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European Medicines Agency

Final Programming Document 2023-2025

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Foreword

I am pleased to present the 2023 EMA single programming document, which summarises the activities and objectives of the Agency for the period 2023-2026.

Over the past two years, EMA has prioritised work to respond to the ongoing COVID-19 pandemic, which has had an unprecedented impact on many EMA activities. Recognition of the importance of this work in the response to this crisis has come in the form of an extension to EMA's legal mandate, including the work of Emergency Task Force, and the engagement with national competent authorities and stakeholders in tackling medicines shortages, as well as new tasks in the field of medicines devices (dealing with shortages in crisis situations and managing expert groups). It has also brought to the fore opportunities for learning and improvement in other areas, and 2023 will be the year to capitalise further on some of the COVID-19 lessons learned in three main areas.

Building on these most recent experiences, which have enabled high-quality, robust and rapid assessment of key medicines, EMA will focus on improving its overall core-business excellence in medicines review. Through more effective stakeholder engagement and efficiencies, we want to help patients access treatments faster. We will achieve this by applying additional regulatory agility, while maintaining high standards for quality, safety and efficacy, and investing in the use of accelerated pathways. Using oncology products as a pathfinder, we will increase the sustainability and availability of expertise in the European Network and explore capabilities for collaborative reviews between international regulators.

We will also use better data and evidence generation to help translate innovation into medicines that reach more patients. What was clearly illustrated over the last years is the need to better support and enable large, well-designed clinical trials that can provide the robust data needed to support decision making, proving that medicines are safe and effective. EMA, together with the Network, will invest in better evidence generation using tools such as ACT-EU and DARWIN, and by optimising scientific advice processes, aiming at reinforcing the coordination between scientific advice on clinical development and the approval of clinical trials. We will support research collaboration and training with academia to build capacity in all aspects of drug development and regulatory science.

We are committed to harnessing the power of real-world evidence by continuing to establish the evidentiary value of RWE to support the transformation to data-driven regulatory decision-making and to advance patient-centred access to better medicines. Enabling novel manufacturing methodology will also support innovation. Our work in this area will help identify potential bottlenecks, as well as strengthen early interaction, transparency and communication with stakeholders on regulatory requirements for novel manufacturing technologies.

Lastly, we intend to reinforce our communication and transparency efforts to showcase EMA as an open, innovative, science-based and trusted organisation, thus promoting EMA as a Reference Authority. We will build on our experience with exceptional transparency measures to make our communications more meaningful to our stakeholders. This will be achieved by increasing our presence and engagement with general media, to broaden our outreach, maximising the knowledge and impact of EMA's work, and being more proactive in targeting misinformation.

All of these activities will be critical in supporting the Commission's work on the Pharmaceutical Strategy.

Our international work remains of fundamental importance. The Agency will use its position as Chair of the International Coalition of Medicines Regulatory Authorities, to support international harmonisation,

reliance, and regulatory convergence. Part of this work follows the decision taken by the European Institutions to support new candidate States. The Agency will prepare to support the new candidate countries through the instrument of pre-accession. This will help ensure the continuity of the current operating model for medicines regulation in the Union, which is a guarantee of quality and transparency to European citizens.

Effective IT systems and governance are the building blocks of future-proofing. During 2023, the Agency will finalise the implementation of the Agile methodology by transferring all the remaining programmes and projects under this new governance. In this way, the organisation will leverage its capacity to continuously deliver innovation and best practices in its operation. Digitalisation and innovation remain two key objectives to future proof EMA, as the organisation has to face an ever-growing portfolio of products.

As 2023 will mark the third year of the COVID-19 pandemic, EMA plans to gradually lift its business continuity status. By monitoring the evolution of the COVID-19 related workload, the Agency will seek opportunities to gradually reinitiate previously suspended or reduced activities, notably phasing back in clinical data publication beyond the scope of COVID-19 and activities of the working parties. In case of significant changes to its business continuity status, this programming document may be amended accordingly.

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
ACE	Analytics Centre of Excellence
AD	administrator category post
ADR	adverse drug reaction
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe project
ADVENT	Ad hoc expert group on veterinary novel therapies
AE	Adverse event
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios (Spain)
AER	Adverse event report
Agency	European Medicines Agency
AI	Artificial intelligence
AIFA	Agenzia Italiana del Farmaco (Italy)
AMR	Antimicrobial resistance
AM & D	Application maintenance and development
ANSM	Agence nationale de sécurité du médicament et des produits de santé (France)
API	Active pharmaceutical ingredient
Art	Article
AST	Assistant category post
AST/SC	Secretarial and clerical category post
ASU	Antimicrobial sales and use
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
ATAm	Alternative to Antimicrobials
BCP	Business continuity plan and public health threat plan
BDSG	Big data steering group
BEMA	Benchmarking of European medicines agencies
BfArM	Federal Institute for Drugs and Medical Devices, Germany (Bundesinstitut für Arzneimittel und Medizinprodukte)
Brexit	Commonly used term for the United Kingdom's planned withdrawal from the European Union
B/R	Benefit/risk
CA	Contract agent
CADVVA	CVMP ad hoc group on veterinary vaccine availability
CAMD	Competent Authorities for Medical Devices
CAP	Centrally authorised product
CAT	Committee for Advanced Therapies
CDP	Clinical Data Publication
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
Commission	European Commission
committee(s)	Scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
CP	Centralised procedure
Council	European Council
CT	Clinical trial
CTIS	Clinical trials information system
CTTI	Clinical trials transformation initiative
CVMP	Committee for Medicinal Products for Veterinary Use

