centrally authorised products beyond the scope of Covid-19 products and this will be extended in a phased approach in 2025, with continued collaboration with Health Canada.

PILLAR 3:

With regards to Agile Network Portfolio, the multi-annual programming will be centred around the following points:

- The European legislation and regulation context continues to be a main driver for the Network Portfolio. 2025 will be marked by the launch of the European Shortages Monitoring Platform (ESMP), the implementation of the New Fee Regulation, the further enhancements of the Clinical Trials with the objective for CTIS to become the WHO primary registry to support dissemination of scientific research, knowledge, and know-how in particular to the benefit of non-commercial sponsors and academia, and the Veterinary Regulation systems,

whereas Regulatory Business Process optimisation and the Data Analytics activities will implement a continuous roll-out for the next 5 years.

- The further digitalisation of core and corporate processes is of paramount importance to allow the Agency and its stakeholders to increase their efficiency and to optimise resources utilisation. In 2025 the Agency had to prioritise key processes and digital implementations due to resources and budget constraints.
- Data Analytics is another key part of strengthening the promotion and protection of public health, by supporting decisions on medicines with evidence derived from robust and standardised data.

The measurement of the activities under Pillar 3 is carried out through the deliverables linked to the specific initiatives. The deliverables planned for 2025 are listed in Chapter 8.

BUSINESS SERVICES

ADMINISTRATION AND CORPORATE MANAGEMENT DIVISION

The European job market is continuously evolving, along with hybrid ways of working and the accelerated technological developments, which open new opportunities. In addition, the ambitions stemming from the Network's strategy, the evolving pharmaceutical legislation, continue to be important factors in human resource management, with a focus on addressing the Agency's capacity and capability needs through strategic resource planning, agility and talent development.

EMA is also affected by the challenging situation whereby the Agency's fee-related and fee-funded activities are increasing due to the growing portfolio of authorised products, while the Agency's establishment plan does not increase to respond to the growing workload. The Agency has endorsed in 2023 its Human Resources strategy, to explore solutions to alleviate these and other challenges and aspirations through actions designed to increase the sustainability of the Agency, talent management and staff wellbeing.

A new fee regulation will take effect at the beginning of 2025. By this time, the work to put the legislation into practice will be completed, and the agency will begin applying the new rules. Additional system integration will be required to increase productivity and will depend on resource availability. Overall, the Division continuously develops its support to the Agency's core tasks by providing revised and improved services across business areas. Achieving this involves a comprehensive approach to processes, work methods, and technology, alongside strategic planning and talent management. Balancing change initiatives with the Agency's capacity is essential for flexibility. Key activities will include implementing the HR strategy, reviewing processes, continuously adopting digital tools, increasing the analytics capacity, and applying the new fee regulation.

INFORMATION MANAGEMENT DIVISION

Information Management will be driving the technology modernisation to support EMA's public and animal health mission and to become an all-digital, innovative, efficient and data-driven Agency of the future.

The Information Management Division at EMA provides the European Medicines Regulatory Network and EMA's core business with IT systems and services to support all activities related to the authorisation and supervision of human and veterinary medicines in the European Union.

To cope with emerging business needs and new legislative requirements in the coming years, it is critical to further build up the organisational change capacity; improve quality of delivery;

modernise data management, collaboration, and advanced analytics capabilities; continue migrating regulatory scientific procedures onto strategic platforms and transform legacy systems to a secure and data-protection compliant cloud-native enterprise architecture.

EMA CONTRIBUTION TO THE IMPLEMENTATION OF EU PRIORITIES AND POLICIES

The Agency, in compliance with Art. 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:

- A new plan for Europe's sustainable prosperity and competitiveness.
- A new era for European Defence and Security.
- Supporting people, strengthening our societies and our social model.
- Sustaining our quality of life: food security, water and nature.
- Protecting our democracy, upholding our values.
- 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 following section *Focus areas*).

Specifically, the contribution of the Agency focuses on the following priorities:

EC Priority (ECP)	EC Policy/Action	EMA MAWP	EMA MAWP Strategic goal	EMA contribution
1. A new plan for Europe's sustainable prosperity and competitiveness	**A clean industrial Deal** • *The European Green Deal focuses on improving the wellbeing and health of citizens and future generations by reducing net greenhouse gas emissions by at least 55% by 2030, compared to 1990 levels.* • *Europe's seas, oceans, and environment are a source of natural and economic wealth for Europe. We must preserve and protect them to ensure that they continue sustaining us in the future.* • *European Green Deal priorities include:* ○ *protecting our biodiversity and ecosystems;* ○ *reducing air, water and soil pollution;* ○ *moving towards a circular economy;* ○ *improving waste management*	**FA 3: Innovation** **FA 4: Antimicrobial resistance and other emerging health threats** **FA 6: Sustainability of the network and operational excellence** **3: Regulatory Science, Innovation and Competitiveness activities**	**S.G. 3.1/3.2** **S.G. 4.1/4.2/4.3** **S.G. 6.2**	As an EU Agency and by way of recognising challenges on the EU budget and the effect on resource allocation that may arise from the need for an increased focus on sustainability, as stated in FA6 of the European medicines' agencies network strategy, EMA integrates the perspective of sustainability as a priority in its activities. e.g., Future-proofing (forecasting, Horizon Scanning, Innovation Task force etc.), addressing regulatory science research needs, EU public private partnerships, collaboration with partners (e.g., EIC, EIT, EIB, DG-RTD, IHI, C-Path), European Partnerships and Joint undertakings (e.g., IHI, OH AMR, ERA4Health), and not-for-profit research organisations (e.g., C-Path), EMA's competitiveness framework planning. The Agency contributes through the execution of actions within its remit under

EC Priority (ECP)	EC Policy/Action	EMA MAWP	EMA MAWP Strategic goal	EMA contribution
	ensuring the sustainability of our blue economy and fisheries sectors.			the EU Strategic Approach on pharmaceuticals in the environment and the implementation of European One Health action plan against antimicrobial resistance. EMA collects, analyses and reports on sales and use of antimicrobials. Report and data collected by Agency are critical to progress on the Farm to Fork activity. Moreover, as a decentralised Agency of the European Commission, the Agency supports leading by example towards the target of 55% reduction of CO_2 emissions by 2030, and for making operations be climate neutral by 2050 through operational excellence.

EC Priority (ECP)	EC Policy/Action	EMA MAWP	EMA MAWP Strategic goal	EMA contribution
	A more circular and resilient economy • *We must make our economy more resilient and less dependent. This is notably important in the health and pharmaceutical sector. The EU has been confronted with severe shortages of medical devices and medicines, with antibiotics, insulin, painkillers and other products becoming particularly difficult to obtain* • *This will be part of our work to complete the European Health Union with diversified supply chains, access to the most advanced treatments, more resilient health systems and strategic inventories of key medicines. We must continue our work on anti-microbial resistance.* • *We will also step up our work on preventive health, in particular for mental health, including at work, and cardiovascular diseases, as well as on treatments for degenerative illnesses and research on autism. This will build on the successful model of the Beating Cancer Plan*	**FA 1: Availability and accessibility of medicines** **FA 2: Data analytics, digital tools and digital transformation** **FA 5: Supply chain challenges** **3: Regulatory Science, Innovation and Competitiveness activities**	**S.G. 1.1/1.2/1.5** **S.G. 2.1/2.2** **S.G. 5.4/5.5**	EMA contributes to the implementation of this priority and policy through its primary role in the support to development, evaluation, and supervision of medicines for human and veterinary use, its strategy to support the availability and accessibility of medicines, its role in addressing supply chain challenges, and in supporting medical device expert panels. To enhance effectiveness in its primary role (above), EMA is strategically conducting activities for: preparedness (forecasting), Horizon Scanning, addressing regulatory science gaps and research needs, engage with publicly funded private-public partnerships and optimise their outputs, collaborate with e.g., EIC, EIT, EIB, DG RTD, European Partnerships and Joint undertakings (e.g., IHI, OH AMR, ERA4Health), and not-for-profit research organisations (e.g., C-Path), EMA's competitiveness framework planning.

EC Priority (ECP)	EC Policy/Action	EMA MAWP	EMA MAWP Strategic goal	EMA contribution
	Boosting productivity with digital tech diffusion • *Through our Artificial Intelligence (AI), Europe is already leading the way on making AI safer and more trustworthy, and on tackling the risks stemming from its misuse. We must now focus our efforts on becoming a global leader in AI innovation.* • *To support the development of AI and other frontier technologies, Europe needs to exploit the untapped potential of data. Access to data is not only a major driver for competitiveness, accounting for almost 4% of EU GDP, but also essential for productivity and societal innovations, from personalised medicine to energy savings. However, too many companies in Europe struggle to get access to the data they need – while large foreign tech companies use European data to fuel their business. While ensuring high standards of data protection, we will support companies by improving open access to data, notably to support SMEs to fulfil reporting*	**FA 2: Data analytics, digital tools and digital transformation**	**S.G. 2.1** **S.G. 2.2**	EMA contributes to the implementation of this priority and policy through the work of the Analytics Centre of Excellence (ACE), DigiLab and the AI Coordination Group activities, as well as through DARWIN EU project, which aims at delivering a sustainable platform to access and analyse healthcare data from across the EU.

EC Priority (ECP)	EC Policy/Action	EMA MAWP	EMA MAWP Strategic goal	EMA contribution
	obligations. Europe needs a data revolution.			
2. A new era for European Defence and Security	**A Preparedness Union** • *Building on the work of the Health Emergency Preparedness and Response Authority, we will present a new strategy to support medical countermeasures against public health threats, such as those linked to CBRN security, including joint procurement and stockpiling.*	**FA 4: Antimicrobial resistance and other emerging health threats**	**S.G. 4.3/4.6**	EMA contributes to this priority through its collaboration with HERA as well through the interpandemic preparedness activities of the ETF.
3. Protecting our democracy, upholding our values	**Protecting our democracy** • *We will also continue to step up digital enforcement to ensure that manipulated or misleading information is detected, flagged and, where appropriate, removed in line with the Digital Services Act.* • *The aim is to increase situational awareness, by detecting, analysing and proactively countering disinformation and information manipulation.* **Putting citizens at the heart of our democracy** • *In the same spirit, we will also step up our engagement with civil society*	**Stakeholders and Communication Activities**		The Agency contributes to this priority through the implementation of its stakeholder's engagement strategy as well by collaborating with other EU institutions, enhancing its social media monitoring to become aware, at an early stage, of dis- and misinformation and to take appropriate action proactively

EC Priority (ECP)	EC Policy/Action	EMA MAWP	EMA MAWP Strategic goal	EMA contribution
	organisations that have expertise and an important role to play in defending specific societal issues and upholding human rights. We must ensure civil society is better protected in its work.			
4. A global Europe: Leveraging our power and partnerships	**Enlargement as a geopolitical imperative** • *In a world of major powers, a larger and stronger Union gives us greater geopolitical weight and influence on the global stage. It helps reduce our dependencies, enhances our resilience and strengthens our competitiveness. It makes us more secure and it can help anchor democracy, stability and the rule of law across Europe* **A new economic foreign policy** • *The Indo-Pacific has become a decisive region for the world's future. Building on our existing strategy, we will deepen our engagement with our partners in the region. We will propose a new Strategic EU-India Agenda and strengthen our cooperation with ASEAN. We need new impetus in our mutual*	**International Activities**		The Agency contributes to this priority within the scope of its mandate, through its international bilateral and multilateral collaboration, and support to EU candidate and potential candidate countries, through funding support of European Commission DG NEAR. With the funding support of European Commission DG INTPA, EMA is leading engagement with African continental, regional and national regulatory authorities, in particular to support the operationalisation of the African Medicines Agency. Enhancing current levels of engagement with Latin American and Caribbean regulatory counterparts is subject to current resource constraints. EMA fosters international collaboration on innovation through

EC Priority (ECP)	EC Policy/Action	EMA MAWP	EMA MAWP Strategic goal	EMA contribution
	partnership with Africa ahead of the next EU-African Union Summit in 2025. We will work together to mutually address Africa's concerns, from the reform of international institutions to the impact of climate change, demography and migration on our continents. We will deepen the cooperation between the EU and Latin America and the Caribbean through Global Gateway investment and cooperation on our shared interests, from security to energy.			the ICMRA Innovation Working Group.

Focus areas

The following tables describe in detail the key drivers for the implementation of public health activities and represent a complete overview of all the elements which constitute the cascading of the multi-annual planning (namely, focus areas, strategic goals, objectives/additional recommendations). The implementation of all the objectives mentioned below will span the multi-annual strategy timeframe (2020-2025) and will be implemented via annual actions. At the time of drafting the Agency and EMRN members are developing an updated/reviewed strategy to 2028. The new strategy will be reflected in the 2026-29 Single Programming Document.

Focus area 1: Availability and accessibility of medicines

Strategic goal	Objectives
1.1. Strengthen the availability of medicines to protect the health of European citizens and animals	Identify the specific root causes of shortages for medicines for human and veterinary use and develop strategies to improve prevention and management of shortages (a better understanding of the specific causes for shortages of generics/off-patent products versus products still under patent protection is essential). Based on the outcome of this study, help identify and suggest areas where changes to EU or national legislation could improve supply.
	Foster the awareness of the public and healthcare professionals on the approval standards, safety, effectiveness, and immunogenicity of similar biological products to facilitate the uptake of biosimilars in healthcare systems.
	Improve coordination of information and actions, including implementation of best practices, both for EU regulatory authorities, stakeholders, and international partners.
	EMA should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply. EMA should also coordinate the activities of the EMRN, to ensure availability of critical medicines in the EU/EEA by supporting increase of production capacity to meet demand.
	Increase transparency on availability/launch to facilitate targeted regulatory actions and communication with patients, HC professionals and HTA bodies.
1.2. Optimise the path from development and evaluation, to access for beneficial medicines (innovative and follow-on)	Develop better scientific evidence which serves different decision-makers along the decision chain (regulators, HTA bodies, payers), including evidence to support post-licensing follow-up of medicinal products, thereby stimulating a lifecycle approach to evidence generation and the possibility to adjust decisions based on new evidence.

through collaboration between medicines regulators and other decision makers	Clear and enhanced communication to patients, healthcare professionals, veterinarians and animal owners, as well as down-stream decision-makers about the regulatory assessment, including information gap inherent for medicinal products approved on the basis of limited scientific data and secondary endpoints (e.g. Orphans, limited market veterinary medicinal products).
	New metrics for accessibility of medicines that better represent real patient access to newly authorised medicinal products in different markets.
	Foster alignment of national implementation of compassionate use programmes, to promote equity in access for patients during late-stage development and improved utilisation of data from such programmes to support later decision making.
Additional RSS recommendations	Reinforce patient relevance in evidence generation.

Focus area 2: Data analytics, digital tools and digital transformation

Strategic goal	Objectives
2.1. Enable access to and analysis of routine healthcare data, analysis of individual patient data from clinical trials, and promote standardisation of targeted data	Deliver a sustainable platform to access and analyse healthcare data from across the EU (DARWIN EU).
	Pilot the analysis of individual patient data from clinical trials in initial marketing authorisation assessments with a view to a targeted roll-out of such analysis.
	Establish collaboration with external stakeholders (including patients, academia, NGOs, and industry) and with international regulatory authorities on Big Data initiatives.
	Establish EU framework for data quality, discoverability, and representativeness, through agreement on meta-data for regulatory purposes, a standardisation roadmap, and registers of real-world data sources and of observational studies.
2.2. Build sustainable capability and capacity within the Network	Build EU Network capability to analyse Big Data.
	Digital transformation of the EU Network's scientific and regulatory processes to enable use of digital tool and analytics and creation of a supporting digital infrastructure (e.g. to support uptake and review of big data (from eHR, registries, devices)

2.3. Promote dynamic regulation and policy learning within the current regulatory framework	Modernise the delivery of scientific advice at central national level by developing Network skills and processes.
2.4. Ensure that data security and ethical considerations are embedded in the governance of data within the Network	Ensure data are managed and analysed within a secure and ethical governance framework.

Focus area 3: Innovation

Strategic goal	Objectives
3.1. Catalyse the integration of science and technology in medicines development and ensure that the network has sufficient competences to support innovators in various phases of medicines development	Support the integration of scientific and technological progress in the development of medicines (e.g. precision medicine, biomarkers, 'omics and ATMPs) and ultimately into patient treatment.
	Transform the regulatory framework for veterinary medicines to support innovation and implementation of veterinary medicines regulation.[2]
	Implement an EU-level model for efficient, timely and coordinated horizon scanning and priority setting that fulfils the needs of both regulators, HTA-bodies, and payers.
	Facilitate the implementation of novel manufacturing technologies.
3.2. Foster collaborative evidence generation, improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTA and	Foster innovation in clinical trials and develop the regulatory framework for emerging clinical data generation.
	Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation and invest in special population initiatives.
	Develop further the collaboration of various groups involved with scientific advice and/or regulatory guidance.

[2] Most of the requested guidelines related to the veterinary regulatory framework have been published.

pricing and reimbursement authorities	
3.3. Enable and leverage research and innovation in regulatory science	Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science.
3.4. Enhance collaboration with other stakeholders including medical device experts, notified bodies, SMEs, and research/academic groups	Increase collaboration with Medical Device Authorities and Notified Bodies, exchange knowledge and facilitate collaboration and sharing of expertise to ensure effective and appropriate regulation of combination products.
	Promote early interaction with academia, researchers, and SMEs with a view to increasing awareness of regulatory requirements and facilitating the translation of research into authorised medicinal products and ultimately into clinical practice.
Additional RSS recommendations	Update Environmental Risk Assessments in line with the latest scientific knowledge.
	Support the development and implementation of a repurposing framework.

Focus area 4: Antimicrobial resistance and other emerging health threats

Strategic goal	Objectives
4.1. Provide high-quality information on antimicrobial consumption and surveillance data on antimicrobial resistance	Implement the requirements for the mandatory collection of sales and use data for antimicrobials used in animals, spread knowledge and ensure better access to data in line with the Veterinary Medicinal Products Regulation.
	Foster more robust surveillance systems in the EU for both antimicrobial consumption and emergence of resistance in veterinary and human medicine, to foster analyses of the potential relationships between antimicrobial consumption and AMR and of co-selection of AMR by use of biocides and feed additives.
	Modernise SmPC of old antibiotics for human and veterinary use[3].

[3] The modernisation of SmPC of older antibiotics will be evaluated under the AMR strategy.

4.2. Contribute to responsible use of antimicrobial agents and effective regulatory antimicrobial stewardship in human and veterinary sectors by putting in place strategies to improve their use by patients, healthcare professionals and national authorities	Define, in close collaboration with the Commission and the authorities for in vitro diagnostics, a roadmap for Point Of Care (POC) diagnostics to support the development of improved diagnostic tests.
4.3. Ensure regulatory tools are available that guarantee therapeutic options (especially for veterinary medicines) while minimising impact of antimicrobial resistance on public health and the environment	Promote guidance on antimicrobial use by adaption of existing and creation of new guidelines and finalise the Agency approach to antimicrobial resistance in the environment.
4.4. Define pull incentives for new and old antimicrobial agents	Define value of new antibacterial agents to inform new business models and cooperate on the establishment of new business models, including the exploration of incentives for continuous manufacturing of old antibiotics.
4.5. Foster dialogue with developers of new antibacterial agents and alternatives to traditional antimicrobials	Foster development of new antimicrobials, including new antibacterial for human use, define regulatory pathways for phage and other innovative products in human and veterinary medicines, and engage with relevant stakeholders to effectively discuss the issue.
4.6. Improve regulatory preparedness for emerging health threats	Refine regulatory activities in inter-epidemics periods to increase preparedness and harmonise regulatory framework and approaches for the investigation of medicinal products during emergencies.
Additional RSS recommendations	Promote and support the development of veterinary vaccines.
	Support innovative approaches to the development, approval, and post-authorisation monitoring of vaccines.

	Implement EMA's health threats plan and ring-fence resources and refine preparedness approaches.
	Engage with stakeholders to minimise the risks of antiparasitic resistance.

Focus area 5: Supply chain challenges

Strategic goal	Objectives
5.1. Enhance traceability, oversight, and security in the human/veterinary medicine supply chain from manufacturing to importation and final use of active pharmaceutical ingredients (APIs) and excipients	Improve and interlink information in current/existing databases to provide supply chain compliance overview.
	Tackle falsified medicines; prevent presence of falsified medicines in the supply chain by strengthening inspections of manufacturers' application of safety features and of the repository systems.
5.2. Enhance inspector capacity building at EU and international level	Enhance capacity building of EU inspectors and assessors, to harmonise approaches to regulatory inspections procedures to address requirements and challenges of APIs, medicinal products, excipients, new technologies and continuous manufacturing.
	Promote a more tailored supervision of API manufacturers through assessment and inspection of their API development and risk management practices in technology transfer; increase supervision of sites that produce medicinal products for a significant number of EEA markets or very significant numbers of products, with dedicated cooperative supervision between MS and strategic partners for these sites.
5.3. Reinforce the responsibility for product quality by harmonising and reinforcing guidance	Develop EU level data integrity guidance.
	Ensure a stable EU-GMP regulatory framework with predictable outcomes by promoting and improving the understanding of EU GMP requirements and preparedness by third country manufacturers and their supervisory authorities. Foster an environmentally friendly level playing field.

5.4. Encourage supply chain resilience and review long-term risks resulting from dependency on limited number of manufacturers and sites	Enhance the reliability of evidence available to regulators for informing the decision-making process on the supply chain and promote supply chain resilience and reliability of supply of APIs and medicinal products.
5.5. Analyse the possible implications of new manufacturing technologies and adapt the regulatory framework to accommodate innovation in manufacturing and distribution	Analyse the regulatory system with respect to new technologies and new tools used in manufacturing and for supply chain management and control; identify opportunities to improve supply chain resilience.

Focus area 6: Sustainability of the Network and operational excellence

Strategic goal	Objectives
6.1. Reinforce scientific and regulatory capacity and capability of the network	Ensure 'fit-for-purpose' scientific capability of the Network.
	Prepare for and implement the Veterinary Medicinal Products Regulation.
6.2. Strive for operational excellence, building on the work done in the current strategy	Optimise the current regulatory framework by ensuring efficiency of existing regulatory operations.
	Introduce governance and IT process improvements to further professionalise prioritising, budgeting, securing, provisioning, and running of technology services.
	Introduce regulatory innovation and flexibilities to accelerate availability of medicines.
6.3. Achieve a sustainable financial and governance model for the network	Contribute to the revision of the current fee regulation, and implement the final solution.
6.4. Develop a digital strategy to drive digital business transformation	Establish an IT operating model and services, in support of the digital strategy and digital business transformation.

6.5. Enable quick, consistent, and adequate response to public and animal health challenges	Build further capacity and capability within the Network to support crisis management.
Additional RSS recommendations	Further develop external engagement and communications to promote trust and confidence in the EU regulatory system.

2 Human and financial resources – outlook for the years 2025 – 2027

2.1 Overview of the past and current situation

Overview

In 2024, the total budget (revenues and expenditure), as adopted by the EMA Management Board on 14 December 2023, amounted to € 478,482,000. During the year, the Management Board adopted three amending budgets for a total of € 13,125,000 to cover part of the rent for the London premises, which increased the budget to a total of € 491,607,000. On the revenue side, this included € 441,910,000 in fee revenues and contributions from the EU budget totalling € 46,031,000 and miscellaneous revenues for € 3,666,000. On the expenditure side, this included € 158,479,000 in Title I: staff expenditure, € 84,168,000, of which € 13,125,000 relates to the rent for 30 Churchill Place in London – in Title II: infrastructure and operating/IT expenditure, and € 248,960,000 in Title III: operational expenditure.

The staffing ceilings in 2024 were 691 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 10 out of 40 time-bound TA posts. The remaining 30 time-bound posts will be reduced gradually in the following years between 2025 and 2026. Throughout the year, the Agency operated an occupancy rate close to 100%.

2.2 Outlook for the years 2025 – 2027

New tasks

The Regulation (EU) 2021/2282 on health technology assessment (HTAR) will apply from 12 January 2025. The Regulation will govern the European cooperation between medicine regulators and HTA bodies. Under the new framework, EMA and the Member State Coordination Group on HTA (HTACG) will collaborate in the context of joint clinical assessments, joint scientific consultations, and the identification of emerging health technologies. The Agency has not received any additional resource to implement these 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. Depending on the outcome of the legislative procedure the Agency will elaborate more specifically on additional new tasks in future Single programming documents. During 2025 the Agency will continue to look into possible ways to anticipate the changes by exploring ways to implement 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 €1.172M of EU contribution for 2026. With regards 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.

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.

As a result, fee income[1] (excluding inflation) and associated workload are expected to grow by 67% in 2026 compared to 2014 baseline, driven by the significant volume of increase in pre- and post-marketing authorisation applications.

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 and Clinical Trials Regulation). 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. The Agency has identified that a minimum of an additional 32 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.

2.3 Resource programming for the years 2025-2027

Financial resources

As of 2025, the new Regulation (EU) 2024/568 on fees and charges payable to EMA will become applicable. The regulation changes the level of fee and charges and the remuneration to the National Competent Authorities. The total revenue from fees in 2025 is forecasted at €549.3 million, which is an increase of €114.6 million (26.4%) compared to the estimated result for 2024.

In 2026, the total revenue from fees is expected to reach €557.7 million based on the new Fee Regulation.

For 2025 the EU/EEA contribution is set at €48.9 million, out of which €13.7 million relates to London premises and the rest is in line with the Multiannual Financial Framework. In 2025 and 2026, the EU contributions are set at the same level as of 2024, however in 2026, the Agency may receive an additional contribution linked to the reform of the EU pharmaceutical legislation.

The orphan medicinal products contribution in the draft budget 2025 and preliminary draft budget 2026 reflects the amount proposed in the EU budget.

Staff expenditures include the salary increase proposed by the European Commission for 2024 and 2025.

Expenditure related to scientific studies and services include a net increase of approximately €6.3 million compared to 2024 expected result, mainly related to DARWIN and Scientific Studies activities continuing into 2025.

[1] In order to maintain comparability with 2014, the data related to fee income and associated workload increased mentioned in this paragraph is calculated on the basis of the Fees and charges regulation in place until 31/12/2024.

The 2025 and 2026 budgets include EU funding for EMA premises in London.

The expenditure related to the running and maintenance of the EMA building in Amsterdam has now stabilised, with mainly annual price revisions and inflation causing the small increases seen.

Rapporteur payments will increase considerably in line with the higher level of remunerations set in the new Fee Regulation and higher number of scientific applications and fee income expected.

IT project development is expected to continue to increase, delivering the portfolio of projects described in detail later in this document, and maintaining the IT operations infrastructure supporting both pan-European databases and Agency-specific applications.

Human resources

The draft budget 2025 includes the 20 time-limited TA posts (a decrease of 20 compared to the initial allocation in 2021) awarded by the EC to cope with the extra workload linked to the response of the COVID-19 pandemic and 23 TA posts linked to the preparatory activities of the new Pharmaceutical Legislation (includes 5 front-loaded from 2026).

In the 2026 preliminary draft budget we see a reduction of the final 20 time-limited TA posts awarded by the EC to cope with the extra workload linked to the response of the COVID-19 pandemic, offset by 10 regular duration TA posts to cover business as usual activities stemming from COVID-19 pandemic and 10 TA posts linked to the preparatory activities of the new Pharmaceutical Law. Moreover, the Agency will request additional 32 TA posts to cater for the growth of existing tasks.

