EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Foreword

I am pleased to present the European Medicines Agency's (hereinafter EMA or the Agency), Single programming document (SPD) for 2024 to 2026. This document, reflecting our expected challenges and goals for the next three years, sets out our final work programme for 2024 as well as our medium- and longer-term objectives.

Over the last year, members of the EU Medicines Regulatory Network, including the European Medicines Agency took the decision to lift their respective COVID-19 business continuity measures. This had been anticipated in our previous SPD and coincided with the announcement from the World Health Organization (WHO), declaring the end of COVID-19 as a public health emergency of international concern.

This SPD takes into account our plans for the gradual resumption of activities that had been previously suspended or reduced as a result of the public health emergency. EMA has already restarted some activities in this respect, including the publication of clinical data for all new active substances.

This SPD also takes into account the expected impact of the European Commission's proposal to revise the existing general pharmaceutical legislation. EMA will work to improve our readiness for the final legal text. We will also explore how we can apply some of the concepts emanating from the revised legislation to streamline and future-proof medicines regulation in the EU and our work within the EU Medicines Regulatory Network.

In addition to the above, in 2024 EMA and Heads of Medicines Agencies (HMA) will review and update the European Medicines Agencies Network Strategy (EMANS) looking ahead to 2028, considering that we are already at the midpoint of the implementation of the EMA Regulatory Science Strategy (RSS) and the European Medicines Agencies Network Strategy to 2025. One of the aims will be to ensure that the necessary preparatory work for the new pharmaceutical legislation is taken into account, along with drivers for change which have emerged in recent years.

While we will continue to deliver on all our strategic priorities, in 2024 we will put particular focus on three areas:

- Firstly, we will build on our focus areas for 2023. We will continue to use haematology and oncology products as pathfinders to reflect on how we can further improve the Agency's approaches to reviewing critical medicines and thereby help patients access treatments faster. We will also continue to explore ways to expedite our evaluations of vital cancer medicines, optimise the use and number of experts available, strengthen international collaboration, and refine our approach for assessing and transparently communicating about the benefits and risks of cancer medicines.
- Secondly, we will continue our efforts in translating innovation into medicines that reach patients based on better data and evidence generation. Building on the COVID-19 learnings and the revolution in technology and data science, in 2024 we will focus on enabling better clinical research and evidence-based regulatory decisions, using initiatives such as Accelerating Clinical Trials in the EU (ACT EU) and Data Analysis and Real World Interrogation Network (DARWIN EU). We will also focus on our engagement with Health Technology Assessment (HTA) bodies, facilitating a wider uptake of advanced manufacturing methods and the use of artificial intelligence.

- Thirdly, as already mentioned, we will focus on preparing for the revision of the general pharmaceutical legislation and seizing the opportunity to future-proof medicines regulation in the EU, and design innovative ways for implementing changes in the legislation.

Finally, I need to mention the ongoing situation as regards the Agency's London premises, which continues to require us to deviate from some of our plans concerning our core business and which could impact some of the activities described in this document.

Emer Cooke,

Executive Director

List of Acronyms

Term/abbreviation	Definition
3Rs	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
ACAA	Agreement on Conformity Assessment and Acceptance of industrial products
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
AER	Adverse event report
Agency	European Medicines Agency
AI	Artificial intelligence
AM	Antimicrobial
AMA	African Medicines Agency
AMEG	Antimicrobial Advice Ad Hoc Expert Group
AMR	Antimicrobial resistance
ANSA	EU Agencies Network on Scientific Advice
ANSM	Agence nationale de sécurité du médicament et des produits de santé (France)
API	Active pharmaceutical ingredient
Art	Article
AST	Assistant category post
ASU	Antimicrobial sales and use
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
AUDA-NEPAD	African Union Development Agency
AWS	Amazon Cloud
BDSG	Big data steering group
BI	Business Intelligence
BREEAM	Building Research Establishment Environmental Assessment Method
CA	Contract agent
CAP	Centrally authorised product
CAT	Committee for Advanced Therapies
CDP	Clinical Data Publication
CDPC	EU Common Data Platform for Chemicals
CEO	Chief Executive Officer
CGREA	Central Government Real Estate Agency
CHMP	Committee for Medicinal Products for Human Use
CIO	Chief Information Officer

Term/abbreviation	Definition
CMD	Coordination Group for Mutual Recognition and Decentralised Procedures
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CO_2	Carbon dioxide
Commission	European Commission
committee(s)	Scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
COSO	Committee of Sponsoring Organizations of the Treadway Commission
Council	European Council
CR	Common Repository
CRM	Customer Relationship Management
CRO	Contract research organisation
CSA	consolidated scientific advice
CT	Clinical trial
CTCG	Clinical Trials Coordination Group
CTIS	Clinical trials information system
CTN	Clinical Trial Navigator
CTR	Clinical Trials Regulation
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	Scientific committees of the Agency
DAP	Data Analytics Platform
DARWIN EU	Data Analytics and Real World Interrogation Network
DC	Data Centre
DCP	Decentralised procedure
DG	Directorate-General of the European Commission
DG INTPA	European Commission Directorate-General for International Partnerships
DG NEAR	Directorate-General for Neighbourhood and Enlargement Negotiations
DG SANTE	Directorate-General for Health and Food Safety
DIA	Drug Information Association
DigiLab	EMA Digital Innovation Lab
DIGIT	EU Commission's Department for Digital Services
DQ	Data quality
DREAM	Document Records Electronic Archive Management system
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

Term/abbreviation	Definition
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EFSA	European Food Safety Authority
EHDS	European Health Data Space
EMA	European Medicines Agency
EMANS	European Medicines Agency Network Strategy
EMAS	EU Eco-Management and Audit Scheme
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
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)
EP	European Parliament
EPAR	European public assessment report
EPPO	European Public Prosecutors Office
ERA	Environmental risk assessment
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
EU	European Union
EU NTC	EU Network training centre
EUDPR	Data protection Regulation for EU institutions and bodies
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EudraGMDP	European Union Drug Regulating Authorities good manufacturing and distribution practice
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EU-IN	EU innovation network
EU-M4all	Medicines for use outside the EU
EUnetHTA	European network for health technology assessment
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	Veterinary EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EXB	EMA Executive Board
FA	Focus Area

Term/abbreviation	Definition
FDA	United States Food and Drug Administration
FG (I, II, III, IV)	Function group (for contract agent staff)
FHIR	Fast Healthcare Interoperability Resources
FTE	Full-time equivalent
GCP	Good clinical practice
GDPR	General Data Protection Regulation
GLP	Good laboratory practice
GMP	Good manufacturing practice
GPP	Green Public Procurement
GVP	Good pharmacovigilance practice
GxP	Good practice (e.g. laboratory, clinical, manufacturing etc)
HC	Healthcare
HERA	Health Emergency Preparedness and Response Authority
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HPAC	Health Policy Agencies Collaboration
HR	Human resources
HS	Horizon Scanning
HTA	Health technology assessment
HTACG	Member State Coordination Group on HTA
HTV	Heath Threats and Vaccines Strategy
ICDRA	International Conference of Drug Regulatory Authorities
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
IMI	Innovative Medicines Initiative
IPA	Instrument for Pre-accession Assistance
IPRP	International Pharmaceutical Regulators Programme
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

Term/abbreviation	Definition
IVDR	In-Vitro Diagnostic Regulation
JIACRA	Joint inter-agency antimicrobial consumption and resistance analysis
JRC	European Commission's Joint Research Centre
KPI	Key performance indicator
LACE	Lean-Agile Centre of Excellence
LMIC	low- and middle- income countries
LMS	EU Network Training Centre Learning Management System
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	marketing authorisation holder
MAV+	Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa
MAWP	EMA Multi-annual work programme
MB	Management Board
MD	Medical devices
MDR	Medical Devices Regulation
Member State (MS)	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
ML	Machine Learning
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 VS	Managing the Agency Value Stream
MUMS	Minor use, minor species
MVP	Minimum viable product
MWP	Methodology Working Party
NAP	Nationally authorised product
NCA	National competent authority
NGO	Non-governmental organisation
NIS	Non-Interventional Study
NITAGs	National immunization technical advisory groups of WHO
NLP	Natural Language Processing
NPAG	Network Portfolio Advisory Group
NRA	National Regulatory Agencies
NTWP	Novel Therapies and Technologies Working Party
NVR	New veterinary regulation
OECD	Organisation for Economic Co-operation and Development
OLAF	European Anti-Fraud Office

Term/abbreviation	Definition
OMCL	Official Medicines Control Laboratories
OPEN	Opening our Procedures at EMA to Non-EU authorities
PAM	Post-authorisation measures
Parliament	European Parliament
PASS	Post-authorisation safety study
PB	EMA Portfolio Board
PDCO	Paediatric Committee
PHE	Public Health Emergency
PHEIC	Public Health Emergency of International Concern
PhV	Pharmacovigilance
PhVWP	Pharmacovigilance working party
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PK/PD	Pharmacokinetic/Pharmacodynamic
PLM	Product Lifecycle Management Value Stream
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma master file
PMO	Office for administration and payment of individual entitlements
PMS	Product Management Services
POC	Point of Contact
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
PSUSA	PSUR single assessment
PUMA	Paediatric-use marketing authorisation
Q (1, 2, 3, 4)	Quarter (1, 2, 3, 4)
Q&A	Questions and answers
QAT	Quality Assurance Test
QIG	Quality Innovation Group
R&D	Research and development
RACI	Responsible, Accountable, Consulted, Informed
RCT	Randomised controlled trials
RFI	Request for information
RMP	Risk Mitigation Plan
RPM	Regulatory Procedure Management
RSS	Regulatory Science Strategy
RWD	Real-world data
RWE	Real-world evidence
SA	Scientific advice

Term/abbreviation	Definition
SAFe	Scaled Agile Framework
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
SC	Scientific committee
SCG	Scientific Coordination Group
SciCoBo	Scientific Coordination Board
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SISAQOL	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints in Cancer Clinical Trials
SME	Small and medium-sized enterprise
SmPC	Summary of product characteristics
SNE	Seconded national expert
SNSA	simultaneous national scientific advice
SPC	Summary of product characteristics
SPD	Single programming document
SPMP	Shortages Prevention and Management plans
SPOC	Single point of contact system on availability/shortages in human and veterinary agencies in the EU
SSA	Signal and Safety Analytics
STAMP	European Commission's Expert Group on Safe and Timely Access to Medicines for Patients
STARS	Coordination and Support Action on Strengthening Training of Academia in Regulatory Science
TA	Temporary agent
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
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
TLM	Technology Lifecycle Management and Information Security Value Stream
TRIP	Topic Relations Information Perspective
TRS	EMA Regulatory Science and Innovation Task Force
TWG	thematic working group
UK	United Kingdom
UPD	Union product database
UPhD	Union Pharmacovigilance Database
US	United States of America
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	EU Vaccines Monitoring Platform

Term/abbreviation	Definition
VS	Value Stream
WEEE	Waste electrical and electronic equipment
WHO	World Health Organization
WHO- SRA	Stringent Regulatory Authority
WOAH	World Organisation for Animal Health
WP	Working party
XEVMPD	Extended EudraVigilance medicinal product dictionary
XML	Extensible Markup Language

Mission Statement

Mission

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

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 the main aim of which was to reinforce pharmacovigilance in the EU. This was supplemented by further legislation in 2012. The main legal acts in this area were: 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. Implementation activities are currently managed under an EMA/EUnetHTA 21 work plan, requested by the European Commission.

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 stimulate 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.

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.

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 2024-2026 planning exercise EMA starts to shift its focus away from crisis management towards upcoming challenges and opportunities, particularly towards ensuring the Agency' preparedness for the implementation of the revised Pharmaceutical Legislation and its continued transition to be a digitally enabled and data driven regulator. The magnitude of change brought by this new legislative initiative represents the most important shift for the general context in which the Agency will operate in the next few years. Another important factor that is likely to affect the general context is the increasingly fast investment by partners and stakeholders in new data sources and in new disruptive technologies (e.g. real-world data and artificial intelligence). The 2024 work programme reflects the first steps the Organisation plans to take to address these changes. Taking the above into account, the following is worth noting:

Pharma Law revision - On 26 April 2023, the EC published its proposal for the reform of the Pharmaceutical Legislation which includes a revision of Directive 2001/83/EC and Regulation (EC) No 726/2004 (referred to as the '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 Agency follows the development of the legislative procedure and 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.

Network resourcing - The COVID-19 pandemic has exposed shortcomings of the current operating model, which suffers from resourcing and expertise constraints. These could be further exacerbated by several factors, including a growing number of ATMPs, combination products, as well as a shift on focus at political level from public health towards other urgent issues. With the upcoming revision of several regulations, the Agency sees an opportunity to address the above-mentioned shortfalls, to support the realisation of the ambitions detailed in the EMANS/RSS strategies. As several initiatives are ongoing within the network to address some of these concerns, the Agency is committed to maintaining its focus on this key priority in the next planning cycles.

Digitalisation of society and AI – Recent years have seen a fast and significant increase in the impact that digitalisation and AI can have in the context of medicines regulation. If on one hand, these technologies could improve the efficiency and effectiveness of the regulatory process (e.g. by streamlining data collection and analysis, making it easier for regulatory authorities to monitor drug safety and efficacy; identify patterns in large datasets to enable better informed decision-making; etc.) on the other hand, the Agency subscribes to the four primary ethical challenges which exist, along with other ethical considerations, regarding the use of artificial intelligence, namely, (1) informed consent to use, (2) safety and transparency, (3) algorithmic fairness and biases, and (4) data privacy and is aware of the potential legal challenges that these would comprise, i.e. (1) safety and effectiveness, (2) liability, (3) data protection and privacy, (4) cybersecurity, and (5) intellectual property law. Therefore, while it is not possible to neglect that these technologies have the potential to revolutionise medicines regulation, it is important that they are used responsibly and in a way that maintains public trust in the regulatory process.

International environment - The two main pieces of work for the Agency stemming from this area are supporting the European Union's political priorities. First, following the major changes in the EU landscape brought by the war in Ukraine, EMA will continue to collaborate to support candidate and neighbourhood countries. The Agency continues to monitor political developments in the political discussions and stand ready to step up enlargement related activities. Secondly, in view of the continued effort to harmonise and strengthen medicines regulation at global level, EMA will continue

the work initiated in 2023 in close collaboration with the European Commission, the WHO and the African Union, of contributing to the establishment of the African Medicines Agency (AMA).

Legislative revisions - Various pieces of EU legislation e.g. Revision of the Fee Regulation, the Artificial Intelligence Act, the European Health Data Space, legislative initiatives under the EU Chemicals Strategy, the new HTA regulation etc. will be adopted or become applicable in the longer term. These may establish new tasks for the Agency and may create new entities both at EU level and in the Member States (e.g. the HTA Coordination Group, notified bodies for AI, health data access authorities under the EHDS) with which the Agency will have to interact. On one hand, all these pieces of new EU legislation represent an unprecedented opportunity for simplification, digitalisation and future-proofing of the regulatory environment and for implementing ambitions detailed in the EMAN and RSS strategies, on the other hand they also represent a big uncertainty for EMA, as it is difficult to foresee all the implications that the upcoming reforms may have (e.g. enlarged remit for EMA, re-allocation of tasks between EMA and NCAs, new IT systems to be developed, etc.).

Access to affordable medicines - healthcare systems are increasingly challenged to provide access to affordable medicines. This also results in inequality across EU Member States and leads to political, economic, and public pressures. New initiatives and structures are emerging, including European HTA corporation, EC-facilitated work of the National Competent Authorities for Pricing and Reimbursement as well as the WHO initiative on access to affordable innovation. These activities may require increased engagement by the Agency, within its role as part of the decision-making chain towards access.

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 dialogue 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 MDR and in vitro 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 monitors the evolution of the medical devices' sector, to better understand required capabilities in this area.

Collaboration with other decision-makers on the path to patient access - The new Regulation on Health Technology Assessment provides a legal mandate for EMA to collaborate with the HTA Coordination Group. This brings the previous voluntary work in a project-based setting in a well-defined and sustainable framework. The Regulation reflects the previous experience in this collaboration and recognises the value of this cross-decision maker collaboration.

Data management and analysis - The relevance of data management and data analytics capabilities continues to emerge rapidly across different areas. EMA will need to further invest in data governance in line with emerging EU policy initiatives and to prepare for the future European Health Data Space regulation. This will provide EMA with a specific framework with clear rules on sharing of health data, common standards, and practices. Leveraging data will involve work on data quality, data standards, data governance, including security and protection. The implementation and operation of EU DPR also plays a key role for the Agency in the context of handling, processing, and sharing of data within and across regions in the interest of public health. Appropriate links will be made with relevant projects funded under the foregoing projects to take note of research results that emerge as and when they do.

Public health emergencies – Despite the normalisation of the COVID-19 related workload, the Agency plans to maintain its preparedness activities in the remit of public health emergencies. This is in line with the extension of the EMA mandate and the new areas of responsibilities of the

Organisation. In this effort, EMA will collaborate with the European Commission, the Health Emergency Preparedness and Response Authority (HERA) and the European Centre for Diseases Control (ECDC). To ensure preparedness, the Agency is also closely following public health threats, such as the outbreak of ebolavirus Sudan strain in Uganda. Working arrangements between EMA and HERA have been finalised in 2023 and set out the areas of collaboration and how the two organisations will coordinate their work in those areas. More specific contact points, arrangements and working methods for the cooperation between EMA and HERA will be developed later in 2023 and in 2024.

London Premises – In 2019, following Brexit, the agency was relocated to the Netherlands. However, the issue of the EMA's former premises remains unresolved and continues to divert resources from its core responsibilities. This ongoing situation may potentially have a negative impact on the organisation's ability to deliver its business objectives. The agency will continue to actively engage with this matter. However, until a long-term solution is reached, human and financial resources will need to be dedicated to this activity, which falls outside of the Agency's legal mandate. Unless an agreement is reached on a long-term solution, the matter will remain a significant risk factor for the Agency and its objectives.

Part II: Multi-annual programming 2024–2026

1 Multi-annual work programme

The EMA Multi-annual work programme 2024-2026 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) 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 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 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 collaborates with international regulators and within the EU medicines regulatory network to produce patient-centred high-quality outputs to ensure patient trust. With the publication of the proposal for a new pharmaceutical legislation for human medicines, the Agency will 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. Through 2024, the Division will maintain oversight for centralised and nationally authorised medicines on the implementation of the measures for managing the presence of nitrosamines in medicinal products, aiming for normalisation by end of 2024. The Division will also continue to deal with the growing number of periodic safety update reports. Moreover, additional tasks entrusted to the Agency in the area of medical devices and companion diagnostics will continue to become increasingly prominent. 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 and on anti-cancer medicines as a pathfinder, to embed the lessons learned from responding to the COVID-19 pandemic for the benefit of public health.

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 now 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:

2023 has marked the mid-point for the implementation of the EMA Regulatory Science Strategy (RSS) and the European Medicines Agencies Network Strategy (EMANS) to 2025. Taking stock of the progress made on the implementation and in view of the publication of the European Commission draft legal proposal for the revision of the Pharmaceutical Law, the Agency and HMA have agreed to review/update the EMAN strategy, with the intention of ensuring that the necessary preparatory work to anticipate the upcoming new Pharmaceutical Legislation is taken into account, along with new drivers emerged in recent years e.g. AI. During 2024 EMA and HMA representatives will work together to draft the revised strategy to 2028. This will be reflected in the 2025-27 Single programming document.