Term/abbreviation	Definition
CxMP	Scientific committees of the Agency
DARWIN EU	Data Analytics and Real World Interrogation Network
DCP	Decentralised procedure
DigiLab	EMA Digital Innovation Lab
DIMSIS II	Development, implementation and maintenance support of information systems
DoI	Declaration of interests
EC	European Commission
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
eCTD	Electronic common technical document
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
EMRN	European medicines regulatory network
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
Enpr-EMA	European Network of Paediatric Research at the European Medicines Agency
EP	European Parliament
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
EPPO	European Public Prosecutors Office
ERA	Environmental risk assessment
ESEC	European Specialised Expert Community
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EU-DPR	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
EudraPharm	European Union Drug Regulating Authorities Pharmaceutical Database
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUnetHTA	European network for health technology assessment
EU-IN	EU innovation network
EU-M4all	Medicines for use outside the EU
EU NTC	EU Network training centre
EU-SRS	EU scientific substance information system
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVVet	veterinary EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EXB	EMA Executive Board
FDA	United States Food and Drug Administration
FG (I, II, III, IV)	Function group (for contract agent staff)
FTE	Full-time equivalent
GCP	Good clinical practice
GDPR	General Data Protection Regulation
GLP	Good laboratory practice
GMP	Good manufacturing practice
GP	General practitioner

Term/abbreviation	Definition
GVP	Good pharmacovigilance practice
GxP	Good practice (e.g., laboratory, clinical, manufacturing etc)
HERA	Health Emergency Preparedness and Response Authority
HCP	Healthcare professional
HCWPW	Healthcare professionals' working party
HMA	Heads of Medicines Agencies
HMPC	Committee on Herbal Medicinal Products
HPRA	Health Products Regulatory Authority (Ireland)
HR	Human resources
HTA	Health technology assessment
HTAN	the HTA network
IAS	Commission's Internal audit service
ICDRA	International Conference of Drug Regulatory Authorities
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
IHI	Innovation Health Initiative
IMI	Innovative Medicines Initiative
IMI-Advance	IMI Accelerated development of vaccine benefit-risk collaboration in Europe project
IMI-Adapt Smart	IMI Accelerated Development of Appropriate Patient Therapies a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes project
IMI-FluCop	IMI project on seasonal flu vaccines (Standardisation and development of assays for assessment of influenza vaccine correlates of protection)
INC	International Neonatal Consortium
IPA	Instrument for Pre-accession Assistance
IPD	Individual patient data
IPRP	International Pharmaceutical Regulators Programme
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
IVDR	In-Vitro Diagnostic Regulation
JIACRA	Joint inter-agency antimicrobial consumption and resistance analysis
KPI	Key performance indicator
MA	Marketing authorisation
MAA	Marketing authorisation application
MAH	marketing authorisation holder
MAWP	EMA multiannual work programme
MDR	Medical Devices Regulation
Member State (MS)	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MLM	Medical literature monitoring
MRA	Mutual recognition agreement
MRL	Maximum residue limit
MRP	Mutual recognition procedure
MUMS	Minor use, minor species
NAP	Nationally authorised product
NCA	National competent authority
Network	European medicines regulatory network
NISG	Nitrosamines International Steering Group
NITAGs	National immunization technical advisory groups of WHO

Term/abbreviation	Definition
NRG	Name review group established by CHMP
NTWP	Novel Therapies and Technologies Working Party
NUI	Non-urgent information
NVR	New veterinary regulation
OIE	World Organisation for Animal Health
OLAF	European Anti-Fraud Office
OMCL	Official Medicines Control Laboratories
PAES	Post-authorisation efficacy study
Parliament	European Parliament
PASS	Post-authorisation safety study
PB	EMA Portfolio Board
PBT	Persistent bioaccumulative and toxic substance
PDCO	Paediatric Committee
PCWP	Patient and consumer working party
PEI	Paul-Ehrlich-Institut, agency of the German Federal Ministry of Health
PHEIC	Public Health Emergency of International Concern
PhV	Pharmacovigilance
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIP	Paediatric investigation plan
PLD	Patient level data
PMDA	Pharmaceuticals and Medical Devices Agency
POC	Point of Contact
PMF	Plasma master file
PMS	Product Management Services
PPHOVA	Pilot project on harmonisation of old veterinary antimicrobials
PQKMS	Pharmaceutical Quality Knowledge Management System
PRAC	Pharmacovigilance Risk Assessment Committee
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
RA	Rapid alert
RCT	Randomised controlled trials
R&D	Research and development
RFI	Request for information
RWD	Real-world data
RWE	Real-world evidence
RSS	Regulatory Science Strategy
SA	Scientific advice
SAG	Scientific Advisory Group
SAWP	Scientific Advice Working Party
SciCoBo	Scientific Coordination Board
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SME	Small and medium-sized enterprise
SmPC	Summary of product characteristics
SMS	Substances Management Services
SNE	Seconded national expert
SPM&S	Substances and product management services
SPOR	Substances, Products, Organisations, Referentials
S-REPS	Scientific and regulatory evaluation procedure support
SUSAR	Serious unexpected suspected adverse reaction
TA	Temporary agent

Term/abbreviation	Definition
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TCS	EMA Clinical Studies and Manufacturing task force
TDA	EMA Data Analytics and Methods task force
TDT	EMA Digital Business Transformation task force
TF	Task force
TF AAM	EMA/HMA joint task force on availability of authorised medicines for human and veterinary use
TGA	Therapeutic Goods Administration, Australia
TOPRA	The Organisation for Professionals in Regulatory Affairs
TRIP	Topic Relations Information Perspective
TRS	EMA Regulatory Science and Innovation Task Force
UEMO	European Union of General Practitioners
UI	User interface
UPD	Union product database
UK	United Kingdom
US	United States of America
VAR	Variation
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
VS	Value Stream
WGEO	HMA Working Group of Enforcement Officers
WHO	World Health Organization
WONCA	World Organization of Family Doctors
WP	Working party

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) 2022/2282) 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

The 2023-2026 planning exercise continues to be impacted by crisis situations. The COVID-19 pandemic remains a high priority for the organisation, along with increasing work around monkeypox, monitoring of the consequences of the war in Ukraine, especially on clinical trials and supply chain and of other public health threats, like the outbreak of ebolavirus Sudan strain in Uganda. Implementation of the 2023 work programme will remain subject to close monitoring, to ensure the timely adaptation to the crisis that could rapidly evolve. In this context, it is worth noting:

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 cycle.