For the 2026 preliminary draft budget, the Agency will request:

- 7 additional TA posts linked to additional requirements included in the adopted legal text for Regulation (EU) 123/2022, and not included in the original EC proposal. Specifically with regard to the additional costs related to the implementation of the ESMP, the Agency had to divert 7 TA posts from medical devices' activities, finding itself unable to satisfy the latest EC request for an increased involvement of EMA in the medical devices' scope.
- 1 additional TA post linked to activities introduced by Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic, for which the Agency did not receive any compensation posts.
- 3 additional TA posts linked to the implementation of Regulation (EU) 2021/2282 on health technology assessment (HTAR). The Agency has never received any compensation posts for the implementation of this piece of legislation.
- 1 TA post to support data protection activities, in relation to the implementation of Regulation (EU) 2016/679, for which the Agency has never received any compensation posts. Currently, resources had to be diverted from the assessment and supervision of medicinal products in order to satisfy the legal obligations set by the Regulation.
- 11 additional TAs for workload linked to the growing product portfolio. Detailed justification for this request is provided above under 2.2 *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.
- 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 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).
- 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.
- 1 post for implementing the Interoperable Europe Act, including interoperability assessments and modernizing regulatory information services for national authorities, stakeholders, and the public.
- 1 post for supporting the implementation of a single medicinal product foundation for the EMRN, covering shortages monitoring, pharmacovigilance, and electronic Product Information.
- 2 posts for decommissioning obsolete technologies and modernizing legacy systems to meet new legislative requirements, ensure business continuity, and reduce operational costs.

As explained in 2.2 *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. This is particularly relevant for proposals such as the New Cybersecurity Regulation, AI Act, EHDS, EUDPS, SoHO, and various cross-sectoral regulations.

2.4 Strategy for achieving efficiency gains

As described in detail under section 2.2 above, applications-related fee income (excluding inflation) and associated workload are expected to grow by 64% in 2026 compared to 2014 baseline[1], driven by the significant volume of increase in pre-and post-marketing authorisation applications (and associated workload). 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.

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 organizations to scale agile

[1] In order to maintain comparability with 2014, the data related to fee income and associated workload increased mentioned in this paragraph is calculated on the basis of the Fees and charges regulation in place until 31/12/2024.

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.

Digitalisation: In a constantly evolving environment, the Agency is embracing digital transformation to ensure a proper response. In 2020, in the context of the future proofing exercise, a Digital Business Transformation Task Force was created with the mandate to develop and execute a digitalisation strategy for the Agency. In 2025, the Agency continued 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 we 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 is running a 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.

2.5 Negative priorities

The purpose of this section, as required by the EC guidelines for the drafting of the Single Programming Document, is to highlight those activities that have been downscaled or deprioritised due to a lack of resources.

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, and also due to significant new tasks that have been assigned to the Agency over the last years with only a minimum increase in EMA's staff establishment plan. Thus far, this 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 in the longer term and is restricting the Agency's ability to optimise our contribution to a robust and sustainable European Health Union.

As EMA has discontinued its Business Continuity status in 2023, a number of areas have marked an increase in workload and despite turning to alternative resourcing streams to fulfil its mission and legal obligations, under-resourcing still hinders the Agency's capacity to adequately deliver on some important activities, notably:

- In light of the ongoing investments in security operations and the implementation of the information security roadmap, it is also critical to expedite the transformation of the IT legacy applications landscape towards a modern infrastructure. This transformation requires an adequate allocation of dedicated staffing. Nonetheless, the Agency is currently unable to fully meet this staffing requirement, which impacts:
    - the Agency's ability to realise the full potential of e.g. the use of data and real world evidence in the context of evaluation and supervision of medicinal products;
    - the progress of innovation initiatives aimed at generating efficiency gains and implementing streamlined processes.
- international regulatory cooperative activities, in particular enhance cooperation with Latin American countries;
- managing the workload with regards to various transparency related activities, including the implementation of EMA Policy 0070 on publication of clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure.

Part III: Work programme 2025

Executive summary

The structure of the Work programme reflects the organisational units of the Agency. The elements of the executive summary are detailed in the related specific sections of the Work programme. A summary of the main drivers and challenges are provided as follows:

- 2025 highlights

In order to address the challenges of a rapidly evolving medicines landscape and to prepare for the transition into the revised/updated EMANS 2028, during 2025 the Agency plans to pay particular attention to three focus areas: accelerate and optimize the assessment of key medicines, facilitate the path to accessibility and strengthening the availability of medicines, and seize the opportunities to future-proofing medicines regulation in the EU. Building on the experience of using cancer medicines as a pathfinder, EMA will seek to apply these learnings to key medicines in other therapeutic areas. The Agency will work to streamline regulatory processes, leverage the potential of artificial intelligence for medicines assessments and generate better clinical and real-word evidence for better assessment. EMA will support the implementation of the Health Technology Assessment (HTA) Regulation and will continue coordinating efforts to prevent and mitigate shortages, with the go-live of the European Shortages Monitoring Platform (ESMP) in January 2025. The Agency will work towards securing supply chains for critical medicines. Preparing for new pharmaceutical legislation, EMA will work on seizing the opportunities to optimise the centralised procedure and refine processes. It will engage with Scientific Committees to prepare for new ways of working and will work on a number of activities to enhance the sustainability of the EU Network. These efforts will ensure that EMA remains adaptive and innovative in meeting the evolving needs of public health and the pharmaceutical sector.

- Human Medicines Division:
    - Facilitate the development of new medicines and assure the quality of the continuous assessment of the benefit-risk of medicines for patients throughout their lifecycle.
    - Anticipate the changes stemming from new pharmaceutical legislation, continue with the implementation of new responsibilities stemming from the Health Technology Assessment regulation, and progress activities for medical devices and regulatory science to keep pace with scientific and technological advances by implementing the objectives of the strategy of the European Medicines Regulatory Network and developing the capabilities of employees and experts with particular focus on supporting the development of innovative medicines.
    - Progress the digitalisation of core regulatory processes to handle the anticipated increase in applications over the coming years and to enable the use of advanced digital tools for a more integrated knowledge management of the lifecycle of medicines.
- Veterinary Medicines Division:
    - Continue working on the follow-up activities related to the implementation of Regulation (EU) 2019/6 (Veterinary Regulation) effective as of 28 January 2022: continuous improvement of IT systems, refinement of processes based on real-life implementation experience, guidance update and revision.

- Continue to support core business activities optimising the use of resources and maintaining timeliness and quality of outputs.
- Continue to support stakeholders and network transitioning into Regulation (EU) 2019/6.

- Stakeholders and Communication Division:
  - The implementation of lessons learned from COVID-19 and the Agency's response to the pandemic continues.
  - Supporting further stakeholder engagement and communication in collaboration with the Network on the implementation of the joint European Medicines Agency Network Strategy, the Regulatory Science Strategy and key focus areas include: clinical trials and ACT EU, data driven legislation, cancer as a pathfinder to support development and approval of innovative medicines, work to address medicines shortages, and preparing for implementation of the HTA regulation and for the review of the EU pharma legislation.
  - Implementation of the Agency's 5-year framework strategy for external communication and stakeholder engagement (2021-2025) will continue to:
    - increase public health impact through timely, accurate and evidence-based information that resonates with a broad audience,
    - strengthen collaboration with partners and stakeholders and promote effective engagement,
    - establish optimised crisis-communication processes,
    - optimise EMA websites and leverage progress in digitalisation,
    - review and adapt operations to ensure sustainability and responsiveness.
  - Continuing to ensure that the patient voice is systematically incorporated throughout medicine development and evaluation, and enhanced interaction with healthcare professionals, industry stakeholders, and academia (in cooperation with TRS).
- Information Management Division:
  - Maximising customer success: enabling the success of the European Medicines Agencies Network and maximise business impact through customer focus. Be recognised as a trusted partner for our stakeholders' information service needs and to play an integral part in achieving EMRN's mission.
  - A modernisation mindset: focusing strategically on innovating IT capabilities and transforming how EMA delivers IT to our customers. Re-designing key business processes by migrating to strategic platforms and transform legacy to secure and cost-efficient cloud infrastructure.
  - Operational excellence and information security as the foundation for well-run IT operations: continuously enhancing information security and data protection compliance and assessing progress based on best practices and frameworks.
- Administration Division:
  - Implement the endorsed HR strategy through a multi-annual implementation plan that focuses on the sustainability of the Agency, talent management and staff wellbeing. The implementation of the HR strategy will follow agile way of working.

- Operate the new fee regulation which enters into force in January 2025. To prepare for the legislation, the agency redesigned its fee-related processes and the updated the relevant IT tools.
- Continue the efforts to gradually digitalise administrative processes, replacing legacy systems focusing on human resource processes. This work involves reviewing and changing processes as well as replacing systems. The replacement of legacy financial systems will also be accomplished in the future.
- Continue to prioritise and implement initiatives which improve the quality of corporate data and facilitate generation of information and analysis based on such data.
- Fill efficiently and effectively the positions granted by the budgetary authority for the new pharmaceutical legislation.

- International affairs:
  - Support to the management of health crises.
  - Extension of US MRA, supply chain, EU-M4all.
  - Promoting reliance on scientific outputs of the EMA scientific committees.
  - Support to priority countries, capacity building (including IPA training) and scientific training.
  - Key activities to support establishment of the African Medicines Agency.
- Advancing the role of the International Coalition of Medicines Regulatory Authorities (ICMRA).Digital Business Transformation (TDT) Task Force:
  - Lead the Agency's digital transformation through Network portfolio oversight, digital change management and digital capability and capacity building. The ambition is to deliver a modern workplace, increase efficiency, make the best use of resources, skills, and competencies, and provide a system that supports integrated scientific and regulatory knowledge management across EMA operations and the Network.
  - Lead the Agency's transitioning to Lean-Agile (SAFe) way of working, and ensure the agile principles and methods are implemented in the Network Portfolio delivery across its Value Streams, with the aim to become a Lean-Agile organisation that adapts to and thrives in a constantly changing environment. Experiment and build pragmatic and innovative solutions for new and existing EMA business needs using novel technologies and process analytics – including artificial intelligence (AI), robotics and machine learning, for further scale up and integration into business operations.
  - Driving strategic implementation of new legislation in cooperation with all relevant stakeholders, with the Medical Device and In vitro Diagnostics Regulations being the primary focus. Contributing to planned targeted evaluation of the MDR/IVDR framework, including supporting the European Commission in exploring possible future proof integrated regulatory pathway with the potential to support and evaluate complex healthcare solutions in real-time by bringing together relevant experts.
- Data Analytics and Methods (TDA) Task Force:
  - Future-proof to ensure the organisation can seize the opportunities from development in the data field, acknowledging the European Data Strategy and related legal proposals,

including the European Health Data Space. Lead data governance within EMA and support the Network Data Steering Group.

- Deliver the objectives to transform to data-driven medicines regulation and support innovation, including data quality and findability, enabling the use and establishing the value of real-world evidence (including through DARWIN EU®), piloting the analysis of clinical study data from clinical trials, building analytics capability for healthcare data including using AI, and training and collaborating on data in medicines regulation.
- Support the regulation of human medicines through methodology advice on the design and interpretation of studies and through the management of EudraVigilance.
- Support the full implementation of the Clinical Trials Regulation (see also Pillar 3) through operation and further development of the Clinical Trial Information System. Innovate in the design and conduct of clinical trials through the ACT EU and its multistakeholder platform.

- Regulatory Science and Innovation (TRS) Task Force:
  - Advance support to innovation through enhanced first-contact functionalities within the Innovation Task Force, Business Pipeline, SME Office, and academic liaison.
  - Develop horizon-scanning and outreach capabilities of EU-IN, SME Office and the academic liaison, and expand business analysis and forecasting to deliver enhanced quality outputs to the Agency and the EU network.
  - Leverage collaborations between academia and network scientists to prepare for engagement with Horizon Europe and IHI enable the exchange of knowledge and expertise.
  - Drive EMA's regulatory science research and establish the European Forum for Regulatory Science research.
  - Deliver the reinforced EMA mandate to facilitate a coordinated EU-level response to health crises and in preparedness by monitoring and mitigating shortages of medicines and of critical medical devices (during a PHE).
  - Enhance European collaboration amongst Regulatory Network (EU-IN) and relevant stakeholder promoting EU competitiveness in pharma (and med-tech) R&D.
- Anticipating the changes stemming from New Pharmaceutical Legislation:
  - Support the European Commission and closely monitor the legislative process to understand amendments to the legal proposal and anticipate the final legislation.
  - Analyse the legal proposal to evaluate the impact on EMA, the Regulatory Network and stakeholders and develop a plan to be ready to implement the final legal text.
  - Design ways to implement the legislative proposal and any emerging significant changes to it and use this opportunity to future-proof medicines regulation in the EU and the work of EMA within the EU Medicines Regulatory Network.
- Following the publication of the European Commission Communication in October 2023 on Addressing medicines shortages in the EU, the Agency plans to undertake the following activities in 2025 and beyond:
  - Support to the European Commission Critical Medicines Alliance to finalise the methodology to assess the supply chain vulnerability of critical medicines.

        - EMA is a CMA member with representatives on the CMA Steering Board and Working Groups 1 and 2. At the operational level, EMA contributes with technical feedback to the broader CMA action plan and working group deliverables. EMA also advises and supports EC services (GROW/HERA) in their undertaking of critical medicine vulnerability assessment work. The work of the EMA MSSG and the HERA CMA is complementary, and cooperation is foreseen to avoid duplication of work. The CMA activities focus on long-term industrial activities, while the MSSG focuses on regulatory actions to address vulnerabilities in the supply chain of critical medicines (i.e., short- to medium-term).
    - Coordinate requests under the Voluntary Solidarity Mechanism for medicines and explore ways to further improve the process and its implementation within the Solidarity Mechanism Working Group of the MSSG, in cooperation with NCAs and EC.
    - Explore ways to facilitate transfer of marketing authorisations to a third party to limit impact of medicines withdrawals.
    - Continue close management of antibiotics availability during autumn/winter 2024/25
    - Develop template and associated guidance for Shortages Prevention and Management plans (SPMPs) and its implementation through a pilot phase.
    - Launch the European Shortages Monitoring Platform by 2025 to enable further information sharing between member states and with EMA and continue to work on expansion of the functionality and scope of the platform.
    - EMA and NCAs, with the support from National Ministries of Health, will issue version 2 of the "Union list of critical medicines" by December 2024. The list will be maintained annually thereafter. EMA will continue to provide support to the EC in the context of broader critical medicines vulnerability assessment and strategic autonomy initiatives, e.g. through the active participation in the various structures of the Critical Medicines Alliance.

1. Human Medicines Division

The European Medicines Agency supports and facilitates the development of human medicines, evaluates these medicines through scientific committees, and advises the European Commission on their marketing authorisation, as well as monitoring the safety, quality, and benefit-risk balance of authorised medicines. It also develops scientific guidelines to facilitate the development of medicines and to protect public health.

The Agency performs the scientific evaluation of applications for EU marketing authorisations for medicines that fall under the scope of the 'centralised procedure' and provides its scientific opinion to the Commission. The Agency is not involved in the assessment of nationally authorised medicines, except regarding pharmacovigilance activities, work-sharing of variations, or to solve disagreements between two or more Member States.[6]

The three main drivers are:

- facilitate the development of new medicines and assure the quality of the continuous assessment of the benefit-risk of medicines for patients throughout their lifecycle, with additional focus on anti-cancer medicines as a pathfinder; additionally fulfil new legal responsibilities under the Health Technology Assessment Regulation and for medical devices;
- anticipate changes resulting from the new pharmaceutical legislation, advance regulatory science to keep pace with scientific and technological advances, and develop the skills of staff and experts with a particular focus on supporting the development of innovative medicines and the use of innovative technologies;
- progress the digitalisation of core regulatory processes to handle the increased legal responsibilities and prepare for the new pharma legislation and to enable the use of advanced digital tools for a more integrated knowledge management of the lifecycle of medicines.

The activities performed by the Human Medicines Division can be clustered in 9 main areas: 1) pre-authorisation; 2) initial evaluation; 3) post-authorisation; 4) referrals; 5) pharmacovigilance; 6) inspections and compliance; 7) committees, working parties and expert management; 8) medical devices; 9) activities required by the HTA regulation. More details on the activities are provided in the following subsections.

The workforce available in 2025 for the Division is currently foreseen at 389 staff (268 TAs, 99 CAs, 20 SNEs). This figure is subject to constant revision to consider staff movements (including part-time regime) and workload fluctuation

[6] Reference: *1.4. Referrals.*

Pillar 1 – Product related activities

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.

Workload indicators

		Results	**Expected results**		**Forecasts**
		2023	**2024**	**2025**	**2026**
Scientific advice and protocol assistance (non-exhaustive list)	Total scientific-advice and protocol-assistance requests	692	733	770	785
	Requests for parallel scientific advice and protocol assistance with international regulators	13	2	4	4
	Requests for joint scientific advice and protocol assistance with HTA	4	3	8	10
	Scientific advice for PRIME products	n/a	34	40	44
	Protocol-assistance and follow-up requests	119	130	137	140
	Requests for qualification of novel methodologies	18	14	16	17
Supporting the development of PRIority MEdicines	PRIME eligibility requests received	52	60	60	60

		Results	Expected results		Forecasts
		2023	2024	2025	2026
Orphan medicinal product designation and related maintenance procedures	Applications for orphan designation received	195	210	210	210
Development of medicines for children	Total paediatric-procedure applications received	713	718	654	656
Classification and certification of advanced therapy medicinal products (ATMPs)	Submitted requests for ATMP classification	43	45	45	45

1.2 Initial evaluation activities

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 (Article 58 applications also called EU-M4all).

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 regards 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).

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2023	**2024**	**2025**	**2026**
Scientific assessment of medicines submitted for centralised marketing authorisation	Non-orphan medicinal products	35	51	49	53
	Orphan medicinal products	23	29	25	22
	Similar biological products	21	36	26	21
	Generics, hybrid, informed-consent applications, etc.	20	17	17	17
	Scientific opinions for non-EU markets (Art 58)	0	1	1	1
	Paediatric-use marketing authorisations	1	3	1	1
	Requests for accelerated assessment accepted	7	12	5	5
	ATMP marketing application authorisation requests received	4	11	5	6
	Companion diagnostics opinions	9	30	15	15
	Reviews on the maintenance of the orphan designation criteria at MAA stage	32	30	30	30

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Scientific assessment of medicines submitted for centralised marketing authorisation	% of initial marketing authorisation applications that had received centralised scientific advice	75.00%	70%	70%	70%
	Average assessment time for new active substances and biosimilars	200.56	205	205	205
	Average clock-stop for new active substances and biosimilars	178.29	180	180	150
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	75.00%	50%	50%	50%

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 regards 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.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Variations to marketing authorisations	Type IA variations	3,864	3,624	4,000	4,000
	Type IB variations	3,332	3,305	3,750	3,750
	Type II variations	1,201	1,261	1,406	1,264
Extensions of marketing authorisations	Extensions of marketing authorisations	43	25	33	41

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Maintenance activities	Average assessment time for variations that include extension of indication	175.50	180	180	150

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.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Referrals	Pharmacovigilance-related referrals	2	3	5	5
	Other referral procedures	8	6	8	8

1.5 Pharmacovigilance

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:

- 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.

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2023	**2024**	**2025**	**2026**
Pharmacovigilance	Signals peer-reviewed by EMA	1,364	1,300	1,200	1,200
	Number of ICSRs for CAPs (reports received)	1,389,710	1,300,000	1,500,000	1,500,000
	Signals assessed by PRAC (validated by EMA)	39	40	40	40
	PSURs (standalone CAPs only) started	584	622	608	613
	PSURs single assessment (CAPs with NAPs) started	38	48	42	43
	PSURs single assessment (NAPs only) started	237	285	373	323

1.6 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 PIC/S, ICH and 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 and 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.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Coordination of inspections	GMP (excluding PMF)	209	327	299	260
	GLP	2	1	1	1
	GCP	75	78	90	98
	Pharmacovigilance	14	17	15	15
	PMF	146	134	76	76
Quality defects	Notifications of suspected quality defects	257	250	216	216
Sampling and testing programme	Medicinal products included in the sampling and testing programme	88	66	59	68
Certificates	Standard certificate requests	4,817	5,367	11,165	11,330
	Urgent certificate requests	1,117	1,125	1,525	1,540
Parallel distribution	Parallel distribution initial notifications	2,092	2,200	2,244	2,300
	Parallel distribution annual updates	5,477	5,430	4,600	4,600

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Certificates	Standard certificates issued within the established timelines (30 working days)	100.00%	90%	90%	90%
	Average days to issue standard certificate	4.40	15	15	15
	Urgent certificates issued within established timelines (2 working days)	99.00%	98%	98%	98%
Parallel distribution	Parallel distribution initial notifications checked for compliance within the established timeline	99.00%	98%	98%	98%

1.7 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 the EMA regulatory science strategy. 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 life-cycle 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 4500 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.

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.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Meeting management	Number of reimbursed meetings	264	323	334	334
	Committee meetings	76	76	76	76
	Working Parties	78	44	29	29
	Workshops, Forum, Seminars, Infoday	87	38	39	39
	Other meetings	142	165	190	190
	Number of virtual meetings (audio-, video- and web conferences)	4,600	6,500	6,500	6,500
	Number of reimbursed delegates	3,476	6,800	5,000	5,000
	Number of non-reimbursed delegates	1,008	1,500	1,500	1,500
Herbal medicinal products	New herbal monographs	1	1	1	1
	Reviewed herbal monographs	19	15	20	20
	Revised herbal monographs	3	8	5	5
	List entries	0	2	1	1

1.8 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, safety, and usefulness of the ancillary medicinal substance in three cases: if the ancillary substance is derived from human blood or plasma; if it has been previously evaluated by EMA; or if it falls within the mandatory scope of the centralised procedure.

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 trainings for regulators in the context of use of medicines.

1.9 Cooperation with the HTA Coordination Group

From January 2025, the Agency has new legal responsibilities to cooperate with the Member State Coordination Group on Health Technology Assessment (HTA Coordination Group, HTACG) under the HTA Regulation (Regulation (EU) 2021/2282). 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.
- **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 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.

Pillar 2 – Public health activities

Beyond product-related activities described under pillar 1, the Human Medicines Division's priorities are to:

- adopt a One Health approach to address emergent and re-emergent biological health threats and to address the threat of antimicrobial resistance with particular attention on fostering collaboration between human and veterinary experts to ensure that scientific opinions restricting the veterinary use of antimicrobials that are considered critical for human use are balanced and evidence based.
- implement measures for medical devices and for the HTA regulation, and progress regulatory science to keep pace with scientific and technological advances by implementing the objectives of the strategy of the European Medicines Regulatory Network as described in the following table.
- expand activities of the medical devices expert panels as per plan prepared by the European Commission.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
3.1/5.5 (ECP 1 *A new plan for Europe*)	Operate the Quality Innovation Group to serve as platform for interactions with developers and academia aiming at identifying bottlenecks and facilitating innovative manufacturing technologies and methods Deliver on International activities relating to Pharmaceutical Quality Knowledge	The implementation of novel manufacturing technologies and capacity enablers is facilitated	2022	2027	Better interaction between developers and academia Better guidance Increased international harmonisation

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Management System (PQKMS) and continue supporting Enable use of risk-based approaches to manufacturing and control strategies by implementing ICH Q12				
3.1 (ECP 1 *A new plan for Europe*)	Deliver tailored engagement with academics and the community of ATMP developers (ATMP support pilot) Strengthen support to developers of ATMPs via the development of targeted training modules, and relevant guidance, e.g. on the safety and efficacy follow-up of ATMPs (guidance)	Increased support for ATMP development and better understanding of academic developers need to enhance the integration of scientific and technological progress in the development of ATMPs	2022	2025	Broad stakeholder engagement during the public consultation of the new/updated ATMP-related guidance Feedback from up to 5 candidates selected for the pilot by 2024, including 2-4 by end of 2023
5.3	Engage actively with International Partners to help increase awareness and facilitate the use of internationally- agreed quality and GxP standards globally. Support Network capacity for 3rd country inspections through reliance, International Regulators collaborative inspection pilots, MRAs extension and stronger EU presence in third countries.	Maintain the effectiveness and efficiency of GMP oversight by leveraging on collective efforts from global Regulators and greater convergence on internationally agreed quality standards	2022	2027	Stronger EU presence in 3rd countries, key for manufacturing of medicines used by EU patients Increased collaboration and reliance on inspection outcomes with International Partners
5.2	Promote dedicated cooperative and enhanced supervision with strategic international partners for manufacturing sites, such as tailored supervision of API manufacturers and/or large sites that supply a significant number of markets or products	Reinforced supervision of API manufacturers	2023	2027	Better exchange of information among MRA and PIC/s partners on inspection outcomes and inspection programmes through international programmes, such as the API International Programme and PICs and ICMRA initiatives

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
					Revision of Annex 15 of the GMP guideline on Qualification and Validation with PIC/s in a global effort to extend scope to API manufacturers.
3.2 (ECP 1 *A new plan for Europe*)	Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual	The ICH E6 (R3) guideline is updated to facilitate a more proportionate application of its principles and the use of alternative trial types/ technologies, and training is available for EU stakeholders	2019	2026	Finalisation of the guideline and development of related training materials
	Delivery of the action plan to strengthen the Qualification of Novel Methodologies framework	Explore involvement of additional decision-makers during QoNM: e.g. HTA, MD/IVD regulators Training for methodology developers less experienced in regulatory interactions, e.g. academics, HCPs and patient representatives Publishing specific unmet needs for novel methodologies as identified by Committees or Working Parties and linking to Regulatory Science Research Needs	2024	2025	Delivery of the activities identified in the implementation action plan (action plan)

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Establish active interaction with more professional societies and patient groups developing COAs Explore feasibility of (automated) monitoring and reporting of evidence generated by qualified methods that has informed regulatory decisions			
Legislation	Defining operational guidance for EMA responsibilities under the HTA Regulation, in cooperation with the HTA structures Contributing to stakeholder trainings on the implementation of the HTA Regulation Engaging in technical cooperation on evidence requirements for regulatory assessment and HTA, respectively	Readiness for the application of the HTA Regulation Effective and efficient interplay between regulatory and HTA processes, respecting remits Support evidence generation plans that address needs for regulatory assessment and HTA Efficient management of resource impact for EMA and the EU Regulatory Network	2023	2025	Specific responsibilities of EMA laid out in the HTA regulation are implemented
Legislation	Prepare for the new pharmaceutical legislation to future proof medicines regulation in the EU	Engage Scientific Committees in the reform and explore ways to optimise regulatory activities	2023	TBC	Readiness for the implementation of the new pharmaceutical legislation by the date of application

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
Legislation	Implementation of the EU Regulation on medical devices and on *in vitro* diagnostic medical devices	Finalise the consultation procedure for medical devices composed of systemically absorbed substances Finalise the process for handling serious incident reports received by Medical Devices National Competent Authorities for ancillary medicinal substances and companion diagnostics Application of Art 117: EMA/CMDh Q&A update	2023	2025	Specific responsibilities of EMA laid out in the Medical Devices and In vitro diagnostics regulations are implemented

2. Veterinary Medicines Division

The European Medicines Agency supports and facilitates the development of medicines for veterinary use, coordinates the assessment of these medicines through a scientific committee, and advises the European Commission on the marketing authorisation of such products. The Agency also monitors the safety, quality, efficacy, and benefit-risk balance of authorised medicines. In addition, the Agency provides support and develops guidelines to stimulate the development and availability of medicines and to protect public and animal health, in close cooperation with the NCAs.