The Agency elected the EMANS priority areas as the key drivers for its activities linked to non-product related public health activities. Since EMA is a significant contributor to the realisation of networks objectives, the network multi-annual goals constitute the framework of EMA's new planning cycle. This principle is corroborated by the integration of the execution of the EMA Regulatory Science to 2025 Strategy with the Network Strategy.

The network strategy 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. Innovation.
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.

In view of the new multi-annual planning cycle, EMA international objectives in terms of international affairs will be the development of new confidentiality arrangements, as well as working with the European Commission in the expansion of the mutual recognition agreement with the US FDA (veterinary products, vaccines, and plasma-derived products, etc.). 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 actively participate in various international platforms (e.g. ICMRA, ICH, PIC/S, VICH, WHO, etc). Health crises (COVID-19, monkeypox, nitrosamines), supply chain issues, Article 58, 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. Communication activities to further increase the visibility of EMA's proactive role at international level 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 Informatics (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 and additional tools to build efficiency in order to 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). 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 2024, 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. 2024 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. A particular focus in the next five years will be on the integration with external stakeholders in view of bringing about a seamless platform for the Network, delivering improved business processes by leveraging digitalisation. In 2024 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 2024 are listed in Chapter 8.

BUSINESS SERVICES:

ADMINISTRATION AND CORPORATE MANAGEMENT DIVISION

The European job market is evolving, along with hybrid ways of working, following the recent years of pandemic and the constantly developing technological trends, which open new opportunities. In addition, the ambitions stemming from the Network's strategy and 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.

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's Human

Resources strategy, endorsed in 2023, addresses these and other challenges and aspirations through actions designed to increase the sustainability of the Agency, talent management and staff wellbeing. These actions and measures include activities which help to implement digital, AI and machine learning capabilities, review and streamlining of processes, as well as increasing the impact of analytics technologies.

A new fee regulation is expected to come into effect at the start of 2025. This will require the Agency to complete implementation activities, including changes to fee-related processes and IT systems, as well as change management activities.

In this context, the Division aims to provide its services for the business areas, enabling efficient and effective delivery of the core tasks of the Agency. Taking a holistic view covering processes, ways of working and technology, together with strategic planning, is key in achieving this objective. The way forward is to balance the change initiatives with the Agency's capacity, ensuring an adequate level of flexibility. Initiatives such as the implementation of the HR strategy, the review of processes and the implementation of digital tools, and the implementation of the fee regulation, will be among the flagship activities of the Division in the coming years.

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 2019-2024, the European Commission has identified the following priorities:

- A European Green Deal.
- A Europe fit for the digital age.
- A stronger Europe in the world.
- An economy that works for people.
- Promoting our European way of life.
- A new push for European democracy.

Due to its mandate, EMA is supporting 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 Focus area	EMA MAWP Strategic goal	EMA contribution
1. Promoting our European way of life	**European Health Union** *The European Commission is building a European Health Union, in which EU countries respond together to health crises, and patients receive the best possible care for diseases such as cancer.*	**FA 1: Availability and accessibility of medicines** **FA 3: Innovation** **FA 4: Antimicrobial resistance and other emerging health threats** **FA 5: Supply chain challenges**	**S.G. 1.1** **S.G. 1.2** **S.G. 1.5** **S.G. 3.1/3.2** **S.G. 4.1/4.2**	EMA contributes to the implementation of this priority and policy through the initiatives established for COVID-19, such as the creation of a scientific emergency task force (COVID-19 ETF) and the creation of the EU Executive Steering Group on shortages of medicines caused by major events. Moreover, EMA provides scientific support to the European Commission in the framework of the Pharmaceutical Strategy for Europe and the EU Beating Cancer Plan.
2. A Europe fit for the digital age	**Artificial intelligence** *Trustworthy artificial intelligence (AI) can bring many benefits, such as better healthcare, safer and cleaner transport, more efficient manufacturing, and cheaper and more sustainable energy. The EU's approach to AI will give people the confidence to embrace these technologies while encouraging businesses to develop them.*	**FA 2: Data analytics, digital tools and digital transformation**	**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.

	Cyber security *The European Union works on various fronts to promote cyber resilience, safeguarding our communication and data, and keeping online society and economy secure.*	**FA 6: Sustainability of the Network and operational excellence**	**S.G. 6.2**	EMA contributes to the implementation of this priority and policy through the execution of its cyber security strategy.
	European Data Strategy • *The European data strategy aims to make the EU a leader in a data-driven society. Creating a single market for data will allow it to flow freely within the EU and across sectors for the benefit of businesses, researchers, and public administrations.* • *People, businesses, and organisations should be empowered to make better decisions based on insights from non-personal data, which should be available to all.*	**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 DARWIN EU project, which aims at delivering a sustainable platform to access and analyse healthcare data from across the EU.
3. A European Green Deal	**European Green 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.* • *EMA is directly involved through its mandate in the action towards environment and oceans. Europe's seas, oceans, and environment are a*	**FA 4: Antimicrobial resistance and other emerging health threats** **FA 6: Sustainability of the network and operational excellence**	**S.G. 4.3**	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. The Agency contributes through the

	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* ○ *ensuring the sustainability of our blue economy and fisheries sectors.*			execution of actions within its remit under the EU Strategic Approach on pharmaceuticals in the environment and the implementation of European One Health action plan against antimicrobial resistance. 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.
4. An economy that works for people	**Internal market** • *The single market is one of Europe's major achievements and its best asset in times of increasing globalisation. It is an engine for building a stronger and fairer EU economy.* • *By allowing people, goods, services, and capital to move more freely, it opens up new opportunities for citizens, workers, businesses and consumers - creating the jobs and growth Europe so urgently needs.*	**FA 1: Availability and accessibility of medicines** **FA 5: Supply chain challenges**	**S.G. 1.1** **S.G. 5.4**	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.

	More integrated and deeper capital markets will channel more funding to companies, especially SMEs, and infrastructure projects. Better worker mobility will let people move more freely where their skills are needed. And combatting tax evasion and tax fraud will ensure that all contribute their fair share			

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.

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) through collaboration between	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.
	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

medicines regulators and other decision makers	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.
	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 pricing and reimbursement authorities	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.
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.
4.2. Contribute to responsible use of antimicrobial agentsand 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	Modernise SmPC of old antibiotics for human and veterinary use.
	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
	Improve and interlink information in current/existing databases to provide supply chain compliance overview.

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	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 2024 – 2026

2.1 Overview of the past and current situation

Overview

In 2023, the total budget (revenues and expenditure), as adopted by the EMA Management Board on 15 December 2022, amounted to €458,003,000. On the revenue side, this included €407,609,000 in fee revenues and contributions from the EU budget totalling €50,027,000. On the expenditure side, this included €158,385,000 in Title I: staff expenditure, €72,741,000 in Title II: infrastructure and operating/IT expenditure, and €226,877,000 in Title III: operational expenditure.

The staffing ceilings in 2023 were 682 temporary agents (TA), 203 contract agents (CA) and 30 national experts on secondment (SNE). This staffing level is determined by an additional 16 workload related TA posts and 4 TA posts related to the Regulation (EU) 2022/123. Moreover, it includes the continuation of the 40 additional time-bound TA posts exceptionally extended until 2023 and then gradually reduced between 2024-2026. Throughout the year, the Agency operated an occupancy rate close to 100%.

2.2 Outlook for the years 2024 – 2026

New tasks

On 26 April, 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 2024 the Agency will start 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 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 (excluding inflation) and associated workload are expected to grow by 67% in 2025 compared to 2014 baseline, driven by the significant volume of increase in pre-and post-marketing authorisation applications (and associated workload), e.g. scientific advice applications are now 57% higher than in 2014.

The COVID-19 related activities continue to have implications on the use of resources.

In addition to application-related workload, significant new tasks, both legislative and non-legislative tasks, have been assigned to the Agency over the last years with only a minimum increase in EMA's staff establishment plan (5 posts for NVR implementation). Such additional tasks have been tracked through EMA's activity-based monitoring, adding up to an annual workload requirement of over 80 FTEs (e.g. tasks related to the new Veterinary Medicinal Products Regulation, 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, but also through increased reliance on short-term staffing contracts, with high reliance on Contract Agents and, of even more concern, increasing reliance on short-term 'interim' contracts and contractors. The granting of 16 additional fee-financed Temporary Agent (TA) posts for 2023 was a welcome step in partially mitigating this resourcing issue, but the Agency has identified that a minimum of an additional 30 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.

The consequences of the shortage of Temporary Agent staff, and the impact on EMA contribution to public health activities, are described under the negative priorities section below (section 2.5).

2.3 Resource programming for the years 2024-2026

Financial resources

An increase in revenue generated by variations applications is forecast in 2024 and 2025. The total revenue from fees in 2024 will amount to €441.9 million, an increase of €34.3 million (8.4%) compared to the 2023 budget, where inflation still has a significant impact.

In 2025, the total revenue from fees is expected to reach €445.8 million based on the final draft Fee Regulation. Moreover, pending the finalisation of the legislative procedure, the Agency should, as of 2025, operate within the framework of the revised fee regulation.

For 2024 the EU/EEA contribution is set at €34.8 million 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 revised Pharmaceutical Law.

The orphan medicinal products contribution in the draft budget 2024 and preliminary draft budget 2025 reflects the amount proposed in the EU budget.

The return of the staff duty travel budget to the pre-relocation levels is driven by the increase of costs of travelling as well as the restart of missions following the lifting of the pandemic restrictions and by the discontinuation of the Agency's business continuity status.

On the other hand, the high level of inflation has been assessed and adjusted for on a line-by-line budget basis, depending on each specific contractual context.

Expenditure related to scientific studies and services include a net increase of approximately €2.0 million compared to 2023 expected result, for a new database for EU drug utilisation for shortages, with DARWIN and Scientific Studies activities continuing into 2024. The net increase of €2.0 million is driven by the fact that the DARWIN set up phase in 2023 was covered by 2022 budget following the procurement procedure.

The 2024 and 2025 budgets do not foresee 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 in line with the 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 2024 includes the 30 time-limited TA posts (a decrease of 10 compared to 2023) awarded by the EC to cope with the extra workload linked to the response of the COVID-19 pandemic and 19 TA posts linked to the preparatory activities of the new Pharmaceutical Law.

For the 2025 the preliminary draft budget includes 20 time-limited TA posts (a decrease of 10 compared to 2024) awarded by the EC to cope with the extra workload linked to the response of the COVID-19 pandemic, 18 TA posts linked to the preparatory activities of the new Pharmaceutical Law, moreover, the Agency will request additional 30 TA posts to cater for growth of existing tasks.

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 67% in 2025 compared to 2014 baseline, driven by the significant volume of increase in pre-and post-marketing authorisation applications (and associated workload), e.g. scientific advice applications are now 57% higher than in 2014, plus 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. However, the impact of the COVID-19 pandemic increased the pressure on staff, whether directly or indirectly involved in scientific activities, and it negatively affected the pace of delivery of efficiency gains initiatives.

Considering the challenges identified 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 SAFe/Agile methodology in the context of the implementation of the new Network Portfolio governance at EMA. The objective is to cope with longer planning horizons, ensuring the necessary level of accountability in the deliverables. 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 the Lean-Agile Centre of Excellence (LACE) team.

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 2024, 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 regulatory network users and applicants;
- 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, 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. The Agency has emphasised the risks associated with the increased reliance on short-term staffing contracts when providing a declaration of assurance in the Annual Activity Reports 2020 and 2021.

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:

- EMA's contribution to the achievements of the objectives set out in the European Commission Chemicals Strategy for Sustainability, in particular on the One Substance-One Assessment approach;
- international regulatory cooperative activities, in particular enhance cooperation with Latin American countries;
- managing the backlog of work with regards to 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 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);
- repurposing of medicines by identifying new uses for existing medicines in indications outside the scope of the original approved product information.

Part III: Work programme 2024

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:

- 2024 highlights

During 2024, the Agency will continue its efforts on anti-cancer medicines as a pathfinder to embed the lessons learned from responding to the COVID-19, with the ambition of applying regulatory agility and explore the capabilities for global collaborative submission reviews by fostering cooperation between international regulators. EMA remains committed to maintaining the highest standards of its assessment to ensure that European citizens have access to safe and effective innovative medicines. Moreover, EMA will keep investing in evidence generation to support faster product-to-patients. The organisation aims to achieve this ambition by supporting clinical trials in the EU through operation of the Clinical Trials Regulation and the clinical trials transformation initiative ACT EU. Furthermore, medicines development and supervision will be supported by access to and analysis of real-world data, to strengthen the evidence base for decisions on the safety and effectiveness of medicines. Through better clinical trials and use of real-world data we can reduce the time to market of innovative products. The Agency will also engage in preparation activities to anticipate the changes stemming from the upcoming new pharmaceutical legislation which aims at ensuring access to medicines, foster innovation for medicines, reduce administrative burden, enhance availability of medicines, address antimicrobial resistance and make medicines more environmentally sustainable.

- 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, with additional focus on anti-cancer medicines as a pathfinder to embed the lessons learned from responding to COVID-19.
    - Anticipate the changes stemming from new pharmaceutical legislation, prepare for 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: expansion of IT systems minimum viable products, 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 to be a priority, including implementation of any lessons learned to date.
  - 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. Additionally, The Agency will implement the hybrid working practices outlined in the model rules for EU agencies.

- Implement the new fee regulation which will enter in to force in January 2025. The implementation includes the redesign of fee-related processes and the update of relevant IT tools accordingly.
- Conclude a number of new contracts in 2023 or in 2024. These contracts are essential for the running of the Agency and aligned with its four-year cycle following its relocation. Once these contracts are finalised, working relations will need to be established with the providers under the said contracts.
- Continue the efforts to digitalise administrative processes, replacing legacy systems and focusing on human resource processes in 2024. 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 (COVID-19 and nitrosamines.
  - Extension of US MRA, supply chain, Article 58.
  - Promoting reliance on scientific outputs of the EMA scientific committees.
  - Support to priority countries, capacity building (including IPA training) and scientific training.
- Digital Business Transformation (TDT) Task Force:
  - Lead the Agency's digital transformation through programme and Agile 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. Leading Agency's (and the Network) transformation in building a future proof infrastructure resulting in an 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.
    - Deliver EU Network Strategy to 2025 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, piloting the analysis of raw data from clinical trials, building analytics capability for healthcare data including using AI, and training and collaborating on data in medicines regulation.
    - Build Network capability and capacity for real world evidence studies, including through DARWIN EU®.
    - Innovate in the conduct of clinical trials through the renovation of GCP, development of multi-stakeholder discussions on clinical trial innovation, including on new clinical trial approaches and designs, and support the full implementation of the Clinical Trials Regulation (see also Pillar 3) through operation and further development of the Clinical Trial Information System.
- 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; 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.
- 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 2024 and beyond:
    - Support to the European Commission Critical Medicines Alliance to assess supply chain vulnerability of critical medicines.
    - Implement the European Voluntary Solidarity Mechanism for medicines.
    - 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 2023/24.
    - Develop template and associated guidance for Shortages Prevention and Management plans (SPMPs) and implementation for all medicines.
    - 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.

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[1].

The three main drivers for 2024 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 to embed the lessons learned from responding to COVID-19;
- anticipate the changes stemming from the new pharmaceutical legislation, prepare for the Health Technology Assessment regulation, and progress activities for medical devices 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 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.

The activities performed by the Human Medicines Division are organised in 8 main domains: 1) pre-authorisation; 2) initial evaluation; 3) post-authorisation; 4) referrals; 5) pharmacovigilance; 6) inspections and compliance; 7) committees and working parties; 8) medical devices. More details on the activities are provided in the following subsections.

The workforce available in 2024 for the Division is currently foreseen at 383 staff (263 TAs, 100 CAs, 20 SNEs). This figure is subject to constant revision to consider staff movements (including part-time regime) and workload fluctuation.

[1] 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. HTA bodies and patient representatives are increasingly involved in these procedures. 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 launched in March 2016, designed 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. The scheme is promoted and benchmarked with the FDA breakthrough designation and Japanese Sakigake.

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). 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	
		2022	**2023**	**2024**	**2025**
Scientific advice and protocol assistance (non-exhaustive list)	Total scientific-advice and protocol-assistance requests	833	710	770	803
	Parallel scientific advice with international regulators requests	5	4	4	4
	Joint scientific advice with HTA bodies requests	4	3	3	3
	Scientific advice for PRIME designated products	37	39	42	44
	Protocol assistance	129	125	136	142
	Novel technologies qualification advice/opinions	21	21	23	23
Supporting the development of PRIority MEdicines	PRIME eligibility requests received	45	55	60	60
Orphan medicinal product designation and related maintenance procedures	Applications for orphan medicinal product designation	269	255	280	280
Development of medicines for children	Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	755	801	718	739
Classification and certification of advanced therapy medicinal products (ATMPs)	Requests for classification of ATMPs	51	50	50	50

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**	
		2022	**2023**	**2024**	**2025**
Scientific assessment of medicines submitted for centralised marketing authorisation	New non-orphan medicinal products	35	43	43	45
	New orphan medicinal products	32	27	30	32
	Similar biological products	11	17	17	18
	Generic, hybrid and abridged products	18	22	22	22
	Scientific opinions for non-EU markets (Art 58)	1	0	1	0
	Paediatric-use marketing authorisations	2	1	0	0
	Number of granted requests for accelerated assessment	4	12	12	12

	ATMP marketing application authorisation requests received	1	8	11	11
	COVID-19 related product applications received	2	4	4	4
	Companion diagnostics opinions	n/a	20	30	30

Performance indicators

		Results	**Expected results**	**Targets**	
		2022	**2023**	**2024**	**2025**
Scientific assessment of medicines submitted for centralised marketing authorisation	Average assessment time for new active substances and biosimilars	189.8	205	205	205
	Average clock-stop for new active substances and biosimilars	182.1	180	180	180
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	31.30%	60%	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	
		2022	**2023**	**2024**	**2025**
Variations to marketing authorisations	Type-IA variations	3,586	3,840	3,985	4,137
	Type-IB variations	3,354	3,495	3,632	3,778
	Type-II variations	1,388	1,202	1,216	1,323
Line extensions of marketing authorisations	Line-extensions of marketing authorisations	31	29	30	33
Maintenance activities	Renewal applications	132	81	80	87
	Annual reassessment applications	27	31	31	31
	Transfer of marketing authorisation applications	74	61	64	66
	Article 61(3) applications	236	200	200	200
	Post Authorisation Measure data submissions	1,278	925	925	925
	Plasma Master File Annual update and variation applications	17	25	25	25

Performance indicators

		Results	Expected results	Targets	
		2022	**2023**	**2024**	**2025**
Maintenance activities	Average assessment time for variations that include extension of indication	175.19	180	180	180

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**	
		2022	**2023**	**2024**	**2025**
Referrals	Pharmacovigilance referrals started	4	5	5	5
	Non-pharmacovigilance referrals started	5	8	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 evaluation (for centrally authorised procedures), post-authorisation referrals, inspections and data management, and therefore related items are found also in those sections of this document.