Public Health Emergencies - The Agency is still facing a significant level of workload stemming from the COVID-19 pandemic. Therefore, EMA priority remains to operate as long as possible under a 'business as usual' scenario, focusing on COVID-19 related activities, while ensuring the highest level of quality in the evaluation and supervision also for non-COVID-19 related medicines. In addressing this workload, EMA still benefits from the 40 additional Temporary Agent staff positions which were exceptionally extended into 2024, with a phasing out starting in 2023. In consideration of the fact that the workload generated by the response to the COVID-19 pandemic (in both pre- and post-authorisation activities) will extend beyond 2022, the Agency welcomes the EC decision to extend the 40 additional timebound TA posts beyond 2023. EMA, in close collaboration with ECDC, EC and Member States, continues the robust monitoring of the COVID-19 vaccines initiated in 2021. This includes obligations placed on marketing authorisation holders (MAH)s through their risk management plans and enhanced signal detection from reports of suspected Adverse Drug Reactions in EudraVigilance. Through its framework contractors, EMA commissioned in 2022 multi-national studies on the effectiveness of COVID-19 booster vaccines, the safety of COVID-19 vaccines in children, and the coverage, safety, and effectiveness of COVID-19 maternal immunisation. These studies added to large retrospective and prospective studies on COVID-19 infections and vaccines commissioned in 2020 and 2021 and running throughout 2022.

Following the decision by the WHO Director-General to escalate the global monkeypox outbreak to Public Health Emergency of International Concern (PHEIC), the Agency started already in Q3/Q4 2022 a number of activities to respond to the outbreak. This is the first new PHEIC to be declared since EMA's mandate has been extended to formalise the Agency's role in crisis preparedness and management of medicinal products and medical devices. The Agency monitored the developing situation and worked proactively to prepare for and support the EU response. One of the early actions taken include the recommendation to approve an extension of indication for the vaccine Imvanex to protect adults from monkeypox disease. In 2023, EMA will keep working on monitoring of supply, demand and shortages of critical medicines for the monkeypox public health emergency (as well as for COVID-19), in accordance with the responsibilities laid out in its extended mandate. In this context, the Agency already expanded the remit of its Emergency Task Force (ETF) to deal with both COVID-19 and monkeypox. The Task Force will be providing scientific advice, coordinating independent

monitoring studies, and providing advice and scientific support for clinical trials for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency.

With these activities, the Agency contributes to the European Commission's effort to ensure a high level of preparedness and adequate response to cross-border health threats. 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 following closely public health threats, like the outbreak of ebolavirus Sudan strain in Uganda.

The priority of the Agency towards staff, delegates and contractors remains the reduction of the risk of infection; however, following a successful pilot carried out in 2022, EMA has introduced an alternation between face-to-face and virtual meetings for all Committees and one physical meeting a year for Working Parties. This new way of working aims at minimising the risk of infections, while providing the opportunity for regular face-to-face interactions. Moreover, in the long term, it will also significantly reduce the Agency's carbon footprint.

International environment. The war in Ukraine has 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 and neighbourhood countries. This activity will remain a priority not only for 2023, but also in coming years. The Agency monitors developments in the political discussion to stand ready to step up enlargement-related activities, e.g., in case of an accelerated accession. In addition to this, the current uncertainties linked to the implementation of the Northern Ireland protocol could greatly impact the Agency, not only due to the risk of shortages of medicines and medical devices this may cause, but also on international cooperation activities. Lastly, the Agency will strive to contribute, in relation to its available resources, to Union priorities by working with the European Commission and international partners, e.g., to support the establishment of the African Medicines Agency.

Legislative revisions. The upcoming two years will bring an unprecedent amount of EU legislative initiatives that will have a significant impact on the Agency. In fact, under the Pharmaceutical Strategy for Europe, the EC is reviewing the main pillars of the human pharmaceutical legislation; i.e., the EMA founding regulation and Directive 2001/83, the orphan and paediatric regulations, the EMA fees regulation, the Variations Regulation, as well as the directives on blood, tissues, and cells in 2022/23. Moreover, other regulations (the Artificial Intelligence Act; the European Health Data Space, etc.) will be adopted or become applicable in the longer term and they will create new entities both at EU level and in the Member States (e.g., notified bodies for AI, health data access authorities under the EHDS) which the Agency will have to interact with. On one hand, this could represent an opportunity for simplification and future-proofing of the regulatory environment and for implementing ambitions detailed in the European Medicines Agency Network and Regulatory Science strategies; on the other hand, it may also represent a challenge for EMA, due to the implications that the upcoming reforms may have in terms of the Agency's scope and resourcing.

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) 123/2022 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. The relevance of data and data management capabilities continues to emerge rapidly across different areas. The European Health Data Space regulation will provide EMA with a specific framework with clear rules on sharing of health data, common standards, practices, and governance. The implementation 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. Following a review of the Agency's data governance and that of the European Medicines Agencies Network, work will be required to tailor a data strategy fit for future. The Agency needs to secure the skills and technological resources needed to keep its data-management analysis capabilities abreast of developments in the field and to facilitate the realisation of the potential of healthcare data and integration of this into the regulatory decision-making procedure. In this context, training initiatives such as the roll out of the data science curriculum and the operation of a newly created Digital academy will be key to benefit the whole European Medicines Agencies Network. The Agency, together with the European Medicines Agencies Network, should seek opportunities to engage under Horizon Europe, EU4Health and European partnerships (e.g., ERA4Health) to help deliver on strategic priorities and topics.