Application of the 'One Health' approach is one of the cornerstones of the Agency's work, particularly important in the area of veterinary medicines. Indeed the fact that about 75 per cent[7] of new diseases that have affected humans over the past decades have been caused by pathogens originating from animals or products of animal origin and the continued emergence of new pathogens reinforce the need for a 'One Health' approach between those regulating human and veterinary medicines.

As part of the evaluation and maintenance of veterinary medicines, the Agency considers not only their impact on animal health, but also any impact they may have on public health through the use of authorised veterinary medicines in food-producing animals, or for the control of diseases transmissible to man. The assessment of benefits and risks of veterinary medicines must therefore include their impact on animals, users, the environment, and consumers of foodstuffs of animal origin.

The main objectives will be:

- continue to support core business activities, maintaining timeliness and quality of outputs, optimising use of resources and processes to reduce the regulatory burden;
- progressing the follow-up activities related to the implementation of Regulation (EU) 2019/6 (Veterinary Regulation): continuous improvement of IT systems, refinement of processes based on real-life experience (e.g., lessons learned from P-SMEG), guidance update and revision;
- following the publication of the Veterinary Big Data Strategy, implement the deliverable to achieve the Veterinary Regulation objectives;
- foster innovation and development of new veterinary medicinal products and address unmet medical needs;
- continue to support veterinary stakeholders and network transitioning into Regulation (EU) 2019/6.

[7] Louise H Taylor, Sophia M Latham and Mark E J Woolhouse, Phil. Trans. R. Soc. Lond. B (2001) 356, 983-989. 'Risk Factors for human disease emergence'

Activities performed by the Veterinary Medicines Division are organised in 6 main domains: 1) Pre-authorisation; 2) Initial evaluation; 3) Post-authorisation; 4) Arbitrations and referrals; 5) Pharmacovigilance; 6) Other specialised areas. More details on these activities are provided in the following subsections.

The Veterinary Division also provides the secretariat and organisational support to the CVMP veterinary working parties; for general details on these activities, please refer to section 1.7 Committees and working parties.

The Veterinary Medicines Division also contributes to activities in the following Value Streams: Product Lifecycle Management, Monitoring and Managing the Agency.

The workforce available in 2025 for the Division is currently foreseen at 64 staff (41 TAs, 18 CAs, 5 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Pillar 1 – Product related activities

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.

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.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Emerging therapies and technologies	ITF briefing meetings requests received	10	5	5	5
Scientific advice	Scientific advice requests received and validated	17	20	20	20
Limited markets	Requests for classification as limited market under article 4(29) and eligibility under article 23	17	10	10	8

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Scientific advice	Scientific advice procedures completed within set timeframes	100.00%	100%	100%	100%

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 regards 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.

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2023	**2024**	**2025**	**2026**
Initial evaluation	Total applications	25	33	23	23
Establishment of MRLs	New MRL applications	0	1	1	1
	MRL extension/modification applications	2	5	1	1
	MRL extrapolations	1	1	1	1
	Review of draft Codex MRLs	0	5	5	5

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Initial evaluation	Initial procedures completed within legal timeframes	100.00%	100%	100%	100%

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.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Variations requiring assessment	Total variations	337	304	318	333
	Variations level 1	2	4	2	2
	Variations level 2	104	80	91	91
	Variations level 3	76	100	95	105
	Variations level 4	155	120	130	135
Maintenance activities	Transfers of marketing authorisations	1	3	1	1

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Maintenance activities	Post-authorisation applications evaluated within the legal timeframes	100.00%	100%	100%	100%

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.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Arbitration procedures	Total arbitrations and referrals	1	2	3	3

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Referrals	Referral procedures managed within the legal timelines	75.00%	100%	100%	100%

2.5 Pharmacovigilance activities

Pharmacovigilance covers the science and activities relating to the detection, assessment, understanding and prevention of adverse reactions to medicines or other medicine-related problems. Pharmacovigilance aims to ensure that post-authorisation monitoring and effective risk-management are continuously applied to veterinary medicines throughout the EU.

The Agency coordinates the EU pharmacovigilance system and constantly monitors the safety of medicines in Europe and acts if information indicates that the benefit-risk balance of a medicine has changed since authorisation. The Agency provides advice to ensure safe and effective use of veterinary medicinal products, for which safety is related to the safety of the animal, the user, and the environment. Activities covered include management and assessment of adverse event (AE) reports, signal detection, post marketing surveillance studies, coordination of safety communication, development, and maintenance of good pharmacovigilance practices. Taking into account lessons learned from P-SMEG, processes reviews are on-going.

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2023	**2024**	**2025**	**2026**
Pharmacovigilance activities	Annual recording of signal management results and outcomes (Annual statements)[8]	n/a	250	260	260
	Total signals submitted by MAHs of which:[8]	n/a	376	381	381
	Emerging safety issues assessed by MAH and leading to regulatory action[8]	n/a	1	1	1
	Signals assessed by MAH leading to regulatory action (variations or other)[8]	n/a	35	40	40
	Signals classified for close monitoring by MAH[8]	n/a	40	40	40
	Signals classified as refuted by MAH[8]	n/a	300	300	300

[8] New indicators introduced in the 2024 work programme.

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
	Signals submitted by Regulatory authorities following risk-based review[8]	n/a	40	40	40
	Targeted signal management processes initiated by regulators[8]	n/a	4	4	4
	Total ADRs:	149,059	120,000	150,000	150,000
	Total CAP ADRs	81,845	70,000	75,000	75,000
	Total non-CAP ADRs	67,214	50,000	75,000	75,000

Pillar 2 – Public health activities

This area covers EMA activities in the veterinary medicines field, other than routine activities related to the evaluation and monitoring of medicines. This includes work in relation to the following:

Implementation of Regulation (EU) 2019/6 (Veterinary Regulation). The Agency is continuing to provide technical and scientific advice to the European Commission (EC) to support the drafting of the EC implementing and delegated acts specified in the legislation. The main focus of the Agency is now on adopting the new processes and guidance created for the new provisions and learning from the first years of implementation, along with maintaining, expanding and developing further the new IT systems required by the Regulation: Union database on veterinary medicinal products (Union product database – UPD), Union pharmacovigilance database (UPhD), Union database on manufacturing, import and wholesale distribution (EudraGMDP) and Collection of Antimicrobial sales and use (ASU).

Antimicrobial resistance. The Agency adopts a 'One Health' approach in the area of antimicrobial resistance, whereby there is close and integrated cooperation between those working in the human and veterinary fields. In the veterinary area, emphasis is placed on maintaining the availability of antimicrobials for the treatment of infectious diseases in animals, while recognising the importance of preserving the efficacy of critically important antimicrobials for human health through responsible and prudent use. The Agency also reports on sales and use of antimicrobials in the EU, and jointly with EFSA and ECDC produces the JIACRA report which looks into the consumption of antimicrobials and occurrence of resistance.

International harmonisation of requirements for authorisation of veterinary medicines. Research and development of veterinary medicines being a global activity, a harmonised approach to authorisation requirements will benefit both the animal health industry and European competitiveness.

In addition to the above, the Veterinary Medicines Division plans to undertake and progress the following additional activities:

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
3.1 (ECP 1 *A new plan for Europe*)	Implement in the veterinary medicines field the recommendations of the 'Report on development of a harmonised approach to exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides in food of animal origin'	Harmonised methodology in place: legislation, guidelines and templates revised Exposure assessment tool made available to CVMP experts	2023	2025 and beyond	New methodology ready to be applied to future MRLs assessments
3.1 (ECP 1 *A new plan for Europe*)	Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database	Guidance for surveillance and signal detection developed Enhanced communication with the network	2020	2025	Increase of reporting Better quality of reporting
3 (additional RSS recommendation)	Contribute to the evaluation of novel approaches to ERA, and the EC considerations on the feasibility of establishing active substance monographs for all substances, including legacy active substances for which there is limited environmental information, providing input as required	Support EC in the monographs feasibility study Pilot study to be performed for VMPs considering relevant provisions in the New Pharma Legislation for human medicines	2020	2025	Feasibility study concluded in 2022. Pilot study concluded.
3 (additional RSS recommendation)	Increase cooperation in the field of ERA with European agencies, particularly ECHA, EFSA and EEA, and establish cooperation with	Establish ERA framework with EU and international partners Harmonised approach on ERA assessment	2021	2025	Increased cooperation between institutions Enhanced flow of information

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	international institutions, academic organisations and relevant initiatives				
3 (additional RSS recommendation)	Provide scientific support to the European Commission and the EU network, upon request, to ensure that a 'One Health' approach is applied to ERA	Support to EC provided "One Health" approach for ERA implemented	2021	2025	Increased use of 'One Health' approach in ERA dossier/assessment
4.1 (ECP 1 *A new plan for Europe*)	Establish contributions to JIACRA under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight	Establish governance for JIACRA report under EMA and CVMP	2021	2025 and beyond	Process and mandate for new working party in place
4.1 (ECP 1 *A new plan for Europe*)	Implement use data collection by animal species	Collection of data on the use of antimicrobials per animal species and animal categories as foreseen in Article 15 of the Commission Delegated Regulation (EU) 2021/578	2021	2025	First EMA report on use data
4.1 (ECP 1 *A new plan for Europe*)	Communicate effectively on consumption data	The outline of the ESVAC report reviewed to improve communication Group of experts to define the outline of the volumes of sales and use of antimicrobials (Article 17 of the Commission Delegated Regulation (EU) 2021/578)	2022	2025	13th ESVAC report published (last ESVAC report) First AMR sales and use report published

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
4.3 (ECP 1 *A new plan for Europe*)	Providing a reflection on the use and availability of diagnostic tests to improve the responsible use of veterinary antimicrobial products	Review availability and characteristics of diagnostic tests	2022	2025	Reflection paper on characteristics of diagnostic tests
4.3 (ECP 1 *A new plan for Europe*)	Communicate on available tools like AMEG categorisation to stakeholders to ensure proper implementation to support responsible AM use	Preparation and delivery of publications, infographics, presentations at conferences, training to network (e.g. EU NTC)	2020	2025	Infographics, trainings and presentations prepared and distributed to relevant stakeholders
4.1 (ECP 1 *A new plan for Europe*)	Participate in international initiatives to reduce the risk of AMR	Actively participating in international fora	2020	2025	Track record of participation to International fora regarding AMR
4.3 (ECP 1 *A new plan for Europe*)	Update existing guidelines, and initiate new guidance concerning development of antimicrobials veterinary medicinal products	Develop and revise relevant guidance	2020	2025	Guidance published
4.3 (ECP 1 *A new plan for Europe*)	Finalise the CVMP reflection paper on antimicrobial resistance in the environment in the light of comments received Invite CHMP to derive conclusions for human medicines based on CVMP reflection paper	Reflection paper finalised and published Review of novel risk assessment methodologies for AMR in the environment	2020	2025	CHMP conclusions on H medicines based on V paper Concept paper for a development of a reflection paper on risk assessment methodologies for AMR
4.3 (ECP 1 *A new plan for Europe*)	Develop a regulatory approach/framework to promote products that can assist in the	Reflection paper developed Communication with stakeholders	2020	2025	Framework established and in use Increase of products that

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	reduction of the use of antimicrobials and novel paradigms				can assist in the reduction of the use of antimicrobials
4.3 (ECP 1 *A new plan for Europe*)	Enhance the promotion of the responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion	Guidance development Communication with stakeholders	2020	2025	Guidance published Awareness raised in the Network
4.3 (ECP 1 *A new plan for Europe*)	Provide scientific and regulatory support to encourage development of veterinary products that can assist in the reduction of the use of antimicrobials, to fill therapeutic gaps, without adversely impacting public health	Guidance development products that can assist in the reduction of the use of antimicrobials	2021	2025	Awareness raised in the Network Increase of products that can assist in the reduction of the use of antimicrobials
4.3 (ECP 1 *A new plan for Europe*)	Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and products that can assist in the reduction of the use of antimicrobials	Cooperation at EU and International level for events Common approach agreed	2021	2025	Specific contribution to TATFAR Action 3.3 Awareness raised in the Network Increase of products that can assist in the reduction of the use of antimicrobials
4.5	Include AMR as a regular topic at meetings with HMA and veterinary stakeholders	Actively propose AMR topics for HMA and stakeholders' meetings	2023	2025	AMR topics included in relevant meetings agendas
	Acknowledge that different benefit-risk approaches are required for assessment of	Identify different benefit-risk approaches per type of	2020	2025	Vaccine B/R assessment targeted per type of

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	specific vaccine types (e.g. vaccines for zoonotic diseases, limited markets, exceptional circumstances)	vaccines Guidance on benefit-risk			vaccine following guidance established
4 (additional RSS recommendation)	Participate actively in international initiatives that aim to develop strategies to combat antiparasitic resistance and to establish best practices on the use of veterinary antiparasitic medicines	Improve interaction with international organisations Best practices embedded in guidance	2020	2025	Track records of participation to international fora concerning antiparasitic resistance Take away points communicated
4 (additional RSS recommendation)	Promote responsible use of antiparasitics in the EU	Awareness events and enhanced dissemination of information	2020	2025	Better use of antiparasitic VMPs for the purpose of reducing antiparasitic resistance
6.2 (ECP 1 *A new plan for Europe*)	Promote systematic application of structured benefit-risk methodology and quality assurance systems in the approach to assessment and consistency of decision-making	Analysis of current methodologies, development of harmonised approach and guidance	2021	2025	Consistent decisions taken for B/R assessment of veterinary products
6.2 (ECP 1 *A new plan for Europe*)	Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies	Analysis of current methodologies, development of harmonised approach and guidance Enhanced communication with stakeholders	2021	2025	Consistent high-quality output from EMA Increased publication of relevant information for stakeholders

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
2 (ECP 1 *A new plan for Europe*)	Coordinate and implement the Veterinary Big Data Strategy by analysing the landscape of veterinary data, engaging stakeholders, and providing training	Compilation of a Veterinary data sources catalogue and metadata analysis	2023	2025 and beyond	Veterinary data sources catalogue and metadata analysis completed
(ECP 1 *A new plan for Europe*)	Contribution to Chemical Strategy for Sustainability, particularly on the 'One substance one assessment' (1S1A) initiative, including the establishment of the EU Common Data Platform for Chemicals (EU-CDPC) Consequently, implement the initiative as/if required	EMA data and legal requirements to be provided in the frame of the EU policy-making process Implementation of the initiative as/if required	2022	2029	Chemicals policy reflecting EMA legal and data requirements as agreed with involved institutions Implementation of the applicable policy provision(s)

3. Task forces

The European Medicines Agency (EMA) has three mission-critical task forces (TF) which support its Human and Veterinary Medicines Divisions, bringing together expertise to drive transformational change in high-priority areas of the Agency's work. The task forces remain flexible to adapt as required by the Agency.

3.1. Digital Business Transformation (TDT)

The Digital Business Transformation Task Force (TDT) drives complex, disruptive change initiatives that have a profound impact on the strategy of EMA, its operational structure and operation in relation to the EU medicines regulatory network, its partners, and stakeholders. This includes adapting EMA operations to fundamental changes brought by legislative initiatives, digital technologies, and global trends to meet stakeholders' needs and expectations. It operates as a hub for innovation, experimentation, and collaboration throughout the phases of digital business transformation, from strategic planning and design, testing and piloting, to full implementation. TDT oversees the delivery of the Network Portfolio through Network Portfolio Management. The Task Force also supports the transition to the Scaled Agile (SAFe) methodology in the context of the implementation of the Network portfolio governance at EMA that began in 2021.

The annual work plan of the Task Force will revolve around the following drivers:

- Lead the Agency's digital transformation through end-to-end programme oversight, digital change management and digital capability and capacity-building. The ambition is to deliver a modern workplace, increase efficiency, make the best use of resources, skills, and competences, and provide a system that supports integrated scientific and regulatory knowledge management across EMA operations and the Network.
- Design and build pragmatic and innovative solutions for new and existing EMA business needs using novel technologies and process analytics, including artificial intelligence (AI), robotics and machine learning.
- Operating a digital innovation framework for hypothesis generation, prioritisation and cross-organisational experimentation with digital technologies.

The workforce available in 2025 for the Task Force is currently foreseen at 35 staff (21 TAs, 12 CAs, 1 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Area of work	Key action	Expected benefit
Analytics Centre of Excellence (ACE) ACE is a digital toolbox experimentation hub in which the Agency experiments and boosts capacity to experiment with new technologies in analytics, such as artificial intelligence (AI) and machine learning in connection with the business-process design, automation, information, and knowledge management.	Pilot, develop and maintain analytics solutions and processes: ACE explores how process analytics can be used to build pragmatic solutions for existing EMA business needs and experiment with new technologies	Leverage innovative technologies in analytics, including artificial intelligence (AI), robotics, machine learning and others The areas of process design, automation, information, and knowledge-management at EMA are improved Decision support is improved using analytics on EMA data assets Cross-Agency work is carried out in an Agile way, in close collaboration with the business and end-users Agency staff benefit from user-friendly solutions that improve efficiency and have a tangible beneficial impact on the day-to-day work
Digital Innovation Lab (DigiLab) Digital innovation and experimentation lab acts as collaboration and experimentation and innovation convergence hub between Business and IT. Its objective is to guide business to critically rethink business processes across the medicines regulation spectrum and redesign them in view of digitalisation opportunities. DigiLab also	Set of services to discover, prioritise, experiment, and develop digital solutions that have the potential to support core business and enable its strategies. Enable and Accelerate digital business transformation.	Management of innovation idea portfolio is supported and centralised and aligned to strategy Maturing organisational ability to leverage scalable emerging technologies applicable to concrete business cases that may change the way EMA works are piloted and enabled

Area of work	Key action	Expected benefit
explores, develops and pilots new solutions that leverage existing and novel digital technology and artificial intelligence to support increase in efficiency and regulatory decision-making. DigiLab was established in 2021, designed to accelerate digital transformation at the Agency by delivering a framework and services to support experimentation with digital innovation. The goal is to find solutions to existing and emerging business needs, where digital technologies can improve or radically change the way we work.		Delivers a framework for experimentation based on good innovation practices that can be leveraged across the organisation for digital and data experimentation Optimises/ transforms business processes as a result of emerging technologies, data analytics, AI implemented solutions Identifies new technologies or new uses of existing technologies with the potential to accelerate digital transformation Pilots of new innovative and pragmatic solutions that can be scaled through Network Portfolio
Change management The Change Management Centre of Expertise develops capabilities, improves EMA's change management toolkit and maintains the governance of change management at the Agency	Operationalise and develop EMA's Change Management Centre of Expertise (CoE) further, to build and grow change management capabilities of staff across the Agency and in the future also for the Network	Agency's staff and Network staff benefit from increased change management capabilities Change management is embedded across the Agency in business operations and technology delivery Improved adoption and stakeholder experience when changes are being implemented from a business and/or technology perspective

Area of work	Key action	Expected benefit
		through integration of change management practices
EU Network Training Centre The EU NTC delivers a learning and knowledge sharing ecosystem for the European Medicines Regulatory Network (EMRN) to build scientific and regulatory expertise and gradually expands EU NTC training to wider audiences outside of the EMRN.	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	Core activities strengthened in capacity and capability building, including development of training in priority areas, clearly linked to identified training needs Initiation of development of training in new areas of scientific development, new technologies, ensuring that the Network is proposed for the future Ensuring sustainability through coordination of related training initiatives in area of capacity building (e.g. EU4Health) whilst working to incentivise development of training and consider new ways of working Increased collaboration with stakeholders, including the extension of target audiences to meet the needs of new stakeholders (in close alignment with activities identified within the strategic priorities of the network) Availability of EU NTC content on regulatory, scientific, data and

Area of work	Key action	Expected benefit
		digital topics available to wider audiences to support regulatory work
Digital Academy The Digital Academy aims to build digital literacy, capability, and capacity at EMA through the development of a digital knowledge-sharing academy, capitalising on the experience of the EU Network Training Centre (EU NTC), including expansion to the EMRN.	Increase digital literacy and stimulate development of digital skills to support digital capability and capacity building at EMA and in the Network by: • defining crucial digital skills • building awareness around these skills and their importance for EMA and the network • creating, maintaining, and growing collections of learning offers to further develop these skills and encouraging staff to explore skills of interest to them Provide these collections to EMA and Network staff through a single platform which acts as entry point to the content	Digital skills crucial for our successful digital transformation are identified and defined, new skills are tracked and added when necessary. There is wide awareness of digital skills and understanding of their potential application at EMA and in the Network. A collection of learning offers is available for each skill (in house, third-party or network content) through a single platform which acts as entry point to the content. A modern, scalable approach to micro-learning is developed that can be applied to address other learning needs in EMA and Network
Transformation / Optimisation of Submissions and Regulatory Processes This is to maintain, continuously support and seek opportunities to digitally transform and integrate electronic	Coordinate and support the eSubmissions portfolio, linking to the Agile portfolio as required to deliver improved systems and processes Implement eCTD v4.0 in the Europe (EU) region according to published timelines	EMA is prepared for adoption of the eCTD v4.0 standard. eSubmissions systems are continuously adapted and improved to optimise how they support regulatory processes.

Area of work	Key action	Expected benefit
submissions, regulatory processes and related systems (Human and Veterinary), underpinning the core regulatory business.	Integrate eSubmissions processes and systems into a holistic, end-to-end product lifecycle management ecosystem	Support delivery of an end-to-end, data centric target operating model for product lifecycle management, creating efficiencies and supporting high-quality decision making processes
Network Portfolio Management	The Task Force oversees and manages the operation of the Network Portfolio through the Portfolio Management Office (PMO). PMO ensures the Network Portfolio is managed according to the Agency's standard methodology and governance arrangements, and monitors, controls, and reports on the progress of the portfolio. It supports EMA's Portfolio Board in ensuring that delivery is done in line with the strategy and meets customer expectations. The Head of Task Force also holds the role of Portfolio Board chair, which reinforces the Task Force's position in ensuring oversight of end-to-end digital transformation at EMA.	The Network Portfolio respects the Agency's standard methodology and governance arrangements. Delivery is done in line with the strategy and meets customer expectations.
Agile transformation	To support the transition to the Scaled Agile (SAFe) methodology in the context of the implementation of the new portfolio governance at EMA, the Lean-Agile Centre of Excellent workstream (LACE), a new entity was created to lead the Agency's transitioning to Lean-Agile (SAFe) way of working, and ensure the agile principles and methods are implemented in the Network Portfolio delivery across its Value Streams.	EMA becomes a Lean-Agile organisation that adapts to and thrives in a constantly changing environment.
Value Streams	To maximise customer success and satisfaction and to deliver value, the Agency has transitioned from a short- to medium-term project/programme approach to establishing a portfolio with five long-lived Value Streams. Three of the five Value Streams, Product	PLM will bring together products that deliver capabilities to authorise and manage the lifecycle of medicines and medical devices.

Area of work	Key action	Expected benefit
	Lifecycle Management (PLM), Monitoring (MON) and Managing the Agency (MTA), are led by the Task Force.	MON will deliver capabilities to monitor the availability and safety of products. MTA will deliver the modernisation and continued integration of corporate planning and management capabilities. MTA will deliver products and capabilities that empower EMA staff and support the Network through implementation of innovative systems, processes and ways of working to increase efficiency, transparency and collaboration.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
EU Network Training Centre (EU NTC)	New scientific, regulatory and network portfolio curricula developed	0	2	2	2
	Number of training events advertised to the EU Network	79	60	75	75
	Number of reimbursed training events to the EU Network	3	8	8	8
	Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	13	10	10	10
Network Portfolio	Number of epics completed or ongoing[9]	n/a	29	33	33

Pillar 2 – Public health activities

In addition to the above, the Digital Business Transformation Task Force plans to undertake and progress the following additional activities:

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Develop a digital skills framework for EMA and lead on digital capability building	Validated Digital Skills framework for EMA	Continuous	Continuous	Number of Digital Academy trainings accessed Number of trainings completed

[9] New indicator introduced in the 2024 work programme.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Creation of introductory training on topics in the digital skills framework with links to further learning on each topic to enable deeper skill development Creation of a platform to act as entry point to the introductory training content Deliver agency-wide awareness campaign to engage staff and create engagement through gamification and events			Number of hits on the platform Participation to events Positive survey feedback
	Support futureproofing of EMA and the Network by developing regulatory capacity through the EU NTC	Training delivered to the EU Network F2F training delivered to the EU Network Extend access to EU NTC training to external audiences including analysis of the existing EU NTC training content Development of processes for providing access to subset of external audiences	Continuous	Continuous	Number of training events advertised to the EU Network Number of reimbursed training events to the EU Network Number of external audiences using EU NTC Number of classified contents Engagement portal set up) or decision taken that current platform meets needs If Engagement portal is set up, number of users accessing training via this portal

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Investigate whether current platform is suitable or whether a new platform should be considered Investigate the setting up of an engagement portal/entry point to the LMS for external audiences Develop a future state learning delivery model and landscape that serves new and existing audiences, in co creation with the EU-NTC			Number of KPIs linked to business needs, with reporting and tracking set up Number of new External audiences with access to certain EU NTC courses Social learning set up (number of courses)
	Lean Portfolio Management	1- EMA portfolio processes related are in line with the lean-Agile SAFE framework 2- Standardisation of VS tools, templates and ways of working	2023	2027	1- To design and implement 1 Network Portfolio process per year 2- Ensure same practices across five value streams
	Team & technical agility	1- Agile roles and responsibilities are defined within the EMA role description framework 2- Define a process to onboard new team members into the agile roles	2023	2027	1- 5 Agile roles and responsibilities are defined and updated within the EMA role description framework per year 2- Ensure EMA staff members to be onboarded as per their Agile role description

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Agile product delivery	1- Rest of portfolio teams and platform teams are transition to Agile way of working 2- Ensure EMA staff are coached based on their defined Agile role	2023	2027	1- Rest of portfolio teams and platform teams are transition to Agile way of working- 90% 2- ensure EMA staff are coached based on their defined Agile role- 90%
	Lead the Delving AI to EMA initiative (Knowledge Mining and AI Use cases initiative) including: 1) collecting EMA and Networks needs to build the AI implementation roadmap of the Agency and the Network 2) designing and delivering different PoCs under this initiative using design thinking principles	Better knowledge and information management at EMA	2024	Continuous	Number of different sources of information implemented in the final solution
	Socialize the use of the power platform to business users and develop and maintain citizen developers framework, service and users community on the Microsoft Power Platform to boost digital acceleration	Operational power platform community Increased use of power platform Minimisation of the dependency on IT for the Automation of manual tasks / activity Efficiency gains due to automation	2024	Continuous	Number of members in the community Number of new automations/ UCs Decreased dependency on IT support for the scope of uses of the platform in the framework

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Develop a business architecture practice to support the alignment of EMA and EMRN strategy with organisational structures, processes, data and execution by introducing a structured approach to our Organisational Business Model design in support of: - Digital Business Transformation - Enterprise Architecture and - Portfolio Management aiming to close the Strategy to Execution Gap	Stronger alignment of digital transformation investments with organisational strategy Enhanced capabilities to leverage opportunities and support the implementation of changes brought about through new legislation and other external factors	2023	2026	*Delivery of business architecture artefacts * improved orchestration of portfolio epics deliverables to achieve maximum value * improved communication and alignment of objectives from strategic to operational levels
	ROG reactivation ROG is a joint HMA/EMA group focused on activities for business/regulatory optimisation within the scope of the respective EMANS goals under key business priority "Optimisation of the regulatory operations' by leveraging digitalisation and innovation	Address prioritisation and challenges faced in the execution of the Network Portfolio building on the strategic needs and priorities	2023	Continuous	- Collaboration framework in place for the Network POs and SMEs that allows them to work efficiently, whilst engaging across the Network to gather critical inputs - Established collaboration model with industry to capture their input (on topics of strategic importance for the EMRN) - Number of business cases supported/ advice given by ROG (e.g. PMS as a trusted source of data for the Network, Central Repository for EU Submissions,

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
					Future of ePI in Europe, IRIS long term roadmap)
	Chair the EUAN Working Group on AI	Collaboration within the European Agencies Network to share knowledge and experience on AI and Digital Solutions	2024	2026	- Number of meetings in the community - Knowledge shared within the network - Number of initiatives where EMA could engage - Activities delivered in the EU Agencies Network
	Virtual reality activity	Users are trained through a realistic training scenario allowing them to increase their decisions and actions	2023	Continuous	- Knowledge shared within the network - Number of initiatives where EMA could engage

3.2. Data Analytics and Methods (TDA)

The Data Analytics and Methods Task Force contributes to the Agency's mission by building capability and capacity in the analysis of data and in study methods that, over time, are embedded within the core operations of the Agency and support delivery of the data, analytics, and innovation objectives of the Network Strategy. The main drivers are:

- Emerging importance and development in the data field, acknowledging the European Data Strategy and related legal proposals, including the European Health Data Space. Strengthening data governance and the Network to allow data to be leveraged for analysis and better regulation, while ensuring data protection and security.
- Need to deliver EU Network Strategy objectives to transform to data-driven medicines regulation and to support innovation. Need to deliver Network Data Strategy and Network Data Analytics Strategy.
- Need to deliver EMRN AI workplan objectives, recognising growing importance of AI tools and systems.
- Opportunity to leverage real-world evidence as a complement to randomised controlled trials (RCTs) and to better assess RCTs through clinical study data analysis.
- EMA's extended mandate, which requires EMA to provide real-world data and evidence and to work with ECDC to operate a vaccine monitoring platform (for the conduct of observational studies on vaccine use, safety and effectiveness).
- Need for innovation in the design and conduct of clinical trials through the multi-stakeholder discussions on clinical trial innovation, including on new clinical trial approaches and designs, GCP and operation of the CTR (see also Pillar 3) through the maintenance and development of the Clinical Trial Information System.