The area covers:

- management of adverse drug reaction reports, periodic safety update reports (PSURs), risk-management plans and oversight 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;
- 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**	
		2022	**2023**	**2024**	**2025**
Pharmacovigilance	Number of signals peer-reviewed by EMA	1,605	1,600	1,800	1,800
	Number of ICSRs for CAPs (reports received)	2,273,735	1,500,000	1.5M-2.5M	1.5M-2.5M
	Number of signal assessed by PRAC (validated by EMA)	39	40	40	40
	PSUSAs (CAPs only) started	n/a	586	643	619
	PSUSAs (mix CAP/NAP) started	n/a	42	48	43
	PSUSAs (NAPs only) started	n/a	255	288	344
	Number of imposed PASS protocol procedures started	5	4	4	4
	Number of imposed PASS result procedures started	2	4	4	4

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.

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**	
		2022	**2023**	**2024**	**2025**
Coordination of inspections	GMP inspections	96	310	300	258
	GLP inspections	1	2	0	0
	GCP inspections	75	89	80	81
	Pharmacovigilance inspections	12	15	12	10
	PMF inspections	84	127	158	89
Quality defects	Notifications of suspected quality defects	206	250	250	250
Sampling and testing programme	Medicinal products included in the sampling and testing programme	85	81	70	70
Certificates	Standard certificate requests received	3,849	4,520	4,588	4,656
	Urgent certificate requests received	1,147	1,186	1,186	1,186
Parallel distribution	Parallel distribution initial notifications received	1,816	2,100	2,125	2,167

	Parallel distribution annual updates received	5,509	5,550	5,640	5,750

Performance indicators

		Results	**Expected results**	**Targets**	
		2022	**2023**	**2024**	**2025**
Certificates	Standard certificates issued within established timelines (30 working days)	100.00%	90%	90%	90%
	Average days to issue standard certificate	3.9	15	15	15
	Urgent certificates issued within established timelines (2 working days)	100.00%	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 panels for medical devices

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 and the Scientific Advice Working Party, 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, by having consistent standards set for the development of medicines across the whole product lifecycle.

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.

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

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.

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	
		2022	**2023**	**2024**	**2025**
Meeting management	Number of reimbursed meetings	106	420	323	323
	Committee meetings	76	75	76	76
	Working Parties[1]	n/a	n/a	44	44
	Workshops, Forum, Seminars, Infoday[2]	n/a	n/a	38	38
	Other meetings[3]	n/a	n/a	165	165
	Number of virtual meetings (audio-, video- and web-conferences)	5,700	6,500	6,500	6,500
	Number of reimbursed delegates	1,980	8,500	6,800	6,800
	Number of non-reimbursed delegates	178	1,500	1,500	1,500
Herbal medicinal products	Herbal monographs, new	3	2	3	3
	Herbal monographs, reviewed	28	20	20	20
	Herbal monographs, revised	2	5	5	5
	EU herbal List entries	0	1	1	1

[1] New indicator introduced in 2024 work programme.
[2] New indicator introduced in 2024 work programme.
[3] New indicator introduced in 2024 work programme.

Performance indicators

		Results	Expected results	Targets	
		2022	**2023**	**2024**	**2025**
Meeting management	Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings	100.00%	100%	100%	100%

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 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. EMA is also piloting the provision of scientific advice to manufacturers of high-risk medical devices.

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.

Pillar 2 – Public health activities

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

- maintain oversight for centralised and nationally authorised medicines on the implementation of the measures for managing the presence of nitrosamines in medicinal products;
- 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.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
1.1 (ECP 1, ECP4)	Support the STAMP scientific advice pilot for repurposing established medicines	Several prioritised established medicines are enlisted in the pilot	2021	2024	Conduct of the Scientific Advice and analysis of selected candidates for the pilot
1.2 (ECP 1)	Provide parallel EMA/HTA body scientific advice, also in anticipation of and with the new HTA Regulation	Scientific evidence for marketing authorisation is serving different decision-makers	2022	2024	Scientific evidence for marketing authorisation is better serving different decision-makers
1.2 (ECP 1)	Provide updated guidance for key regulatory outputs (assessment reports, labelling) to enhance usefulness for down-stream decision makers Conduct product-specific reviews with HTA assessors at time of licensing/launch for products of mutual interest and review the experience: perform debriefings of payers on regulatory outcomes	Stakeholder communication about regulatory assessment is enhanced	2022	2024	Increased interactions between EMA and HTA and payers Better guidance

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
3.1 & 5.5 (ECP 1)	Set up and operate a 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 Management System (PQKMS) Enable use of risk-based approaches to manufacturing and control strategies by implementing ICH Q12	The implementation of novel manufacturing technologies and capacity enablers is facilitated	2022	2025	Better interaction between developers and academia Better guidance Increased international harmonisation
3.1 (ECP 1)	Deliver tailored engagement with academics and the community of ATMP developers (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 to the integration of scientific and technological progress in the development of ATMPs	2022	2025	Better support for the development, manufacturing and accessibility of ATMPs Up to 5 candidates selected for the pilot by 2024, including 2-4 by end of 2023
5.3	Adaptation of GMP guidance, delivery of strategic priorities for harmonisation/convergence of practices and training with the Pharmaceutical Inspection Co-operation Scheme, extend EU-US mutual recognition agreement to other medicines, and implement recognition of FDA's third country inspections for products already in scope of US MRA	Reinforced responsibility for product quality by harmonising and reinforcing guidance	2022	2025	Effectiveness and efficiency of GMP inspections in the context of globalisation of pharmaceutical manufacturing
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	The exchange of information among MRA and PIC/s partners is being actively promoted through international programmes, such as the API International Programme and PICs and ICMRA initiatives on hybrid inspections,	2023	2026	Reinforced supervision of API manufacturers

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		in order to increase collaboration on reliance and hybrid inspections. As part of the implementation of the Sartans Lesson Learnt Exercise recommendations, Annex 15 of the GMP guideline on Qualification and Validation has been agreed to be revised with PIC/s in a global effort to extend scope to API manufacturers. Furthermore, the PIC/s PICs aide memoire "Evaluating management of quality risks at GMP facilities" has been revised for inclusion of reference to development of APIs and identification of impurities.			
6.2 (ECP 2)	Undertake pilots applying quantitative benefit-risk assessment for initial marketing authorisations and select and pilot communication tools for quantitative benefit-risk assessment	Improved benefit/risk communication	2022	2024	Several pilots are concluded, and lessons learned communicated
Legislation	Management of Medical Devices Expert Panels: Conduct a pilot for providing scientific advice to medical device manufacturers and have lessons learnt to establish an effective scientific advice service	Experience gained to establish scientific advice for medical devices	2023	2024	Pilot concluded

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
3.2 (ECP 1)	Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1)	2019	2025	ICH guideline
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	Anticipate the changes stemming from the new pharmaceutical legislation by exploring possible ways to implement the legislative proposal and use this opportunity to future proof the operations of EMA.	Identify process improvements/increase in efficiency and gain experience with piloting some proposals	2023	TBC	Readiness for the implementation of the new pharmaceutical legislation by the date of application
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.

Application of the 'One Health' approach is one of the cornerstones of the Agency's work in the area of veterinary medicines. The fact that about 75 per cent[5] 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 for the year 2024 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): expansion of IT systems minimum viable products, refinement of processes based on real-life experience, 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;
- continue to support veterinary stakeholders and network transitioning into Regulation (EU) 2019/6.

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.

[5] 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'

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 2024 for the Division is currently foreseen at 63 staff (41 TAs, 17 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 have agreed and are implementing an action plan to help increase the availability of veterinary vaccines in the EU.

Workload indicators

		Results	Expected results	Forecasts	
		2022	2023	2024	2025
Emerging therapies and technologies	Innovation Task Force briefing requests (Vet)	0	5	5	5
Scientific advice	Scientific advice requests received	39	20	20	20
Limited markets	Requests for classification as limited market under article 4(29) and eligibility under article 23	21	20	20	20

Performance indicators

		Results	Expected results	Targets	
		2022	2023	2024	2025
Scientific advice	Scientific advice procedures completed within set timeframes	100%	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, PI 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	
		2022	**2023**	**2024**	**2025**
Initial evaluation	Initial evaluation applications	22	30	18	18
Establishment of MRLs	New MRL applications	0	1	2	2
	MRL extension and modification applications	1	1	2	2
	MRL extrapolations	0	1	1	1
	Art 10, Biocides	0	0	0	0
	Review of draft Codex MRLs	16	0	5	5

Performance indicators

		Results	Expected results	Targets	
		2022	**2023**	**2024**	**2025**
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**	
		2022	**2023**	**2024**	**2025**
Variations requiring assessment	Variations requiring assessment, of which	252	278	267	147
	Variations level 1	2	2	2	2
	Variations level 2	75	97	90	80
	Variations level 3	70	59	55	65
	Variations level 4	105	120	120	135
Maintenance activities	Transfers of marketing authorisations	0	2	5	5

Performance indicators

		Results	Expected results	Targets	
		2022	2023	2024	2025
Maintenance activities	Post-authorisation applications evaluated within the legal timeframes	100%	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	
		2022	2023	2024	2025
Arbitration procedures	Arbitrations and Community referral procedures initiated	5	3	2	2

Performance indicators

		Results	Expected results	Targets	
		2022	2023	2024	2025
Referrals	Referral procedures managed within the legal timelines	100.00%	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.

Workload indicators

		Results	Expected results	Forecasts	
		2022	2023	2024	2025
Pharmacovigilance activities	Annual recording of signal management results and outcomes (Annual statements)[6]	n/a	n/a	250	260
	Total signals submitted by MAHs of which:[7]	n/a	n/a	416	411
	Emerging safety issues assessed by MAH and leading to regulatory action	n/a	n/a	1	1
	Signals assessed by MAH leading to regulatory action (variations or other)	n/a	n/a	35	40

[6] New indicator introduced in 2024 work programme.
[7] New indicators introduced in 2024 work programme.

	Signals classified for close monitoring by MAH	n/a	n/a	80	70
	Signals classified as refuted by MAH	n/a	n/a	300	300
	Signals submitted by Regulatory authorities following risk-based review[8]	n/a	n/a	80	80
	Targeted signal management processes initiated by regulators[9]	n/a	n/a	4	4
	Total AERs, of which:	167,546	75,000	100,000	100,000
	Adverse-event reports (AERs) for CAPs	95,959	37,500	50,000	50,000
	Adverse-event reports (AERs) for NAPs	71,587	37,500	50,000	50,000

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

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, attention is particularly focused on ensuring the continued availability of antimicrobials for the treatment of infectious diseases in animals, while recognising the need to preserve the efficacy of certain critically important antimicrobials for human use. The Agency also reports on sales and use of antimicrobials in EU and jointly with EFSA and ECDC produce the JIACRA report which looks into the consumption of antimicrobial 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)	Produce further guidance to implement the annex to the new veterinary legislation (Regulation (EU) 2019/6) that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals	Guidance for novel therapies and biologicals developed	2020	2024	Increase of innovative veterinary products applications Better quality of dossier submitted
3.1 (ECP 1)	Assess the possible impact of any change in approach to consumer exposure estimation on CVMP guidance, approach to MRL assessment and existing MRLs, and initiate the necessary preparatory and follow-up work	Analysis of impact and plan for future work on guidance and processes	2022	2024	Impact analysis presented to CVMP

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
3.1 (ECP 1)	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)	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
3.1 (ECP 1)	Using data on the sales of veterinary products, develop methodology to collate, analyse and communicate information about the incidence of adverse reactions related to medicines' use	Methodology established and guidance developed	2020	2024	Better understanding of distribution of incidence of AEs Use of incidence distribution to identify clusters
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	2020	2025	Feasibility 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 international institutions, academic organisations and relevant initiatives	Establish ERA framework with EU and international partners Harmonised approach on ERA assessment	2021	2025	Increased cooperation between institutions Enhanced flow of information
3 (additional RSS recommendation)	Provide scientific support to the European Commission and the EU network 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)	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	Implement use data collection by animal species	Collection of data on the use of antimicrobials per animal species and animal categories as foreseen in	2021	2025	First EMA report on use data

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Article 15 of the Commission Delegated Regulation (EU) 2021/578			
4.1	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
4.2	Foster development of POC diagnostics for veterinary use	Review availability and characteristics of diagnostic tests	2022	2025	Reflection paper on characteristics of diagnostic tests
4.2	Prioritise and trigger referral procedures and/ or support MS in activities to review available data on emerging AMR risks, clinical effect, PK/PD, dose regimens	Support CVMP on VMP referrals and act on the recommendations from the 'Reflection paper on dose review and adjustment of established veterinary antibiotics in the context of SPC harmonisation'	2022	2025	Achievements of the recommendations listed in the RP
4.3	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)	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 3)	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 3)	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 3)	Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms	Reflection paper developed Communication with stakeholders	2020	2025	Framework established and in use Increase of alternative products submission

MAWP Strategic Goal(EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
4.3 (ECP 3)	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 3)	Provide scientific and regulatory support to encourage development of veterinary antimicrobials and alternatives, to fill therapeutic gaps, without adversely impacting public health	Guidance development on ATAm	2021	2025	Awareness raised in the Network Increase of alternative products submission
4.3 (ECP 3)	Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and their alternatives	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 alternative products submission
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
4 (additional RSS recommendation)	Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types (e.g. vaccines for zoonotic diseases, limited markets, exceptional circumstances)	Identify different benefit-risk approaches per type of vaccines Guidance on benefit-risk	2020	2024	Vaccine B-R assessment targeted per type of 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 2)	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 2)	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 2)	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 3	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 new 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.
- 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 2024 for the Task Force is currently foreseen at 36 staff (22 TAs, 13 CAs, 1 SNE). 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	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

technologies in analytics, such as artificial intelligence (AI) and machine learning in connection with the business-process design, automation, information, and knowledge management.		(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 • Colleagues benefit from user-friendly solutions that improve efficiency and have a tangible beneficial impact on the day-to-day work
Digital Innovation Lab (DigiLab) DigiLab is a framework 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.	Set of services to discover, prioritise, experiment, and develop digital solutions that have the potential to support core business and enable its strategies	• 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

		• Delivers a framework for experimentation based on good innovation practices that can be leveraged across the organisation for digital and data experimentation
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 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 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	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	• 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

Training Centre (EU NTC), including expansion to the EMRN.	• 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	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 submissions, regulatory processes and related systems (Human and Veterinary), underpinning the core regulatory business.	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 Integrate eSubmissions processes and systems into a holistic, end-to-end product lifecycle management ecosystem	• 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. • 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	• The Network Portfolio respects the Agency's standard

	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.	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 is transforming its portfolio from a short- to medium-term project/programme approach to establishing long-lived Value Streams. Three of the five Value Streams, Product Lifecycle Management (PLM), Monitoring (MON) and Managing the Agency (MTA), are led by the Task Force.	• PLM will bring together products that deliver capabilities to authorise and manage the lifecycle of medicines and medical devices. • 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.

Workload indicators

		Results	Expected results	Forecasts	
		2022	**2023**	**2024**	**2025**
EU Network Training Centre (EU NTC)	New scientific, regulatory and network portfolio curricula developed	1	1	2	2
	Number of training events advertised to the EU Network	76	60	60	60
	Number of reimbursed training events to the EU Network	4	5	8	8
	Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	11	6	10	10
Network Portfolio	Number of epics completed or ongoing[10]	n/a	34	29	33

[10] New indicator introduced in 2024 work programme.

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 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	Continuous	Continuous	Number of Digital Academy trainings accessed Number of trainings completed Number of hits on the platform Participation to events Positive survey feedback
2.2 (ECP 2)	Establish an EU collaboration on AI with other Agencies in the EU Network	Develop and promote the AI community Increase synergies, re-use, and efficiency Share knowledge and increase maturity Collaborate for the implementation of common AI initiatives and projects	2021	2025	Number of meetings in the community Knowledge shared within the network Number of initiatives where EMA could engage
	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 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	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 content 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
		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)

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 to 2025.

The main drivers for 2024 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 ensure data protection security and data can be leverage better regulation;
- need to deliver EU Network Strategy to 2025 objectives to transform to data-driven medicines regulation and to support innovation;
- opportunity to leverage real-world evidence as a complement to randomised controlled trials (RCTs) and to better assess RCTs through raw 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);
- innovation in the design regulation and conduct of clinical trials through the development of 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 CTIS.

The workforce available in 2024 for the Task Force is currently foreseen at 73 staff (46 TAs, 13 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	Main activities	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	• EMA data governance established and operational including oversight & business-critical data management, enabling advanced analytics, access to data of good quality & transparency; EMA and EMRN data strategies and EMRN data

	• 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 governance groups	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 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.	• 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 maintain confidence of health care professionals and the public on the effectiveness of the regulatory system in this field

	• Provides methodological advice on RWD sources (including disease registries), non-interventional study designs and analytical methods • Performs rapid data analytics to support EMA Scientific Committees in databases available in-house	• RWE used in regulatory decision-making is adequate, valid and reliable
	• 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
	• Develops and maintains tools and learning materials to support the use of valid and reliable RWE, including a library of phenotypes and the Big Data pharmacoepidemiology training curriculum	• Better and faster regulatory decision making is enabled through the provision of the high-quality RWE
	• Coordinates framework contracts with academic service providers and 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)[11] 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 international methodological guidelines

[11] EP report on 'Artificial intelligence in healthcare: Applications, risks, and ethical and societal impacts'.

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 • Robust decision-making enabled for 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) and on training (Development of the Big Data biostatistics and clinical trials curricula)	• Clinical trials data standards developed • Data exchange capability based on clinical trial data standards built • Clinical trial data standards implemented for high-priority use cases • Clinical trial guidance development across the European network resulting in 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 other external stakeholders. Specific activities include EMA-funded studies and external research collaborations with academia	• Stakeholder needs prioritised and fostered • 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. Also leads on the operation of a public catalogue of EU RWD sources and observational studies.	• 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
	• 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 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 ensured
	• 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
	• Coordinates of the EMA Pharmacogenomics Community	• Pharmacogenomics ESEC Specialised Interest Area established • 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 user experience with CTIS as these remain top priorities for EMA	• The CTR is effectively supported and 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 related to the clinical trials information systems; manages secretariats of the ACT EU multi-stakeholder platform and the Clinical Trials Coordination Group (CTCG).	• Provides programme management for ACT EU.	• ACT EU programme established and operational. • Clinical trials activities across the EMRN coordinated.
	• Leads or supports delivery of the ACT EU priorities.	• EU governance on CT matters strengthened. • CTR successfully implemented through regular monitoring and stakeholder engagement. • 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. • Trainings on clinical trial concepts and guidance developed and delivered. • Large and multinational clinical trials facilitated to promptly tackle public health emergencies. • The two focus areas of ACT EU – to develop the governance rationalisation strategy and to issue monthly KPIs to quantify the uptake of the Clinical Trials Regulation – ensured.
	• 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

		Results	**Expected results**	**Forecasts**	
		2022	**2023**	**2024**	**2025**
Healthcare Data	Number of RFI and Service Desk requests received related to EudraVigilance and to Art.57/PhV Fees data analyses	1,201	1,000	1,100	1,200
	Number of EudraVigilance Quality Assurance Test (QAT) requests received	132	130	130	130
Real World Evidence	Number of non-interventional studies performed	21	25	70	150
Methodology	Number of methodological advice provided on product procedures	n/a	n/a	80	80
	Number of active methodology guideline drafting groups led by MWP	n/a	n/a	15	15
	Number of methodological contributions to guidelines led by other committees and working parties	n/a	n/a	10	10
Clinical Trials Systems	Number of business validation for CTIS releases	11	18	18	18
	Number of KPIs reports published	8	11	12	12
	Number of EudraCT reports and number of CTIS data analyses and reporting[12]	80	110	110	110
	Number of ACT EU multi-stakeholder workshops[13]	2	4	12	12

[12] Including ad-hoc and regular reporting (weekly dashboards for bi-weekly newsflash, MB monthly reports, ACT EU KPI reports, CTCG).
[13] Led and co-organised events; including multi-stakeholder platform (MSP) advisory group.