Part II: Multi-annual programming 2023–2025

1 Multi-annual work programme

The EMA multi-annual work programme 2023-2025 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 and 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. The workload for 2023 is still influenced by the COVID-19 pandemic: especially with regard to post-authorisation activities, which will generate additional workload on top of the overall growing trend of non-COVID-19 medicines applications from year to year. Through 2023, the Division will keep working for centralised and nationally authorised medicines on the implementation of the process for managing the presence of nitrosamines in medicinal products, as well as dealing 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 become more and more prominent in 2023 and beyond. 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 entered a new phase, marked by the implementation of Regulation (EU) 2019/6 (Veterinary Regulation), which had a significant impact on business processes, scientific procedures, and IT systems. The division implemented 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 (EVVet3), 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:

The current Multiannual work programme includes 2026, which will be the first year after the conclusion of the EMA Regulatory Science Strategy (RSS) and the European medicines agencies network strategy (EMANS) to 2025. The Agency will update the key strategic lines in due course, once it is clearer whether some of the current activities may take longer to implement. In the wider context of the EU Pharmaceutical Strategy for Europe, which is the overarching policy initiative setting the direction of future EU pharmaceutical policy, the Agency will take into account the revision of the EU general pharmaceutical legislation and of the orphan and paediatric regulations, which are planned to be proposed by the European Commission in 2023. This is expected to be the biggest update of the EU medicines framework since 2004, and is set to re-shape medicines regulation for the next decades.

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. 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 the expansion of the Mutual Recognition Agreement with the US FDA (veterinary products, vaccines, and plasma-derived products, etc). Along with the promotion of Parallel Scientific Advice and fellowships, the Agency will foster collaborative engagement with regulatory counterparts, including the OPEN initiative, and will promote reliance on EMA scientific output by other regulators, in particular through WHO facilitated pathways. Currently, EMA is actively participating in several international platforms (e.g., ICMRA, ICH, VICH, WHO, PIC/S, etc). Health crises (COVID-19, monkeypox, nitrosamines), supply chain, Article 58, support to priority countries, capacity building (including IPA training 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. We recognise that transparency is key to reinforcing trust in regulatory decisions, and exceptional measures to maximise the transparency of its regulatory activities on treatments and vaccines for COVID-19 remain in place.

The Agency will continue to tackle vaccine hesitancy by supporting extensive proactive public communication, webinars, meetings in close cooperation with EU partners and Member States (Working Group of Communication Professionals), and information on the EMA website on COVID-19 vaccines and regular interactions with ECDC and NITAGs. EMA will also continue to provide high-quality responses to public requests for information. Beyond COVID-19, 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 in the Agency MAWPs.

Requests for access to documents (ATD) have increased in number and complexity. To support COVID-19 related activities, measures have been introduced to manage incoming requests (limited number of documents requested per request and a system of queueing) and work is ongoing to introduce process improvements and additional tools to build efficiency. Clinical Data Publication (CDP) for COVID-19 related medicines will continue with other exceptional transparency activities, such as the publication of RMPs. Once measures linked to business continuity are lifted, a strategy will be agreed for resourcing and relaunch of CDP for other medicinal products as per Policy 0070, with continued collaboration with Health Canada.

PILLAR 3:

With regards to 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. 2023 will be marked by the enhancements of the Clinical Trials 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. Such an ambitious portfolio of changes will require a substantial human effort of approximately 120 FTEs on annual basis for the next 5 years.
- The digitalisation of the Regulatory Business 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;
- 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. Furthermore, EV modernisation will increase scalability and efficiency in the processing of signals and safety data.

The measurement of the activities under Pillar 3 is carried out through the deliverables linked to the specific initiatives.

BUSINESS SERVICES:

ADMINISTRATION AND CORPORATE MANAGEMENT DIVISION

The evolution of the European job market, following the recent years of pandemic and the constantly evolving technological trends, remains a major change factor. To respond to this continuous change, the Administration Division regularly revises its processes to adapt and benefit from emerging opportunities. The objective of the Division remains to improve its services for the business areas enabling efficient and effective delivery of the core tasks of the Agency. A holistic view covering processes, ways of working and technology, together with strategic planning, plays a pivotal role in achieving this objective. While ensuring an adequate level of flexibility, the way forward is to balance the change initiatives with the Agency's capacity. As a result, initiatives directed to EMA staff will remain the focus for the division and will encompass updating of the human resources (HR) strategy, continuing to embed the ongoing initiatives in the performance and development domain, facilitating the use of the Agency's resources, and progressing a number of information technology solutions in line with the Agency's cloud strategy.

The strategy of the Division brings together the following 4 dimensions:

1. **Employee lifecycle**: EMA views its staff as the key asset of its organisation, hence significant transformation took place in this domain over the last years, including the review of the recruitment and onboarding processes, the implementation of the revised performance management, staff development and competency frameworks. A comprehensive update of the human resources strategy, taking into account the expectations of staff and managers, as well as of the new trends following the recent pandemic, is taking place. It aims to ensure continuous development of the Agency's talent and staff wellbeing, among other objectives. Implementation of measures will take account of the ability of the Agency to implement the change programme, and will run over a number of years.
2. **Short- and long-term planning:** This dimension aims to continuously improve and adjust the effective planning and optimise the resource management. This includes the improvement of data and processes that support decision-making. The initiatives include process revision, data quality enhancement, and increased deployment of supporting tools.