The workforce available in 2025 for the Task Force is currently foreseen at 73 staff (46 TAs, 12 CAs, 14 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Area of work	Key action	Expected benefit
Data Governance Leads EMA efforts in data governance, data strategy and data standardisation.	Leads and coordinates the gradual evolution of data governance at EMA towards a federated data governance model, including the organisation of the EMA Data Board. Maintains and monitors the implementation of the EMA data strategy. Supports EMRN data governance through development and implementation of an EMRN data strategy and data standardisation strategy as well as providing support to the Network Data Steering Group.	EMA data governance established and operational including clear data responsibilities, oversight & business-critical data management, enabling advanced analytics, access to FAIR data of agreed quality, transparency, EMA and EMRN data strategies and EMRN data standardisation strategy developed and implemented. Organisational preparedness for future legislation in the data context including e.g. EHDS. Streamlined EMRN collaboration on data matters.
Data Protection Drives EMA Data Protection activities and ensures compliance with the European Union Data Protection Regulation (EU DPR).	Under the supervision of the EMA Data Protection Officer leads a community of data protection coordinators for the operation of EU DPR. Provides advice on all data protection related matters at the Agency and additional support through training for the EU Network.	Full compliance with EU DPR. Assistance and guidance to Internal Controllers regarding data protection provided. Annexes to the Internal Guidance on Personal Data Protection with focus on implementing generative artificial intelligence (AI) in support of EMA business processes adopted. Data protection trainings developed and delivered.
Real World Evidence The workstream supports decisions on medicines made by EMA Scientific	Further develops the monitoring system for the post-authorisation safety and effectiveness monitoring of vaccines (Vaccine Monitoring Platform).	Safety and effectiveness of vaccines are adequately monitored to allow timely regulatory decision-making to protect public health and

Area of work	Key action	Expected benefit
Committees, the Network and stakeholders by analysing real-world data (RWD) and generating reliable real-world evidence (RWE) on disease epidemiology and medicines utilisation, safety and effectiveness. The work involves enabling the use of RWD and establishing its value across the lifecycle of medicines.	Provides methodological advice on RWD sources (including disease registries), non-interventional study designs and analytical methods related to the analysis of RWD. Performs rapid data analytics to support EMA Scientific Committees in databases available in-house.	maintain confidence of health care professionals and the public on the effectiveness of the regulatory system in this field.
	Maintains the Data Analytics and Real World Interrogation Network (DARWIN EU®) and ensure appropriate processes are in place internally to deliver as per plan.	DARWIN EU® established and fully operational delivering impactful evidence to committees and the Network.
	Develops and maintains tools and learning materials to support the generation and use of valid and reliable RWE, including a library of phenotypes and the Big Data pharmacoepidemiology and RWE training curriculum.	Better and faster regulatory decision making is enabled through the provision of high-quality RWE.
	Coordinates framework contracts with academic service providers. Coordinates the ENCePP network.	A pan-European network of centres and expertise available to support regulatory needs.
	Develops good practice for statistical and epidemiological methods and collaborates with the Digital Business Transformation Task Force (TDT) to ensure the provision of artificial intelligence (AI) advice service to the Agency.	The full potential of healthcare data realised and innovation fostered. The Health Data Lab established (using a common process with the Digital Innovation Lab).
	Cooperates with EMA Scientific Committees, Working Parties and other regulators worldwide (e.g. Health Canada, US FDA) on the drafting of regulatory guidance in the field of RWD and RWE.	The quality and acceptability of generated RWE improved. European standards and high-quality scientific principles considered and included in

Area of work	Key action	Expected benefit
		international methodological guidelines.
Methodology The workstream provides expert advice and training to EMA scientific committees and the EU Network 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.	Provides expert advice to EMA scientific committees and working parties (CHMP, COMP, SAWP, PDCO, etc.) through methodological input across all stages of product development and evaluation, across all procedures and all therapeutic areas.	Higher quality and clearer regulatory assessment outputs. More robust decision-making by scientific committees.
	Cooperates with EMA committee and working party members on the drafting of and commenting on regulatory guidance, both at the European and international level (e.g. ICH or ICMRA).	Capability of the EU Network for applications with complex methodology improved International methodological guidelines aligned with European standards and high-quality scientific principles.
	Provides strategic and scientific input to the Methodology Working Party (MWP) activities, including drafting groups and product-related requests; coordinates its activities in partnership with EMA AI, clinical pharmacology, modelling and simulation, pharmacogenomics and real-world evidence functions.	Methodology vision and priorities accounting for network and stakeholder needs established. Regulatory science to inform future MWP outputs enabled. Methodology European Specialised European Community (ESEC) functional.
	Leads or supports ACT EU priority actions with focus on methodologies (implementation of guidelines and convergence of regulatory needs between clinical trial application and authorisation)	Clinical trials data standards developed.

Area of work	Key action	Expected benefit
	and on training (Development of the Big Data biostatistics and clinical trials curricula).	Data exchange capability based on clinical trial data standards built. Clinical trial data standards implemented for high-priority use cases. Clinical trial high impact guidance documents implemented in practice. Trainings on clinical trial concepts and guidance developed and delivered.
	Fosters research on biostatistics, promoting scientific exchange within the ESEC and external stakeholders. Specific activities include EMA-funded studies and external research collaborations with academia.	Awareness of European network and stakeholder needs and priorities in the area of biostatistics. Regulators up to date with state-of-the-art experimental design and biostatistical methods.
Healthcare Data The workstream supports the scientific assessment of medicines by EMA Committees by means of collecting, managing, quality assuring, publishing and analysing EudraVigilance (EV) and Art.57 data; performs data analyses to support PhV fees computation and shortages; leads on the operation of a public catalogue of EU RWD sources and observational studies; drives the Pharmacogenomics specialised interest area of MWP.	Collects, manages, provides and analyses EV data; produces the electronic Reaction Monitoring Reports (eRMRs). Maintains the ADR Report website. Manages the Medical Literature Monitoring (MLM) service. Maintains the substance grouping related to Clinical trial register in CTIS.	EV data received from NCAs, MAHs and Sponsors, according to PhV legislation, quality assured and available for data analysis. MLM service fully operational. Signal detection supported by robust data analysis. EV data publicly available through the ADR Report website. CTIS safety analysis system to compute accurate metrics enabled.

Area of work	Key action	Expected benefit
	Conducts data analysis on medicinal product information collected in Art.57 database to support computation of PhV fees; supports the PSUR scope definition, referral procedures and the maintenance of the EURD List.	PhV fees computed for the generation of the advice notes and invoices. Scope of referral and PSUR procedures defined. EURD list published. Disputes and queries related to PhV Fees addressed.
	Contributes to the work on establishing medicine shortages reporting to ensure compliance with EMA's extended mandate.	Data analysis activities to support shortages processes ensured.
	Collects metadata information on RWD sources and studies and drives the development of the EU Data Quality Framework.	RWD source discoverability enhanced. New RWD catalogues available and maintained. EU Data Quality Framework published.
	Coordinates EU regulatory involvement in international data standardisation activities within ICH, ISO, and HL7; assists with the development of implementation guides for data standards and the use of terminologies.	Expert advice to ISO, ICH, HL7 standardisation activities provided.
	Coordinates stakeholder training on EV system and provides expert advice by replying to the queries raised via AskEMA and EMA Service Desk.	Stakeholders supported, informed and trained. User guidance and training materials maintained.
	Leads EMA pharmacogenomics specialised interest area (PGx SIA) of the Methodology Working Party (MWP).	Pharmacogenomics ESEC Specialised Interest Area established.

Area of work	Key action	Expected benefit
		Guideline on predictive biomarker-based assay development in the context of drug development and lifecycle adopted by MWP. Report on pharmacogenomics use cases throughout the medicine lifecycle delivered.
Clinical Trials Systems Workstream The workstream operates and leads the further development of the Clinical Trials Information System (CTIS) and provides operational support for EudraCT.	Proactively supports sponsors with their submitted trial applications by providing advice to the queries raised. Provides operational support to the stakeholders and addresses questions raised via AskEMA. Supports the product owner and subject matter experts to manage and prioritise requirements and bugs; tests bug fixes and new functionalities prior to deployment; updates and publishes release notes along with lists of known issues and suggested workarounds. Proactively supports stability and improve user experience with CTIS as these remain top priorities for EMA.	The CTR and CTIS are effectively supported and are operating. Clinical Trials sponsors and Member State CTIS users are supported. Continued monitoring though KPI reports, regular reporting to ACT EU steering group and MB.
	Leads the finalisation and publication of relevant guidance documents, including guidance on the protection of personal data and commercially confidential information in CTIS.	Guidance developed and published.
Clinical Trials Transformation The workstream manages Accelerating Clinical Trials in the EU (ACT EU); coordinates change management activities to support the transformation of the EU clinical trials environment, including activities related to the Clinical Trials Information Systems and the Clinical	Provides programme management for ACT EU.	ACT EU programme established and operational. Clinical trials activities across the EMRN coordinated.

Area of work	Key action	Expected benefit
Trials Regulation; manages the secretariats of the ACT EU multi-stakeholder platform advisory group and the Clinical Trials Coordination Group (CTCG).		
	Leads or supports delivery of the ACT EU priorities.	EU governance on CT matters strengthened. CTR successfully implemented through regular monitoring and stakeholder engagement. Regular monitoring the clinical trial environment in the EU is implemented with defined target. Academic multi-national clinical trials conducted in the EU supported. Good clinical practice aligned with the increasingly diverse range of clinical trial types and data sources. Robust and data-driven regulatory decision-making and research to answer important public health questions enabled. Coordination between clinical trial approval and clinical trial design improved. Clinical trial guidance developed resulting in high impact guidance documents implemented in practice.

Area of work	Key action	Expected benefit
		Trainings on clinical trial concepts and guidance developed and delivered. Large and multi-national clinical trials facilitated to promptly tackle public health emergencies.
	Provides project management for the CTR Collaborate initiative.	Coordination between NCAs and ethics committees, including during public health emergencies, improved.
	Provides organisational and secretarial management for the operation of the ACT EU Multi-stakeholder platform and its Advisory group, and the CTCG.	Enhanced dialogue between clinical trial stakeholders and regulators ensured. Coordination between EMA, ACT EU and CTCG improved.
	Coordinates communications and change management activities including publication of (updated) training materials, organisation of regular trainings.	Stakeholders' knowledge and competencies developed. Relevant, timely and targeted information for CT stakeholders ensured.

Workload indicators[10]

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Healthcare Data	Number of RFI and Service Desk requests received related to EudraVigilance and to Art.57/PhV Fees data analyses	n/a	1,100	1,200	1,000
	Number of EudraVigilance Quality Assurance Test (QAT) requests received	n/a	130	140	140
Real World Evidence	Number of non-interventional studies initiated	n/a	70	60	60
Methodology	Number of methodological advice provided on product procedures	n/a	80	150	150
	Number of active methodology guideline drafting groups led by MWP	n/a	15	15	15
	Number of methodological contributions to guidelines led by other committees and working parties	n/a	10	15	15
Clinical Trials Systems	Number of business validation for CTIS releases	n/a	18	18	18
	Number of KPIs reports published	n/a	12	12	12
	Number of EudraCT reports and number of CTIS data analyses and reporting[11]	n/a	110	110	110
	Number of ACT EU multi-stakeholder workshops[12]	n/a	12	12	12
Clinical Trials Transformation	Number of regular CTIS/CTR events[13]	n/a	86	86	86

[10] New indicators introduced in the 2024 work programme.
[11] Including ad-hoc and regular reporting (weekly dashboards for bi-weekly newsflash, MB monthly reports, ACT EU KPI reports, CTCG).

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

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
	Number of CTIS newsflashes and CT highlights newsletters	n/a	26	26	26

Performance indicators[14]

		Results	Expected results	Targets	
		2023	2024	2025	2026
Healthcare Data	ATD/RFI and Service Desk requests related to EudraVigilance and to Art.57/PhV Fees data analyses addressed according to set timelines	n/a	90%	90%	90%
	Percentage of monthly updates of the ADR report website performed according to the timelines	n/a	90%	90%	90%
Real World Evidence	Studies performed within less than 26 weeks[15]	n/a	70%	60%	60%
	Non-Interventional Study (NIS) protocols and summary results registered in EMA NIS registry within a month after finalisation	n/a	90%	90%	90%
Methodology	Product procedure requests for methodological support completed as per timelines	n/a	90%	90%	90%
	Planned MWP contribution to guidelines led by other committees and working parties	n/a	75%	75%	75%
Clinical Trials Systems	ATD/RFI and Service Desk requests related to CTIS and EudraCT Business addressed within set timelines	n/a	90%	90%	90%

[14] New indicators introduced in the 2024 work programme.
[15] Excluding framework contract studies.

		Results	Expected results	Targets	
		2023	2024	2025	2026
	WHO XML upload for CTIS (monthly) and EudraCT (weekly) with the expected scope of records	n/a	90%	90%	90%
Clinical Trials Transformation	ACT EU multi-stakeholder workshops organised according to workplan	n/a	80%	80%	80%
	News flash to CTIS users	n/a	90%	90%	90%
	Support to the secretariat for CTCG and physical hosting 4 times per year	n/a	100%	100%	100%
	Provide secretariat for CTCG weekly assessors round table	n/a	100%	100%	100%

Pillar 2 – Public health activities

In addition to the above, the Data Analytics and Methods Task Force plans to undertake and progress the following additional activities:

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
2.1 (ECP 1 *A new plan for Europe*)	Build capacity and capability to receive, store, manage and analyse clinical study data	Proof-of-concept clinical study data pilot protocol developed CHMP proof-of-concept clinical study data pilot operated Updated pilot report on learnings and recommendations developed Guidance for applicants updated	2021	2026	5 additional regulatory procedures included in the CHMP proof-of-concept clinical study data pilot completed by end of 2025 Guidance to applicants/MAHs updated by Q1 2025

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Workshop on the submission and analysis of clinical study data			Updated pilot report published in 2026 Business requirements for the to-be processing of clinical study data (from submission to analysis) collected by Q3 2025 Software for validation and analysis based on business requirements selected by Q3 2025 Workshop on clinical study data organised by Q4 2025 Public workshop organised by Q4 2026
	Manage the EMA-HMA-EC co-led initiative Accelerating Clinical Trials (ACT EU) to transform CT in Europe. This includes strengthening EU level governance of CT and the CTR implementation; modernisation of CT design and good clinical practice; leveraging data on CT to support regulatory decision making; supporting non-commercial sponsors to conduct more multi-national clinical trials;	Strengthened EMA/EC/HMA collaboration within ACT EU via rationalised governance Launch of an action plan to support non-commercial sponsors External stakeholders engaged through the establishment of the multi-stakeholder platform and its advisory group	2021	2026	Multi-stakeholder platform advisory group meets quarterly Action plan to support non-commercial sponsors adopted Launch CT helpdesk Areas for funding proposals linked to the research priorities on CT analytics agreed - Q1 2025

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	enhanced dialogue between clinical trial stakeholders.	Implementation of revised ICH E6(R3) GCP modernisation in the EU region supported Research priorities for better use of clinical trials data defined Stand-alone ACT EU website managed Consolidated scientific and regulatory advice pilots operated and results reviewed and made public Methodological aspects on CT design supported by a best practice on guidance Clinical trials safety aspects, trainings and clinical trials in emergency settings (PHE) delivered			Communication public on end of transition period - Q1 2025 Yearly measurement of the clinical trial environment evolution in the EU - Q1 2025
	Business support to operations to Clinical Trials regulation including business support to CTIS.	Provide hands on support to the numerous sponsors and MS users of CTIS through the business service desk Assure the business testing of the candidate releases	2022	Continuous	Number of investigational test substances with saMS selection triggered and completed
	Change management activities related to CTR/CTIS.	Regular communications in the form of newsletters and news flashes, maintenance of the	2020	2026	At least 5 stakeholder support webinars.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		CTIS training catalogue, and running of regular CTIS events e.g. walk-in clinics, bite size talks, CTIS forum			4 CTIS forum meetings in 2025. 5 CT highlights newsletters and 20 newsflashes released at a minimum with each CTIS deployment Change management strategy in place to support activities related to CTIS simplification - Q1 2025
2.2 (ECP 1 *A new plan for Europe*)	Lead the development of the Big Data curriculum on Data Science for the EU Regulatory Network	Training modules published on the EUNTC portal	2021	2026	At least 3 modules delivered by end 2025
2.1 (ECP 1 *A new plan for Europe*)	Development of the EU Data Quality Framework for big data used in the regulatory context and of the DQ considerations for Real World Data (RWD) and for Adverse Drug Reactions (ADRs)	Common framework for data quality available for EMRN and industry Specific and implementable guidelines for ADR and RWD data are available	2023	2026	RWD chapter published in 2025 ADR chapter published in 2025
	Ensure compliance with the European Union Data Protection Regulation (Regulation (EU) 2018/1725) and guidance of the European Data Protection Supervisor (EDPS) and the European Data Protection Board (EDPB)	Full compliance with Data Protection legislation Risks managed	Continuous	Continuous	Yearly report on data protection activities to EMA Management Board 3 data protection trainings organised annually Quarterly reports on EMA data protection activities to

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	and provide advice on data protection related matters at EMA				the attention of the Executive Director, Internal Controllers, Head of AF-INS and Data Protection Controllers provided 4 meetings with Data Protection Coordinators organised annually
2.2 (ECP 1 *A new plan for Europe*)	Strengthen the EU Network on methodology in committee advice and assessment through: guideline development and implementation; the provision of methodological expertise to support EMA scientific committees; capacity building. Harmonisation of international methodological standards Programme management of the Methodology domain Understand and account for external stakeholders' needs	Guidance documents on emerging methodological topics delivered Estimands from ICH E9(R1) implemented in newly written or updated clinical and methodological guidelines, where appropriate Draft methodology research needs listed Operational expert groups established and managed Systematic lessons-learnt process for procedures with complex methodology Training modules for EMRN developed and delivered	2021	2027	Milestone of 50% priority MWP guidelines and workshops achieved by Q3 2025 Estimands input for 80% clinical guidelines where MWP was consulted MWP work plan updated by Q4 2025 At least one Methodology Domain governance meeting held by Q3 2025 Draft overview of all cluster meetings available by Q2 2025 At least one Interested Parties meeting held by Q4 2025

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		ICH E6(R3) Annex 2 drafted. ICH E20 step 2 reached. EMA Q&A of ICH M12 drafted Yearly revised Methodology Work Plan Embed identification of committee requests with complex methodological aspects into EMA forecast and tracking processes Clear roles and responsibilities in the Methodology Domain to maximise resource efficiency established. Draft Methodology stakeholder interaction plan. Cluster meetings and Interested Parties meetings organised			
	Improve development and implementation of clinical trial methodology guidance in the EMRN. Development of an inventory of training needs.	Methodology workshops, or webinars, with external stakeholders to scope and prioritise clinical trial methodology guidance topics Process for aligning guideline development on multidisciplinary methodology	2021	2026	Regular strategic exchange between CTCG, MWP and HTACG Chairs established by Q2 2025 Best practice document for guidance development finalised by Q2 2025 Training material drafted by Q4 2025

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		topics involving a large variety of Network expert groups Training plan for new guidance documents and associated process Completion of training needs assessments for regulators and defined stakeholder groups. Elaboration of training curriculum			Clinical trial training needs assessments published by Q2 2025 Clinical trial training curriculum published by Q1 2026
2.1 (ECP 1 *A new plan for Europe*)	Further develop and maintain a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis and Real World Interrogation Network - DARWIN EU). To support better decision-making on medicines by informing those decisions with robust and reliable evidence based on appropriate real-world data.	DARWIN EU Coordination Centre maintained Access to various real-world data sources in terms of data type, population covered and geographical coverage increased DARWIN EU pilot with EHDS conducted and informed next steps Processes for EMA oversight of DARWIN EU activities operated and optimised, including review of DARWIN EU deliverables and outputs DARWIN EU studies delivered in line with contract	2020	2026	At least 100 studies initiated in DARWIN EU in 2025 10 additional Data Partners onboarded in 2025

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
2.4	Build appropriate EMA business processes to identify the need for RWE and to generate and deliver that evidence in order to support the regulatory decision-making process.	Processes to prioritise and triage study requests established Development of a phenotype's library Users' training on utilisation of IHD and analytical templates	2022	2025	RWE report (including all use cases) updated and published annually. Training delivered to all new IHD users.
	Coordinate implementation of HMA EMA AI multiannual workplan. Contribute to implementation of actions led by TDA.	Successful experimentation on the extraction of information using AI/ NLP techniques Reporting to HMA and MB on workplan progress	2023	2028	Report on lessons learnt from test use cases shared with EMRN 6 monthly report to HMA and MB
	Further development and use of a monitoring system for the post-authorisation safety and effectiveness monitoring of vaccines (Vaccine Monitoring Platform).	Processes for the prioritisation, launch and supervision of vaccine studies in place Working arrangements with ECDC operated Processes to identify a need for studies in place Results of studies made available to EU decision-makers and the public	2022	2025	Minimum of 4 studies under the VMP conducted annually Joint advisory board meets twice a year
	Establish Health Data Lab to apply advanced analytics to develop innovative techniques to analyse, interpret and communicate on healthcare data	Health Data Lab operates as a stream under the DigiLab's framework Pilot the experimentation	2023	2025	Two pharmacovigilance use cases piloted

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		framework with two pharmacovigilance-related use cases			
	Development and implementation of EMA and EMRN data strategies as part of data governance activities and evolution of EMA data governance including policies, procedures, procedures and responsibilities as well as management of the EMA Data Board and Network data governance	Finalised Network Data Strategy Established plans and activities to implement EMA data strategy EMA data governance structures and activities are in place Plan for EMRN and EMA communications, trainings and stakeholder engagement	2021	Continuous	By end of 2025: Network Data Strategy adopted Evolved EMA data roles family, structure, processes and data community in place EMA data catalogue and glossary in place New EMRN data governance group established through merger of network Data Board and Big Data Steering Group data strategy agreed, work plan agreed and prioritised activities initiated
	Support EMA operations and committees/working parties with advice and epidemiological expertise on: - methods for RWD collection, analysis and reporting in the fields of healthcare and medicinal products evaluation; - portfolio of RWD sources existing in Europe and elsewhere to answer research questions;	Reflection paper on methodological aspects, formats and contents of RWE used for regulatory purposes Templates and check-lists for feasibility analyses on appropriateness of RWD sources used in regulatory decision-	2023	Continuous	Process to screen marketing authorisation applications established Final reflection paper on RWE published Template and check list on feasibility analyses published.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	- identification of research questions appropriate for further investigation and their translation into study protocols; - evidentiary standards and formats and contents of RWE submitted by MAAs/MAHs; - lessons learnt from review of RWE submitted by MAAs/MAHs; - literature review of published articles with RWE on utilisation, safety and effectiveness of medicinal products.	making (e.g. registries, electronic healthcare records) Process of procedure identification, from relevant committees/WPs that require methodological input, participation and contribution to SAWP, pre-submission, PRIME and any other relevant meetings where RWE is addressed			
	Implement the Clinical Trials Safety Monitoring regulation	Assure the simplified functional specs of the safety implementation regulation are up to date Provide regular support to the Member States for the safety assessments	2021	Continuous	saMS selection triggered for the vast majority of investigational test substances eligible for worksharing, based on newly authorized trials
	Deliver simpler CTIS business rules, which will support future modernisation of CTIS to improve user experience and streamline the operation of the system	Identified areas of the CTIS business rules are covered by Simplification Task Force	2024	2025	At least 4 topics for simplification analysed Simplification proposals for at least 3 topics finalised
	Enable the use of clinical trials data to support medicinal product development, leveraging data standards and the Data Analytics Platform (DAP)	KPIs for regular measurement via DAP Yearly measurement of ACT EU performance indicators	2021	2025	Monthly dissemination of KPIs to EMRN and to the public Publication of ACT EU monitoring by end of year

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Make available interactive maps for patients			Interactive map available on website by end of Q1
	Enable clinical trial data standards in EMA and Network systems and processes	Lead the European contribution to ICH M11 activities Change management strategy developed	2021	2025	Roadmap of clinical trial standardisation epics adopted - Q1 2025 Technical Implementation Guide (TIG) for public consultation developed - Q2 2025

3.3. Regulatory Science and Innovation (TRS)

The Regulatory Science and Innovation Task Force enables the continuous futureproofing of the Agency and of the European Medicines Regulatory Network through the operation of a regulatory science observatory, addressing key scientific and technological trends and their translation through the development of regulatory-science strategy, planning and governance. The annual work plan of the Task Force will revolve around the following drivers:

- Advance support to innovation through enhanced first-contact functionalities within the Innovation Task Force, Business Pipeline, SME Office, and academic liaison.
- Develop horizon-scanning and outreach capabilities of EU-IN, SME Office and the academic liaison, and expand business analysis and forecasting to deliver enhanced quality outputs to the Agency and the EU network.
- Leverage collaborations between academia and network scientists to prepare for engagement with Horizon Europe and IHI; define EMA's regulatory science research agenda and enable the exchange of knowledge and expertise.
- Deliver the reinforced EMA mandate to facilitate a coordinated EU-level response to health crises by monitoring and mitigating the risk of shortages of critical medicines and medical devices.
- Enhance European collaboration amongst Regulatory Network (EU-IN) and relevant stakeholder promoting EU competitiveness in pharma (and med-tech) R&D.