Clinical Trials Transformation	Number of regular CTIS/CTR events[14]	70	91	86	86
	Number of CTIS newsflashes and CT highlights newsletters	20	38	26	26

Performance indicators

		Results	**Expected results**	**Targets**	
		2022	**2023**	**2024**	**2025**
Healthcare Data	RFI and Service Desk requests related to EudraVigilance and to Art.57/PhV Fees data analyses addressed according to set timelines	~99%	~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 24 weeks[15]	95%	60%	70%	70%
	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	n/a	90%	90%
	Planned MWP contribution to guidelines led by other committees and working parties	n/a	n/a	75%	75%
Clinical Trials Systems	AtD/RFI and Service Desk requests related to CTIS and EudraCT Business addressed within set timelines	90%	90%	90%	90%
	WHO XML upload for CTIS (monthly) and EudraCT (weekly) with the expected scope of records	90%	90%	90%	90%
Clinical Trials Transformation	ACT EU multi-stakeholder workshops organised according to workplan	80%	80%	80%	80%
	News flash to CTIS users	90%	90%	90%	90%
	Support to the secretariat for CTCG and physical hosting 4 times per year	100%	100%	100%	100%
	Provide secretariat for CTCG weekly assessors round table	100%	100%	100%	100%

[14] 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.
[15] Excluding framework contract studies.

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 Start	Timeframe End	Performance indicator
2.1 (ECP 2)	Build capacity and capability to receive, store, manage and analyse raw data.	CHMP proof-of-concept pilot for individual patient level data from clinical trials and non-clinical data launched and carried out Proof-of-concept pilot protocol developed Interim and final pilot reports developed Guidance for applicants developed	2021	2025	10 'raw data' pilot procedures by end 2024 Presentation to CHMP of interim pilot findings in Q1-Q2 2024. Publication of interim pilot report in Q2 2024
	Implement the Clinical Trials Safety Monitoring Implementing regulation	Assure the functional specs of the safety implementation regulation are up to date Provide regular support to the Member States for the safety assessments	2021	2024	Member State experts are procedurally capable of performing safety assessments related to clinical trials (in terms of support)
	Support an initiative with the EC and HMA to transform CT in Europe. This includes: modernisation of CT design and good clinical practice; strengthening EU level governance of CT; improved coordination between NCAs and ethics committees through the 'CTR Collaborate' project, including during public health emergencies; leveraging data on CT to support regulatory decision making;	Strengthen EMA support to ACT EU Project manage the "CTR Collaborate" project which will deliver enhanced collaboration between NCAs and Ethics Committees to support sponsors/CROs, develop effective procedures and training/information sharing and support the development of an EU forum for ethics committees to come together	2021	2026	Multi-stakeholder advisory group established in Q1 2024 Regulatory helpdesk for academic sponsors in place by Q2 2024 Publish research agenda and business case for CT data analytics by Q3 2024 Communication plan on CTR transition adopted by Q1 2024 3rd survey on CTR implementation launched by Q3 2024

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	supporting non-commercial sponsors to conduct more multi-national clinical trials; enhanced dialogue between clinical trial stakeholders.	Support communication and change management including training on operation of CTR and CTIS Launch scheme to support large multinational CTs, including a one stop-shop for academic sponsors Engage external stakeholders and establish a multi-stakeholder platform and advisory group Adopt a plan for GCP modernisation Further develop and manage a stand-alone ACT EU website Develop a CT research agenda Develop a pilot for consolidated pre-clinical trial application (CSA) advice (CHMP SA linked with SNSA/CTCG advice) Develop RACI matrix for network governance groups Strengthened process and regulatory approval of large, multinational clinical trials in the EU during public health emergencies			CTR Collaborate project launched by Q1 2024
	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	2022	Continuous	Supported users perform their tasks efficiently according to the CTR in CTIS

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Assure the business testing of the candidate releases			
	Change management activities related to CTR/CTIS	Regular communications in the form of newsletters and news flashes, maintenance of the CTIS training catalogue, and running of regular CTIS events e.g. walk-in clinics, bite size talks, CTIS forum	2020	2026	10 bite size talks and walk-in clinics in 2024 4 CTIS forum meetings in 2024
2.2	Deliver a data science curriculum for the EU Regulatory Network	Lead the work of the contractor to which the Data science curriculum has been outsourced	2021	2026	Deliver at least 3 modules by end 2024 Deliver at least 3 modules by end 2025
2.1	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)	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)	2023	2025	EU DQ framework published by early 2024 Draft RWD considerations of the EU Data Quality framework published in 2024 Draft Adverse Drug Reactions considerations of the EU Data Quality framework 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) and provide advice on data protection related matters at EMA	Yearly report on data protection activities to EMA Management Board	Continuous	Continuous	Organise 3 data protection trainings annually Data protection notifications in line with EUDPR
2.2.	Enable clinical trial data standards in EMA and Network systems and processes	Coordination of European contribution to ICH M11 activities Roadmap on clinical trial standardisation	2021	2024	Workshop to engage stakeholders on clinical trial analytics in Q1 2024 Roadmap of clinical trial standardisation epics adopted by Q2 2024

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Identification of use cases for clinical trial analytics Network experts' contribution in clinical trial standards Updated version of the FHIR standards			Clinical trial logical model updated based on ICH M11 output by Q3 2024 FHIR extension messages created by Q4 2024
2.2	Provide methodological expertise to support EMA scientific committees in alignment with external stakeholders' needs Strengthen the EU Network on methodology in committee advice and assessment Harmonisation of international methodological standards.	Revised Methodology Work Plan. Draft Methodology stakeholder interaction plan Draft methodology research needs Deliver guidance documents on emerging methodological topics Systematic lessons-learnt process for procedures with complex methodology, deliver first modules of the training curriculum in biostatistics, embed identification of committee requests with complex methodological aspects into EMA forecast and tracking processes Drafting groups and operational expert groups established and managed Clear roles and responsibilities in the Methodology domain to maximise resource efficiency Drafting of ICH E6(R3) Annex 2, E11A and E20	2021	2025	MWP work plan in Q1 2024. Stakeholder interaction plan in Q2 2024 Milestone achieved for 50% priority MWP guidelines by Q3 2024 Operational instructions written for the ESEC and MWP by Q4 2024 Draft ICH E20 finalised by Q4 2024 Final version of E11A by Q2 2024.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		guidelines. Organisation of cluster meetings			
	Improving development and implementation of clinical trial methodology guidance in the EMRN. Contributing to the delivery of CT curriculum.	Methodology workshops with external stakeholders to scope and prioritise clinical trial methodology guidance topics Methodology guidance roadmap Process for aligning guideline development on multidisciplinary methodology topics involving a large variety of relevant Network expert groups Training plan for new guidance documents and associated process Completion of training needs assessments for regulators and defined stakeholder groups Training curriculum elaboration	2021	2025	Methodology workshop report published in Q1 2024 Draft Methodology roadmap developed by Q4 2024 Process for guidance development sent for consultation to relevant expert groups by Q4 2024 Process for systematic creation of a training module for new guidance by Q3 2024 Publication of training needs assessments Q4 2024 Publication of training curriculum Q1 2025
2.1	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 evidence based on appropriate real-world data.	DARWIN EU® Coordination Centre maintained Access to various real-world data sources in terms of data type and geographical coverage DARWIN EU® pilot with EHDS conducted Processes for EMA oversight of DARWIN EU® activities	2020	2025	60 studies performed by DARWIN EU® in 2024 10 additional Data Partners onboarded in 2024 (giving a total of 30 data partners by the end of 2024)

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		operated, incl. review of all deliverables and DARWIN EU® outputs			
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 for prioritising analytical requests established Development of a phenotypes library Users' training on utilisation of IHD and analytical templates	2022	2025	Initiation of 75 (incl. 60 through DARWIN EU®) studies in 2024 Training of IHD users performed for each new user, and if relevant to all to maintain updated usage
	Pilot the use of AI/ML to increase efficiency to extract information in EMA documents and real-world data	Successful experimentation on the extraction of information using AI/NLP techniques Report on lessons learnt from test use cases shared within EMRN Planning of additional experimentation with AI/NLP at EMA considering the lessons learnt	2023	2025	Test analytical package to extract information on 100 documents finalised 2 research projects initiated 1 application developed 1 scientific paper published
	Further development of a monitoring system for the post-authorisation safety and effectiveness monitoring of vaccines (Vaccine Monitoring Platform)	Core infrastructure for the prioritisation, launch and supervision of vaccine studies in place Working arrangements with ECDC established and operational EU networks with capacity to perform representative and reliable studies identified	2022	2025	Conduct of minimum of 4 studies under the VMP joint advisory board meets twice annually

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		Processes in place to identify need for studies Results of studies made available to EU decision-makers and the public			
	Establish Health Data Lab to apply advanced analytics to develop innovative techniques to analyse, interpret and communicate on healthcare data	Establishment of the Health Data Lab as a stream following DigiLab's framework Pilot the experimentation framework with two pharmacovigilance-related projects	2023	2025	Number of FTE impacted by solutions produced by the Health Data Lab, in absolute and relative time
	Perform the EMA data governance and support EMRN data governance through development and implementation of an EMA and EMRN data strategy and data standardisation strategy as well as relevant policies, procedures as part of implementing a federated data governance at EMA, ensuring gradual evolution	Plans and activities to implement EMA data strategy, EMRN data standardisation strategy and EMA data governance including roles, responsibilities, processes, policies, structures and a data catalogue & glossary EMRN data strategy Communications, trainings and stakeholder engagement	2021	Continuous	For prioritised data assets by end of 2024: Evolved EMA data roles, structure, processes and data catalogue in place Data community in place Data catalogue and glossary in place Basic Data Quality metrics and monitoring in routine use
	Perform a capability and capacity assessment for big data use cases, as per BDSG work plan 2022-2025	A report including recommendations for actions	2023	2024	Deliver report in line with BDSG workplan (https://www.ema.europa.eu/en/documents/work-programme/workplan-2023-2025-hma/ema-joint-big-data-steering-group_en.pdf)
	Support EMA operations and committees/working parties with advice and epidemiological expertise on:	Draft guideline on methodological aspects, formats and contents of	2023	Continuous	Process to screen marketing authorisation applications and extension of indication applications

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	methods for RWE collection, analysis and reporting in the fields of healthcare and medicinal products evaluation; portfolio of real-world data sources existing in Europe and elsewhere to answer research questions; 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.	RWE used for regulatory purposes Templates and checklists for feasibility analyses on appropriateness of real-world data sources used in regulatory decision-making (e.g. registries, electronic healthcare records) Process for identification of procedures from relevant committees/WPs that need methodological input, participation and contribution to SAWP, pre-submission, PRIME and other relevant meetings where RWE is addressed			including main/supportive RWE and pilot for automation using natural language processes is established

3.3. Regulatory Science and Innovation (TRS)

The Regulatory Science and Innovation Task Force enables the continuous future-proofing 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 2024 for the Task Force is currently foreseen at 32 staff (19 TAs, 7 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 provision of translation assistance for marketing authorisation applications Organise SME briefing meetings Provide regulatory, procedural and administrative assistance Organisation of workshops/training events	Addressing the specific needs of smaller pharmaceutical companies, with the aim of promoting innovation and development of new human and veterinary medicines

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	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 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* Identifies future innovations and trends in a comprehensive and systematic manner enabling and facilitating innovations to reach the market	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 (SA-ANSA) etc Develop a systematic horizon-scanning capability to identify scientific and technological trends that will impact the regulatory system Develop the regulatory science observatory by activating a matrix of subject-matter experts across the product-development lifecycle	Systematic collation of regulatory information to prepare authorisation activities and resources 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

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 plan and coordinate engagement with Horizon Europe and IHI Disseminate EMA's regulatory science research needs, develop stakeholder consultation and update and review mechanisms 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 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	Implementation of the extended legal mandate of the Agency in the area of shortages of medicines and medical devices Coordination of required actions in case of anticipated or ongoing shortages of centrally authorised products Coordination of required actions for Covid-19 related to shortages of CAPs and high-impact medicines used in intensive care setting for Covid-19 patients (CAPs and NAPs) Coordination of activities of the EU SPOC Network (single points of contact in NCAs for shortages)	Key operational structures established as foreseen within the adopted legislation Short to medium term tactical IT solutions Scoping of the EU-level platform addressing supply of medicines Fulfilment of the requirements established by EMA's extended mandate for availability of medicines: EU Executive Steering Group on Shortages of Medicines Caused by Major Events Forecasting demand for medicinal products in the EU/EEA

	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 International collaboration on shortages-related strategic topics and shortages case-management at the level of the Global Regulatory Shortage Network	Enhanced monitoring system for medicines used for treating COVID-19 patients Continuous monitoring of supply chains Guidelines for EU Member States Guidance for companies
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 Improving and streamlining coordination processes, focusing on removing hurdles, and facilitating service delivery for all applicants	Chairs and organises the Scientific Coordination Board (SciCoBo)	Strategic advisory role Identifying key strategic priorities where new or enhanced engagement is essential to the continued success of the Agency's mission, and consequently identifying and influencing the vision for the next EMA regulatory science strategy and EU Medicines Agencies Network Strategy Coordination role Ensuring that there is sufficient coordination between the committees, so the standards they set for the development of medicines are consistent across the whole

		product lifecycle, for increased robustness and predictability of benefit-risk assessment

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2022	**2023**	**2024**	**2025**
Research and innovation: innovation and emerging therapies	Innovation Task Force briefing meetings	34	35	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	1	4	4	4
Research and innovation: business and analysis forecasting	Business Pipeline briefing meetings	21	18	20	20
SME Office	Regulatory assistance, including SME briefing meetings	207	183	192	192
	Requests for SME qualification	412	516	541	541
	Request for SME status renewal	1,432	1,260	1,323	1,323
Supply and Availability of Medicines and Devices	Management of shortages of CAPs	366	800	1,600	2,000
	Number of notifications of critical shortages (CAPs and NAPs, human + vet) circulated via SPOC Working Party	54	40	60	120
	Number of requests for information received from the SPOC Working Party and international partners	20	40	70	80
	Number of SPOC Working Party meetings (including subgroups)	38	30	40	50
	Number of MSSG meetings	10	11	12	12
	Number of HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use meetings + TW1	12	12	12	12

Performance indicators

		Results	**Expected results**	**Targets**	
		2022	**2023**	**2024**	**2025**
SME Office	Satisfaction level of SMEs	n/a	80%	80%	80%

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)	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)	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
3.4	Establishment of platform for systematic dissemination and exchange of knowledge and expertise on emerging innovation	Network systematically informed of evolving trends in innovation via platform meetings and facilitated by development of the TRIP system	2021	2024	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
	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 (International Affairs, Internal Audit, Legal Department, Institutional and Policy Department, Information Security, Heath Threats and Vaccine Strategy Office)

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.

The **Internal Audit Function** reviews and evaluates risk-management, governance, and internal control processes at the Agency, to provide to 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 EMCDDA, under the existing Working Arrangements between EMA and these agencies. The key institutional activities planned in 2024 will relate to coordinating the technical input and support to EU institutions for the implementation of various initiatives under the Pharmaceutical Strategy for Europe, with a particular focus on the revision of the general pharmaceutical legislation, as well as other public health related files, such as the European Health Data Space and the regulation on substances of human origin. Other activities planned for this period will include the revision of the Working Arrangements between EMA and other EU agencies, notably ECDC and EFSA, 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 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 also oversees and coordinates the Agency's overall information security, improving its efficiency and effectiveness, through security awareness initiatives and training.

The **Heath Threats and Vaccines Strategy** is an office supporting and managing scientific activities related to preparedness and response to public health emergencies. HTV 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, HTV acts as scientific lead for preparedness and response for emerging health threats of biological, chemical, or environmental origin. In addition, HTV coordinates and leads vaccine strategies and is responsible for the Agency's AMR strategy, in coordination with the Human and Veterinary Divisions. HTV conducts intelligence activities on countermeasures for emergent pathogens and collects information across the Agency and outside to maintain databases on products and product statuses shared with EU institutions (SANTE, HERA or the cabinet).