3. **Resourcing the organisation**: This dimension focuses on ensuring the optimisation of the use of available resources. This entails maintaining a high level of budget implementation and the required funding of activities and projects. It encompasses the focus on strategic initiatives that ensure the long-term financial sustainability of the Agency and the network. In addition to this, centralisation of procurement support and coordination of contract management practices will continue to provide effective support to the organisation.
4. **Corporate oversight measures and operational excellence:** The results of the ongoing review of the risk management process will be implemented, process reviews in the financial domain will continue to augment system interoperability and master data management, and the management and continuous improvement of the internal control framework will be undertaken.

INFORMATION MANAGEMENT DIVISION

Information Management underpins everything we do and is a key enabler for moving towards EMA's vision to become an all-digital, modern, efficient, and data-driven Agency of the future. To cope with emerging business needs and new legislative requirements, 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 transition legacy systems to a secure and data-protection compliant cloud-native enterprise architecture. The goal is to become a digital hub providing high-quality data and information services by enabling a connected, interoperable medicines regulatory platform for the Network and its stakeholders. On this journey, we will focus on the following pillars for success:

- **Maximising customer success**: We aim to enable success of the European Medicines Regulatory Network and maximise business impact through customer focus. We operate in a diverse internal and external stakeholder landscape which requires a well-coordinated demand management process, so Information Management can fully contribute to the success of each stakeholder. Our aim is to be recognised as a trusted partner for our stakeholders' information service needs and to play an integral part in achieving EMRN's mission. We will enable this by having customer-focused, multidisciplinary teams with the right level of business understanding and technology expertise, demonstrating a customer-centric, can-do, and agile attitude delivering business value incrementally and quickly.
- **A modernisation mindset**: We will strategically focus on innovating IT capabilities and transforming how we deliver IT to our customers. We will introduce and foster best-in-class technology ecosystems, leveraging best-of-breed, standard technologies where possible, adapting our processes to the strengths of the technologies. We will provide opportunities for staff to grow and be proficient in emerging technologies and empower them to recommend the right technologies for the right use cases. We will continue the journey in bringing data together and making it actionable. We will enable the re-design of key business processes by migrating to strategic platforms and transform legacy to secure and cost-efficient cloud infrastructure. We will collaborate with stakeholders to enable interoperability of data and business processes.
- **Operational excellence and information security** are the foundations for well-run IT operations. We will continuously enhance information security and data protection compliance and will assess progress based on best practices and frameworks. We work to enhance performance and responsiveness of our systems. We will apply a risk-based approach to ensure focus where it is needed the most first and leverage cloud-enabled services to enhance security monitoring and threat protection using latest technologies supported by artificial

intelligence and machine learning. We will meet customers' expectations through Service Level Agreements that are fit for purpose and provide services in accordance with procurement functions. I Division will pursue a flexible, scalable IT sourcing contract portfolio that covers the breadth of skills and profiles required to optimise delivery and address growing business demand. This is achieved through establishing capability-based IT sourcing contracts that incentivise vendors to provide high-quality products efficiently and drive continuous improvement. The planning function will be further matured to coordinate and manage these contracts.

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:

1. A European Green Deal.
2. A Europe fit for the digital age.
3. A stronger Europe in the world.
4. An economy that works for people
5. Promoting our European way of life.
6. 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) Digi Lab 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. More integrated and deeper capital*	**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.

	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 antibacterial agents´ 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 antibacterial agents and effective regulatory antimicrobial stewardship in human and veterinary sectors by putting in place strategies to improve their use by patients, healthcare professionals and national authorities	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 antibacterial 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 2023 - 2025

2.1 Overview of the past and current situation

Overview

In 2022, the total budget (revenues and expenditure), as adopted by the EMA Management Board on 16 December 2021, amounted to €417,471,000. On the revenue side, this included €357,702,000 in fee revenues and contributions from the EU budget totalling €55,231,000. On the expenditure side, this included €135,169,000 in Title I: staff expenditure, €58,523,000 in Title II: infrastructure and operating/IT expenditure, and €223,779,000 in Title III: operational expenditure.

On 19 August 2022, an amending budget was adopted, increasing the initial budget by €4,344,000, to a total of €421,815,000. The amending budget included an increase in fee income of €14,574,000 while the EU contributions were decreased by €10,230,000 due to the positive evolution of the fee revenues and detailed reviews of all the budget lines. The Agency proposes to defer the utilisation of the savings on EU contributions to 2024 to fund the work on EMA's extended mandate tasks, such as the development of the European Shortages Monitoring Platform and the completion of the final milestones of the setup phase of DARWIN EU.

The staffing ceilings in 2022 were 662 temporary agents (TA), 223 contract agents (CA) and 30 national experts on secondment (SNE); this level of staffing was determined after additional 17 TA posts were not granted by the budgetary authority. The staffing level still included 40 additional time-bound TA posts exceptionally granted for 2021 and 2022. Throughout the year, the Agency operated an occupancy rate close to 100%.

2.2 Outlook for the years 2023 – 2025

New tasks

On 25 January 2022, the final legal proposal for the extension of the Agency's mandate was adopted by the European Parliament, entrusting EMA with a set of new activities, namely: management of expert panels for medical devices, duty to monitor and mitigate shortages of medicines and preparedness activities and management of public health emergencies. These activities had been supported with financial and human resources and have been implemented within the legal deadline. However, the final text included an amendment to the original draft legal text, requiring the Agency to establish a European Shortages Monitoring Platform, for which no additional human nor financial resources have been foreseen. For 2023, to comply with the legal obligation, EMA will keep working on the set up of such platform along with the Network, industry, and stakeholders, while continuing its work on preparation for implementation of the activities to monitor and mitigate medical devices shortages, as per the legal text. Resources to implement the platform will be diverted from other activities and this will be reflected in the priorities of the work programme.