The workforce available in 2025 for the Task Force is currently foreseen at 38 staff (24 TAs, 8 CAs, 6 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Area of work	Key action	Expected benefit
SME Office Workstream Addresses the unique needs of micro, small, and medium-sized enterprises	Deliver EMA's SME office business operations Review initial SME status qualifications and renewals Coordinate the provision of translation assistance for marketing authorisation applications Organise SME briefing meetings Provide regulatory, procedural and administrative assistance	Addressing the specific needs of smaller pharmaceutical companies, with the aim of promoting innovation and development of new human and veterinary medicines

Area of work	Key action	Expected benefit
	Organise workshops and training events	
Innovation & Development Accelerator Workstream *Innovation and emerging therapies* Provides a platform to support and facilitate innovation in medicines development through its Innovation Task Force (ITF) and its co-chairmanship of the EU Innovation Network	Organisation and conduct of regular ITF briefing meetings with all stakeholders including SME, Academia, non-for-profit and big pharma Reports to Committees Develop and deliver the EU-IN action plan, including workshops, horizon scanning, repurposing, borderline classification, simultaneous national scientific advice (SNSA) processes and education programs to developers. Engage authorities under other EU legal frameworks at appropriate moments (SoHO, medical devices, AI Act, Biotechnology (anticipated), food, chemicals).	Provision of a discussion platform for early dialogue with applicants, identifying scientific, legal, and regulatory issues of emerging therapies and technologies, as well as scanning the horizon, exchanging information, and establishing networks to develop and maintain expertise in the field. Engage authorities under other EU legal frameworks at appropriate moments (SoHO, medical devices, AI Act, Biotechnology (anticipated), food, chemicals). The EU Innovation Network facilitates the development of innovative medicines and related technologies and methods by addressing gaps in early regulatory support to innovation.
Innovation & Development Accelerator Workstream *Business and analysis forecasting* Provides the Network with forecasts and business intelligence on upcoming marketing-authorisation applications	Compilation of monthly, quarterly, yearly, and three-year reports to inform the system of upcoming submissions Organisation and conduct of Portfolio and Technology meetings Expand business analysis and forecasting to deliver enhanced quality outputs to the Agency and the EU network	Enables accurate NCA and EMA resource allocation and budgeting facilitating internal operations
Innovation & Development Accelerator Workstream *Horizon scanning*	Further develop horizon-scanning and outreach capabilities of the EU-IN and SME Office, also in collaboration with stakeholders, e.g. HTACG, IHSI, JRC, ICMRA, ESPAS (EU-ANSA) etc.	Systematic collation of regulatory information to prepare authorisation activities and resources

Area of work	Key action	Expected benefit
Identifies future innovations and trends in a comprehensive and systematic manner enabling and facilitating innovations to reach the market	Develop a systematic horizon-scanning capability to identify scientific and technological trends that will impact the regulatory system. Inform and engage the authorities under other EU legal frameworks (medical devices, SoHO, AI Act, Biotechnology (anticipated), food, chemicals). Develop the regulatory science observatory by activating a matrix of subject-matter experts across the product-development lifecycle.	Systematic examination of information to detect early signs of important developments with previously unknown regulatory challenges and / or public health opportunities Creation and implementation of systems to inform on trends in science and technology informing the regulatory system Inform and engage the authorities under other EU legal frameworks (medical devices, SoHO, AI Act, Biotechnology (anticipated), food, chemicals)
Regulatory Science and Academia Workstream *Academia liaison and external regulatory research projects* Aims to allow for an Agency-wide interaction with academia within the established framework of collaboration, together with Agency engagement with regulatory science research projects	Execute the Agency-wide plan for interactions with academia to: (1) support governance and oversight of interactions with externally funded research and networks; (2) identify academic disciplines/research topics; (3) support the establishment of staff-exchange programmes and placements; (4) create academia-targeted materials to promote existing regulatory tools; (5) set up a communication strategy Continue support to IMI2's closing projects and strengthen engagement with Horizon Europe and IHI Modernize EMA's regulatory science research needs Support the establishment of the European Forum for Regulatory Science research Coordinate the conduct and/or commissioning of impact-assessment studies	Delivers the Agency's Academic Matrix Action Plan, with particular focus on a coordinated response to and regular engagement with regulatory science research projects Fulfilling one of the strategic goal areas within the Regulatory Science Strategy to 2025 Raise awareness of EMA's role within the European medicines regulatory network Promote and further develop regulatory support for translating academic research into novel methodologies and medicines Ensure that the best scientific expertise and academic research is available to inform regulatory decision-making Collaborate on areas of research on regulatory science, such as novel approaches, endpoints, and methodologies
Supply and Availability of Medicines and Devices Workstream	Implementation of the extended legal mandate of the Agency in the area of shortages of medicines and medical devices	Anticipate and accelerate the implementation of the New Pharmaceutical Legislation in the management of critical shortages and security of supply of critical medicines.

Area of work	Key action	Expected benefit
Delivering the reinforced EMA mandate to facilitate a coordinated EU-level response to health crises by monitoring and mitigating the risk of shortages of critical medicines and medical devices	Coordination of required actions in case of anticipated or ongoing shortages of centrally authorised products Coordination of required actions for critical shortages (CAPs and NAPs) Coordination of activities of the Medicine shortages SPOC Working Party (single points of contact in NCAs for shortages) Coordination of activities of the Executive Steering Group on shortages and safety of medicinal products (MSSG) Coordination of activities of the i-SPOC system (single points of contact in industry for shortages) Coordination of the implementation of the EMANS to 2025 in the area of availability of medicines Co-chairmanship and secretariat of the HMA/EMA Task Force on the Availability of authorised medicines Deliver the European Shortage monitoring platform (ESMP), and further expend interoperability with other existing Databases and overall functionalities. International collaboration on shortages-related strategic topics and shortages case-management at the level of the Global Regulatory Shortage Network EMA will propose a stress testing in relation to key actions on the implementation of the extended legal mandate of the EMA in the area of shortages of medical devices. For medicines shortages EMA has	Fulfilment of the requirements established by EMA's extended mandate for availability of medicines Coordinate the activities of the HMA/EMA TF AAM in its function as a "supply and availability Hub" to track progress on supply and availability activities ongoing under the EMRN to streamline processes, ensure synergies and avoid duplication of work Preparation for the delivery of the ESMP database. Extended mandate activities on shortages of medicinal products. Guidelines for EU Member States Guidance for companies Overall, ability to rapidly manage on-going shortage and prevent new shortage of Critical medicines efficiently Supply chain of critical medicines will be strengthened and diversified

Area of work	Key action	Expected benefit
	already experience with 2 different PHEs and ongoing stress testing is being carried out in the context of the development of the ESMP. Implementation of the extended legal mandate of the Agency in the area of shortages of medicines and medical devices, including undertaking stress testing of structures and IT tool implemented to address shortages of medical devices during PHEs. In case a PHE is declared before the stress test is conducted, EMA will undertake a lessons' learned exercise. Deliver regulatory expertise and insight in support of the work of the Critical medicine alliance toward the development of recommendation for Industrial Policy measures and the Critical Medicine's Act	
Regulatory Science and Innovation Task Force Provide scientific and strategic input to the EMA secretariat and escalates scientific topics to the SciCoBo, as required	Supports the activities of the Scientific Coordination Group (SCG)	Acting as the Agency's coordination body for collaboration on scientific topics Supporting the Scientific Coordination Board (SciCoBo) in achieving its objectives
Regulatory Science and Innovation Task Force Enhance EU competitiveness within EMA's mandate by developing and implementing a framework plan that aligns with the European Commission's	Define competitiveness within EMA's mandate Conduct a gap analysis of current EMA processes and initiatives Initiate targeted actions within EMA's mandate	Establish a unified understanding of competitiveness across EMA, aligning with the European Commission's initiatives Enhance focus in EMA's strategic actions to support EU competitiveness Identify high-impact areas for improvement to strengthen EMA's role in fostering EU competitiveness Align EMA's activities with EU competitiveness objectives

Area of work	Key action	Expected benefit
initiatives. This activity is critical for the future of the EU and its citizens in the global competitive context, ensuring that Europe remains a leader in health innovation, regulatory excellence, and sustainability.		Support a sustainable and competitive future for the EU in the global context

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Innovation and emerging therapies	Innovation Task Force briefing meetings conducted	29	40	40	40
	Innovation Task Force consultation: CHMP opinion requests according to Regulation (EC) No 726/2004 Art. 57 and MDR Art. 4 / IVDR Art. 3	0	4	4	2
	Portfolio and Technology meetings[16] conducted	21	20	20	20
Regulatory Science Research and Academia	Academia briefing meetings conducted[17]	n/a	12	16	20
	New involvements in externally-funded regulatory science projects managed[17]	n/a	10	10	10
	Collaborating experts onboarded or deliverables managed[17]	n/a	16	16	20

[16] Previously known as "Business Pipeline meeting".
[17] New indicators introduced in the 2024 work programme.

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Supply and Availability of Medicines and Devices	Number of MSSG meetings	n/a	12	12	12
	Management of shortages of CAPs	n/a	1,600	2,000	2,000
	Number of notifications of critical shortages (CAPs and NAPs, human + vet) circulated via SPOC Working Party	n/a	60	120	120
	Number of requests for information received from the SPOC Working Party and international partners	n/a	70	80	80
	Number of SPOC Working Party meetings (including subgroups)	n/a	40	50	50
	Number of Solidarity Mechanism cases[17]	n/a	10	20	20
SME support	Regulatory assistance, including SME briefing meetings	230	192	205	225
	Requests for SME qualification	428	541	410	451
	Requests for SME status renewal	1,432	1,323	1,389	1,458

Pillar 2 – Public health activities

In addition to the above, the Regulatory Science and Innovation Task Force plans to undertake and progress the following additional activities:

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
3.1 (ECP 1 *A new plan for Europe*)	Improve expertise to accommodate rapid evolution of the regulatory system	Relevant areas of emerging science and technology identified Steps taken to increase expertise availability both within EMA and the Network	2022	2025	Target delivered
3.1 (ECP 1 *A new plan for Europe*)	Identification of new technologies via HS and scientific advice activities and their integration into the EU-NTC	New technologies identified and integrated within EU-NTC	2021	2025	Target delivered
6.1	Integrate EMA's Regulatory Science Strategy into the EMRN strategy, conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, identify gaps in expertise and provide continuous training through the EU Network Training Centre	RSS integrated within EMAN Strategy Implementation tracked systematically to ensure delivery	2020	2025	Target delivered
	Innovation relevant preparation for the implementation of new legislation (Sandbox, Borderline Classification)	Proposals for re-designed processes to prepare for the implementation of new pharma legislation	2023	2026	Target delivered
	Preparation for ESMP database Extended mandate activities on shortages of MPs and MDs	Extended mandate activities on shortages of MPs and MDs	2022	2025	Operational ESMP database

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
	Union list of critical medicines SPMPs organisations of SC meetings of the TFAAM (4 per year) TWG1 meetings (30 per year)	Human product availability, veterinary product availability / MUMS	2022	2025	Co-Chairing of task force meeting and fulfilment of follow-up actions Activities included in the revised legislation that have been already allocated to the TFAAM (TWG1) that are being coordinated by EMA - Union list of critical products

4. Advisory functions & Office of the Executive Director (International Affairs, Internal Audit, Legal Department, Institutional and Policy Department, Information Security, Chief Medical Officer Public Health Threats)

The **International Affairs Department** is responsible for the development and implementation of the Agency's long-term international strategy and of the coordination of the Agency's international activities, in particular with regard to participation and contribution to international forums and international standardisation activities. The function deals with 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.

The international focus in the coming planning period is expected to be on forward preparations for future public health crises, supporting the extension of the scope of the EU-US mutual recognition agreement, international supply chain integrity, raising awareness and use of the Article 58 (EU-M4all) pathway and other reliance and collaborative pathways including through working with WHO, promoting international reliance on scientific outputs of the EMA scientific committees, implementing the OPEN initiative, supporting the establishment of the African Medicines Agency, support to EU candidate countries and potential candidates, capacity building and engagement with priority regulatory partnerships, and providing the secretariat for the International Coalition of Medicines Regulatory Authorities (ICMRA). The function will also explore opportunities to support the EU Global Health Strategy and foster cooperation with WHO, including active engagement in the WHO Coalition of Interested Parties.

The **Internal Audit Function** reviews and evaluates risk-management, governance, and internal control processes at the Agency, to provide the Executive Director and the Management Board with independent and objective assurance and consulting services designed to add value and improve the Agency's operations.

The **Legal Department** is responsible for the provision of legal advice on matters related to pharmaceutical law, contracts and procurement, staff-related matters, financial matters, data protection and corporate governance, as well as matters related to anti-fraud issues. The tasks of the Legal Department also include dealing with complaints submitted to the European Ombudsman and representing the Agency before the European Court of Justice. The Legal Department cooperates with the European Commission and provides advice and support, among other things, on the implementation of new legislation; the drafting and implementation of new internal guidance and policies; the working arrangements with other regulatory bodies and other EU institutions and agencies; the assessment of potential conflict of interests of scientific experts, Management Board members and EMA staff; the decisions on access to documents and the replies to requests for information. The Legal Department also performs the legal scrutiny of scientific opinions for both human and veterinary medicinal products. It also interacts regularly with OLAF and EPPO and is responsible for the preparation and implementation of the Agency's anti-fraud strategy and the related action plan.

The Institutional and Policy Department coordinates the Agency's interactions with the EU institutions, in particular the European Commission, the European Parliament, the Council, and other EU agencies. This includes coordinating the Agency's 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. The Department also acts as a general contact point and coordinator of interactions between EMA and other EU agencies, such as ECDC, EFSA, ECHA and EUDA , under the existing Working Arrangements between EMA and these agencies. The key institutional activities planned in 2025 will relate to introducing EMA to and cooperating with the new European Parliament and European Commission, coordinating the technical input and support to EU institutions during the ongoing legislative process on the revision of the general pharmaceutical legislation and on the 'one-substance-one-assessment' legal proposals. Other activities planned for this period will include the revision of the Working Arrangements between EMA and other EU agencies, notably ECDC,EFSA and EUDA, to align them to the new tasks of these bodies and to reflect new topics of common interest.
The Department is also responsible for the organisation of EMA's Management Board and for coordinating EMA's interactions with the Heads of national human and veterinary Medicines Agencies (HMA), including contributing to joint activities and meetings. EMA also interacts with the MB Secretariat of other EU Agencies to share best practices and streamline processes. EMA continues to build and maintain important relations with HMA and National Competent Authorities through common projects and initiatives to help fulfil the Agency's and the NCAs' mandates. The Department also coordinates the development, implementation monitoring and revision of EMA policies. Policies are kept under regular review, in line with the quality management system and as required, to comply with relevant Court rulings. Furthermore, linked to the EMANS strategy Focus Area 6 'Sustainability of the Network and operational excellence' and integrating sustainability priorities into the EMA budget, the Department is responsible for the coordination of the Agency's environmental management activities, with activities such as including green criteria in the Agency procurements where applicable, embedding environmental considerations into our processes and procedures, with a target to register to EMAS. EMA also aligns with the European Climate Law and with the Commission's long-term commitment of reaching climate neutrality by 2030 and of leading by example (see also Annex VI).

The **Information Security** advisory function develops and implements the Agency's 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. The service manages and coordinates the Agency's information security, enhancing its efficiency and effectiveness through **security and risk assessments, audits and compliance procedures, as well as security awareness initiatives and training.**

The **Public Health Threats Department** is supporting and managing scientific activities related to preparedness and response to public health emergencies. AF-HT is responsible for the 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 office could run specific studies to support the Agency's response to public health emergencies. As such, AF-HT acts as scientific lead for preparedness and response for emerging health threats of biological, chemical, or environmental origin. In addition, AF-HT coordinates and leads vaccine strategies and is responsible for the Agency's

AMR strategy, in coordination with the Human and Veterinary Divisions. AF-HT conducts intelligence activities on countermeasures for emergent pathogens and collects information across the Agency and outside on products and product statuses shared with EU institutions (SANTE, HERA or the cabinet).

The **Chief Medical Officer** (CMO) advises on matters relating to the Agency's mission for the protection and promotion of public and animal health. The CMO also provides clinical subject matter expertise in working with the EU Network to deliver on its core business and implementation of the Agency's Regulatory Science strategy. The CMO's office works on projects relating to the quality and coordination of scientific decisions, has a role in the scientific competency development of Agency staff, and the publication peer review process.

The workforce available in 2025 for the Advisory Functions is currently foreseen at 67 staff (50 TAs, 12 CAs, 4 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2023	**2024**	**2025**	**2026**
International Affairs	Number of product-related interactions with international stakeholders – including requests for information and requests for documents	279	250	250	250
	Number of participations in external forums	34	40	40	40
	Number of external participants in training organised by International Affairs	630	700	500	500
	Number of visits to EMA / fellowships organised by International Affairs	15	15	15	15

Pillar 2 – Public health activities

In addition to the above, the Advisory functions plan to undertake and progress the following additional activities:

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
1.1 (ECP 1 *A new plan for Europe*)	ICMRA secretariat management, including operational and financial contribution to ICMRA summit and plenary meetings Participation in and coordination of ICMRA Regulatory Forum, and work streams	Continue demonstrating leadership of ICMRA: Regulatory convergence and in particular, aligning COVID-19 global response and collaboration Regulatory communication	Continuous	2025	Number of TCs Number of collaborative workstreams Number of support workstreams for governance & membership, and communications
1.2 (ECP 1 *A new plan for Europe*)	Support and foster use of the EU-M4all pathway Support applications and scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European	Support to developers and promotion of parallel art 58 and centralised submissions	Continuous	Continuous	Number of parallel submissions Number of Article 58 opinions and new approvals

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Union (EU) in collaboration with WHO This includes early engagement with product developers and related sponsors.				
1.2 (ECP 1 *A new plan for Europe*)	Support and foster use of collaborative registration with WHO Engagement with WHO, NRAs and applicants, to promote and support use of the WHO collaborative registration procedure, facilitated approvals, prequalification and other pathways	Capacity building in low and middle income countries	Continuous	Continuous	Number of new products ongoing with the CRP with contribution from International Affairs
5.2	Support continued implementation of the EU-US FDA MRA	Support for several operational meetings (internal, EC, FDA and NCAs) related to the finalisation of the MRA implementation for veterinary medicines, increase in the efficiency of the MRA for human medicines and preparations for the potential extension to	Continuous	Continuous	Number of EMA/FDA meetings participation

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		vaccines and plasma derived medicines			
6.1	Provide assistance to candidate countries and potential candidates (IPA), to align their standards and practices with those established in the European Union, and to further foster their integration process	Participating authorities are better prepared for future potential EU accession, and integration to the European medicines regulatory network	2024	2026	Number of trainings organised Meeting with contact points arranged
1.1 (ECP 1 *A new plan for Europe*)	Opening our Procedures at EMA to Non-EU authorities: Implementation of new working model as agreed by Management Board March 2022	Collaborative assessment involving OPEN participating regulators Alignment or convergence in regulatory outcomes Accelerated assessment and products approval by OPEN partners WHO participation facilitates PQ approvals and availability in low- and middle-income countries markets	2023	Continuous	Number of experts Number of procedures
1.1 (ECP 1 *A new plan for Europe*)	Maintenance, exchange of information and engagement with existing	Facilitate and foster International cooperation	Continuous	Continuous	Number of CAs

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Confidentiality Arrangement partners Establishment of new Ad Hoc Confidentiality Undertakings				Number of Ad Hoc CAs Number of product-related received Bilateral and strategic engagements with partners
1.1 (ECP 1 *A new plan for Europe*)	Active participation in international forums and communication to stakeholders, including but not limited to DIA, ICH, IPRP	Greater visibility of the Agency and of its activities	Continuous	Continuous	number of presentations number of meetings
1.1 (ECP 1 *A new plan for Europe*)	Organisation of awareness sessions and engagement workshops for international regulators	- Increase Awareness of the EU system - Agency public image	Continuous	Continuous	Number of sessions organised Number of participants
	Data protection impact assessment and simplification of personal data redaction for exchange with international partners	Protection of personal data	Continuous	Continuous	Finalised Administrative Arrangement with Health Canada Agreed process and responsibility for redaction of documents shared with international partners
6.1	Under the DG INTPA contract, support creation of AMA and regulatory	Establishment of the AMA	Continuous	2027	Meeting objectives of LogFrame agreed under DG INTPA contract

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	system strengthening at African continental, regional and national levels				
	- Communication of information, answer to queries, internal coordination - Monitoring and tracking of interactions - Preparations of visits, missions' preparation, support to international partners, fellowships and expert visits	Streamline and promote awareness of international activities within the Agency	Continuous	Continuous	Number of interactions with CAs partners Number of documents exchanged Number of interactions with other international stakeholders number of meetings/teleconference organised Number of guidance created/updated
1.1 (ECP 1 *A new plan for Europe*)	Collaboration with WHO to support availability of child-friendly TB medicines in the EU	Approval and availability of paediatric anti-TB medicines for unmet medical needs in the EU	2021	Continuous	Number of TB products applications Success of DG HERA tender
1.1 (ECP 1 *A new plan for Europe*)	Sustained development and operation of the Internation Cooperation Platform	To promote an EU approach consistent with the European pharmaceutical strategy, regulatory framework for pharmaceuticals and global health strategy	2022	Continuous	Number of meetings

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
1.1 (ECP 1 *A new plan for Europe*)	Implementation and support to engagement with US FDA	Maintain and develop relationship between EMA and FDA. Identify and develop existing and new areas of cooperation.	Continuous	Continuous	Number of product-related requests received from FDA Number of product-related requests made by EMA Number of FDA and EMA visits Number of fellows
	Organisation of the 2025 ICMRA Summit	Reaffirm importance of global regulatory convergence and collaboration Articulate achievements and impact of 6-years of leadership of ICMRA Promote regulatory communication	2025	2025	Summit is organised in time and within budget
1.2 (ECP 1 *A new plan for Europe*)	Promoting reliance on EMA scientific outputs	Position and promote EMA role as a leading reliance partner for non-EU regulators and pharmaceutical industry, in line with its responsibilities as a WLA designed authority	Continuous	Continuous	Number of reliance pilots initiated. Number of national approvals granted based on reliance on EMA scientific outputs

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Define approaches for review of data with international regulator 1.Explore options for innovative regulatory science to support regulatory decisions before epidemics 2.Define approaches for review of data with international regulator	Improved public health preparedness and protection	2021	Continuous	Intelligence gathering, studies, workshops and reports on regulatory science and for platform technology. - summary documents on emerging pathogens and bioterror countermeasures. - 4/5 meetings per year with international regulators and stakeholders.
	Communicate proactively with key stakeholders on benefit-risk using evidence-based tools to tackle vaccine hesitancy	Better public understanding and confidence in the safety and efficacy of vaccines	2021	Continuous	Update of the European Vaccination Information Portal (EVIP) EMA communication and engagement activities delivered Outcome of ICMRA discussion published Measures of vaccine uptake and of public intent for future vaccination
	Engage with public health authorities and NITAGs to	More consistent recommendations on vaccinations strategy	2021	2025	Improved processes for the development of vaccination strategies

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	better inform vaccine decisions				
	Establish a platform for EU benefit-risk monitoring of vaccines post-approval	Evidence to drive benefit risk evaluation and vaccination policy	2021	Continuous	Conduct of studies of safety and effectiveness of vaccines in accordance with the research agenda developed by the vaccine platform board
	Develop and implement the AMR EMA strategy	Have suitable vaccines and therapeutics for treatment of infection including those caused by multi-drug resistant organism	2021	Continuous	Increased numbers of medicines in development and authorised
	Operate the ETF during a declared public health emergency and to ensure preparedness	Provide scientific advice to developers, engage in discussions with Academia and relevant EU bodies or International regulators, support sponsors of CT to conduct larger trials	2021	Continuous	Number of scientific advice procedures done by ETF, number of large multinational trials that started after ETF support, number of TCs held by HTV or ETF with Academia and other entities, platform trials developed
1.1 (ECP 1 *A new plan for Europe*)	Launch tailored communications on biosimilars and provide updated guidance on the evidence needs for biosimilars	Increased awareness to facilitate the uptake of biosimilars	2022	2025	Better communication on biosimilars and better guidance
	30 years anniversary conference of EMA	Create awareness of the Agency and its scientific work including the developments over the past 30 years	2024	2025	Conference delivered

5. Stakeholders and Communication Division

The Stakeholders and Communication Division supports the achievement of EMA's strategic goals through consistent, high-quality communication, using a diverse range of channels, with the aim of facilitating understanding and awareness of EMA's role, work and outputs among its publics, and of ensuring its key stakeholders are adequately informed about how to work with the Agency. The Division facilitates engagement and dialogue with the European Medicines Regulatory Network and with stakeholders who develop, prescribe, supply, and use medicines. Its ultimate goal is to provide European Union citizens with relevant information on medicines, to build and safeguard the Agency's reputation, and to develop society's trust in the EU regulatory system. The Division is also responsible for management of the Agency's crisis preparedness and response.

The main drivers are:

- the implementation of lessons learned from COVID-19 and the Agency's response to the pandemic;
- further stakeholder engagement and communication in collaboration with the Network on the implementation of the joint European Medicines Agency Network Strategy and the Regulatory Science Strategy, and key focus areas, including: clinical trials and ACT EU, data driven legislation, cancer as a pathfinder to support development and approval of innovative medicines, work to address shortages, and preparing for implementation of the HTA regulation and for the review of the EU pharma legislation;
- implementation of the framework strategy for communication and engagement 2021-2025, which aims to establish optimised crisis-communication processes, to leverage progress in digitalisation and to review, and adapt operations to ensure efficiency, sustainability and responsiveness. Also, the implementation of a strategy for the restart of clinical data publication will be progressed;
- continuing to ensure that the patient voice is systematically incorporated throughout medicine development and evaluation, and enhanced interaction with healthcare professionals, industry stakeholders, and academia (in cooperation with TRS).

Activities performed by the Stakeholders and Communication division are organised in 3 domains: 1) Communication; 2) Public and Stakeholder Engagement; and 3) Transparency. More details on these activities are provided in the following subsections.

Communication activities

The Agency's communication activities aim to support the Agency's 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.

The Division is responsible for the maintenance of the corporate website's content, features and functionalities, as well as overseeing and guiding the design, development and content of other websites that EMA maintains for the benefit of their users and the European public at large.

Through its information Centre, S-Division also provides the knowledge resources needed to support the work of the Agency's 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.

Public and stakeholder engagement

EMA maintains an EU wide network of stakeholder organisations. It is continuously expanding this network, in order to allow enhanced interaction and dialogue with patients, consumers, healthcare professional organisations and industry associations, with the ultimate goal of 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.

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 recently established an Industry Standing Group.

Transparency

The Agency places high importance on the transparency, openness, and efficiency of its interactions its 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.

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.

In case of a crisis, including any public health emergency, S Division will ensure day-to-day coordination of the overall Agency's overall response to it, so that actions required in the context of the crisis event are carried out in an efficient and coordinated manner.

S Division will continue its activities to support the streamlining, harmonisation and rationalisation of processes in response to crises and incidents, in particular though organising necessary training and through coordinating implementation of EMA's Overarching Crisis Preparedness and Response Framework throughout the Agency. With a view to reinforcing the effective communication within EMA and Network to communicate effectively during a crisis, EMA will also continue the review and improvement of the crisis communication processes in close cooperation with the Network, building on the lessons learnt from COVID-19 and other past crises.