The workforce available in 2024 for the Advisory functions is currently foreseen at 60 staff (44 TAs, 12 CAs, 4 SNE). 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**	
		2022	**2023**	**2024**	**2025**
International Affairs	Number of product-related interactions with international stakeholders – including requests for information and requests for documents	n/a	130	130	130
	Number of participations in external forums	n/a	60	60	60
	Number of external participants in training organised by International Affairs	n/a	150	150	150
	Number of visits to EMA / fellowships organised by International Affairs	n/a	10	10	10

Pillar 2 – Public health activities and Business Services

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		Performance indicator
			Start	End	
1.1 (ECP 1, ECP4)	Launch tailored communications on biosimilars and provide updated guidance on the evidence needs for biosimilars	Increased awareness to facilitate the uptake of biosimilars	2022	2024	Better communication on biosimilars and better guidance
4.2 (ECP 1)	Define approaches for review of data with international regulators	Build on the experience acquired with COVID to establish the approach for future emergencies.	2021	Continuous	Develop a proposal for the improvement of the framework with EC and Member States.
4 (additional RSS recommendation)	Communicate proactively with key stakeholders on benefit-risk using evidence-based tools to tackle vaccine hesitancy	Interaction with the ECDC and public health authorities and ICMRA	2021	Continuous	Update of the vaccination information portal
4 (additional RSS recommendation)	Engage with public health authorities and NITAGs to better inform vaccine decisions	Attend meetings of the NITAG and contribute	2021	2025	At least two meetings per year.
4 (additional RSS recommendation)	Establish a platform for EU benefit-risk monitoring of vaccines post-approval	Set up the platform and conduct first studies	2021	Continuous	Studies of safety and effectiveness of vaccines
	Operate the ETF during COVID-19 public health emergency. As a working assumption for this MAWP, it is assumed that the COVID pandemic PHE will end December 2024	Proper regulatory decisions in the context of an emergency	2021	2024	Number of advice and recommendations and product authorised to address the PHE
	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 COVID-19 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

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
					Number of TCs held by HTV or ETF with Academia and other entities, platform trials developed
1.1	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	2019	2025	Number of TCs Number of collaborative workstreams Number of support workstreams for governance & membership, and communications
1.2	Support and foster use of the EU-M4all pathway Support applications scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU) in collaboration with WHO This includes early engagement with product developers and related sponsors	Support to developers and promotion of parallel art 58 and centralised submissions	N/A	Ongoing	Number of parallel submissions Number of Article 58 opinions and new approvals
1.2	Support and foster use of collaborative registration with WHO Engagement with WHO, NRAs and applicants, to promote and support use of the WHO-SRA collaborative registration procedure, facilitated approvals and other pathways	Capacity building in low- and middle-income countries	N/A	Ongoing	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) related to discussions in preparation for the extension of the MRA to veterinary medicines, increase in the efficiency of the MRA for human medicines and	2019	Ongoing	Number of EMA/FDA meetings participation

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
	Support extension of EU-US FDA MRA to include vaccines and veterinary medicines	preparations for the potential extension to 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	2027	Number of trainings organised Meeting with contact points arranged
1.1	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 LMIC markets.	2023	Ongoing	Number of experts Number of procedures
1.1	Organisation of awareness sessions for international regulators	Increase Awareness of the EU system Agency public image	2016	Ongoing	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	2019	Ongoing	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 system strengthening at African continental, regional and national levels	Establishment of the AMA	N/A	2027	Meeting objectives of LogFrame agreed under DG INTPA contract
	Communication of information, answer to queries, internal coordination	Streamline and promote awareness of international activities within the Agency	N/A	Ongoing	Number of interactions with CAs partners

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
	Monitoring of the matrix of the tracking of interactions Preparations of visits, missions' preparation, support to international partners, fellowships and expert visits				Number of documents exchanged Number of interactions with other international stakeholders Number of meetings/teleconference organised Number of guidance created/updated
1.1	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	Ongoing	Number of TB products applications Success of DG HERA tender
1.1	Sustained development and operation of the International Cooperation Platform	To promote an EU approach consistent with the European pharmaceutical strategy, regulatory framework for pharmaceuticals and global health strategy	2022	Ongoing	Number of meetings
1.1	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	N/A	Ongoing	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
1.1.	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.	Maintenance, exchange of information and engagement with existing Confidentiality Arrangement partners Establishment of new Confidentiality Arrangements	Facilitate and foster International cooperation	Continuous	Continuous	Number of CAs Number of Ad Hoc CAs Number of product-related received Bilateral and strategic engagements with partners

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Establishment of new Ad Hoc Confidentiality Undertakings				

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 it 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 for 2024 are:

- the implementation of lessons learned from COVID-19 and the Agency's response to the pandemic, including implementation of any lessons learned to date;
- 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.

The division is also responsible for crisis management.

The workforce available in 2024 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.

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.

To meet the high demand for information on COVID-19 related topics, EMA created a special COVID-19 section on its website that is regularly updated, initiated bi-weekly press conferences, and strengthened its social media activities, including communication via a Twitter account and regular updates on LinkedIn and YouTube. 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 Agency has organised public stakeholder meetings and put in place a dedicated, centralised service to respond to queries received from patients, healthcare professionals and academia.

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 available, oversees EMA's branding, corporate identity and online visibility, and organises media and communication training for EMA staff.

Workload indicators

	Results	Expected results	Forecasts	
	2022	**2023**	**2024**	**2025**
Number of EPAR summaries and EPAR summaries updates published	204	160	160	160
Number of documents published on EMA website	6,403	7,500	7,500	7,500
Number of pages published and updated on EMA website	2,851	3,500	3,500	3,500
Number of press releases and news items published	164	140	120	120
Numbers of press and other external briefings conducted[16]	15	5	5	5
Number of social media posts published	704	1,300	1,300	1,300
Number of completed interviews[17]	36	30	30	30
Number of media queries responded[18]	1,269	1,200	1,200	1,200
Number of reports, brochures, leaflets laid out or printed, social media visuals	811	800	800	800

Performance indicators

	Results	Expected results	Targets	
	2022	**2023**	**2024**	**2025**
Average rating given to pages on corporate website during the year	3.2	3.6	3.7	3.8

[16] New indicator introduced in 2024 work programme.
[17] New indicator introduced in 2024 work programme.
[18] New indicator introduced in 2024 work programme.

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.

Workload indicators

	Results	**Expected results**	**Forecasts**	
	2022	**2023**	**2024**	**2025**
Number of professional membership organisation events attended by participating Agency staff	36	30	25	25
Number of sessions with Agency representatives	158	158	120	120
Number of patients and consumers eligible organisations[19]	n/a	n/a	42	42
Number of healthcare professionals eligible organisations[20]	n/a	n/a	38	38
Active patients expert nominated by EMA[21]	n/a	n/a	145	145
Active healthcare professionals experts nominated by EMA[22]	n/a	n/a	80	80
Number of messages circulated via 'Early Notification System'	646	500	500	500
Number of EMA communications pro-actively sent to stakeholders	206	200	200	200

[19] New indicator introduced in 2024 work programme.
[20] New indicator introduced in 2024 work programme.
[21] New indicator introduced in 2024 work programme.
[22] New indicator introduced in 2024 work programme.

Performance indicators

	Results	Expected results	Targets	
	2022	**2023**	**2024**	**2025**
Satisfaction level of patient and consumer organisations	n/a	90%	n/a	80%
Satisfaction level of Healthcare Professionals organisations	n/a	85%	n/a	80%

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.

Workload indicators

	Results	Expected results	Forecasts	
	2022	**2023**	**2024**	**2025**
Access to documents, requests received	676	750	750	750
Access to documents, documents released	1,128	1,500	2,000	2,000
Requests for information received	7,342	8,000	10,000	10,000
Clinical Data Publication (CDP), Procedures published	n/a	45	45	45

Clinical Data Publication (CDP), Documents published	n/a	750	750	750

Performance indicators

	Results	**Expected results**	**Targets**	
	2022	**2023**	**2024**	**2025**
Triage of incoming requests received via AskEMA within set timelines	99.00%	100%	100%	100%
Response to ATD within set timelines[23]	88.50%	90%	90%	90%
Response to RFI within set timelines (for EMA)	87.00%	95%	95%	95%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	68.00%	75%	75%	75%
Satisfaction level of partners/stakeholders with EMA communications as per 'EMA perception survey for communication'	76%	n/a	80%	n/a

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.

[23] 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, the 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	
	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
	Planning of communication activities and campaigns in key topic 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	Maximise public health impact of communication	2024	2024	Timely delivery and implementation of communication campaigns
	Implementation of scientific publication strategy	Maximise public health impact of communication	2024	2026	Timely delivery of scientific publications in key topic areas
	Manage and further develop EMA's social media activities	Expand outreach to broader targeted audience			Implementation of EMA's social media strategy
	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

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Coordination of International Coalition of Medicines Regulatory Authorities (ICMRA) communications	Increase the visibility of international collaboration of regulatory authorities	2023	2024	Implementation of communication action plan of ICMRA communication sub-group
	Continue work on automation of processes for requests for information and access to documents from third parties	Increased efficiency of ATD, RFI and CDP	2024	2024	IT tools delivered in collaboration with the relevant value stream
	Implementation of phase 2 of the strategy for CDP re-launch beyond COVID-19	Increased transparency by providing access to clinical documents supporting EMA decisions on CAPs	2024	2024	Finalise approach for CDP in consultation with relevant stakeholders
	Develop a more proactive approach to countering misinformation	Better and earlier awareness of mis- and/or disinformation, enabling tailored counter-information/transparency	2024	2026	EMA Framework for handling mis/disinformation 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

In 2024, the Information Management Division will focus on the delivery of critical capabilities to support the European Medicines Shortages Platform, the implementation of the new Fee Regulation and capabilities to enable the continued implementation of the ISO IDMP standard for all medicinal products in the EU.

Furthermore, the Information Management Division will start preparing for the changes stemming from the new pharmaceutical legislation by accelerating the modernisation and consolidation of IT systems into fewer strategic platforms while improving service levels and expanding information services to address the emerging needs of the European Medicines Regulatory Network. This will facilitate the implementation of new requirements and enable an integrated approach for managing all regulatory procedures under the anticipated new legislation.

The Information Management Division will also contribute to the development of the European Health Data Space (EHDS) through further development of a modern Data Analytics Platform, which will centralise the 'datasets' that EMA will submit to the EU Health Data Access Body. The DAP will include the tools for data governance to support implementation of the anticipated EHDS regulation.

The Information Management Division will continue to collaborate across the Agency to deliver brand-new enterprise-wide artificial intelligence capabilities and pursue the data protection impact assessment for the Microsoft Azure OpenAI service.

Another milestone for next year is the establishment of a major IT framework contract that builds on agile delivery principles, quality and supports implementation EMA's Technology Capability Investment Plan (TCIP).

In addition, the Information Management Division at EMA is undertaking several initiatives to ensure optimal collaboration with our key stakeholders across the Network, including both National Competent Authorities and the European Commission. Two annual meetings are co-organised by EMA with the EU Presidency team for the NCA IT Directors and Experts where best practices, risks and opportunities are explored and shared. In 2024, the Belgian Presidency will host a meeting in Antwerp, Belgium in February, and a meeting hosted by the Hungarian Presidency is foreseen for the second half of 2024. Moreover, the Network ICT Advisory Committee, a representative body consisting of NCA IT Directors and Experts as well as a Commission representative will meet six times in 2025, to advise on current and upcoming technical and interoperability matters that will impact the Network.

EMA continues its collaboration with the Health Policy Agencies Collaboration (HPAC), as facilitated by DG SANTE. In addition, in 2024, EMA will host an inter-agency meeting of EU agency IT Directors and senior IT experts to explore future business opportunities cases and potential areas for collaboration across the EU agencies and the European Commission.

In addition, the Information Management division will continue to be a key contributor in the area of data standardisation efforts linked to ISO and HL7 collaborating with international organisations and regulatory authorities (e.g. WHO, USA, Japan, Canada, etc.) to further advance the global implementation of medicinal product standards.

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** focus on providing best-in-class service management for digital workplace, infrastructure, and regulatory data management. 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** is responsible for the operational and strategic management of IT services and comprises sourcing, planning, governance and assurance, communications and enterprise IT architecture functions, supporting strategic planning, road mapping, and application portfolio optimisation.

The workforce available in 2024 for the Division is currently foreseen at 101 staff (76 TAs, 25 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**	
		2022	**2023**	**2024**	**2025**
Network Portfolio	Number of information services/IT systems provided by EMA	n/a	28	28	28

Performance indicators

		Results	**Expected results**	**Targets**	
		2022	**2023**	**2024**	**2025**
Network Portfolio	Satisfaction of EMA internal and external users	96.00%	80%	80%	80%
	Availability of IT systems and corporate website	98.20%	98%	98%	98%

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 the proper governance 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. An additional item of focus will be the implementation of the hybrid working practices outlined in the model rules for EU agencies;
- the new fee regulation which will enter in to force in January 2025. The implementation includes the redesign of fee-related processes and the update of relevant IT tools accordingly;
- several new contracts essential for the running of the Agency will conclude in 2023 or in 2024, in line with the four-year cycle following the Agency's relocation, and working relations will need to be established with the providers under the said contracts;
- 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 process 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.

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, ex ante 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.

The workforce available in 2024 for the Division is currently foreseen at 152 staff (119 TAs, 29 CAs, 4 SNE). 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**	
		2022	**2023**	**2024**	**2025**
Human Resources	Total TA staff recruited against vacant posts	45	50	50	50
	Staff turnover rate (staff leaving against total no. of staff TA & CA)	5.3%	5%	5%	5%
	Total TA, CA, END at the Agency	n/a	930	950	950
	Onboarding of staff (TAs, CAs, ENDs)	n/a	n/a	75	75

Finance	Financial transactions authorised (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing) (in thousands)[24]	n/a	n/a	72	67
	Procurement procedures finalised[25]	39	56	46	46
	Financial commitments initiated[26]	1,533	1,500	1,500	1,500
	Payment transactions initiated[27]	25,044	27,000	27,000	27,000
	Number of sales orders[28]	n/a	40,000	50,000	45,000
	Number of registration activities[29]	n/a	15,000	14,000	14,000
	PRE financial queries and disputes[30]	n/a	400	250	500
	Receivable overdue for more than 30 days (including provision for bad debts)	2.54%	<10%	<10%	<10%

Performance indicators

		Results	**Expected results**	**Targets**	
		2022	**2023**	**2024**	**2025**
Human Resources	Posts on the Agency establishment plan filled	99.40%	100%	100%	100%
	Average time to run selection procedures from vacancy notice to establishment of reserve list	n/a	100% <3 months	100% average < 3 months	100% average < 3 months
Planning and Monitoring	Revenue appropriations implemented	98.35%	97%	97%	97%
	Expenditure appropriations implemented	96.80%	95%	95%	95%

[24] New indicator introduced in 2024 work programme.
[25] New indicator introduced in 2024 work programme.
[26] New indicator introduced in 2024 work programme.
[27] New indicator introduced in 2024 work programme.
[28] New indicator introduced in 2024 work programme.
[29] New indicator introduced in 2024 work programme.
[30] New indicator introduced in 2024 work programme.

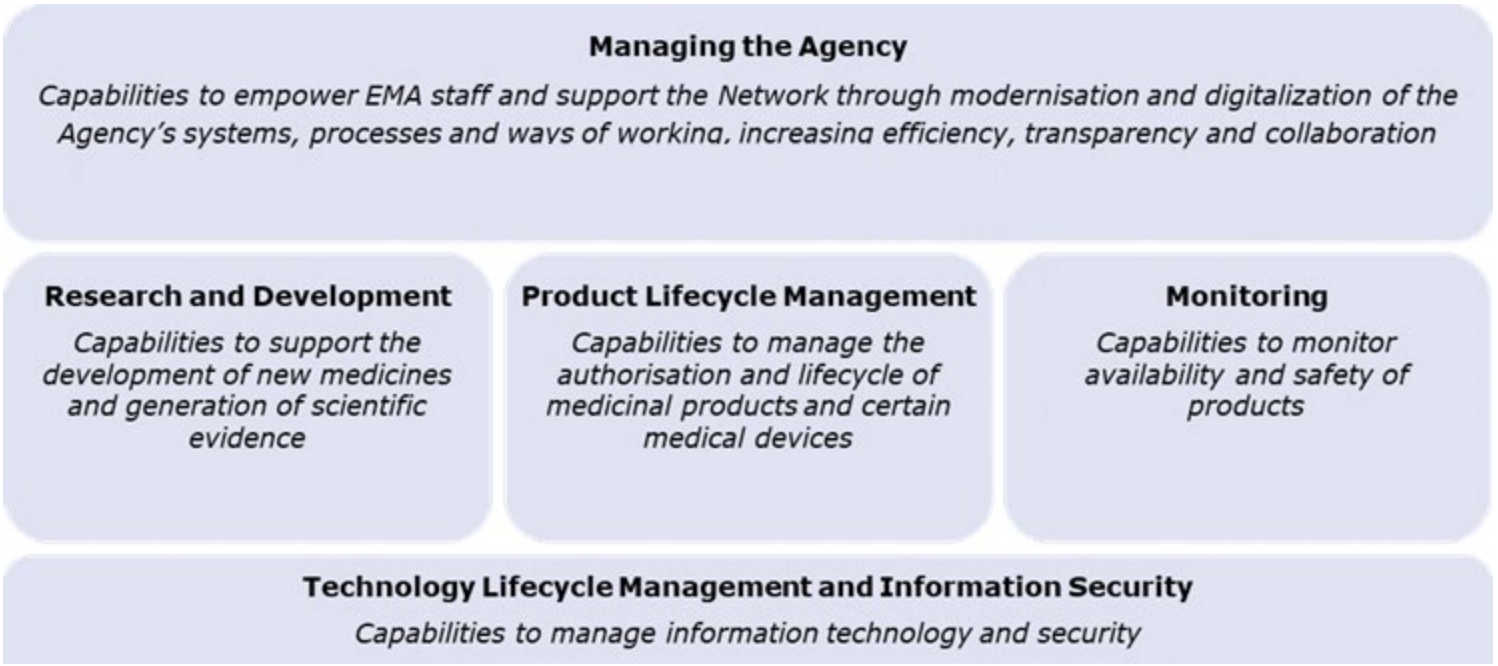
	Payments against appropriations carried over from year N-1	95.11%	95%	95%	95%
	The maximum rate of carryover to year N+1, of total commitments within the title				
	Title 1	4.34%	10%	10%	10%
	Title 2	26.38%	20%	20%	20%
	Title 3	40.06%	30%	30%	30%
Finance	Payments made within 30 days' time	97.98%	98%	98%	98%
	Balance sheet volume (as proxy for treasury mgmt., accounts receivable/payable transactions, audits, financial analysis, and reporting) (in million EUR)	n/a	n/a	405	405

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 Start	Timeframe End	Performance indicator
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 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.	2023	2025	Agile approach to delivery of products/ambitions prioritised for 2024: 1. Sustainable organisation: Improved resource planning & allocation through design of resource allocation framework and resource decision tree 2. Talent management: Development paths for future leaders, Talent review process, Exchange & rotation programme, Delivery of Agency-wide Development Day 3. Wellbeing: Implementation of the Wellbeing programme (including training, communication and events), Renewed social and employee assistance 4. Optimised work environment: Adjustment of the office workplace to enable the new ways of working; Establish framework for Manager's community. 5. One Agile HR: HR Processes review and improvement: mapping and analysing HR processes; within HR digitalisation: delivery of Fieldglass to support contractor and interim workforce processes, OpenText HR workflows and 75% of capabilities for the Employee Central
6.4	Review of options for a replacement of the finance system Replacement of the human resource management system SAP and review of HR management processes	Gradual replacement of the financial and HR system in line with the future project plan	2023	2025	Implementation of the project plan once confirmed
6.3	Implementation of the new Fee Regulation: Review of processes Implementation of the tools enabling of the new fee regulation (3 epics)	Support provided to the EU institutions in the review of the new fee regulation to ensure sustainability of the Agency and the European Medicines Regulatory Network	2021	2024	Implementation of the Fee Regulation following the mandatory deadlines

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 2024, to be reviewed during quarterly Programme Increment Planning ceremonies. The planned deliverables for 2025 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 2025, based on the progress made in 2024.