With regards to human resources, the final legal text confirmed the original proposal of 21 TAs and 8 CAs granted in 2021, growing to a total of 30 TAs and 10 CAs by 2024. In 2022, the Agency continued the execution of all the foreseen recruitment, to be able to meet the deadlines set in the Regulation.

As for financial resources, the draft proposal includes €26.5M EU contribution for 2023, decreasing to €15.3M in 2024, as a stable subsidy after the bulk of investment is realised in the first 3 years of the initial implementation. In October 2021, the Agency, in agreement with the EC, postponed to 2022 and 2023 approximately €17.8 million of the 2021 contribution to align with the legislative procedure timeline.

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 100 new products each year.

Fee income and associated workload have grown by 69% since 2014, 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 workload continues to have implications on workload and the use of resources. Around 47 FTEs were used in the first part of 2022, down from some 80 FTEs in the previous period.

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 2023-2025

Financial resources

An increase in revenue generated by variations applications is forecast in 2023 and 2024. The total revenue from fees in 2023 will amount to €407.6 million, an increase of 35.3 million (9%) compared to the amended 2022 budget, where inflation has a significant impact.

In 2024, the total revenue from fees is expected to reach €445.8 million due to a continued increase in the number of submissions of variations applications and inflation.

EU/EEA contributions are set to stabilise in line with the multi-annual financial framework, at €50.1 million, adjusted for an increase of €3.8 million linked to activities under the Agency's extended mandate and carried forward from 2021 in agreement with the European Commission. In line with the principle of sound financial management, the funds will be made available in 2023, when they will be consumed. In 2024, the EU contributions are set to €45.2 million, including the contribution for the extended mandate.

It should be noted that EMA returned EUR 10.3 million from its Union contribution line to the EU 2022 budget, based on the positive evolution in terms of fee revenue and also driven by the timing of the implementation of EMA's extended mandate. EMA would like to have this amount instead deferred for utilisation during the 2023 - 2024 period, to fund work on EMA's extended mandate tasks, such as development of the medicines shortages monitoring platform and completion of the final milestones of the set-up phase of DARWIN. These deferral discussions are ongoing with the European Commission and subject to further review, and the amounts are therefore not included at this time in either 2023 or 2024 budget submissions. The orphan medicinal products contribution in the draft budget 2023 and preliminary draft budget 2024 reflects the amount proposed in the EU budget.

Minor long-term impact of the pandemic is expected to be felt in lower cost of staff duty travel and meetings, due to the move towards virtual and hybrid meeting participation.

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.

The working assumption for 2022-23 is that the contractual arrangements concerning 30 Churchill Place continue without disruption.

Expenditure related to scientific studies and services will decrease compared to 2022, with DARWIN activities for 2023 being funded from 2022 appropriations (automatic carry-forward). 2023 appropriations include a provision for studies on vaccines, amounting to €9.2 million.

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.

Business consultancy related to review of business processes and various (IT) projects will increase, with more projects and activities related to processes and re-organisation foreseen in 2023.

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 2023 includes the 40 time-limited TA posts awarded by the EC to cope with the extra workload linked to the response of the COVID-19 pandemic, 4 TA posts linked to the extended mandate new tasks, as well as 16 TA posts granted for additional product-related workload.

For the 2024 preliminary draft budget, the Agency will request 12 additional TA posts linked to additional requirements included in the adopted legal text for Regulation (EU) 123/2022; moreover, in view of the ever-increasing product portfolio, the Agency will request 18 TAs posts to cater for additional product-related workload both for human and veterinary medicines. This increase is estimated at 4.5% (without inflation), half of which will be covered through efficiency gains, while the other half needs to be resourced through fee funded posts. These posts will not only support the increase in workload but also provide the Agency with some additional capacity to address the negative priorities refereed below in paragraph 2.5.

2.4 Strategy for achieving efficiency gains

As described in detail under section 2.2 above, applications-related fee income and associated workload have grown by 69% since 2014, 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.

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.

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 2021, 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.

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 procedures 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.

Due to establishment plan staffing constraints, EMA is managing to absorb, in part, the increase in the level of activities both fee-related and legislation-related, referred to in section 2.2 above. Thus far, this has been managed through efficiency gains and effective staff reallocation, and through increased reliance on short-term staffing contracts, with high reliance on Contract Agents and on short-term 'interim' contracts and contractors. This solution is, however, not sustainable in the longer term and is not enabling the Agency to contribute to a robust and sustainable European Health Union, due to the high costs and lack of long-term stability associated with of using these types of resources. 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.

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, namely:

- 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, including support to the development of the African Medicines Agency and enhancing cooperation with Latin American countries;
- Compliance with Treaty on the Functioning of the European Union (Article 15) with regard to the right of access to EU documents within the timelines established by Regulation (EC) No. 1049/2001 (Articles 7 and 8);
- 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;
- Identification of new uses for existing medicines in indications outside the scope of the original approved product information;
- Support the European Commission in all activities requested for Environmental Risks Assessments of veterinary medicines.

Part III: Work programme 2023

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:

- 2023 highlights

  During 2023, the Agency intends to focus 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 and medicines' developers to generate, with insights from RWE, data that can reduce the time to market of innovative products. The Agency will continue its effort to ensure the highest transparency level, by providing timely, accurate and evidence-based information that resonates with a broader audience. Lastly, depending on the development of the epidemiological situation and of the relative restrictive measures, EMA plans in 2023 to explore solutions to gradually lift its business continuity status.

- 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.
  - 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.

- 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:
    - COVID-19 and the Agency's response to the pandemic continues to be a priority for communication, stakeholder engagement and enhanced transparency measures, 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 the extension of EMA's mandate will be other key focus areas.
    - 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.