The workforce available in 2025 for the Division is currently foreseen at 87 staff (58 TAs, 25 CAs, 4 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Communication activities	Number of EPAR summaries and EPAR summaries updates published	173	170	170	180
	Number of documents published on EMA website	6,611	7,500	7,500	7,500
	Number of pages published and updated on EMA website	5,105	3,500	3,500	3,500
	Number of press releases and news items published	124	120	120	120
	Numbers of press and other external briefings conducted[18]	n/a	6	5	5
	Numbers of social media posts published	1,016	650	650	650
	Number of completed interviews[18]	n/a	20	20	20
	Number of media queries responded[18]	n/a	1,000	1,200	1,200
	Number of reports, brochures, leaflets laid out or printed, social media visuals	586	1,000	1,200	1,200
Public and stakeholder engagement	Number of professional membership organisation events attended by participating Agency staff	28	25	25	25
	Number of sessions with Agency representatives	168	150	150	150
	Number of patients and consumers eligible organisations[18]	n/a	41	41	41

[18] New indicators introduced in the 2024 work programme.

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
	Number of healthcare professionals eligible organisations[18]	n/a	41	41	41
	Active patients expert nominated by EMA[18]	n/a	180	180	180
	Active healthcare professionals experts nominated by EMA[18]	n/a	81	80	80
	Number of messages circulated via 'Early Notification System'	616	500	500	500
	Number of EMA communications pro-actively sent to stakeholders	225	200	200	200
Transparency	Access to documents, requests received	709	650	750	750
	Access to documents, documents released	1,037	1,500	2,000	2,000
	Requests for information received	6,965	7,500	8,000	8,000
	Clinical Data Publication (CDP), Procedures published	41	80	120	120
	Clinical Data Publication (CDP), Documents published	714	5,600	10,000	10,000

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Communication activities	Average rating of pages on corporate website during the year	3.8	3.7	3.8	3.9
Public and stakeholder engagement	Satisfaction level of patient and consumer organisations[19]	100.00%	n/a	80%	n/a
	Satisfaction level of Healthcare Professionals organisations[19]	88.00%	n/a	80%	n/a
Transparency	Triage of incoming requests received via AskEMA within set timelines[20]	99.30%	100%	100%	100%
	Responses to ATD within set timelines	93.00%	90%	90%	90%
	Responses to RFI within set timelines (for EMA)	83.00%	95%	95%	95%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	76.00%	75%	75%	75%
	Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"	n/a	80%	n/a	80%

[19] Survey carried out every 2 years.
[20] 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.

Pillar 2 – Public health activities

In addition to the above Stakeholders and Communication Division plans to undertake and progress the following additional activities:

MAWP Strategic Goal (EC policy/action	Action	Expected result	Timeframe		Performance indicator
			Start	End	
	Manage and further develop EMA's social media activities	Expand outreach to broader targeted audience	Continuous	Continuous	Implementation of EMA's social media strategy
	Planning of communication activities and campaigns in key topic areas in the annually determined strategic business priority areas	Maximise public health impact of communication	2025	Continuous	Timely delivery and implementation of communication campaigns media survey ran and results analysed
	Development of a European medicines web portal	High-quality product meeting both user and business needs, containing information on all medicines authorised in the European Union	2024	2028	Satisfaction among main users
	Finalise strategy and implement phase 2 of the CDP re-launch beyond COVID-19	Increased transparency by providing access to clinical documents supporting EMA decisions on CAPs	2024	2025	Finalise approach for CDP in consultation with relevant stakeholders
	ePI: electronic product information for EU medicines	Generation of all tools and guidance needed for: -Updates to tools and processes based on pilot outcome -Implementation of ePI into business for CAPs and potentially some NAPs -Initiation of phased implementation across member states	2021	2026	Achievement of deliverables defined in the project management documentation

MAWP Strategic Goal (EC policy/action	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		-Readiness for revision of the pharmaceutical legislation			
	Contribute to the implementation of EMANS (European Medicines Agencies Network Strategy) and RSS (Regulatory Science Strategy) ensuring that the views of stakeholders are brought into the process	Implementation of strategic plan for stakeholder engagement Support monitoring of implementation, reporting, and review and update of EMANS to 2028	2021	2025	Strategic plan for stakeholder engagement being implemented and continuously updated Mid-term reporting of EMANS strategy to 2025 published Delivery of updated EMANS for 2026-2028
	Implementation of scientific publication strategy	Maximise public health impact of communication	2024	2026	Timely delivery of scientific publications in key topic areas
	Collaboration with EC (Sante & HERA)/ECDC and HCIN, to share information and update on communication plans	Aligned and streamlined approach to communication across EU	2022	2026	Regular (weekly) planning meetings with communication counterparts Further development and update of EVIP
	Work with Working Group of Communication Professionals (WGCP) to agree communication plans and appoint joint leads with EMA, as appropriate	Tailored communication at national level supported by strong co-ordination at EU level	2024	2025	Joint communication plan with WGCP
	Develop a more proactive approach to countering misinformation	Better and earlier awareness of mis- and/or disinformation, enabling	2024	2026	EMA Framework for handling mis/disinformation

MAWP Strategic Goal (EC policy/action	Action	Expected result	Timeframe Start	End	Performance indicator
		tailored counter-information/transparency			Work on Vaccine Outreach Strategy reinitiated
	Ensure day-to-day coordination of the overall Agency's response to ongoing crises, including public health emergencies	Ensure that actions required in the context of ongoing crisis events are taken in an efficient and coordinated manner	2024	2026	Training on crisis framework delivered, scenario planning for testing EMAs response
	Review and improve crisis communication processes based on lessons learnt from COVID-19	EMA's ability to communicate effectively during a crisis is reinforced	2023	2026	Development of a joint EMA/HMA crisis communication approach and adopt the crisis communication plan 2024-2026

6. Information Management Division

During 2025, the Information Management Division will undertake several initiatives to simplify and streamline how scientific and regulatory knowledge is provided to the European Medicines Regulatory Network and its stakeholders through the advancement (and where possible acceleration) of the work being done on key systems e.g. Product Management Service, Union Product Database, and IRIS.

A key focus will be expanding the security posture of EMA's technology landscape to protect EMA and the network against security threats. This includes the modernisation of high-risk legacy systems and their transition to a secure, data protection compliant cloud-native enterprise architecture.

The Division will ensure the smooth transitioning to a new IT framework contract (ACDC -Agile capabilities delivery contract). This contract emphasises agile delivery principles, high-quality standards, and supports the implementation of EMA's Technology Capability Investment Plan (TCIP). Another significant activity will be the refresh and publication of the TCIP 2025-2028, which outlines the strategic direction for IM delivery for the next three years. The TCIP will guide the Enterprise Architecture Board in making recommendations on technology selection, technology adoption, and target enterprise architecture. In support of the data strategy implementation, the Information Management Division will drive the development of a data architecture in collaboration with key stakeholders.

To comply with the EU Interoperability Framework and enable a connected, interoperable medicines regulatory platform for the Network, the Information Management Division will continue to implement best practices, such as interoperability-by-design principles, for all new solutions. In addition, an application programming interface (API) portal will be developed as a one-stop-shop for all EMA data services. The Division is working with the Network to establish a well-defined API change and release management process.

In collaboration with other divisions and task forces, the Information Management Division will leverage AI-powered solutions while ensuring compliance with EMA's information security, data protection, and records management principles. Similarly, with the use of cloud computing resources (FinOps), the Division will continuously drive efficiencies in the overall software development lifecycle, as well as transparency over operational efforts and costs.

The Information Management Division will continue its collaboration with key stakeholders including the Network ICT Advisory Committee (NICTAC), the NCA IT Directors and Experts community and the Network Data Steering Group (NDSG). NICTAC will meet six times in 2025, with two meetings held face-to-face. In addition, two NCA IT Directors meetings will be hosted by the Polish and Danish EU Presidencies.

Finally, the Division will continue the collaboration with EU health policy agencies (ECHA, EFSA, ECDC) and provide support in the organisation of the next Inter-Agency Technology Innovation Workshop, building on the success of the first edition organised in April 2024. This initiative provides a platform for sharing experiences, best practices, and exploring opportunities for collaboration on topics of common interest such as interoperability, artificial intelligence and technology innovation.

The workforce available in 2025 for the Division is currently foreseen at 100 staff (76 TAs, 24 CAs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Network Portfolio	Number of information services/IT systems provided by EMA	28	28	33	33

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Network Portfolio	Availability of EMA IT systems	99.96%	98%	98%	98%
	Satisfaction of EMA internal and external users	94.70%	80%	80%	80%

Business Services

- The Information Management delivery and maintenance of information systems is customer-focused, agile, integrated, and innovative, to serve our stakeholders with the right information management tools, technologies, and services to facilitate the delivery of quality medicines to the public.
- **Customer Advocacy and Delivery Services** builds client relationships and manages business demand from stakeholder groups for IT services. We ensure that the potential business value of the services is captured, optimised and recognised. We also make sure that business strategies fully leverage IT capabilities. A key focus is to align requirements to common capabilities, instead of implementing in silos. Focus on domain expertise and solution architecture and addressing customers' needs holistically.
- **Strategic Platform Services** respond to demand for IT, evaluate and propose technology options and opportunities, drive innovation, and focus on consistency, integration, and optimising technology. We oversee the development and maintenance of core IT platforms and partners with a network of external IT integrators to deliver best-in-class services and solutions. Focus on application and platform architecture of sustainable platforms and meeting customer needs at the operational level.
- **Core Services** focuses on providing foundational and infrastructure services and high-productivity collaboration tools. We lead the way to the cloud, provide state-of-the-art collaboration and communication tools, and manage the core regulatory data for the Network.
- **Office of the CIO** provides services to ensure the efficient delivery and maintenance of information-management systems, through proper planning and strong partnerships across the Agency and the European medicines regulatory network. CIO is responsible for the operational and strategic management of IT services and comprises sourcing, planning, governance and assurance, stakeholder engagement, cross-Agency collaboration and communications, records management, and enterprise IT architecture, supporting strategic planning, road mapping, and application portfolio optimisation.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
2.1 (ECP 1 *A new plan for Europe*)	Centralising Data Standards	Enable semantic interoperability and exchange of data through the use of standards, terminologies and master data across EMRN and stakeholders	2023	2028	Contribution and leadership in international standardisation activities
2.2 (ECP 1 *A new plan for Europe*)	Develop and maintain EMA and EMRN Enterprise Architectures	Business-driven and strategic Enterprise Architecture supporting implementation of the legislative	2025	2028	Successful implementation of key legislations. Protecting the Agency and Network against

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
		priorities, security and technology landscape modernisation, data-driven initiatives, and ensuring operational efficiency of the Network			cybersecurity and business continuity threats and issues. Safe deployment of AI-technologies.
2.4	Records management	Ensuring the efficient and systematic control of all EMA records throughout their entire life cycle, regardless of format, location, or hosting system, while maintaining regulatory compliance, operational efficiency, and the preservation of institutional memory	2024	2028	Successfully implementing a network of Records Management Coordinators Approving the new Records Management and Archives policy and related procedures, including retention list, filing plan, records disposition, identification and transfer of historical records, disaster recovery plan, etc. Supporting the implementation of records management capabilities for the new records management system, SharePoint and other technological platforms across the agency.
2.4	Cybersecurity and Security Operation Centre	Enhancement of the EMA cyber security posture	Continuous	Continuous	Include newly introduced systems in the monitoring perimeter. Adapt monitoring

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
		Efficient monitoring of Agency's perimeter and systems Fast adaptation on mitigating the risks stemming from the continuously changing threat landscape			rules to be able to better identify attacks
2.1 (ECP 1 *A new plan for Europe*)	Data Management Services Data Stewardship Data Quality services Data related customer service Data Governance Activities	EMA stakeholders have data registered in time and as needed to support their regulatory processes and qualified data that can be reliably used for decision making EMA stakeholders and users are informed and their questions in relation to data are answered Effective and Efficient Managing of enterprise/network data	Continuous	Continuous	Number of tasks processed (CRs, ETLs, validation), SLA compliance -yearly KPI reports Quality of service & DQ incidents reported yearly KPI reports Number of data related services provided, SLA compliance - yearly KPI reports
2.2 (ECP 1 *A new plan for Europe*)	Administration of Cloud services	Effective and efficient Delivery and Acceleration of Cloud Services EMA stakeholders get reliable and continuous access to the Cloud services Allow EMA to further transform its business and way of working in support	Continuous	Continuous	•Modernisation of EMA's IT landscape, offering the ability to enable cloud-based features to facilitate innovation Increased operational efficiency at scale to save money and foster innovation

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
		of its mission towards public and animal health in the EU			Performance improvement through increased elasticity and availability of computing resources Maximise the business value of cloud, paving the way to timely data-driven decision making Empower cloud consumers or cloud teams to make best-in-class decisions, promoting cost optimisation awareness
2.2 (ECP 1 *A new plan for Europe*)	Administration of digital productivity and collaboration services – Service Desk	Quicker and more effective fulfilment of EMA services to its stakeholders Service desk as operational excellence (SLAs, customer satisfaction) - provide high quality end user services			Increase the efficiency of customer-related response time across the end-user omni channel
II - Public health activities	CTIS	Stakeholders (Public, Sponsors and National Competent Authorities) can use the CTIS for their intended purpose in line with the Clinical Trials Regulation	Continuous	Continuous	System Availability % of availability during business hours Performance of the system
2.2 (ECP 1 *A new plan for Europe*)	Driving the communication with I-Div stakeholders [external]: Inter-agency collaboration and NCA IT	Foster positive relationship with the Network (NCAs and EU agencies) through regular engagement and communication to facilitate	Continuous	Continuous	Meeting at a regular cadence and providing input

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
	Directors stakeholder engagement and NICTAC secretariat	collaboration and knowledge sharing on different subjects e.g. information security, interoperability, sharing and reuse			
II - Strategies (EMANS and RSS)	Maintenance and optimisation of existing platforms	Ensure platforms are performant, stable and resulting in fewer incidents	Continuous	Continuous	Number of P1 user satisfaction
II - Strategies (EMANS and RSS)	Promotion of IT value	Enhanced stakeholder understanding and advocacy for IT's role in driving business performance, optimizing regulatory processes, and supporting the strategic goals	Continuous	Continuous	Increase in stakeholder engagement measured through perception surveys
II - Strategies (EMANS and RSS)	IT Demand management	All IT demand coming from both Portfolio and Operations activities is appropriately captured, recorded and priorities, and EMA stakeholders have an overview of the demand	Continuous	Continuous	Number of IT items requested that were effectively analysed and systematically classified and prioritised Portfolio KPIs

7. Administration Division

The Administration and Corporate Management Division is responsible for managing revenue, expenditure, and accounts, according to existing rules and regulations; for recruiting, managing, and administering staff and seconded personnel, as well as for a range of governance activities to ensure effective functioning of the Agency.

The Division and its Departments cooperate closely with the European Parliament and the Council (Budgetary Authority), as well as the Commission and the Court of Auditors, on matters relating to administration, budget, personnel, rules and regulations on finances, audit and accounting.

The key drivers for the Annual work programme are:

- the endorsed HR strategy, covering areas of sustainability of the Agency, talent management and staff wellbeing.
- the new fee regulation which enters into force in January 2025. The implementation included the redesign of fee-related processes and the update of relevant IT tools;
- several administrative IT systems will have to be replaced with new systems due to the developments in the information technology market and strategy of service providers. In parallel, the technology market offers new opportunities in the talent management, financial, procurement, transactional and other domains. The division will contribute to the implementation of the relevant epics included in the value streams. The work will entail reviewing and changing processes in conjunction with replacing systems;
- the Division will continue to implement initiatives aimed at improving the quality of corporate data and look for ways to facilitate generation of information and analysis based on such data;
- efficiently and effectively filling the positions granted by the budgetary authority for the new pharmaceutical legislation;
- supporting the organisation in relation to the former premises in London following the Brexit process and the relocation of the Agency.

The workforce available in 2025 for the Division is currently foreseen at 154 staff (120 TAs, 29 CAs, 4 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Workload indicators

		Results	Expected results	Forecasts	
		2023	2024	2025	2026
Human Resources	Total TA staff recruited against vacant posts	35	50	50	50
	Staff turnover rate (staff leaving against total no. of staff TA & CA)	4.10%	3%	4%	5%
	Total TA, CA, END at the Agency	928	950	950	950
	Onboarding of staff (TAs, CAs, ENDs)	121	75	75	75
Finance	Financial transactions authorised (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing)	n/a	72,000	67,000	67,000
	Procurement procedures finalised	43	46	46	46
	Financial commitments initiated	1,575	1,500	1,200	1,200
	Payment transactions initiated	35,403	38,426	41,116	43,172
	Number of sales orders	34,500	50,000	45,000	45,000
	Number of registration activities	13,200	14,000	14,000	14,000
	PRE financial queries and disputes	300	250	500	500
	Receivable overdue for more than 30 days (including provision for bad debts)	4.15%	<10%	<10%	<10%

Performance indicators

		Results	Expected results	Targets	
		2023	2024	2025	2026
Human Resources	Posts on the Agency establishment plan filled	97.00%	100%	99%	99%
	Average time to run selection procedures from the publication of the vacancy notice to establishment of reserve list	36% <= 3 months, average 3.5 months	100% average < 3 months	3 months	3 months
Planning and Monitoring	Revenue appropriations implemented	97.82%	97%	97%	97%
Finance	Expenditure appropriations implemented	99.00%	95%	95%	95%
	Payments against appropriations carried over from year N-1	95.16%	95%	95%	95%
	The maximum rate of carryover to year N+1, of total commitments within the title				
	Title 1	4.89%	10%	10%	10%
	Title 2	24.86%	20%	20%	20%
	Title 3	32.59%	30%	30%	30%
	Payments within the regulation time limits	98.03%	98%	97%	97%
	Value of the budget for the given year	341	405	405	405

Business Services

The area of administration and corporate management covers the general functions and activities that are necessary to ensure the Agency's continuous operations that are not business specific. The Administration Division's business services include the following:

Planning and monitoring: These activities encompass the corporate planning cycle, including the planning processes (strategy, Annual work programmes and budget) and the subsequent monitoring and reporting activities.

Human resources: Human resources deal with all staff-related matters, including developing and maintaining HR strategy and policies, conducting recruitment and procurement, managing personnel administration and payments, running a traineeship programme, managing staff declarations of interests, providing training opportunities as well as staff and career development frameworks, and dealing with staff complaints and appeals.

Finance: Finance refers to financial support, implementation of the budget, maintenance of the accounts, payment management and collection of revenue, management of cash resources, exante verification of transactions, as well as procurement and contract management support.

Quality- and risk-management and internal-control coordination: Quality management includes both the integrated quality-management activities and risk-management activities within the Agency. A risk review is conducted annually, with risks being assessed at a residual level, i.e. taking into account controls and mitigations already in place. Conducting self-assessments (as part of the EU Agencies benchmarking programme), annual reviews of sensitive functions and ex post controls also fall within this area, as does maintaining a register of exceptions.

Infrastructure services: These cover activities related to the Agency's premises and office accommodation, security, business continuity, health and safety, reception and switchboard, mail management, reprographics, and off-site archives, as well as catering. The service also contributes to the environmental management activities of the Agency.

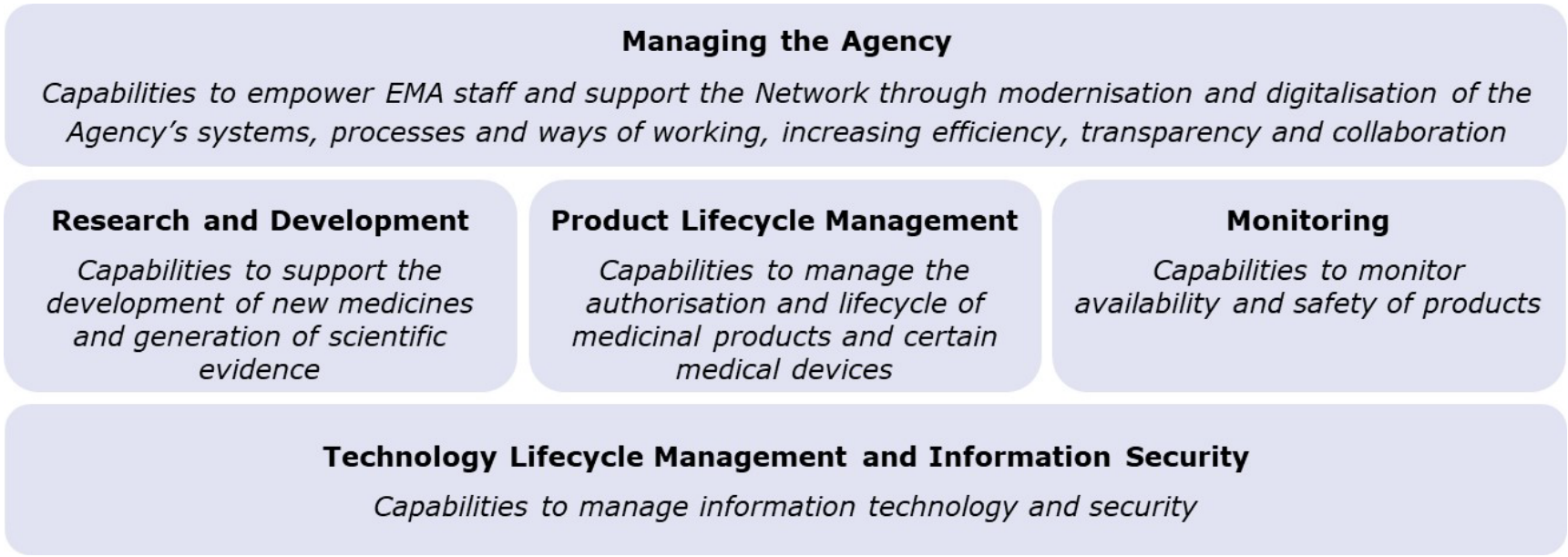
In addition to the above, the Administration Division plans to undertake and progress the following strategic activities:

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
6.2	Implementation of the HR strategy & priorities 2023-2025	The following improvements are expected by strategic ambition: Sustainable organisation will see improvement in resources	2023	2025	Agile approach to delivery of products/ambitions prioritised for 2025: 1. Sustainable organisation: Improved resource planning & allocation through strategic resource planning, and the piloting and review of the resource allocation framework

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		and competencies needed versus actually available Talent management will see further improvements in career development tools provided by the Agency Optimised work environment will translate into an increased net promoter score Wellbeing activities will further improve staff wellbeing Staff and managers will show improved satisfaction with HR services			2. Talent management: Development paths for future leaders, pilot talent review process, apply the exchange & rotation programme (which includes job shadowing, secondments and fellowships) 3. Wellbeing: Renewed social and employee assistance 4. One Agile HR: HR Processes review and improvement; ; gradual implementation of the Employee Central system replacing the current HR tool; updating data management processes and systems supporting data analysis 5. Implementation of the gender equality plan 6. Lead and support the HR strategy community within the network of EU agencies
6.4	HQ efficiency	Environmental matters, campaigns, data collection, data analysis, reporting, improvement identification, action implementation	Continuous	Continuous	Environmental and Energy efficiency Legal compliance to maintain relevant credentials
	Historical Archives - EMA 30th Anniversary	EMA Historical Archives identified and available at EUI from January 2025 at the anniversary of the Agency	2022	2025	EMA Historical Archives identified and available at EUI from January 2025 at the anniversary of the Agency

8. Pillar III Network Portfolio

The Agency's Network Portfolio is organised under five Value Streams. These reflect the fundamental purpose of the organisation and 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.). Value streams help organise the portfolio into sub-portfolios that do not have to compete with each other, and that support long-term strategic goals of the Agency. Value streams are stable and long-lived, with fixed budget, leadership, resources and capacity:



To support the Agency's work and achievement of set objectives, several Agile initiatives are undertaken. The table below details the main products and deliverables (epics) currently planned for 2025, to be reviewed during quarterly Planning Interval ceremonies. The planned deliverables for 2026 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 2026, based on the progress made in 2025.

Note 1: The budget figures for 2025 show the total estimated cost, including internal and external costs for the Value Stream. Budget allocation to products within the Value Stream is reviewed regularly during the year.