Note 1: The budget figures for 2024 show the total estimated cost of the project, 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.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (epics) 2024	Budget 2024 (M€)
Product Lifecycle Management Value Stream (PLM VS) *Capabilities to authorise and manage lifecycle of medicines and medical devices*					**13.6**
Electronic Application Form *(part of the Product Lifecycle Management Portal)*		2021	2025	– Human Variations Form go-live and support for centrally and non-centrally authorised products – Progression of work on the Initial Marketing Authorisation form for Human and Veterinary products	
Product Data Management User Interface *(part of the Product Lifecycle Management Portal)*		2023	2025	– Capabilities for viewing product data – Initial introduction of functionalities for submission and correction of product data	
Regulatory Procedure Management (RPM) for PLM *(part of the IRIS portal)*		2022	2026	– RPM capabilities for Variations, Transfers, Art 61.3 – RPM capabilities for PSUR, PSUSA, PAMs – Support for implementation of the New Fee Regulation	
Electronic Product Information (ePI) *(part of the Product Lifecycle Management Portal)*		2022	2024	– ePI Pilot with volunteer National Competent Authorities and industry – Preparations for further implementation of ePI	
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	2024	– IDMP Implementation (Data migration/transformation into ISO IDMP format) – XEVMPD integration with PMS – SIAMED data integration with PMS – FHIR Adaptor (Capabilities to import IDMP compliant product data to PMS) – XEVMPD replacement strategy: Analysis and roadmap towards a simplification and replacement of the existing Article 57 legacy submission systems	
eCTD4 (eSubmissions incl. EURS/CR)		2021	2026	– Completion of eCTD v4.0 specification and implementation guide update for the Europe (EU) region – Progression towards pilot and optional use support of eCTD v4.0 submissions for centrally authorised products	

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (epics) 2024	Budget 2024 (M€)
Veterinary Union Product Database (UPD)		2021	2025	– UPD maintenance and improvements to meet legislative requirements, improve usability and support improved data quality	
European Medicines Web Portal (EMWP)	– Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010, Article 26(1)	2024	2026	– Refresh of the strategy towards a European Medicines Web Portal for medicinal products for human use, in alignment with the existing portal for veterinary medicines	
Research and Development Management Value Stream (R&D VS) *Capabilities to foster the development of medicines and generate scientific evidence*					**12.6**
Regulatory Procedure Management (RPM) for R&D		2023	2024	– Paediatrics procedure – Support for implementation of the New Fee Regulation – Maintenance and improvements	
Clinical Trials Information System (CTIS)	– Regulation (EC) 536/2014, art.80-82 – Art. 11(3) of Implementing Regulation to Regulation (EC) 536/2014	2014	tbc	– CTIS maintenance and improvements – CTIS Business Intelligence (CTIS BI) maintenance and improvements	
Clinical Trial Navigator (CTN)		2023	2025	– Development of Clinical trial study protocol conceptual and logical data model (ICH M11)	
Real World Metadata Catalogues		2021	2024	– Go-live of the Catalogue of real-world evidence data sources and studies in Q1/2024 – Maintenance and improvements	
Scientific Explorer		2020	2024	– Completion of the Minimum Viable Product (MVP) for the interrogation of regulatory and scientific documents and Go-live in Q1/2024 – Maintenance and improvements	
T.R.I.P. (Horizon Scanning)		2023	2024	– Completion of the Minimum Viable Product (MVP) for the horizon scanning capability (identify futures innovations and trends earlier to support development) and Go-live in Q1/2024 – Maintenance and improvements	
Data Analytics Platform		2024	2024	– Support generation of scientific evidence	

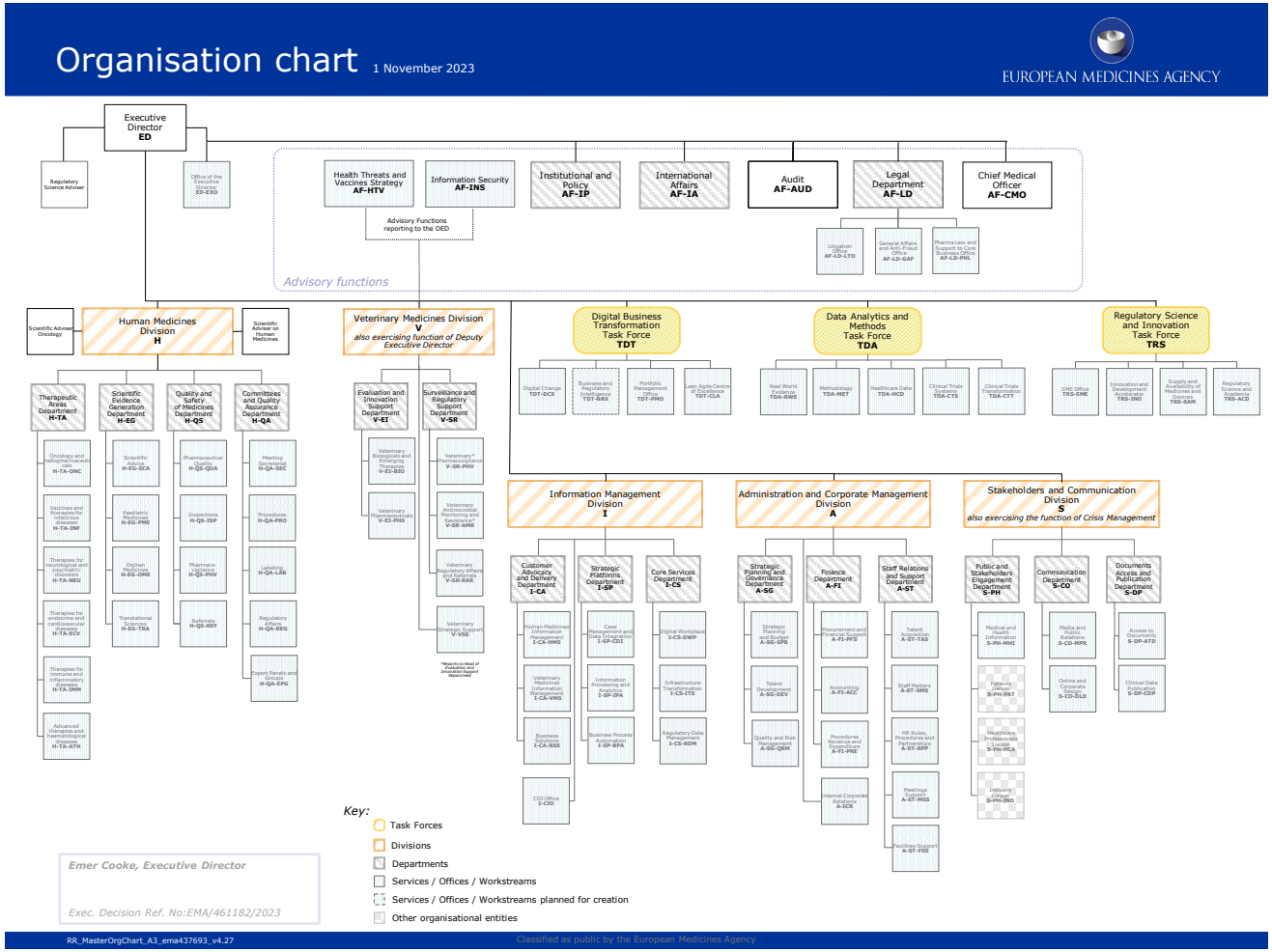
Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (epics) 2024	Budget 2024 (M€)
Monitoring Value Stream (MON VS) *Capabilities to monitor availability and safety of products*					**9.3**
European Shortages Monitoring Platform (ESMP)	– Regulation (EU) 2022/123	2022	2025	– Monitoring of events in preparation for major crisis or Public Health Emergency (PHE) – Monitoring of Critical Medicines during PHE/major events – Interoperability of ESMP	
Inspections		2023	2025	– Maintenance, improvements and support for implementation of the New Fee Regulation	
Parallel Distribution		2023	2025	– Maintenance, improvements and support for implementation of the New Fee Regulation	
Union Pharmacovigilance Database (UPhD, formerly EVVet3)	– Regulation (EC) 726/2004, art.57(d) – Regulation (EU) 2019/6; associated implementing acts	2017	2024	– Maintenance and improvements	
Antimicrobial Sales & Use (ASU)	– Article 57 of Reg (EU) 2019/6, Commission Delegated Act 2021/578 – Commission Implementing act 2022/209	2021	2024	– Minimum viable product completion – Maintenance and improvements	
Signal and Safety Analytics (SSA)[31]		2023	2024	– Signal and Safety Analytics – minimum viable product	
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*					**12.5**
SAP Finance replacement		2023	2025	– Finalise Analysis and technology selection	
SAP HR replacement		2023	2025	– Kick off implementation of HR Data Organisation and processes	
New Fee Regulation	*(Regulation expected to be adopted in December 2023)*	2023	2025	– Implementation of new fee process in existing EMA applications – Pre-payment process implementation for some procedures	

[31] When the product is fully implemented, computation of eRMRs for all substances will be enabled.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (epics) 2024	Budget 2024 (M€)
				– Vet pharmacovigilance fees implementation	
EU Network Training Centre (EU NTC)		2022	2024	– EU NTC engagement portal for public	
Document Management System replacement		2023	2024	– Kick off implementation of DREAM replacement	
Ask EMA		2023	2024	– Ask EMA replacement implementation	
Customer Relationship Management (CRM) tool		2024	2026	– Kick off analysis for an Agency CRM tool	
Technology Lifecycle Management and Information Security Value Stream (TLM VS) *Capabilities to manage information technology and security*					**4.2**
Information Security and Cyber Security enhancements		2022	2024	– Cyber & Information Security enhancements – Operational Security enhancements – Application Security enhancements	
Remaining legacy application modernisation analysis		2023	2024	– Analysis on the future-proof solutions the current legacy apps could be migrated to – Prioritization of the legacy apps – Proof of Concept for one app	
Data Centre 2.0 (DC 2.0)		2023	2024	– Migration of all workloads in the AWS cloud – Migration/activation of the infrastructure components – Decommissioning of the current physical equipment (physical DC)	

Annexes

Annex I Organisational Chart



Annex II – Resource allocation per activity 2024 - 2025

Activity-based budget 2024

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	Articles 302 & 303		
1 Evaluation activities for human medicines	**282**	**109**	**67,582**	**37,841**	**5,461**	**161,158**	**8,087**	**280,129**	**59%**
1.1 Pre-authorisation activities	78	31	19,805	6,406	2,963	29,156	54	58,384	12%
1.2 Initial evaluation activities	50	13	11,180	3,284	30	18,275	1,050	33,818	7%
1.3 Post-authorisation activities	73	24	15,769	14,361	-	96,776	1,960	128,867	27%
1.4 Referrals	6	1	1,044	384	9	-	160	1,596	0%
1.5 Pharmacovigilance activities	45	23	11,343	10,186	1,616	16,950	4,470	44,565	9%
1.6 Other specialized areas and activities	25	15	7,401	2,253	843	-	7	10,504	2%
1.7 Medical Devices	4	1	1,040	967	-	-	387	2,394	1%
2 Evaluation activities for veterinary medicines	**33**	**16**	**8,176**	**6,322**	**625**	**7,074**	**535**	**22,732**	**5%**
2.1 Pre-authorisation activities	1	0	302	123	317	301	2	1,045	0%
2.2 Initial evaluation activities	9	2	1,678	526	25	1,368	263	3,859	1%
2.3 Post-authorisation activities	10	3	1,996	869	-	2,585	235	5,684	1%
2.4 Arbitrations and Referrals	1	1	238	95	-	-	7	340	0%
2.5 Pharmacovigilance activities	5	4	1,614	3,978	122	2,821	27	8,562	2%
2.6 Other specialized areas and activities	7	6	2,350	731	161	-	-	3,242	1%
3 Horizontal activities and other areas	**212**	**92**	**53,925**	**42,954**	**10,026**	**6,544**	**19,933**	**133,381**	**28%**
3.1 Committee coordination	53	27	13,432	8,652	5,231	-	2,000	29,316	6%
3.2 Inspection and Compliance	24	20	6,887	2,880	860	6,544	34	17,205	4%
3.3 Partners and Stakeholders	34	11	8,788	2,522	1,868	-	658	13,837	3%
3.3a Transparency and access to documents	15	9	4,071	1,401	-	-	-	5,472	1%
3.3b Information	37	16	9,091	7,532	991	-	119	17,734	4%
3.4 International activities	15	1	3,650	960	227	-	-	4,837	1%
3.5 Information Management (incl. EU Telematics)	34	9	8,005	19,005	848	-	17,122	44,981	9%
4 Corporate Governance and Support activities	**139**	**32**	**28,796**	**13,004**	**431**	**-**	**8**	**42,239**	**9%**
4.1 Governance, quality management and internal audit	24	5	6,233	2,360	431	-	-	9,023	2%
4.2 Finance	31	10	6,290	3,140	-	-	8	9,438	2%
4.3 Information technology	26	5	5,693	1,761	-	-	-	7,454	2%
4.4 Human resources	47	11	8,746	5,043	-	-	-	13,789	3%
4.5 Infrastructure services	11	1	1,834	701	-	-	-	2,535	1%
Total	**666**	**248**	**158,479**	**100,121**	**16,543**	**174,776**	**28,563**	**478,482**	**100%**

FTEs are calculated as follows:	FTEs
Temporary Agents	691
Less vacancy	25
Estimated Temporary Agents	666
Contract Agents	203
Seconded National Experts	45
Total Staff	**914**

Annex III: Financial Resources 2024 – 2026

Table 1 – Revenue

General revenues

Revenues	2023	2024	2025	2026
	Revenue estimated by the agency	Budget forecast	Budget forecast	Budget forecast
EU contribution	€ 50,136,561	€ 34,844,000	€ 35,218,000	€ 35,217,000
Other revenue	€ 388,674,715	€ 443,638,000	€ 531,794,000	€ 542,430,000
PROVISIONAL REVENUE				
Total revenue	**€ 438,811,276**	**€ 478,482,000**	**€ 567,012,000**	**€ 577,647,000**

REVENUES	General Revenues		General Revenues						
	Executed 2022[1]	Estimated by the agency 2023[2]	2024		VAR 2024/2023 (%)	2025		VAR 2025/2024 (%)	forecast 2026
			agency request	budget forecast		agency request	budget forecast		
1 Revenue from services rendered	€ 364,882,044	€ 387,090,033.71	€ 441,910,000	€ 441,910,000	14.16%	€ 530,081,000	€ 530,081,000	19.95%	€ 540,682,000
2 EU and EEA contribution	€ 49,679,960	€ 50,136,560.86	€ 34,844,000	€ 34,844,000	-30.50%	€ 35,218,000	€ 35,218,000	1.07%	€ 35,217,000
- of which special contribution for orphan medicinal products	€ 12,895,240	€ 10,733,120	€ 14,502,000	€ 14,502,000	35.11%	€ 14,502,000	€ 14,502,000	0.00%	€ 14,501,000
- of which assigned revenues deriving from previous years' surpluses	€ 4,368,321	€ 24,982,177.86	€ 10,459,000	€ 10,459,000	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	€ 55,129	€ 1,359,529.4	€ 1,453,000	€ 1,453,000	6.88%	€ 1,438,000	€ 1,438,000	-1.03%	€ 1,467,000
- 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	€ 245,477	€ 225,152.03	€ 275,000	€ 275,000	n/a	€ 275,000	€ 275,000	p.m.	€ 281,000
TOTAL REVENUES	**€ 414,862,610**	**€ 438,811,276.00**	**€ 478,482,000**	**€ 478,482,000**	9.04%	**€ 567,012,000**	**€ 567,012,000**	18.50%	**€ 577,647,000**

1) Data as per final 2022 accounts

2) Data updated in accordance with the provisional outturn

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

REVENUES	2023	2024	2025	2026
	Budget forecast	Budget forecast	Budget forecast	Budget forecast
TOTAL REVENUES	€ 342,000	€ 342,000	€ 0	€ 0

REVENUES	General Revenues					General Revenues				
	Executed 2022[1]	Estimated by the agency[2] 2023	2024		VAR 2024/2023 (%)	Estimated by the agency 2025	2025		VAR 2025/2024 (%)	Forecast 2026
			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 2022

2) Data updated in accordance with the provisional outturn

Table 2 – Expenditure

Expenditure	2022 [1]		2023		2024		2025		2026	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1 - Staff expenditure	€ 138,841,910	€ 138,841,910	€ 157,063,463	€ 157,063,463	€ 158,479,000	€ 158,479,000	€ 166,383,000	€ 166,383,000	€ 169,709,000	€ 169,709,000
Title 2 - Infrastracture and operating expenditure	€ 52,245,279	€ 52,245,279	€ 71,713,992	€ 71,713,992	€ 71,043,000	€ 71,043,000	€ 76,122,000	€ 76,122,000	€ 77,645,000	€ 77,645,000
Title 3 - Operational expenditure	€ 217,237,648	€ 217,237,648	€ 215,269,672	€ 215,269,672	€ 248,960,000	€ 248,960,000	€ 324,507,000	€ 324,507,000	€ 330,293,000	€ 330,293,000
Title 9 - Provisional appropriations			€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 408,324,837**	**€ 408,324,837**	**€ 444,047,128**	**€ 444,047,128**	**€ 478,482,000**	**€ 478,482,000**	**€ 567,012,000**	**€ 567,012,000**	**€ 577,647,000**	**€ 577,647,000**

1) Data as per final 2022 accounts

Expenditure	2022			2023			2024			2025			2026		
	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	€ 69,774,615	€ 69,067,295	€ 138,841,910	€ 79,446,224	€ 77,617,239	€ 157,063,463	€ 97,780,012	€ 60,698,988	€ 158,479,000	€ 102,646,651	€ 63,736,349	€ 166,383,000	€ 104,698,560	€ 65,010,440	€ 169,709,000
Title 2 - Infrastructure and operating expenditure	€ 25,329,830	€ 26,915,449	€ 52,245,279	€ 31,872,109	€ 39,841,883	€ 71,713,992	€ 39,499,490	€ 31,543,510	€ 71,043,000	€ 42,940,858	€ 33,181,142	€ 76,122,000	€ 43,799,991	€ 33,845,009	€ 77,645,000
Title 3 - Operational expenditure	€ 194,235,776	€ 23,001,872	€ 217,237,648	€ 189,723,454	€ 25,546,218	€ 215,269,672	€ 229,138,976	€ 19,821,024	€ 248,960,000	€ 303,304,462	€ 21,202,538	€ 324,507,000	€ 308,712,419	€ 21,580,581	€ 330,293,000
Title 9 - Provisional appropriations	€ 0		€ 0	€ 0		€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 289,340,221**	**€ 118,984,616**	**€ 408,324,837**	**€ 301,041,787**	**€ 143,005,341**	**€ 444,047,128**	**€ 366,418,478**	**€ 112,063,522**	**€ 478,482,000**	**€ 448,891,971**	**€ 118,120,029**	**€ 567,012,000**	**€ 457,210,969**	**€ 120,436,031**	**€ 577,647,000**
% of total expenditure	**71%**	**29%**	**100%**	**68%**	**32%**	**100%**	**77%**	**23%**	**100%**	**79%**	**21%**	**100%**	**79%**	**21%**	**100%**
* Full-time Equivalent	478	408	**886**	494	421	**915**	583	331	**914**	596	341	**937**	625	357	**982**
% of total FTEs	54%	46%	**100%**	54%	46%	**100%**	64%	36%	**100%**	64%	36%	**100%**	64%	36%	**100%**

* From 2021 it includes the additional Staff as stated in draft extension of the Agency's mandate