  The increased visibility of EMA's mandate and activity, resulting from its role during the pandemic including the implementation of any lessons learned, will be built upon further and applied to other important areas of work.
- 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:
    - Supporting staff management and development and launching the competency framework to facilitate performance management, including the appraisal process, and staff development, and act as the foundation for further staff-related initiatives; launching the revised HR strategy and working through the multi-annual implementation plan; launching the new intranet and gradual review of the content.
    - Enhancing administrative processes, including procurement (sourcing, centralised support, vendor management, market research, tools facilitating procurement processes), planning and resourcing of the Agency (exploring further outsourcing options, monitoring workload evolution), accounts receivable processes and tools and

managing associated master data; implementing Agile programme management processes; revised risk management process and tools.

- Efficiently and effectively filling the positions granted by the budgetary authority for the extended mandate.
- Efficiently and effectively managing additional budgeting, procurement and contracting stemming from the extension of the Agency's mandate. Implementing administrative processes (procurements, payments, support systems) associated with medical device expert panels.
- Working with the Institutions to support the revision of the Fee regulation.

- 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 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.
  - 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.
  - 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:
  - Emerging importance and development in the data field, acknowledging the European Data Strategy and related legal proposals, including the European Health Data Space.
  - Need to deliver EU Network Strategy to 2025 objectives to transform to data-driven medicines regulation and 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.
  - Innovation 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 preparation for the application of the Clinical Trials Regulation (see also Pillar 3) through 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 the 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.

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, or to solve disagreements between two or more Member States[1].

The three main drivers for 2023 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.
- 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 7 main domains: 1) pre-authorisation; 2) initial evaluation; 3) post-authorisation; 4) referrals; 5) pharmacovigilance; 6) inspections and compliance; 7) Committees and working parties, including expert panels for medical devices. More details on the activities are provided in the following subsections.

The workforce available in 2023 for the division is currently foreseen at 381 staff (268 TAs, 92 CAs, 21 SNEs). This figure is subject to constant revision to consider staff movements (including part-time regime) and workload fluctuation.

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

[1] Reference: *1.4. Referrals*

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**	
		2021	**2022**	**2023**	**2024**
Scientific advice and protocol assistance (non-exhaustive list)	**Total scientific-advice and protocol-assistance requests**	**853**	**865**	**865**	**865**
	Parallel scientific advice with international regulators requests	3	6	4	4
	Joint scientific advice with HTA bodies requests	2	8	3	3
	Scientific advice for PRIME products	59	30	42	44
	Protocol assistance	163	146	146	146
	Novel technologies qualification advice/opinions	25	22	21	23
Supporting the development of PRIority MEdicines	PRIME eligibility requests received	52	50	55	60
Orphan medicinal product designation and related maintenance procedures	Applications for orphan medicinal product designation	251	280	280	280
Development of medicines for children	Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	778	801	801	838
Classification and certification of advanced	Requests for classification of ATMPs	66	60	60	60

		Results	Expected results	Forecasts	
		2021	**2022**	**2023**	**2024**
therapy medicinal products (ATMPs)					

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).

The Agency, through its committees, provides opinions to Notified Bodies on ancillary medicinal substances in medical devices, on companion diagnostics, on medical devices that are composed of substances that are systemically absorbed to achieve their intended purpose, and on borderline products upon request of the European Commission. The Agency also considers updated dossier requirements for a medicinal product with an integrated medical device.

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2021	**2022**	**2023**	**2024**
	New non-orphan medicinal products	43	42	46	49

		Results	Expected results	Forecasts	
		2021	2022	2023	2024
Scientific assessment of medicines submitted for centralised marketing authorisation	New orphan medicinal products	29	29	29	33
	Similar biological products	10	15	15	16
	Generic, hybrid and abridged products	28	19	19	20
	Scientific opinions for non-EU markets (Art 58)	3	1	1	1
	Paediatric-use marketing authorisations	0	1	1	1
	Number of granted requests for accelerated assessment	12	12	12	12
	ATMP marketing application authorisation requests received [1]	3	8	8	11
	COVID-19 related product applications received[2]	14	11	4	4
	Companion diagnostics opinions	n/a	3	20	30
	Reviews on the maintenance of the orphan designation criteria at MAA stage	31	30	30	30

Performance indicators

		Results	Expected results	Targets	
		2021	2022	2023	2024
Scientific assessment of medicines submitted for	Average assessment time for new active substances and biosimilars	183	205	205	205

[1] New indicator introduced in 2021 work programme
[2] New indicator introduced in 2021 work programme

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
centralised marketing authorisation	Average clock-stop for new active substances and biosimilars	149	180	180	180
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	27%	60%	60%	50%
	% of initial marketing authorisation applications that had received centralised scientific advice	78%	80%	80%	70%

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**	
		2021	**2022**	**2023**	**2024**
Variations to marketing authorisations	Type-IA variations	3,809	3,870	4,100	4,300
	Type-IB variations	3,102	3,013	3,200	3,300
	Type-II variations	1,390	1,319	1,300	1,400
Line extensions of marketing authorisations	Line-extensions of marketing authorisations	27	28	30	30
Maintenance activities	Renewal applications	123	73	65	70
	Annual reassessment applications	27	31	31	31
	Transfer of marketing authorisation applications	95	60	55	70

		Results	Expected results	Forecasts	
		2021	**2022**	**2023**	**2024**
	Article 61(3) applications	396	200	200	200
	Post Authorisation Measure data submissions	1,272	925	925	925
	Plasma Master File Annual update and variation applications	20	25	25	25