Note 2: Necessary maintenance and improvements to newly developed systems are foreseen, even when not specifically listed as a deliverable.
Note 3: End date column indicates the year when the product development is expected to end, after which the product enters maintenance phase.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Budget 2025 (M€)
Product Lifecycle Management Value Stream (PLM VS)					**13.6**
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	2027	Enable industry, through an application programming interface (API), to enrich PMS with ISO-IDMP compliant medicinal product data needed for ESMP go-live Enable industry, through an API, to enrich PMS with ISO-IDMP compliant medicinal product data beyond the data fields needed for ESMP go-live Enable read access to PMS to the public through an API Perform analysis for a roadmap to replace and decommission the Art. 57/XEVMPD	
Product Data Management User Interface *(part of the Product Lifecycle Management Portal)*		2023	2025	Enable industry, through the Product User Interface (PUI), to enrich medicinal product data in PMS needed for ESMP go-live Enable industry, through the PUI, to enrich medicinal product data in PMS beyond the data fields needed for ESMP go-live	
Electronic Application Form (eAF) *(part of the Product Lifecycle Management Portal)*		2021	2026	Go-live for eAF for human variations for non-CAPs Maintenance of the eAF for human variations for CAPs and non-CAPs	
Veterinary Union Product Database (UPD)	Regulation (EU) 2019/6; associated implementing act	2021		UPD maintenance and improvements, i.e. enhance functionalities, usability and user experience for NCA and Industry.	
Regulatory Procedure Management (RPM) for PLM *(part of the IRIS portal)*		2022	2027	Go-live for the management of post-authorisation procedures (H & V) in IRIS and implementation of the New Fee Regulation Develop capability for procedure management of initial marketing authorisation applications (H & V) (+ Medicines for All & ancillary substances) in IRIS	
Electronic Product Information (ePI) *(part of the Product Lifecycle Management Portal)*		2022	2026	Implementation of features following findings from ePI pilot Development of functionalities that are essential for go-live	
eCTD4 (eSubmissions incl. EURS/CR)		2021	2026	Completion of eCTD v4.0 specification and implementation guide update for the Europe (EU) region	

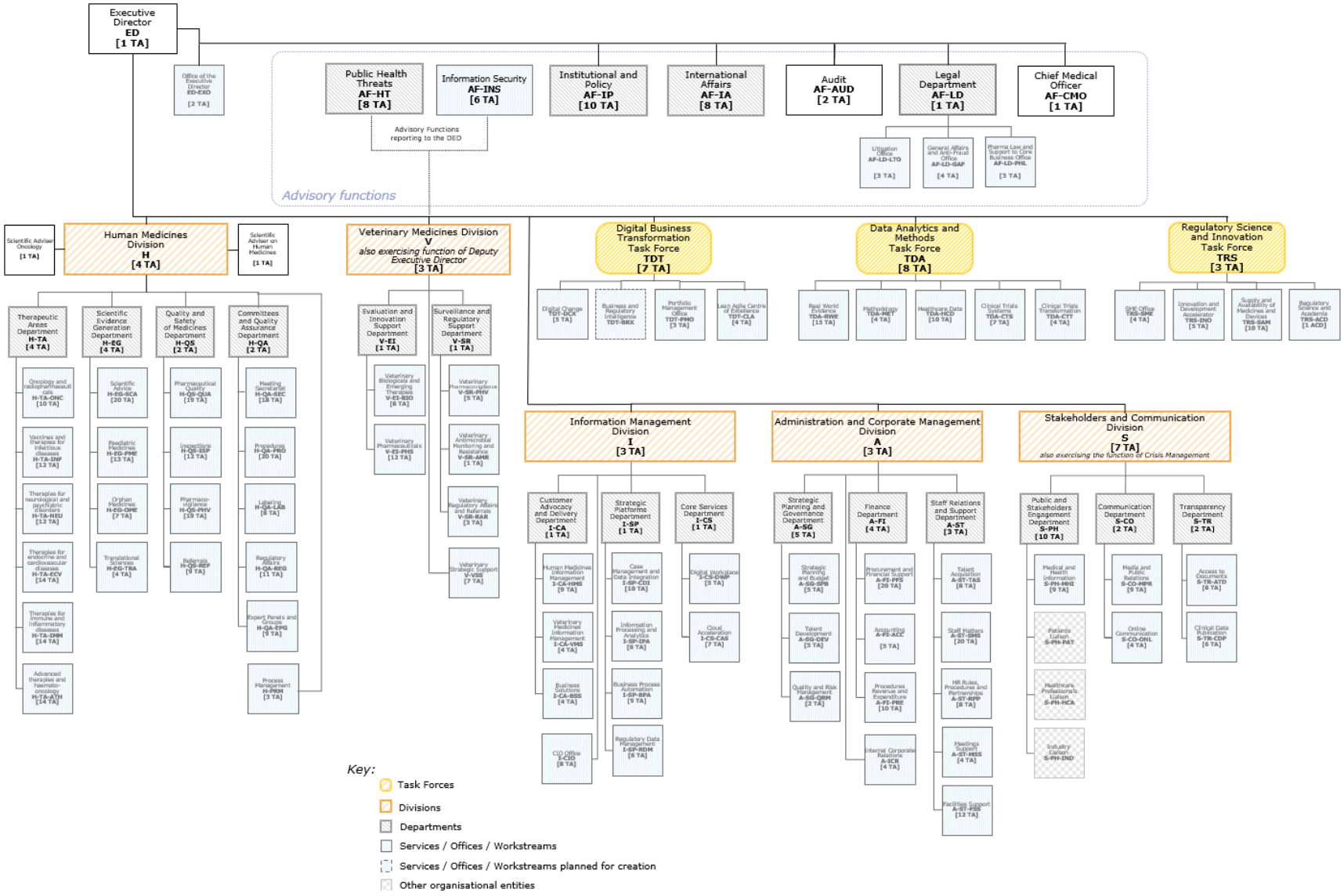
Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Budget 2025 (M€)
				Progression towards pilot and optional use support of eCTD v4.0 submissions for centrally authorised products	
European Medicines Web Portal (EMWP)	Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, Article 26(1)	2024	2027	Perform user research and initial UX design to support the design and future development of EMWP	
Research and Development Management Value Stream (R&D VS) *Capabilities to foster the development of medicines and generate scientific evidence*					**13.6**
Regulatory Procedure Management (RPM) for R&D *(part of the IRIS portal)*		2023	2026	Pre-authorisation processes onboarding onto IRIS	
Clinical Trials Information System (CTIS)	– Regulation (EC) 536/2014, art.80-82	2014	tbc	CTIS maintenance and continuous improvements, further improve stability, usability and user satisfaction CTIS Public Portal maintenance and improvements Continue the simplification principles of CTIS functionalities in preparedness for CTIS modernisation in 2025 and beyond Deliver new epics based on business value to enable CTIS modernisation over time CTIS Business Intelligence (CTIS BI) maintenance, improvement and further development to ensure alignment with CTIS improvement activities	
Scientific Explorer		2020	2025	Scientific Explorer II to expand capabilities of Scientific Explorer I to bridge evidence generation and evaluation support	
Knowledge Mining		2025	2025	Develop knowledge mining and AI capabilities for EMA and the Network (custom products)	
Monitoring Value Stream (MON VS) *Capabilities to monitor availability and safety of products*					**4.7**
European Shortages Monitoring Platform (ESMP)	Regulation (EU) 2022/123	2022	2025	ESMP minimum viable product (MVP) go-live in February 2025 allowing the entry into force of the regulation Maintenance and improvements to MVP	

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Budget 2025 (M€)
Regulatory Procedure Management (RPM) for Monitoring *(part of the IRIS portal)*		2023	2025	Maintenance and improvements on inspections and parallel distribution, including New Fee Regulation (NFR)	
Union Pharmacovigilance Database (UPhD, formerly EVVet3)	Regulation (EC) 726/2004, art.57(d) Regulation (EU) 2019/6; associated implementing acts	2017	2024	Product development completed in 2024, maintenance to continue in 2025 ESVAC decommissioning	
Antimicrobial Sales & Use (ASU)	Article 57 of Reg (EU) 2019/6, Commission Delegated Act 2021/578 Commission Implementing act 2022/209	2021	2024	Product development completed in 2024, maintenance to continue in 2025	
Managing the Agency Value Stream (MTA VS) *Capabilities to empower EMA staff and support the Network through modernisation and digitalization of the Agency's systems, processes and ways of working, increasing efficiency, transparency and collaboration*					**5.0**
SAP Finance replacement		2023	2026	Finalise Analysis and technology selection	
SAP HR replacement		2023	2025	SAP HR Core replacement	
New Fee Regulation	Regulation (EU) 2024/568 on fees and charges payable to the European Medicines Agency	2023	2025	Go-live in January 2025 Integration of latest regulatory processes with the new fee system	
Document Management System replacement		2023	2025	Implementation of document management system replacement	
AskEMA replacement		2024	2025	AskEMA replacement implementation	
Anonymisation@EMA		2025	2025	Enable automated anonymisation of commercially confidential information (CCI) in large sets of documents	
Customer Relationship Management (CRM) tool		2025	2026	Start analysis and technology selection	
Workplace Experience		2024	2027	Finalise analysis and technology selection	

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2025	Budget 2025 (M€)
Technology Lifecycle Management and Information Security Value Stream (TLM VS) *Capabilities to manage information technology and security*					**3.0**
Information Security and Cyber Security enhancements		2022	2025	Cyber & Information Security enhancements Operational Security enhancements Application Security enhancements	
Legacy application modernisation		2023	2025	Horizon 25 Modernisation Factory: move the legacy applications that are running on outdated technologies into a modern, stable and secure environment (“re-platforming”)	

Annexes

Annex I Organisational Chart



Annex II Resource allocation per activity 2025

Activity-based budget 2025

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	**279**	**102**	**73,131**	**42,351**	**5,357**	**215,291**	**8,872**	**345,002**	**59%**
1.1 Pre-authorisation activities	69	23	18,691	11,051	3,270	36,366	379	69,758	12%
1.2 Initial evaluation activities	53	12	13,099	3,435	11	52,607	1,156	70,308	12%
1.3 Post-authorisation activities	76	26	17,767	16,144	-	107,364	2,696	143,971	25%
1.4 Referrals	7	2	1,783	537	10	212	170	2,712	0%
1.5 Pharmacovigilance activities	46	22	12,699	8,542	1,395	18,304	4,137	45,078	8%
1.6 Other specialized areas and activities	23	17	7,885	1,987	670	-	2	10,545	2%
1.7 Medical Devices	5	2	1,206	654	-	440	332	2,632	0%
2 Evaluation activities for veterinary medicines	**30**	**14**	**7,433**	**4,801**	**275**	**17,234**	**595**	**30,337**	**5%**
2.1 Pre-authorisation activities	2	0	357	215	34	500	7	1,113	0%
2.2 Initial evaluation activities	9	3	2,217	665	28	2,648	147	5,705	1%
2.3 Post-authorisation activities	9	3	1,935	1,702	-	2,354	268	6,259	1%
2.4 Arbitrations and Referrals	0	0	126	50	-	116	112	405	0%
2.5 Pharmacovigilance activities	3	3	1,189	1,750	186	11,615	60	14,800	3%
2.6 Other specialized areas and activities	6	3	1,609	419	27	-	-	2,055	0%
3 Horizontal activities and other areas	**237**	**100**	**67,626**	**48,955**	**9,835**	**15,706**	**22,325**	**164,446**	**28%**
3.1 Committee coordination	61	28	17,117	6,244	4,274	-	1,209	28,844	5%
3.2 Inspection and Compliance	24	17	7,072	4,124	953	15,706	104	27,959	5%
3.3 Partners and Stakeholders	45	16	13,706	3,184	1,767	-	838	19,496	3%
3.3a Transparency and access to documents	16	9	4,390	1,671	-	-	800	6,861	1%
3.3b Information	42	21	11,689	13,622	667	-	219	26,197	4%
3.4 International activities	19	2	5,217	1,094	1,747	-	-	8,059	1%
3.5 Information Management (incl. data and scientific studies)	31	8	8,434	19,015	426	-	19,155	47,031	8%
4 Corporate Governance and Support activities	**151**	**32**	**34,938**	**11,218**	**521**	**-**	**10**	**46,687**	**8%**
4.1 Governance, quality management and internal audit	22	4	6,390	2,529	521	-	4	9,444	2%
4.2 Finance	30	11	7,117	2,343	-	-	7	9,466	2%
4.3 Information technology	36	6	9,324	2,207	-	-	-	11,531	2%
4.4 Human resources	50	9	9,831	3,483	-	-	-	13,314	2%
4.5 Infrastructure services	12	1	2,276	656	-	-	-	2,932	0%
Total	**697**	**248**	**183,127**	**107,325**	**15,987**	**248,231**	**31,802**	**586,472**	**100%**

FTEs are calculated as follows:	FTEs
Temporary Agents	704
Vacancy	7
Total Temp	697
Contract Agents	203
Seconded National Experts	45
Total Staff	**945**

Rent London premises (funded by EU contribution)	**13,758**
Budget 2025	**600,230**

Annex III Financial Resources 2025 – 2027

Table 1 – Revenue

General Revenues

Revenues	2024	2025	2026	2027
	Revenue estimated by the agency	Budget forecast	Budget forecast	Budget forecast
EU contribution	€ 46,283,191	€ 48,914,000	€ 50,373,000	€ 51,395,000
Other revenue	€ 445,844,593	€ 551,316,000	€ 559,401,000	€ 570,589,000
PROVISIONAL REVENUE				
Total revenue	**€ 492,127,784**	**€ 600,230,000**	**€ 609,774,000**	**€ 621,984,000**

REVENUES	General Revenues		General Revenues						
	Executed 2023[1]	Estimated by the agency 2024[2]	2025		VAR 2025/2024 (%)	2026		VAR 2026/2025 (%)	forecast 2027
			agency request	budget forecast		agency request	budget forecast		
1 Revenue from services rendered	€ 387,090,034	€ 441,834,526.90	€ 549,320,000	€ 549,320,000	24.33%	€ 557,393,000	€ 557,393,000	1.47%	€ 568,541,000
2 EU and EEA contribution	€ 50,136,561	€ 46,283,191.14	€ 48,914,000	€ 48,914,000	5.68%	€ 50,373,000	€ 50,373,000	2.98%	€ 51,395,000
- of which special contribution for orphan medicinal products	€ 10,733,120	€ 12,899,760	€ 14,391,000	€ 14,391,000	11.56%	€ 15,596,000	€ 15,596,000	8.37%	€ 14,391,000
- of which assigned revenues deriving from previous years' surpluses	€ 24,982,178	€ 10,459,043.14	€ 21,000	€ 21,000	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	€ 1,359,529	€ 1,825,870.3	€ 1,803,000	€ 1,803,000	-1.25%	€ 1,803,000	€ 1,803,000	0.00%	€ 1,839,000
- 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	€ 225,152	€ 2,184,195.39	€ 193,000	€ 193,000	n/a	€ 205,000	€ 205,000	p.m.	€ 209,000
TOTAL REVENUES	**€ 438,811,276**	**€ 492,127,783.68**	**€ 600,230,000**	**€ 600,230,000**	21.97%	**€ 609,774,000**	**€ 609,774,000**	1.59%	**€ 621,984,000**

1) Data as per final 2023 accounts.
2) Data updated in accordance with the provisional outturn.

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

REVENUES	2024	2025	2026	2027
	Budget forecast	Budget forecast	Budget forecast	Budget forecast
TOTAL REVENUES	p.m.	p.m.	p.m.	p.m.

REVENUES	General Revenues	General Revenues								
	Executed 2023[1]	Estimated by the agency[2] 2024	2025		VAR 2025/ 2024 (%)	Estimated by the agency 2025	2026		VAR 2026/2025 (%)	Forecast 2027
			Agency request	Budget forecast			Agency request	Budget forecast		
ADDITIONAL EU FUNDING STEMMING FROM GRANTS (FFR Art.7)	€ 634,895	€ 342,000	€ 342,000	p.m.	0.00%	p.m.	p.m.	p.m.	n/a	p.m
ADDITIONAL EU FUNDING STEMMING FROM CONTRIBUTION AGREEMENTS (FFR Art.7)	-	p.m.	p.m.	p.m.	*n/a*	p.m.	p.m.	p.m.	n/a	p.m.
ADDITIONAL EU FUNDING STEMMING FROM SERVICE LEVEL AGREEMENTS (FFR Art. 43.2)	-	p.m.	p.m.	p.m.	*n/a*	p.m.	p.m.	p.m.	n/a	p.m.
TOTAL	€ 634,895	€ 342,000	€ 342,000	€ 0	0%	€ 0	€ 0	€ 0	0%	€ 0

1) Data as per final accounts 2023
2) Data updated in accordance with the provisional outturn

Table 2 – Expenditure

Expenditure	2023[1]		2024		2025		2026		2027	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1 - Staff expenditure	€ 157,063,463	€ 157,063,463	€ 165,632,413	€ 165,632,413	€ 183,127,000	€ 183,127,000	€ 188,367,000	€ 188,367,000	€ 192,134,000	€ 192,134,000
Title 2 - Infrastructure and operating expenditure	€ 71,713,992	€ 71,713,992	€ 81,835,616	€ 92,067,000	€ 92,067,000	€ 92,067,000	€ 91,255,000	€ 91,255,000	€ 93,080,000	€ 93,080,000
Title 3 - Operational expenditure	€ 215,269,673	€ 215,269,673	€ 243,017,321	€ 243,017,321	€ 325,036,000	€ 325,036,000	€ 330,152,000	€ 330,152,000	€ 336,051,000	€ 336,051,000
Title 9 - Provisional appropriations			€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 444,047,128**	**€ 444,047,128**	**€ 490,485,351**	**€ 491,607,000**	**€ 600,230,000**	**€ 600,230,000**	**€ 609,774,000**	**€ 609,774,000**	**€ 621,265,000**	**€ 621,265,000**

1) Data as per final 2023 accounts

Expenditure	2023			2024			2025			2026			2027		
	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	€ 79,446,224	€ 77,617,239	€ 157,063,463	€ 102,193,599	€ 63,438,814	€ 165,632,413	€ 109,410,846	€ 73,716,154	€ 183,127,000	€ 144,491,925	€ 43,875,075	€ 188,367,000	€ 147,642,309	€ 44,831,691	€ 192,474,000
Title 2 - Infrastructure and operating expenditure	€ 31,872,109	€ 39,841,883	€ 71,713,992	€ 38,202,698	€ 30,507,918	€ 68,710,616	€ 45,090,206	€ 33,218,794	€ 78,309,000	€ 56,497,578	€ 21,255,422	€ 77,753,000	€ 58,668,493	€ 21,680,507	€ 80,349,000
Title 3 - Operational expenditure	€ 189,723,454	€ 25,546,218	€ 215,269,672	€ 223,669,425	€ 19,347,896	€ 243,017,321	€ 295,367,917	€ 29,668,083	€ 325,036,000	€ 253,251,886	€ 76,900,114	€ 330,152,000	€ 258,316,893	€ 78,438,107	€ 336,755,000
Title 9 - Provisional appropriations	€ 0		€ 0	€ 0		€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 301,041,787**	**€ 143,005,341**	**€ 444,047,128**	**€ 364,065,722**	**€ 113,294,628**	**€ 477,360,351**	**€ 449,868,969**	**€ 136,603,031**	**€ 586,472,000**	**€ 454,241,389**	**€ 142,030,611**	**€ 596,272,000**	**€ 464,627,695**	**€ 144,950,305**	**€ 609,578,000**
% of total expenditure	**68%**	**32%**	**100%**	**76%**	**24%**	**100%**	**77%**	**23%**	**100%**	**76%**	**24%**	**100%**	**76%**	**24%**	**100%**
Expenditure related to London premises (30 Churchill Place)						€ 13,125,000			€ 13,758,000			€ 13,502,000			€ 12,731,000
Total expenditure			**€ 444,047,128**			**€ 490,485,351**			**€ 600,230,000**			**€ 609,774,000**			**€ 622,309,000**
* Full-time Equivalent	498	411	**909**	507	432	**939**	582	370	**952**	626	358	**984**	631	361	**992**
% of total FTEs	55%	45%	**100%**	54%	46%	**100%**	61%	39%	**100%**	64%	36%	**100%**	64%	36%	**100%**

EXPENDITURE	Commitment appropriations								
	Executed budget 2023[1]	Estimated by the Agency, 2024[2]	Draft budget 2025		VAR 2025/2024 (%)	Preliminary draft budget 2026		VAR 2026/2025	Forecast 2027
			Agency request	Budget forecast		Agency request	Budget forecast		
Title 1 - Staff Expenditure									
11 Staff holding a post provided for in the list of posts	131,978,689	€ 140,476,516	€ 155,135,000	€ 155,135,000	17.28%	€ 160,264,000	€ 160,264,000	3.31%	€ 163,469,000
- of which establishment plan posts	*€ 110,626,417*	*€ 117,868,604*	*€ 131,168,000*	*€ 131,168,000*	*11.28%*	*€ 134,435,000*	*€ 134,435,000*	*2.49%*	*€ 137,408,669*
- of which external personnel	*€ 21,352,272*	*€ 22,607,911*	*€ 23,967,000*	*€ 23,967,000*	*6.01%*	*€ 25,829,000*	*€ 25,829,000*	*7.77%*	*€ 26,400,331*
12 Expenditure relating to staff recruitment	132,726	€ 95,928	€ 360,000	€ 360,000	20.00%	€ 375,000	€ 375,000	4.17%	€ 383,000
13 Duty travel expenses and incidental expenditure	903,948	€ 784,546	€ 1,150,000	€ 1,150,000	-24.84%	€ 1,150,000	€ 1,150,000	0.00%	€ 1,173,000
14 Socio-medical infrastructure	2,886,491	€ 3,494,147	€ 3,983,000	€ 3,983,000	10.52%	€ 4,216,000	€ 4,216,000	5.85%	€ 4,300,000
15 Staff training	1,064,662	€ 1,445,000	€ 1,445,000	€ 1,445,000	15.60%	€ 1,455,000	€ 1,455,000	0.69%	€ 1,484,000
16 External services	19,977,047	€ 19,579,447	€ 20,769,000	€ 20,769,000	6.79%	€ 20,708,000	€ 20,708,000	-0.29%	€ 21,122,000
17 Receptions and events	119,900	€ 142,000	€ 285,000	€ 285,000	150.00%	€ 199,000	€ 199,000	-30.18%	€ 203,000
Total Title 1	**€ 157,063,463**	**€ 165,632,413**	**€ 183,127,000**	**€ 183,127,000**	15.52%	**€ 188,367,000**	**€ 188,367,000**	**2.86%**	**€ 192,134,000**
Title 2 - Infrastructure and operating expenditure									
20 Investment in immovable property, renting of buildings and associated costs	17,363,332	€ 30,522,832	€ 32,622,000	€ 32,622,000	-2.50%	€ 32,498,000	€ 32,498,000	-0.38%	€ 33,148,000
21 Corporate information and communication technology	45,193,610	€ 43,591,156	€ 48,600,000	€ 48,600,000	10.09%	€ 48,062,000	€ 48,062,000	-1.11%	€ 49,023,000
22 Movable property and associated costs	635,874	€ 626,236	€ 754,000	€ 754,000	11.54%	€ 717,000	€ 717,000	-4.91%	€ 731,000
23 Current administrative expenditure	1,412,687	€ 1,642,998	€ 1,448,000	€ 1,448,000	-17.54%	€ 1,648,000	€ 1,648,000	13.81%	€ 1,681,000
24 Postal and delivery services	19,065	€ 19,800	€ 30,000	€ 30,000	-9.09%	€ 31,000	€ 31,000	3.33%	€ 32,000
25 Other meetings	90,691	€ 102,841	€ 109,000	€ 109,000	-10.66%	€ 128,000	€ 128,000	17.43%	€ 131,000
26 Restaurant and catering	2,028,975	€ 963,425	€ 1,724,000	€ 1,724,000	64.35%	€ 1,723,000	€ 1,723,000	-0.06%	€ 1,757,000
27 Information and publishing	1,700,226	€ 1,458,011	€ 2,454,000	€ 2,454,000	60.92%	€ 2,855,000	€ 2,855,000	16.34%	€ 2,912,000
28 Business consultancy and audit services	3,269,532	€ 2,908,317	€ 4,326,000	€ 4,326,000	49.59%	€ 3,593,000	€ 3,593,000	-16.94%	€ 3,665,000
Total Title 2	**€ 71,713,992**	**€ 81,835,616**	**€ 92,067,000**	**€ 92,067,000**	**7.48%**	**€ 91,255,000**	**€ 91,255,000**	**-0.88%**	**€ 93,080,000**
Title 3 - Operational expenditure									
300 Meetings	4,743,997	€ 4,952,000	€ 5,793,000	€ 5,793,000	2.57%	€ 5,908,000	€ 5,908,000	1.99%	€ 6,026,000
301 Evaluation of medicinal products	153,968,032	€ 177,099,498	€ 247,000,000	€ 247,000,000	42.46%	€ 250,501,000	€ 250,501,000	1.42%	€ 255,511,000

EXPENDITURE	Commitment appropriations								
	Executed budget 2023[1]	Estimated by the Agency, 2024[2]	Draft budget 2025		VAR 2025/2024 (%)	Preliminary draft budget 2026		VAR 2026/2025	Forecast 2027
			Agency request	Budget forecast		Agency request	Budget forecast		
302 Translations	4,201,264	€ 4,957,129	€ 4,602,000	€ 4,602,000	10.63%	€ 4,467,000	€ 4,467,000	-2.93%	€ 4,556,000
303 Scientific studies and services	12,176,253	€ 54,934,558	€ 28,431,000	€ 28,431,000	11.86%	€ 29,282,000	€ 29,282,000	2.99%	€ 29,868,000
31 Expenditure on business related IT projects	40,180,126	€ 1,073,955	€ 39,210,000	€ 39,210,000	1.00%	€ 39,994,000	€ 39,994,000	2.00%	€ 40,090,000
Total Title 3	**€ 215,269,673**	**€ 243,017,321**	**€ 325,036,000**	**€ 325,036,000**	**31.37%**	**€ 330,152,000**	**€ 330,152,000**	**1.57%**	**€ 336,051,000**
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	**€ 444,047,128**	**€ 490,485,351**	**€ 600,230,000**	**€ 600,230,000**	**22.10%**	**€ 609,774,000**	**€ 609,774,000**	**1.59%**	**€ 621,265,000**

1) Data as per final accounts 2023.
2) Update in accordance to the provisional outturn and includes under title 2 and 3 an amount of EUR 350 000 and 450 000 respectively, which will be carried forward non-automatically to 2025.

Table 3 – Budget outturn and cancellation of appropriations 2021-2024

Budget outturn	2021	2022	2023[1)]	2024[2)]
Revenue actually received (+)	€ 407,602,229.94	€ 435,940,241.40	€ 461,524,567.24	€ 502,584,564.00
Payments made (-)	-€ 294,778,931.08	-€ 323,521,935.71	-€ 372,652,447.84	-€ 421,656,092.00
Carry-over of appropriations (-)	-€ 96,439,937.44	-€ 111,229,771.50	-€ 98,509,524.66	-€ 81,568,908.00
Cancellation of appropriations carried over (+)	€ 5,372,131.21	€ 4,455,177.77	€ 5,174,935.87	€ 2,782,128.67
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 282,281.55	€ 5,349,241.90	€ 4,401,553.29	€ 2,282,868.97
Exchange rate differences (+/-)	€ 2,944,406.68	-€ 533,910.72	€ 81,854.69	€ 170,422.56
Adjustment for negative balance from previous year (-)	€ 0.00	€ 0.00	€ 0.00	
Total	**€ 24,982,180.86**	**€ 10,459,043.14**	**€ 20,938.59**	**€ 4,594,984.20**

1) Data as per final 2023 accounts.
2) Data updated in accordance with provisional outturn.

The financial outturn for 2024, a surplus of EUR 4 594 984, representing 0.93% of the approved budget (including Amending budgets), i.e. EUR 491.9 million, cf. the draft budget outturn for fund sources (C1, C11).

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

Budget implementation 2024 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 was 0.3%, resulting in a final implementation of 99.7%, which is considered a good result;
- Title III - operational expenditure: cancellation of commitment appropriation was 0.2%, resulting in a final implementation of 99.8%, which is considered a good result.

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

- Title I (indicative ceiling of 10%), where 3.07% of committed appropriations were carried forward to 2025.
- Title II (indicative ceiling of 20%), 13.31% of committed appropriations were carried forward to 2025.
- Title III (indicative ceiling of 30%), 26.00% of committed appropriations were carried forward.

Annex IV Human Resources – Quantitative

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

A. Statutory staff and SNEs

Staff	2024			2025	2026	2027
ESTABLISHMENT PLAN POSTS	**Authorised Budget**	**Actually filled as of 31/12/2024***	**Occupancy rate %**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**
Administrators (AD)	500	500	100%	505	534	541
Assistants (AST)	191	191	100%	199	202	203
Assistants/Secretaries (AST/SC)	0	0	0%	0	0	0
TOTAL ESTABLISHMENT PLAN POSTS	**691**	**691**	**100%**	**704**	**736**	**744**
EXTERNAL STAFF	**Envisaged FTE**	**Executed FTE as of 31/12/2024**	**Execution Rate %**	**Envisaged FTE[1]**	**Envisaged FTE[1]**	**Envisaged FTE[1]**
Contract Agents (CA)	203	211	104%	203	203	203
Seconded National Experts (SNE)	45	48	107%	45	45	45
TOTAL EXTERNAL STAFF	248	259	104%	248	248	248
TOTAL STAFF	**939**	**950**	**101%**	**952**	**984**	**992**

*) 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.