EXPENDITURE	Commitment appropriations								
	Executed budget 2022[1]	Estimated by the Agency, 2023[2]	Draft budget 2024		VAR 2024/2023 (%)	Preliminary draft budget 2025		VAR 2025/2024	Forecast 2026
			Agency request	Budget forecast		Agency request	Budget forecast		
Title 1 - Staff Expenditure									
11 Staff holding a post provided for in the list of posts	117,411,847	€ 131,978,689	€ 132,281,000	€ 132,281,000	0.23%	€ 140,016,000	€ 140,016,000	5.85%	€ 142,816,000
- of which establishment plan posts									
- of which external personnel									
12 Expenditure relating to staff recruitment	202,880	€ 132,726	€ 300,000	€ 300,000	126.03%	€ 200,000	€ 200,000	-33.33%	€ 204,000
13 Duty travel expenses and incidental expenditure	388,680	€ 903,948	€ 1,530,000	€ 1,530,000	69.26%	€ 2,200,000	€ 2,200,000	43.79%	€ 2,244,000
14 Socio-medical infrastructure	2,433,756	€ 2,886,491	€ 3,604,000	€ 3,604,000	24.86%	€ 3,822,000	€ 3,822,000	6.05%	€ 3,898,000
15 Staff training	1,011,818	€ 1,064,662	€ 1,250,000	€ 1,250,000	17.41%	€ 1,416,000	€ 1,416,000	13.28%	€ 1,444,000
16 External services	17,301,239	€ 19,977,047	€ 19,400,000	€ 19,400,000	-2.89%	€ 18,565,000	€ 18,565,000	-4.30%	€ 18,936,000
17 Receptions and events	91,691	€ 119,900	€ 114,000	€ 114,000	-4.92%	€ 164,000	€ 164,000	43.86%	€ 167,000
Total Title 1	**€ 138,841,910**	**€ 157,063,463**	**€ 158,479,000**	**€ 158,479,000**	0.90%	**€ 166,383,000**	**€ 166,383,000**	**4.99%**	**€ 169,709,000**
Title 2 - Infrastructure and operating expenditure									
20 Investment in immovable property, renting of buildings and associated costs	14,880,714	€ 17,363,332	€ 17,999,000	€ 17,999,000	3.66%	€ 19,011,000	€ 19,011,000	5.62%	€ 19,391,000
21 Corporate information and communication technology	30,449,340	€ 45,193,610	€ 42,996,000	€ 42,996,000	-4.86%	€ 45,091,000	€ 45,091,000	4.87%	€ 45,993,000
22 Movable property and associated costs	581,136	€ 635,874	€ 759,000	€ 759,000	19.36%	€ 659,000	€ 659,000	-13.18%	€ 672,000
23 Current administrative expenditure	1,333,674	€ 1,412,687	€ 1,939,000	€ 1,939,000	37.26%	€ 1,798,000	€ 1,798,000	-7.27%	€ 1,834,000
24 Postal and delivery services	19,636	€ 19,065	€ 33,000	€ 33,000	73.09%	€ 33,000	€ 33,000	0.00%	€ 34,000
25 Other meetings	165,255	€ 90,691	€ 122,000	€ 122,000	34.52%	€ 125,000	€ 125,000	2.46%	€ 128,000
26 Restaurant and catering	1,023,101	€ 2,028,975	€ 1,172,000	€ 1,172,000	-42.24%	€ 2,241,000	€ 2,241,000	91.21%	€ 2,286,000
27 Information and publishing	1,807,772	€ 1,700,226	€ 1,410,000	€ 1,410,000	-17.07%	€ 2,118,000	€ 2,118,000	50.21%	€ 2,160,000
28 Business consultancy and audit services	1,984,652	€ 3,269,532	€ 4,613,000	€ 4,613,000	41.09%	€ 5,046,000	€ 5,046,000	9.39%	€ 5,147,000
Total Title 2	**€ 52,245,279**	**€ 71,713,992**	**€ 71,043,000**	**€ 71,043,000**	**-0.94%**	**€ 76,122,000**	**€ 76,122,000**	**7.15%**	**€ 77,645,000**
Title 3 - Operational expenditure									
300 Meetings	2,193,316	€ 4,743,997	€ 5,648,000	€ 5,648,000	19.06%	€ 7,391,000	€ 7,391,000	30.86%	€ 7,539,000
301 Evaluation of medicinal products	145,993,812	€ 153,968,032	€ 174,776,000	€ 174,776,000	13.51%	€ 239,715,000	€ 239,715,000	37.16%	€ 244,509,000
302 Translations	4,072,491	€ 4,201,264	€ 4,160,000	€ 4,160,000	-0.98%	€ 4,495,000	€ 4,495,000	8.05%	€ 4,585,000
303 Scientific studies and services	27,604,840	€ 12,176,253	€ 24,403,000	€ 24,403,000	100.41%	€ 31,937,000	€ 31,937,000	30.87%	€ 32,576,000
31 Expenditure on business related IT projects	37,373,189	€ 40,180,126	€ 39,973,000	€ 39,973,000	-0.52%	€ 40,969,000	€ 40,969,000	2.49%	€ 41,084,000
Total Title 3	**€ 217,237,648**	**€ 215,269,672**	**€ 248,960,000**	**€ 248,960,000**	**15.65%**	**€ 324,507,000**	**€ 324,507,000**	**30.35%**	**€ 330,293,000**
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	**€ 408,324,837**	**€ 444,047,128**	**€ 478,482,000**	**€ 478,482,000**	**7.75%**	**€ 567,012,000**	**€ 567,012,000**	**18.50%**	**€ 577,647,000**

1) Data as per final accounts 2022

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 2024

Table 3 – Budget outturn and cancellation of appropriations 2019 - 2023

Budget outturn	2019	2020	2021	2022[1)]	2023[2)]
Revenue actually received (+)	€ 339,889,499.26	€ 376,246,022.54	€ 382,156,343.70	€ 414,862,609.76	€ 438,811,276.00
Payments made (-)	-€ 292,769,994.74	-€ 290,132,295.87	-€ 274,400,002.19	-€ 301,496,618.72	-€ 347,820,472.27
Carry-over of appropriations (-)	-€ 59,150,354.42	-€ 75,300,936.06	-€ 91,090,698.54	-€ 106,828,218.21	-€ 96,226,655.69
Cancellation of appropriations carried over (+)	€ 2,744,268.82	€ 2,423,908.71	€ 5,372,131.21	€ 4,455,177.77	€ 5,174,935.87
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 0.00	€ 0.00	€ 0.00	€ 3.26	€ 0.00
Exchange rate differences (+/-)	€ 1,003,466.80	-€ 585,264.08	€ 2,944,406.68	-€ 533,910.72	€ 81,854.68
Adjustment for negative balance from previous year (-)	€ 0.00	-€ 8,283,114.28	€ 0.00	€ 0.00	
Total	**-€ 8,283,114.28**	**€ 4,368,320.96**	**€ 24,982,180.86**	**€ 10,459,043.14**	**€ 20,938.59**

1) Data as per final 2022 accounts

2) Data updated in accordance with the provisional outturn. Expenditure includes EUR 800 000 non-automatic carry forward (C2 - 2024)

The financial outturn for 2023, a surplus of approximately EUR 20 939, representing 0.005% of the approved budget (including Amending budget 01-2023), i.e. EUR 448.6 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 2023 is as follows:

- Title I -Staff expenditure - final implementation was 99.5%, which is considered a good result;
- Title II - infrastructure and operating expenditure - final implementation was 98.8%, which is considered a good result;
- Title III - operational expenditure - final was 98.7%, which is considered a good result.

The agency managed to comply with the indicative ceiling for the amounts carried forward (C1 to C8):

- Title I (indicative ceiling of 10%), where 4.89% of committed appropriations were carried forward to 2024.
- Title II (indicative ceiling of 20%), 24.86% of committed appropriations were carried forward to 2023. The main contributors were IT budget lines (CH21), restaurant and canteen and business consultancy.

- Title III (indicative ceiling of 30%), 32.59% of committed appropriations were carried forward. The main contributors were budget lines 3030, scientific studies and budget line 3105, business IT development.

For both titles II and III, the high carry forward were to a large extent caused by contracts which for procedural reasons were concluded late in the year as well delay in delivering the services.

Annex IV: Human Resources – Quantitative

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

- A. Statutory staff and SNEs

Staff	2022			2023			2024	2025	2026	2027
ESTABLISHMENT PLAN POSTS	**Authorised Budget**	**Actually filled as of 31/12/2022**	**Occupancy rate %**	**Authorised Budget**	**Actually filled as of 31/12/2023***	**Occupancy rate %**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**
Administrators (AD)	477	473	99%	495	477	96%	500	531	532	539
Assistants (AST)	185	185	100%	187	187	100%	191	198	202	203
Assistants/Secretaries (AST/SC)	0	0	0%	0	0	0%	0	0	0	0
TOTAL ESTABLISHMENT PLAN POSTS	**662**	**658**	**99%**	**682**	**664**	**97%**	**691**	**729**	**734**	**742**
EXTERNAL STAFF	**FTE corresponding to the authorised budget**	**Executed FTE as of 31/12/2022**	**Execution Rate %**	**FTE corresponding to the authorised budget**	**Executed FTE as of 31/12/2023***	**Execution Rate %**	**Envisaged FTE**	**Envisaged FTE[1]**	**Envisaged FTE[1]**	**Envisaged FTE[1]**
Contract Agents (CA)	223	192	86%	203	204	100%	203	206	206	206
Seconded National Experts (SNE)	30	25	83%	30	42	139%	45	45	45	45
TOTAL EXTERNAL STAFF	253	217	86%	233	245	105%	248	251	251	251
TOTAL STAFF	**915**	**875**	**96%**	**915**	**909**	**99%**	**939**	**980**	**985**	**993**

1) Includes 3 Contract Agents in view of the EC proposal for a Regulation establishing a common data platform on chemicals published on 7 December 2023

- B. Additional external staff expected to be financed from grant, contribution or service-level agreement

Human Resources	2023	2024	2025	2026
	Envisaged FTE	Envisaged FTE	Envisaged FTE	Envisaged FTE
Contract Agents (CA)	1.01	1.01	0.81	0.81
Seconded National Experts (SNE)				
TOTAL	1.01	1.01	0.81	0.81

- C. Other human resources
    - Structural service providers

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

1) Building maintenance: included in the rental package

    - Interim workers

	Total FTEs in year 2023
Number	110

Table 2 – Multi-annual staff policy plan 2022, 2023, 2024, 2025, 2026

Function group and grade	2022				2023				2024		2025		2026	
	Authorised budget		Actually filled as of 31/12/2022		Authorised budget		Actually filled as of 31/12/2023		Authorised budget		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
AD 16		0		0		0		0		0		0		0
AD 15		3		0		3		0		3		3		3
AD 14		10		9		12		3		12		12		12
AD 13		13		13		12		11		12		15		18
AD 12		50		50		57		52		61		64		67
AD 11		52		52		49		49		50		49		48
AD 10		50		50		53		53		57		59		61
AD 9		62		62		66		66		82		94		106
AD 8		77		77		87		87		78		88		91
AD 7		97		97		89		89		90		85		80
AD 6		60		60		67		67		55		62		46
AD 5		3		3		0		0		0		0		0
AD TOTAL	**0**	**477**		**473**	**0**	**495**		**477**	**0**	**500**	**0**	**531**		**532**
AST 11		2		2		2		2		3		3		3
AST 10		7		7		7		7		7		7		7
AST 9		10		10		10		10		10		13		16
AST 8		13		13		14		14		15		19		23
AST 7		19		19		25		25		29		38		47
AST 6		26		26		31		31		35		26		17
AST 5		43		43		43		43		49		56		63
AST 4		42		42		43		43		32		22		12
AST 3		23		23		12		12		11		14		14
AST 2		0		0		0		0		0		0		0
AST 1		0		0		0		0		0		0		0
AST TOTAL	**0**	**185**		**185**	**0**	**187**		**187**	**0**	**191**	**0**	**198**		**202**
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**
GRAND TOTAL	**0**	**662**	**0**	**658**	**0**	**682**		**664**	**0**	**691**	**0**	**729**	**0**	**734**

External personnel

Contract Agents

Contract agents	FTE corresponding to the authorised budget 2022	Executed FTE as of 31/12/2022	Headcount as of 31/12/2022	FTE corresponding to the authorised budget 2023	Executed FTE as of 31/12/2023	Headcount as of 31/12/2023	FTE corresponding to the authorised budget 2024	Envisaged FTE 2025[2]	Envisaged FTE 2026[2]
Function Group IV	122	94	107	122	107	114	125	131	134
Function Group III	81	89	91	81	97	102	78	75	72
Function Group II	0	1	1	0	0	0	0	0	0
Function Group I	0	0	0	0	0	0	0	0	0
Additional CA[1]	20	8	8	0	0	0	0	0	0
TOTAL	**223**	**192**	**207**	**203**	**204**	**216**	**203**	**206**	**206**

1) Additional staff to cover Brexit-related additional work (FTE)

2) Includes 3 Contract Agents in view of the EC Proposal for a Regulation establishing a common data platform on chemicals published on 7 December 2023

Seconded National Experts

Seconded National Experts	FTE corresponding to the authorised budget 2022	Executed FTE as of 31/12/2022	Headcount as of 31/12/2022	FTE corresponding to the authorised budget 2023	Executed FTE as of 31/12/2023	Headcount as of 31/12/2023	FTE corresponding to the authorised budget 2024	Envisaged FTE 2025	Envisaged FTE 2026
Total	30	25	30	30	42	47	45	45	45

Table 3 – Recruitment forecasts 2024 (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			AD08 and above	AD08	
Visual Designer					FGIV
Procurement and Contract Management Coordinator			AST3 and above	AST3	
Senior Scientific Specialist (Quality)			AD08 and above	AD08	

HR Specialist			AD06 and above	AD06	
Scientific Specialist (Veterinary Division)			AD06 and above	AD06	
Procurement and Contract Management Officer					FGIV
Access to Documents/Clinical Data Publication Officer					FGIV
Head of Department S-CO			AD08 and above	AD10	
Computer Scientist					FGIV
Scientific Officer (Veterinary)					FGIV
Head of Workstream TRS			AD06 and above		

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						
	2019	2020	2021	2022	2023	Actual average over 5 years	Average over 5 years (According to decision C(2015)9563)
AD05	4.23	2.27	2.21	2.00		3.4	2.8
AD06	4.96	3.47	2.81	3.13	3.6	3.7	2.8
AD07	3.61	4.37	4.81	3.23	3.75	4	2.8
AD08	4	4.96	3.25	3.93	5.1	4.3	3
AD09	5.09	5	4.62	3.33	6.12	4.8	4
AD10	2.97	4.71	5.2	4.95	3.54	4.4	4
AD11	3	6.33	8	2.92	5	5.7	4
AD12	7.1	10	2.84		7	6.9	6.7
AD13		6	9.5			8.3	6.7
AST1	5.24				8.58	5.6	3
AST2	5.43	3	4.28	3.12	4	4	3
AST3	3.41	4.73	3.89	3.53	3.69	3.8	3
AST4	5.43	3.33	4.91	3.72	3.5	4.1	3
AST5	5.66	4	5.2	3.75	3.8	4.3	4
AST6	7	7.75	5.14	3.50	3.67	4.9	4
AST7	4.5	7.5	11	3.00	5.25	5.9	4
AST8	2	5	0	3.00		3.3	4
AST10 (Senior assistant)	0	0	0	0		0	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 1.01.2021	How many staff members were reclassified in 2022	Average number of years in grade of reclassified staff members 2022	How many staff members were reclassified in 2023	Average number of years in grade of reclassified staff members 2023	Average number of years in grade of reclassified staff members according to Decision C(2015)9561
CA IV	17	2					Between 6 and 10 years
	16	12			1	2	Between 5 and 7 years
	15	15	1	2			Between 4 and 6 years
	14	54	5	2.91	9	3	Between 3 and 5 years
	13	16	1	2.54			Between 3 and 5 years
CA III	11	1	1		1	2	Between 6 and 10 years
	10	27	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	11	2	2.98	1	3.5	Between 3 and 5 years
CA II	6	15					Between 6 and 10 years
	5	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 31/12/2023 (only officials, TA and CA)

		2023							
		Official		Temporary		Contract Agents		Grand Total	
		Staff	%	Staff	%	Staff	%	Staff	%
Female	Administrator level	0	N/a	219	33%	80	37%	299	34%
	Assistant level (AST & AST/SC)	0	N/a	192	29%	84	39%	276	31%
	Total	**0**	**0**	**411**	**62%**	**164**	**76%**	**575**	**65%**
Male	Administrator level	0	N/a	217	33%	34	16%	251	29%
	Assistant level (AST & AST/SC)	0	N/a	36	5%	18	8%	54	6%
	Total	**0**	**0**	**253**	**38%**	**52**	**24%**	**305**	**35%**
Grand Total		**0**	**0**	**664**	**100%**	**216**	**100%**	**880**	**100%**

Table 2 – Data regarding gender evolution over 5 years of the middle and senior management*

*Staff who is defined as middle manager by the applicable General Implementing provisions on middle management

	2019		2023	
	Number	%	Number	%
Female Managers	**11**	**37%**	**10**	**38%**
Male Managers	**19**	**63%**	**16**	**62%**

D. Geographical balance

Table 1 – Data on 31/12/2023 – statutory staff only (officials, TA and CA)

Nationality	2023					
	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	17	3%	2	1%	19	2%
Bulgaria	10	2%	9	3%	19	2%
Croatia	7	1%	2	1%	9	1%
Cyprus	0	0%	3	1%	3	0%
Czech Republic	3	1%	14	4%	17	2%
Denmark	3	1%	5	2%	8	1%
Estonia	1	0%	7	2%	8	1%
Finland	6	1%	5	2%	11	1%
France	73	13%	29	9%	102	12%
Germany	40	7%	16	5%	56	6%
Greece	46	8%	30	9%	76	9%
Hungary	12	2%	16	5%	28	3%
Ireland	20	4%	4	1%	24	3%
Italy	70	13%	42	13%	112	13%
Latvia	2	0%	9	3%	11	1%
Lithuania	5	1%	11	3%	16	2%
Luxembourg	0	0%	0	0%	0	0%
Malta	0	0%	0	0%	0	0%
Netherlands	14	3%	7	2%	21	2%
Norway	3	1%	0	0%	3	0%
Poland	14	3%	33	10%	47	5%
Portugal	45	8%	11	3%	56	6%
Romania	28	5%	7	2%	35	4%
Slovakia	6	1%	16	5%	22	3%
Slovenia	2	0%	2	1%	4	0%
Spain	86	16%	32	10%	118	13%
Sweden	7	1%	5	2%	12	1%
United Kingdom	22	4%	12	4%	34	4%
Other	1	0%	0	0%	1	0%
TOTAL	550	100%	330	100%	880	100%

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

Most represented nationality	2019		2023	
	Number	%	Number	%
Spanish	**96**	**12.0%**	**118**	**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. Environment management

EMA's environmental management activities were pursued in 2023 in line with the Agency's Environmental Policy[32] and the Environmental Roadmap 2020 to 2024.

During the Winter 2023/2024, an internal environmental audit is scheduled to be performed, as the next step towards obtaining the EU Eco-Management and Audit Scheme (EMAS) registration. During 2024 the findings of the audit will be worked through with implementation of necessary improvement actions identified. During the year, the external verification audit will be scheduled ahead of seeking registration to EMAS.

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. The Commission made further commitment in its Communication EC (2022) 2230 to reach climate neutrality in its operations by 2030, 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 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	Environmental targets	Actions to achieve environmental objectives
Direct	Energy efficiency: "EMA drives energy efficiency in line with good practices"	100% renewable energy for electricity achieved. Actions targeted to directly support the objective	Replacement scheme of electronic equipment such as laptops[33] and small electricity for further energy efficiency, when technically and financially justifiable
	Material efficiency: "EMA drives material efficiency in line with good practices"	Monitor the consumption of materials used (paper, plastic)	Promote reduced use of single-use materials along 'circularity approach' Promote paper-less workflows and digitalisation

[32] Policy 78: Environmental Policy (europa.eu)

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

Aspect	Environmental objectives	Environmental targets	Actions to achieve environmental objectives
	Material sustainability	Monitor the environmental impact and reduction of hazards by choice of materials used	Promote choice of EU Ecolabel or equivalent products and sustainable/fair-trade and seasonal produce.
	Water – not relevant due to the water efficiency at the EMA building	N/A	N/A
	Waste: "EMA drives waste reduction in line with good practices"	Monitor the generation of waste, non-recyclable waste and hazardous waste	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
	Emissions: "EMA drives emission reduction, including carbon zero by 2050"	Emissions of greenhouse gases [t] through office occupancy and delegate and staff duty travel	Monitor travel by staff and delegates to align with internal interim mission rules, for a balanced approach between face-to-face and virtual meetings. Enable agile working for employees, thus reducing transport needs by providing support to remote and home working.
Indirect	Environmental effects of medicines for human and veterinary use (ERA)	As included in the Single programming document (SPD) 2024-2026	Actions as included in the SPD 2024-2026

Further measures to support a more sustainable administration and to address the specific challenges of public administration also include:

- focus on further implementation of Green Public Procurement (GPP) in line with the integrated procedure for green criteria in the Agency's public procurements, consulting and implementing recommendations from the GPP Toolkit and/or GPP Helpdesk, when relevant;
- further consider introducing the option for carbon removals for remaining emissions in the procurement of goods and services in 2024;
- maintaining part of the scientific committee meetings and working parties as virtual meetings;

- maintaining an interim approach to staff missions by promoting virtual participation, limiting the number of staff participating in person at the same event, and supporting sustainable means of transport where feasible.

EMA acknowledges 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.

For 2024 several 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 verified as part of EMAS registration.

Through the EMA Green Group, several awareness and communication campaigns are planned for 2024 to support the monitored areas above.

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

Annex VII: Building policy – year 2024

#	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 Government Real Estate Agency)	Y (condition to terminate)	The Lease can be terminated - At any time by mutual consent of the parties - At any moment by the Lessee/EMA with a notice period of 6 months if a decision is made to transfer EMA headquarters to another EU location - By either party after a consecutive period of 6 months of force majeure events which make the performance of the aggrieved Party impossible.	EUR 18 million inducement of which EUR 15 million were for enhancements to fitting out the premises and EUR 3 million are for rent reductions over the term of the lease.
2	Previous EMA premises, London – **sub-let**	30 Churchill Place, Canary Wharf, London E14 5EU	17,946	12,394	30,340	Sub-let	25 years from 1 July 2014 to 30 June 2039	Lease agreement with Canary Wharf Mgt	N	No break-clause	none
TOTAL			40,520	23,231	63,751	11,159,597					

Building projects in planning phase

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 sublet the premises in 2019 (respective building dossiers EMA/104158/2019 of 21/02/2019 and EMA/119300/2019 of 28/02/2019). For 2024, the Agency anticipates a building dossier in the context of the Agency's office premises in London following the challenging macro-economic situation in the wake of the COVID-19 pandemic:

- on 8 August 2023 the current sub-undertenant's results for the second quarter of 2023 were published. The quarterly report disclosed that there is doubt about the company's ability to continue as a going concern unless it succeeds in its execution of 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 sub-undertenant's CEO announced to its stakeholders across all countries where WeWork operates that it had appointed a Real Estate advisor to review the Company's leasehold commitments and to lead the Company'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.

If the current sub-undertenant terminates the whole or part of the premises or in any other way fails to honour the existing lease this could lead to a need to initiate further sub-letting activities of the building. In the current market situation where the Canary Wharf sub-market has an open declared vacancy of 15% (Q2, 2023) it would be expected that such sub-lettings could take substantial amount of time and resources, and have a significant economic effect on the Agency's budget in the short and possibly long term.

As the letting of buildings is not part of the Agency's mission, the financing of the potenial costs for vacancies at the London premises will need to be evaluated together with the European Commission and the Budgetary Authority.

Building projects submitted to the European Parliament and the Council

None.

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.

European Commission's evaluation of experience with the operation of the Orphan and Paediatric Regulations

As part of the implementation of the European Commission's Pharmaceutical Strategy for Europe which was published on 24 November 2020, in 2021 the European Commission launched the preparation of a targeted revision of the orphan (Regulation (EC) No 141/2000) and paediatric (Regulation (EC) No 1901/2006) regulations. This revision addresses shortcomings identified in a recent evaluation, results of which were published by the European Commission on 11 August 2020 (more details **here**). This is the first comprehensive evaluation of the two regulations since their adoption in 2000 and 2006 respectively. They were evaluated together, given that the majority of rare diseases may appear already in children and many children's diseases are also rare. The implementation of the recommendations included in the paediatric report of 2017 is being planned by EMA, in coordination with the European Commission, in the context of the EMA-HMA Action plan for supporting development of medicines for children, as far as non-legislative aspects are concerned. Further implementation activities will depend on the ongoing revision of the EU orphan and paediatric regulations.

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

On 26 April 2023 the Commission adopted a proposal for a new Directive and a new Regulation, which revise and replace the existing general pharmaceutical legislation. The proposal adopted by the Commission 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.

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 gated procedure, under the Agile approach EMA retains a proportionate approach to evaluations and avoids burdening the system with unnecessary levels of evaluation, control and reporting, and epics oversight is responsibility of the Portfolio Board (PB), and ultimately of the Executive Board (EXB).

The PB is responsible for approving the start of epics and monitor their progress throughout the stages in their lifecycle, via monthly and quarterly reports. In exceptional circumstances, the PB may escalate other 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 the approval of an epic lean business case. Oversight of progress and steering of the epic development is provided by PB via reporting through Agile Ceremonies, with escalation to 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 exceed EUR 1 million, the evaluation is conducted by the PB against pre-defined criteria, aiming at reassurance of a remaining sound business case. As follow-up actions, quarterly reporting ceremonies take place until the epic is finalised.

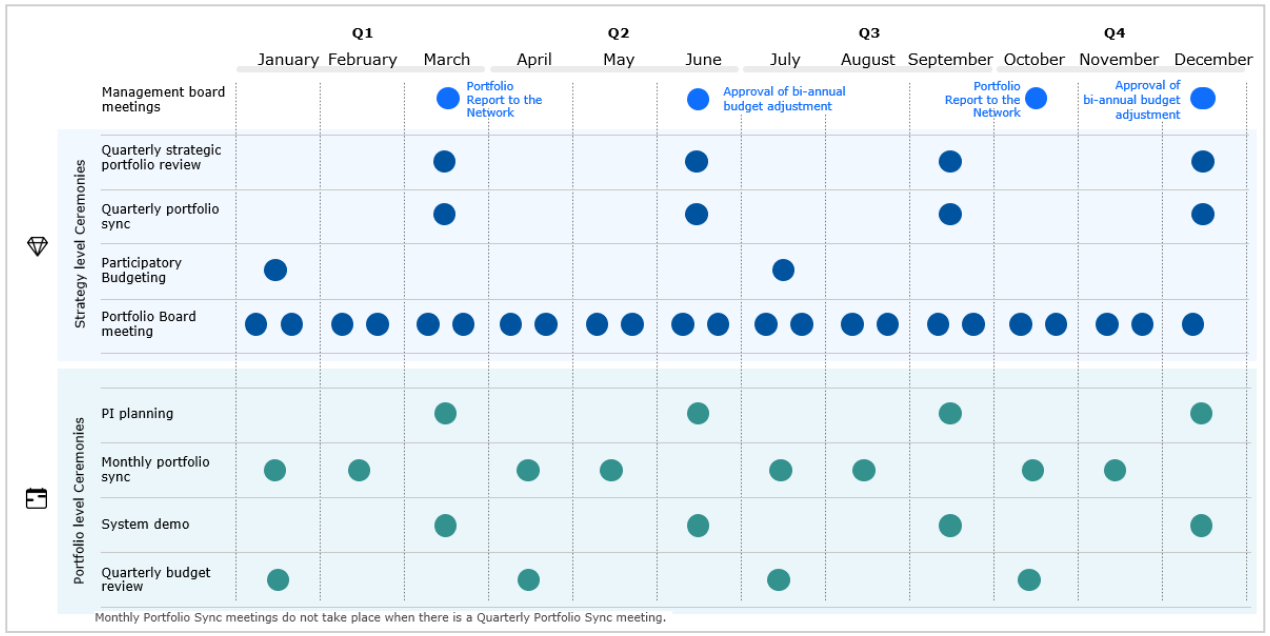
Retrospective evaluations are conducted when an epic is being formally concluded. When actual costs at epic closure exceed EUR 3 million, the retroactive evaluation is conducted by the PB against pre-defined criteria.

Interim evaluations are conducted by the PB when the status of an epic is reviewed due to relevant modifications to scope, timeline and/or budget. Whenever the initial cost estimate at the time of epic approval does not exceed EUR 1 million, but is later exceeded, the PB conducts an interim evaluation against pre-defined criteria.

The results of ex ante and retrospective evaluations are reported as part of the Quarterly Portfolio Review ceremony, on 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 in this annex may change.

The picture below illustrates the flow after an epic is approved by the Portfolio Board on 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 from 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 systems[34]

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 compliance with legal, financial and regulatory requirements.
- **Simplicity, efficiency and effectiveness** of the controls.
- **Flexibility and risk tolerance**. The controls implemented are risk-based and flexible and easy to adapt to environment changes fast and efficiently.
- **A quality focus and mind-set**. The Agency is committed to quality and excellence in everything it does, both in terms of delivering high quality results and outputs in its scientific work, and infusing quality mind-set in every aspect of running the organisation.
- **Continuous improvement** of systems, structures, processes and procedures, in line with recognized quality standards.
- **Transparency, fairness and independence**. The systems and processes not only of the internal controls but of all Agency operations are built to be fair, objective and independent, leading to just outcomes and results.
- **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.
- **Holistic and integrated approach** and ways of working. Internal control system is comprised of a number of elements that are all interconnected and work together, to provide an encompassing view of and assurance over the Agency's operations.
- Firm commitment to **high standards and levels of integrity**, continuously demonstrated through consistent attitudes, words and actions, starting from the top leadership and permeating every level and aspect of Agency's work.

Internal controls are aimed toward achievement of several objectives:

- **Operational** objectives - related to the effectiveness and efficiency of operations, including operational and financial performance goals, and safeguarding any assets and information against loss.
- **Reporting** objectives - related to internal and external financial and non-financial reporting and its reliability, timeliness, transparency, or meeting of other requirements that may be established by EMA.
- **Compliance** objectives - related to the EMA's adherence to applicable policies, rules, and regulations.
- **Risk management** objectives – related to prevention, detection, correction and follow-up of fraud and irregularities, and adequate management of the risks relating to the legality and regularity of the underlying transactions.

EMA internal control framework is based on the COSO[35] model of internal control, and consists of five integrated internal control components, supported by seventeen principles.

Organisational management

Internal control governance, roles, and responsibilities

[34] Information included in this Annex represents the executive summary of the EMA strategy for the organisational management and internal control system.
[35] Committee of Sponsoring Organizations of the Treadway Commission (COSO) Internal Control - Integrated Framework, June 2017.

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.

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**, Since June 2021, 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 or service-level agreements

	General information					Financial and HR impact				
	Actual or expected date of the signature	Total amount of contribution	Duration	Counterpart	Short description		2023	2024	2025	2026
1. STARS	17/07/2019 (EMA's accession)	EUR 6,000	3.5 years from 01/01/2019	European Commission, DG Research & Innovation, Health, Administration & Finance	Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice	Amount	-	-	-	-
						Number of Cas/FTE	0	-	-	
						Number of SNEs/FTE	0	-	-	-
2. 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	17,000	-	-
						Number of CAs/FTE	0.2	0.2	-	-
						Number of SNEs/FTE	0	0	0	0
3. 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	Amount	8,000	8,000	8,000	7,000
						Number of CAs/FTE	0.06	0.06	0.06	-

					the Environment	Number of SNEs/FTE	0	0	0	-
4. SISAQOL	30/10/2020	EUR 76,800	4 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	18,000	-	-
						Number of CAs/FTE	0.75	0.75	0	-
						Number of SNEs/FTE	0	0	0	-
Total grant received						Amount	44,700	43,000	43,000	8,000
						Number of CAs/FTE	1.41	1.01	1.01	1.01
						Number of SNEs/FTE	0	0	0	0
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	84,919		-	
						Number of CAs/FTE	tbc	tbc	-	
						Number of SNEs/FTE	0	0	0	
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 CAs/FTE				
						Number of SNEs/FTE				

3. ePi I	13/04/2022	EUR 1.5 million	05/04/2022-31/12/2023	European Commission, DG SANTE/ EU4Health	Development of electronic product information (ePI) for EU medicines	Amount	750,000	-	-	-
						Number of CAs/FTE	tbc	0	0	0
						Number of SNEs/FTE	Tbc	0	0	0
4. ePi II	Q1 2024	EUR 3.29 million	2 years from signature in 2024	European Commission, DG SANTE/ EU4Health	Development of electronic product information (ePI) for EU medicines	Amount	-	1,645,000	1,645,000	-
						Number of CAs/FTE	-	tbc	tbc	0
						Number of SNEs/FTE	-	tbc	tbc	0
5. MAV+	Q4 2023	EUR 10 million	5 years from signature in 2023	European Commission, DG INTPA	Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa	Amount	2,000,000	2,000,000	2,000,000	2,000,000
						Number of CAs/FTE	0	1	1	1
						Number of SNEs/FTE	tbc	tbc	tbc	tbc
Total contribution agreements						Amount	835,000	2,834,919	3,845,000	3,845,000
						Number of CAs/FTE	tbc	tbc	tbc	tbc
						Number of SNEs/FTE	0	0	0	0
EMA does not provide services to other EU entities, hence has no corresponding service level agreements						Amount	-	-	-	-
						Number of CAs/FTE	-	-	-	-

	Number of SNEs/FTE	-	-	-	-
Total service-level agreements	Amount	0	0	0	0
	Number of CAs/FTE	0	0	0	0
	Number of SNEs/FTE	0	0	0	0
Total	Amount	879,700	2,877,919	3,888,000	3,853,000
	Number of CAs/FTE	1.41	1.01	1.01	1.01
	Number of SNEs/FTE	-	-	-	-

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 2024 – 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) training to candidate countries and potential candidates.

The 2004 revision of the Agency's founding through Regulation (EC) No 726/2004 introduced a more comprehensive recognition of the Agency's international role, in particular through the introduction of the EU-M4all pathway to address public health needs in non-EU countries in cooperation with WHO. This pathway builds on the principle of reliance, aimed 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.

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 crisis such as the COVID-19 pandemic challenged medicines regulators worldwide and demonstrate 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 through the International Coalition of Medicines Regulatory Authorities (ICMRA) and other international forums.

The EU Global Health Strategy adopted in 2022 further highlighted 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

According to WHO, 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.

The two recent crises (nitrosamines and COVID-19) and the 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 Ukraine and Moldova have been granted candidate status. In line with EU political priorities, the Agency will collaborate to support candidate countries and potential candidates. 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 establishment of the African Medicines Agency and regulatory systems capacity.

Two countries, 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, 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

Promotion of reliance and convergence of regulatory approaches for pharmaceutical approvals and monitoring to reduce the regulatory burden on regulators (lack of resources or specific competences) and manufacturers and avoid duplication of work.

Speed up patients' access to new and/or affordable products.

Vision

EMA pursues the mission to **establish strong, effective and purposeful partnerships with non-EU regulators to protect public and animal health in the EU and around the globe** through communication, scientific and regulatory convergence, as well as information exchange. More specifically, four objectives guide 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 and Switzerland 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[36], and further arrangements are currently being explored. Most relate to medicines for human use only.

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

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

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.

Mutual recognition agreements

Complementary to the confidentiality arrangements in place, the European Union has operational mutual recognition agreements (MRAs) since 2002, allowing EU Member States and the MRA partner to mutually recognise conclusions 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 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.

Parallel scientific advice

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

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).

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.

Experts from these partners may participate actively in the 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 couple 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, but have rapidly extended to a wide range of areas and now include other partners with whom a confidentiality arrangement was 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 expected 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 a number of 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 are directly responding to multiple 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.

Exchange of information on Committee outputs takes place on a regular and systematic basis.

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 collaborates with EMA, and the EMA Executive Director is currently the chair of ICMRA (2022-2025).

ICH – 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.

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;
- establish collaboration on big data initiatives and Real-World Evidence;
- establish collaboration on innovative areas, such as advanced manufacturing, application of AI throughout lifecycle of medicinal products;
- improve the exchange of information among 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
- develop confidentiality arrangements with other regulatory and international counterparts as appropriate

Objective 2: Enhance international regulatory cooperation, convergence and reliance

Considering the globalisation of pharmaceutical development and manufacturing as well as the increasing regulatory burden, EMA aims to develop a global approach to authorisation and supervision of medicine. 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 benchmarking with projects such as Project Orbis and the Access Consortium;
- 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 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 child-friendly TB medicines;
- Cooperate with marketing authorisation holders and international regulators in pilots to demonstrate feasibility and public health benefit of regulatory reliance.

Objective 3: Strengthening regulatory science expertise and capacity building

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

- contribute to international forums and the European approach to scientific excellence through workshops, training activities, and awareness sessions, participation in international conferences such as ICDRA, DIA, etc., and national initiatives in priority countries (resources and priorities permitting);
- working under the European Commission DG INTPA grant, support the establishment of the African Medicines Agency and regulatory system strengthening at continental, regional and national levels;
- 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 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 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 (e.g. COVID-19 and nitrosamines).
    - Public Health Emergency Clinical Trials Working Group.
- leverage the learnings from the OPEN during COVID-19 pandemic and advance the framework to serve as a platform for regulatory collaboration in case of emergency.

Annex XIII: Global budgetary envelope reserved for procurement and grants

Introduction

In accordance with Article 72 of the Agency's Financial Regulation[37]

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* (page 14)

[37] 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
AMA EDQM Grant: Fostering African-regional reliance	100,000
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 3,823,000
Budget line 3000, current budget C1 and assigned revenue R0, excluding daily allowances (1/3 of total expenditure)	

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 organised based on the 6 EMANS focus areas and covers also and	EUR 21,495,000

Pillar II	Indicative Budget
non-product related public health tasks (e.g. communication, international cooperation, etc.)	
Budget line 3003, current budget C1	
Budget line 3030, current budget C1 and assigned revenue R0	

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 42,706,000
Budget line 3031, current budget C1	
Budget line 3105, current budget C1	