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

Human Resources	2024	2025	2026	2027
	Envisaged FTE	Envisaged FTE	Envisaged FTE	
Contract Agents (CA)	2.8	9.6	10.0	8.5
Seconded National Experts (SNE)	0	0	0	0
TOTAL	2.8	9.6	10.0	8.5

C. Other human resources

Structural service providers

	Actually in place as of 31/12/2022	Actually in place as of 31/12/2023
Security	21	23
IT service desk	17	29
IT maintenance and support 'time&means' contracts only	3	4
Reception	10	10
Building maintenance[1]	n/a	n/a
Cleaning	26	26
Catering	27	27
Reprographics and mail services	7	7

1) Building maintenance: included in the rental package

Interim workers

	Total FTEs in year 2022	Total FTEs in year 2023	Total FTEs in year 2024
Number	114	110	123

Table 2 – Multi-annual staff policy plan 2023, 2024, 2025, 2026, 2027

Function group and grade	2022				2023				2024				2025		2026		2027	
	Authorised budget		Actually filled as of 31/12/2022		Authorised budget		Actually filled as of 31/12/2023		Authorised budget		Actually filled as of 31/12/2024*		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		0		3		3		3		3		3
AD 14		10		9		12		3		12		12		12		13		13
AD 13		13		13		12		11		12		12		15		18		18
AD 12		50		50		57		52		61		61		64		64		64
AD 11		52		52		49		49		50		50		49		51		51
AD 10		50		50		53		53		57		57		59		60		60
AD 9		62		62		66		66		82		82		94		109		109
AD 8		77		77		87		87		78		78		81		79		81
AD 7		97		97		89		89		90		90		85		93		93
AD 6		60		60		67		67		55		55		43		44		49
AD 5		3		3		0		0		0		0		0		0		0
AD TOTAL	**0**	**477**		**473**	**0**	**495**		**477**	**0**	**500**		**500**	**0**	**505**		**534**		**541**
AST 11		2		2		2		2		3		3		3		3		3
AST 10		7		7		7		7		7		7		7		7		7
AST 9		10		10		10		10		10		10		13		15		15
AST 8		13		13		14		14		15		15		19		23		23
AST 7		19		19		25		25		29		29		38		41		41
AST 6		26		26		31		31		35		35		26		40		40
AST 5		43		43		43		43		49		49		56		42		42
AST 4		42		42		43		43		32		32		22		16		16
AST 3		23		23		12		12		11		11		15		15		16
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**	**185**		**185**	**0**	**187**		**187**	**0**	**191**		**191**	**0**	**199**		**202**		**203**
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**	**0**		**0**
GRAND TOTAL	**0**	**662**	**0**	**658**	**0**	**682**		**664**	**0**	**691**		**691**	**0**	**704**	**0**	**736**		**744**

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	Envisaged FTE 2025	Envisaged FTE 2026	Envisaged FTE 2027
Function Group IV	125	111	119	128	131	134
Function Group III	78	100	99	75	72	69

Function Group II	0	0	0	0	0	0
Function Group I	0	0	0	0	0	0
Additional CA[1]	0	0	0	0	0	0
TOTAL	**203**	**211**	**218**	**203**	**203**	**203**

Seconded National Experts

Seconded National Experts	FTE corresponding to the authorised budget 2024	Executed FTE as of 31/12/2024	Headcount as of 31/12/2024	Envisaged FTE 2025	Envisaged FTE 2026	Envisaged FTE 2027
Total	45	48	53	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	
Scientific Specialist (Veterinary Division)		Vacancy due to internal reassignment of tasks	AD06 and above	AD06	
Senior Scientific Specialist ERA			AD08 and above	AD08	
Head of V-SR Dept	Mobility of incumbent		AD08 and above	AD10	
Head of V-SR-PHV Office	Mobility of incumbent		AD06 and above		
Accounting Coordinator	Resignation of incumbent		AST3 and above	AST3	
Procurement and Contract Management Officer	Resignation of incument				FGIV

Service Lead (ServiceNow)		Requirement for skills and knowledge in managing one of the EMA platforms	AD06 and above	AD06	
Project Officer		Short-term additional post for AMA project			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	

*Indication of both is required
** Justification to be added

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 TA/promotion of officials

Grades	Average seniority in the grade among reclassified staff						
	2020	2021	2022	2023	2024	Actual average over 5 years	Average over 5 years (According to decision C(2015)9563)
AD05	2.27	2.21	2.00			2.2	2.8
AD06	3.47	2.81	3.13	3.6	3.37	3.3	2.8
AD07	4.37	4.81	3.29	3.75	3.48	3.9	2.8
AD08	4.96	3.25	3.88	5.1	3.57	4.2	3
AD09	5	4.62	3.33	6.12	3.4	4.5	4
AD10	4.71	5.2	4.95	3.54	6.67	5.1	4
AD11	6.33	8	2.92	5	6.25	6	4
AD12	10	2.84		7	8.38	7.5	6.7
AD13	6	9.5			3	7	6.7
AST1				8.58		8.6	3
AST2	3	4.28	3.12	4		3.6	3
AST3	4.73	3.89	3.57	3.69	3.4	3.8	3
AST4	3.33	4.91	3.73	3.5	3.63	3.8	3
AST5	4	5.2	3.75	3.8	3.58	4	4
AST6	7.75	5.14	3.50	3.67	4.22	4.6	4
AST7	7.5	11	3.00	5.25	5	6.1	4
AST8	5		3.00		4.5	4.3	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 1.01.2022	How many staff members were reclassified in 2023	Average number of years in grade of reclassified staff members 2023	How many staff members were reclassified in 2024	Average number of years in grade of reclassified staff members 2024	Average number of years in grade of reclassified staff members according to Decision C(2015)9561
CA IV	17	4					Between 6 and 10 years
	16	14			1	2	Between 5 and 7 years
	15	15	1	2			Between 4 and 6 years
	14	57	5	2.91	9	3	Between 3 and 5 years
	13	8	1	2.54			Between 3 and 5 years
CA III	11	7	1		1	2	Between 6 and 10 years
	10	41	4	3.34	3	3.61	Between 5 and 7 years
	9	50	4	2.79	10	3.66	Between 4 and 6 years
	8	8	2	2.98	1	3.5	Between 3 and 5 years
CA II	6						Between 6 and 10 years
	5						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, AT and AC)

		2024							
		Official		Temporary		Contract Agents		Grand Total	
		Staff	%	Staff	%	Staff	%	Staff	%
Female	Administrator level	0	N/a	239	34%	87	39%	326	36%
	Assistant level (AST & AST/SC)	0	N/a	196	28%	83	38%	279	30%
	Total	**0**	**0**	**435**	**63%**	**170**	**77%**	**605**	**66%**
Male	Administrator level	0	N/a	225	32%	35	16%	260	28%
	Assistant level (AST & AST/SC)	0	N/a	35	5%	16	7%	51	6%
	Total	**0**	**0**	**260**	**37%**	**51**	**23%**	**311**	**34%**
Grand Total		**0**	**0**	**695**	**100%**	**221**	**100%**	**916**	**100%**

Table 2 - Data regarding gender evolution over 5 years of the Middle and Senior management[1]

	2020		2024	
	Number	%	Number	%
Female Managers	10	38%	12	44%
Male Managers	16	62%	15	56%

1) Staff who is defined as middle manager by the applicable General Implementing provisions on middle management.
2) To be updated in January 2025

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, AT and AC)

Nationality	2024					
	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	19	3%	2	1%	21	2%
Bulgaria	10	2%	9	3%	19	2%
Croatia	8	1%	3	1%	11	1%
Cyprus	0	0%	2	1%	2	0%
Czech Republic	4	1%	14	4%	18	2%
Denmark	3	1%	5	2%	8	1%
Estonia	1	0%	7	2%	8	1%
Finland	7	1%	5	2%	12	1%
France	74	13%	28	8%	102	11%
Germany	42	7%	17	5%	59	6%
Greece	51	9%	29	9%	80	9%
Hungary	12	2%	16	5%	28	3%
Ireland	18	3%	4	1%	22	2%
Italy	77	13%	42	13%	119	13%
Latvia	2	0%	9	3%	11	1%

Lithuania	**8**	**1%**	**12**	**4%**	**20**	**2%**
Luxembourg	**0**	**0%**	**0**	**0%**	**0**	**0%**
Malta	**0**	**0%**	**0**	**0%**	**0**	**0%**
Netherlands	**25**	**4%**	**8**	**2%**	**33**	**4%**
Norway	**3**	**1%**	**0**	**0%**	**3**	**0%**
Poland	**14**	**2%**	**32**	**10%**	**46**	**5%**
Portugal	**47**	**8%**	**11**	**3%**	**58**	**6%**
Romania	**28**	**5%**	**7**	**2%**	**35**	**4%**
Slovakia	**7**	**1%**	**16**	**5%**	**23**	**3%**
Slovenia	**2**	**0%**	**2**	**1%**	**4**	**0%**
Spain	**87**	**15%**	**31**	**9%**	**118**	**13%**
Sweden	**7**	**1%**	**6**	**2%**	**13**	**1%**
United Kingdom	**22**	**4%**	**12**	**4%**	**34**	**4%**
Other	**1**	**0%**	**0**	**0%**	**1**	**0%**
TOTAL	**586**	**100%**	**330**	**100%**	**916**	**100%**

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

Most represented nationality	2019		2024	
	Number	%	Number	%
Italian	**99**	**13%**	**119**	**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**
Contribution agreements signed with the EC on type II European schools	**Yes**	**Yes, with European School The Hague**
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

An updated Environmental Policy 2024 to 2027[21] was approved by the EMA Executive Board on 16 March and signed and published on the EMA website on 15 May 2024, setting out the objectives for the Agency's approach to implementing its sustainability ambitions.

The internal environmental audit was performed during the period December 2023 to January 2024 and identified one minor non-conformity and some observations for improvements, and confirmed the Agency's readiness to proceed with the EMAS audit as the next and final step towards obtaining the EU Eco-Management and Audit Scheme (EMAS) registration.

The EMAS validation audit was sourced under an inter-institutional framework contract for certification to Management Standards and performed on 9-10 September 2024. The audit concluded a need to further develop some of the supporting documentation, to improve parts of the internal audit planning and to review the process for preparing the legal compliance register and the obligations applicable to EMA as well as to document verification of compliance, all in line with the EMAS regulation. These improvements are currently being implemented with a target to be in place by the year end 2024, to proceed towards EMAS registration.

The European Union has within its Green Deal and the European Climate Law, Regulation (EU) 2021/1119 set a target of a 55% reduction of the net greenhouse gas emissions by the year 2030 compared with 1990 and achieving climate neutrality by the year 2050, which EMA aligns with.

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 2 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 2025 - 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.

[21] https://www.ema.europa.eu/system/files/documents/other/policy-0078-ema-environmental-policy-2024-2027_en.pdf

Aspect	Environmental objectives	Key Performance indicator	Target 2025 - 2028	Actions to achieve environmental objectives
				Replacement scheme of electronic equipment such as laptops[22] 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 work-flows 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	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] through office occupancy; Emissions from meetings with external participants reimbursed by the Agency;	Target to reduce emissions from delegates travel with **40%** compared with 2015[23] i.e. carbon budget of 1600 TCO2e. Long term target to	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

[22] 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.

[23] 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 regarding staff missions.

Aspect	Environmental objectives	Key Performance indicator	Target 2025 - 2028	Actions to achieve environmental objectives
			reduce with **50%** by 2030, i.e. carbon budget of 1335 TCO2e	and virtual participation in meetings and other events.
		Emissions from staff duty travel, and	Target of **5%** annual reduction of emissions from staff travel, during the programming period[24]	
		Emissions from staff commuting and teleworking	Emissions from staff commuting and teleworking will be monitored over the programming period	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) 2025-2028	n/a	Actions as included in the SPD 2025-2028

In June to July a first staff survey was performed to capture the carbon emissions from commuting and teleworking. The results from this survey will be included in the annex for environmental management reporting in the Agency's 2024 Annual Activity Report, and a similar staff survey will be repeated on an annual basis.

As part of the Agency's induction training new-starters will receive information of the environmental friendly credentials of the EMA building, how to work at the EMA offices by taking consideration to a sustainable behavior, 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 2025 to support the monitored areas above.

For 2025 further environmental performance indicators are monitored for calculation of the Agency's CO^2 emissions with the purpose to report and communicate on an annual basis in an Environmental Statement, to be published once EMAS validation has been verified and the Agency has achieved EMAS registration.

For this purpose 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

[24] Carbon budget for staff travel: 304 TCO2e in 2025, 289 TCO2e in 2026, 274 TCO2e in 2027, 260 TCO2e in 2028.

from the JRC publication on Best Environmental Management Practice for the Public Administration Sector (BEMP), since that is the Management Practice closest to our 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	11,159,597	20 years 1.5 months from commencement date of 15/11/2019 to 31/12/2039	Lease agreement with CGREA (Central Governement 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
TOTAL			40,520	23,231	63,751	11,159,597 (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

During the Brexit discussions between the EU and the UK government, the matter of EMA's London premises was removed from the negotiation package. This resulted in the Agency having to maintain its contract for its former headquarters in London following the EU decision to relocate the Agency to a new host Member State.

The Agency had managed to sub-underlet the premises in 2019 (respective building dossiers EMA/104158/2019 of 21/02/2019 and EMA/119300/2019 of 28/02/2019) with the Agency's sub-undertenant covering fully the rent and costs that the Agency is contractually obliged to pay to its landlord (Canary Wharf Limited). The COVID-19 pandemic and changes in the global economy following the pandemic, affected the office sector and the parent company of the Agency's sub-undertenant who experienced difficulties as of Q3 2023. Specifically:

- On 8 August 2023, the parent company of the Agency's current sub-undertenant published the results for the second quarter of 2023. The quarterly report disclosed that there is doubt about the group's ability to continue as a going concern unless it succeeds in the execution of the management's plan to improve liquidity and profitability over the next 12 months by reducing tenancy cost, increasing revenue, controlling expenses and limiting capital expenditure and seeking additional capital.
- On 6 September 2023, in a call to landlords, the CEO of the sub-undertenant's parent company announced to its stakeholders that it had appointed a real estate advisor to review the group's leasehold commitments and to lead the group's efforts and negotiations with almost all landlords to "right-size" these lease commitments by lease modifications, terminations, assignments, subleases and other modifications to both economic and non-economic lease terms.
- On 7 November, the parent company of the Agency's sub-undertenant filed for Chapter 11 proceedings in the United States.
- While the Agency's sub-undertenant was not part of the Chapter 11 proceedings, the parent company's situation in the United States and the financial outcome of the activities at 30 Churchill Place resulted in the Agency's sub-undertenant reassessing its operations at EMA's former premises and its obligations vis-à-vis EMA under the sub-underlease. During the Chapter 11 bankruptcy process, the company vacated numerous global and London locations.

The Agency submitted to the Budgetary Authority a pre-information note on 5 December 2023 (pre-information note EMA/546071/2023) for the purpose of providing early information to the European Parliament and the Council on the developments in the Agency's sub-underlease, as listed above.

Following extensive negotiations to reach the best possible outcome, the new terms of agreement between the Agency and the sub-undertenant (amending the previous sub-underlease) were agreed on 20 March 2024.

On 27 March 2024, the Agency submitted a building dossier to the Budgetary Authority (building dossier EMA/122997/2024) seeking the authorisation of the Budgetary Authority to amend the sub-underlease of the Agency's pre-Brexit office premises in London. The European Parliament approved the building dossier in the meeting of the Committee on Budgets held on 8 April 2024, while the Council's approval was confirmed on 24 April 2024.

The Agency continues to call on the institutions to resolve the matter of the London building 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 revisions of: (i) the EU Pharmaceutical legislation including the regulations on medicines for rare diseases and on medicines for children; and (ii) the Regulation on the European Medicines Agency's fee system. 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, in 2020 the European Commission started to prepare to update the legal framework on EMA fees. The impact assessment of future policy options to update the legal framework on fees and the European Commission legal proposal for the revised EMA's fees regulation were published at the end of 2022 here.

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 pharmaceuticals 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, the 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, the EMA now performs evaluation of Agile epics.

Similarly to the original projects gated procedure, under the Agile approach the 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.

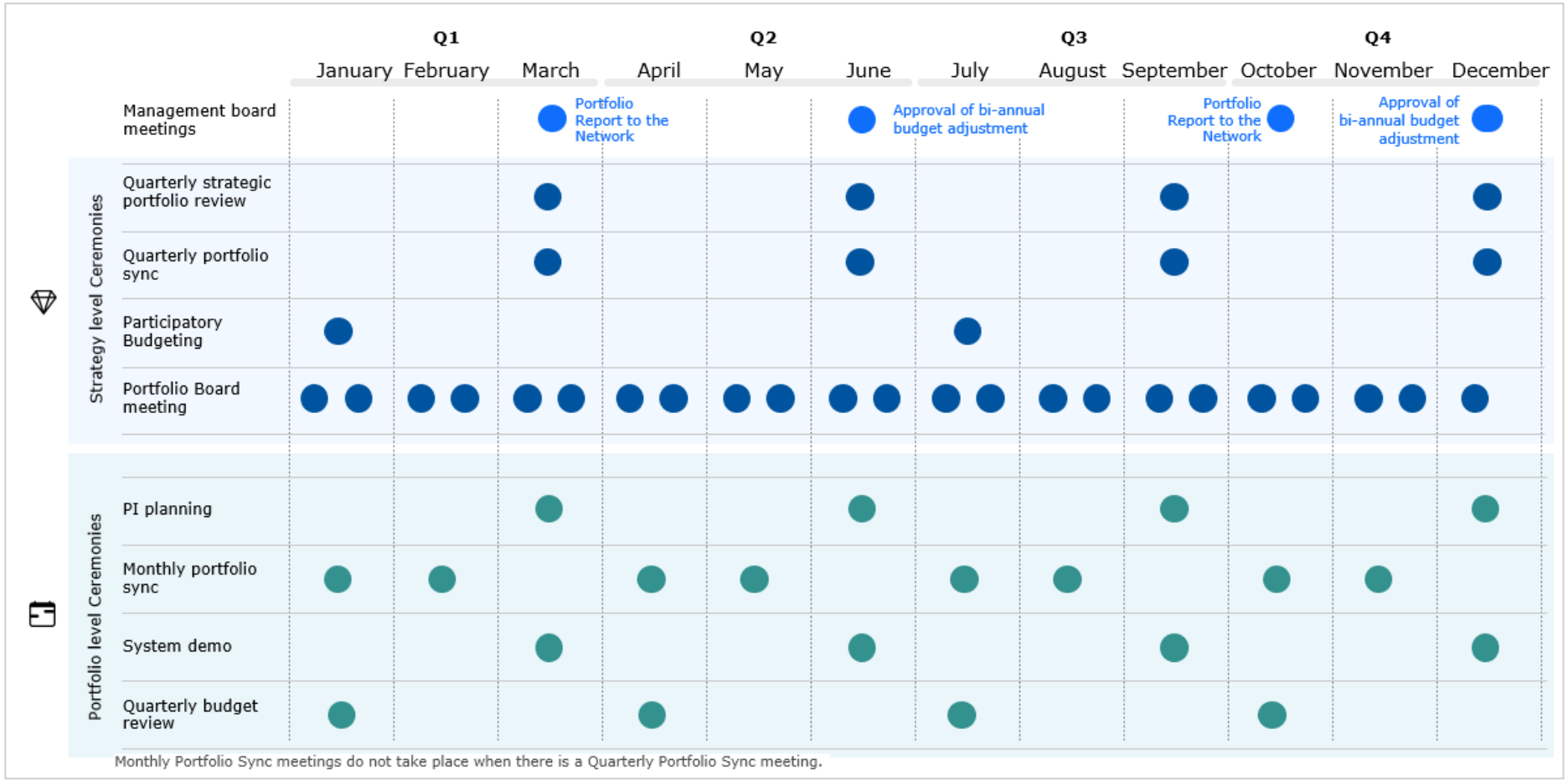
Retrospective evaluations are conducted when an Epic is formally concluded. When actual costs at Epic closure exceed EUR 3 million, the retroactive evaluation is conducted by the PB against pre-defined criteria.

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.



Annex X Strategy for the organisational management and internal control system[25]

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.

[25] Information included in this annex represents the executive summary of the EMA strategy for the organisational management and internal control system

- **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[26] 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.

[26] 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 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. Management review of the internal control system is conducted annually, to ensure its continued suitability, adequacy, and effectiveness, while addressing the possible need for changes. The Executive Director can also request specific assessments if deemed necessary, considering changes in the control environment and recommendations of the Internal Control Coordinator.

The results of the internal control assessments, including significant weaknesses identified and any differences as compared to internal and external audit findings, are disclosed in the Annual Activity report.

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**		**2024**	**2025**	**2026**	**2027**
Grants received										
1. ConcePTION	26/04/2019	EUR 85,000	5 years from 01/04/2019	Innovative Medicines Initiative 2 Joint Undertaking	Building an ecosystem for better monitoring and communicating of medication safety in pregnancy and breastfeeding: validated and regulatory endorsed workflows for fast, optimised evidence generation	Amount	17,000			
						Number of CA/FTE	0.2			
						Number of SNEs/FTE				
2. 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	8,000	3,500	3,500	
						Number of CA/FTE	0.1	0.1		
						Number of SNEs/FTE				
3. 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	18,000	10,000		
						Number of CA/FTE	0.8			
						Number of SNEs/FTE				
4. IHI RealiseD	Est. Q4-2024	Est. EUR 539,000	Est. 5 years from 01/01/2025	tbc	tbc	Amount		108,000	108,000	108,000
						Number of CA/FTE	1.0	1.0	1.0	tbc
						Number of SNEs/FTE				
Total grants received						**Amount**	**43,000**	**313,500**	**303,500**	**300,000**
						Number of CA/FTE	**2.02**	**1.07**	**1.01**	**0.00**
						Number of SNEs/FTE	**0**	**0**	**0**	**0**
Contribution agreements										
1. IPA 2020-2022	19/12/2019	EUR 254,919	4 years from 01/01/2020	European Commission DG NEAR	Participation of candidate countries and potential candidates in EMA trainings and activities	Amount				
						Number of CA/FTE	p.m.			
						Number of SNEs/FTE				
2. IPA 2024-2026	Q4 2023	EUR 600,000	3 years from 01/01/2024	European Commission DG NEAR	Participation of candidate countries and potential candidates in EMA trainings and activities	Amount	200,000	200,000	200,000	
						Number of CA/FTE				
						Number of SNEs/FTE				
3. ePi I	13/04/2022	EUR 1.5 million	5 years from 01/01/2024	European Commission, DG SANTE/ EU4Health	Implementation of the action 'electronic Product Information (ePI) for medicinal products'	Amount	-	-	-	-
						Number of CA/FTE	0	0	0	0
						Number of SNEs/FTE	0	0	0	0

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2024**	**2025**	**2026**	**2027**
4. ePi II	31/05/2024	EUR 1.7 million	5 years from 01/01/2024	European Commission, DG SANTE/ EU4Health	Implementation of the action 'electronic Product Information (ePI) for medicinal products'	Amount	1,500,000	50,000	50,000	50,000
						Number of CA/FTE	tbc	tbc	0	0
						Number of SNEs/FTE	tbc	tbc	0	0
5. 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	1	6	6	6
						Number of SNEs/FTE	p.m.	p.m.	p.m.	p.m.
5. TBC	Est. 2025	Est. EUR 900,000	Est. 5 years from 01/01/2025	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		467,000	467,000	467,000
						Number of CA/FTE	0.0	3.0	3.0	3.0
						Number of SNEs/FTE				
Total contribution agreements						**Amount**	**3,700,000**	**2,717,000**	**2,717,000**	**2,517,000**
						Number of CA/FTE	**1**	**9**	**9**	**9**
						Number of SNEs/FTE	**0**	**0**	**0**	**0**
Service-level agreements										
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	225,000		
						Number of CA/FTE				
						Number of SNEs/FTE				
2. AMA EMRN Grant	Expected Q4 2024	EUR 450,000 + EUR 596, 000 (1)	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		150,000 +198,666 (1)	150,000 +198,666 (1)	150,000 +198,666 (1)
						Number of CA/FTE				
						Number of SNEs/FTE				
3 AMA EDQM Grant	Expected Q1 2025	up to 1.5m EUR 36 months	34 months from	Direct award to EDQM	Fostering African-regional reliance	Amount		450,000	350,000	200,000
						Number of CA/FTE				
						Number of SNEs/FTE				

	General information					Financial and HR impacts				
	Date of signature	**Total amount**	**Duration**	**Counterpart**	**Short description**		**2024**	**2025**	**2026**	**2027**
		from signature in 2024	signature in 2025							
Total grants provided						**Amount**	**225,000**	**1,023,666**	**698,666**	**548,666**
						Number of CA/FTE				
						Number of SNEs/FTE				

(1) Subject to successful amending budget of the contribution agreement. Expected to be tabled in December 2024.

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 for 2025.

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 1990's 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 candidates 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 also saw 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. In 2020, WHO encouraged all countries and governments to invest in preparedness capacities to prevent, detect and mitigate health emergencies of all kinds.

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 the outbreak of MPOX 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.

The implementation of the so-called Windsor Framework and future relations between the EU and United Kingdom are expected to impact the Agency, including in the area of management of shortages of medicines and medical devices, and wider international cooperation activities.

EMA will also contribute to the EU Global Gateway Initiative 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.

Additionally, convergence of regulatory approaches can help standardize 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

The 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[27]. 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.

The use of ad hoc confidentiality undertakings, which are time-bound and limited in scope, proved an invaluable tool during the COVID-19 pandemic and the mpox crisis.

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. The scope of the EU-US MRA was expanded to include veterinary medicines in 2023 and work is ongoing to include vaccines and plasma-derived pharmaceuticals in the coming years. 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 includes provisions that permit mutual recognition of GMP inspections between the two jurisdictions.

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

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 optimize product development and avoid unnecessary differences in methodology, endpoints, comparators, statistical analysis, etc.

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.

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.

Representatives from these partners may also participate as experts in committee meetings under the OPEN programme,

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 teams in charge.

Additionally, EMA and FDA have seconded staff members (Liaison Officials) to each other's Agency; Japan MHLW/PMDA has a Liaison Official at the EMA 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). A review of the current clusters and their operation is taking place during the period 2024-26.

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 any case, all documents are redacted to protect personal data.

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, such as the COVID-19 pandemic. 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, and the EMA Executive Director is currently the chair of ICMRA (2022-2025).

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 co-operation 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 the next years (2024-2026)

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, the EMA will support research, innovation and early development to stimulate global development of better medicine. Activities to achieve objective 1 are:

- 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.
- 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 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 optimizing 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 initiative, and explore engagement through projects such as Project Orbis.
- Explore the capabilities for global collaborative submission reviews for anti-cancer medicines by fostering cooperation between international regulators.
- Support the development of MRAs
- 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
    - 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: Strengthen 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 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 DG NEAR 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 with 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[28]

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.*

[28] EMA/MB/911312/2019)

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

	Indicative Budget
AMA AUDA-NEPAD Grant: Pilot to test continental process, procedures and guidelines of the Evaluation of Medicinal Products Technical Committee (EMP-TC) AND Good Manufacturing Practices Technical Committee (GMP TC)	450,000
AMA EMRN Grant: Strengthening of the African regional and / or national scientific and regulatory capacity	450,000 + 596,000[29]
AMA EDQM Grant: Fostering African-regional reliance	up to 1,500,000[29]
Budget line 3032, assigned revenue R0	

Operational Procurement by Pillar

Pillar I	Indicative Budget
Pillar I (detailed description see Part II, Chapter 1) **Product-related activities**: this block encompasses objectives concerning medicines lifecycle, working parties and guidelines.	EUR 9,361,000
Budget line 3000, current budget C1 and assigned revenue R0, excluding daily allowances (70% of total expenditure) Budget line 3030 (Medical Literature Monitoring) Budget line 3031 (Eudravigilance data management) Budget line 3032 (external experts) Budget line 3033 (testing and sampling)	

Pillar II	Indicative Budget
Pillar II (detailed description see Part II, Chapter 1) **Strategies (EMANS and RSS) and Public health activities**: the block includes objectives taken onboard by EMA to contribute to the implementation of the overall Network strategy. This section is organized based on the 6 EMANS focus areas and covers also and non-product related public health tasks (e.g., communication, international cooperation, etc.)	EUR 19,961,000
Budget line 3003, current budget C1	
Budget line 3030, current budget C1 and assigned revenue R0	

[29] Subject to successful amending budget of the contribution agreement. Expected to be tabled in December 2024.

Pillar III	Indicative Budget
Pillar III (detailed description see Part II, Chapter 1) **Network Portfolio and business services**: this block covers development activities aiming at enhancing the efficiency and effectiveness of the current operations.	EUR 40,654,000
Budget line 3031, current budget C1	
Budget line 3105, current budget C1	