Performance indicators

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
Maintenance activities	Average assessment time for variations that include extension of indication	177	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 result	Forecasts	
		2021	**2022**	**2023**	**2024**
Referrals	Pharmacovigilance referrals started	3	5	5	5
	Non-pharmacovigilance referrals started	10	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**	
		2021	**2022**	**2023**	**2024**
Pharmacovigilance	Number of signals peer-reviewed by EMA	2,477	1,600	1,800	1,800
	Number of ICSRs for CAPs (reports received)	2,989,903[1]	2.7 M	1.5M-2.5M	1.5M-2.5M
	Number of signals assessed by PRAC (validated by EMA)	55	40	40	40
	PSUSAs (CAPs only) started[2]	568	555	593	626
	PSUSAs (mix CAP/NAP) started[3]	49	46	43	49
	PSUSAs (NAPs only) started[4]	287	256	238	206
	Number of imposed PASS protocol procedures started	7	4	3	3
	Number of imposed PASS result procedures started	11	6	6	6

[1] New indicator introduced in 2021 Work Programme.
[2] New indicator introduced in 2022.
[3] New indicator introduced in 2022.
[4] New indicator introduced in 2022.

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. The evolution of the activity is subject to the implementation of an envisaged extension of the mandate of the Agency. This is also addressed with ICMRA andat IPRP.

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**	
		2021	**2022**	**2023**	**2024**
Coordination of inspections	GMP inspections	247	205	326	300
	GLP inspections	0	1	1	1
	GCP inspections	36	87	92	100
	Pharmacovigilance inspections	15	11	14	12
	PMF inspections	122	122	80	120
Quality defects	Notifications of suspected quality defects	178	250	250	250
Sampling and testing programme	Medicinal products included in the sampling and testing programme	75	94	81	70

		Results	Expected results	Forecasts	
		2021	2022	2023	2024
Certificates	Standard certificate requests received	3,753	3,928	4043	4163
	Urgent certificate requests received	1,659	1,260	1,475	1,575
Parallel distribution	Parallel distribution initial notifications received	2,555	2,100	2,400	2475
	Parallel distribution annual updates received	4,816	5,300	5620	5800

Performance indicators

		Results	Expected results	Targets	
		2021	2022	2023	2024
Certificates	Standard certificates issued within established timelines (30 working days)	99%	90%	90%	90%
	Average days to issue standard certificate	12.81	15	15	15
	Urgent certificates issued within established timelines (2 working days)	99%	98%	98%	98%
Parallel distribution	Parallel distribution initial notifications checked for compliance within the established timeline	99%	99.8%	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.

Expert panels for medical devices. Based on the European Commission's legal proposal of 11 November 2020 on a reinforced role for EMA, from 1 March 2022, the Agency is expected to host and support the expert panels on medical devices designated under Commission Implementing Decision (EU) 2019/1396 to provide independent scientific and technical assistance to the Member States, the Commission, the Medical Device Coordination Group (MDCG), notified bodies and manufacturers.

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**	
		2021	**2022**	**2023**	**2024**
Meeting management	Number of reimbursed meetings	311	94	420	420
	Committee meetings	99	31	75[1]	75
	Trainings[2]	6	1	22	22
	Workshops	7	1	13	13
	Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	199	61	310	310
	Number of virtual meetings/connections (audio-, video- and web-conferences)	6,854	6,500	6,500	6,500
	Number of reimbursed delegates	6,226	2,500	8,500	8,500
	Number of non-reimbursed delegates	13,227	250	1,500	1,500

[1] In 2023 committee meetings will be held physically and remotely.
[2] Includes EU Network training centre meetings.

		Results	Expected results	Forecasts	
		2021	**2022**	**2023**	**2024**
Herbal medicinal products	Herbal monographs, new	3	3	5	3
	Herbal monographs, reviewed[1]	18	28	22	20
	Herbal monographs, revised	2	3	6	5
	EU herbal List entries	0	1	1	1

Performance indicators

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
Meeting management	Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings.	100%	100%	100%	100%

Pillar 2 – Public health activities

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

- Manage the presence of nitrosamines in medicinal products in accordance with the CHMP art 5(3) Scientific Opinion and the HMA approved process;
- 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.

Constant monitoring of the division's workload and human resources will be deployed to pace the implementation of discretionary public health activities to continue to prioritise product-related activities and, in particular, the continued response to the COVID-19 public health crisis.

[1] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published

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
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	2023	Conduct of the Scientific Advice and analysis of selected candidates for the pilot
1.2 (ECP 1)	Provide parallel/joint EMA/HTA scientific advice, also in anticipation of and with the new HTA Regulation Progress with the HTA consortium the objectives of and tools for post-licensing evidence generation Launch a pilot for prospective evidence planning with payers' representative to explore potential scope and feasibility Strengthening guidance through scientific advice, also aiming at reinforcing the coordination with guidance on clinical trial conduct	Scientific evidence for marketing authorisation is serving different decision-makers	2022	2023	Scientific evidence for marketing authorisation is better serving different decision-makers

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
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	2023	Increased interactions between EMA and HTA and payers Better guidance
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	2023 2024 2024	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 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	Increased support to the integration of scientific and technological progress in the development of ATMPs	2022	2025 2024	Better support for the development, manufacturing, and accessibility of ATMPs

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
					Academic enhanced support pilot launched in 2022
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 and 2)	2019	2024	ICH guideline
3.2 (ECP 1)	Drive development and adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance at EU and international level	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2)	2019	2024	ICH guideline
3.2 (ECP 1)	Promote the inclusion of neglected populations in clinical trials, such as pregnant and lactating women, the elderly and those of diverse ethnicity	Use the revision of ICH E8 and E6 to remove barriers and to encourage inclusion of neglected populations in clinical trials	2020	2024	ICH guideline
5.2	Promote more tailored supervision of API manufacturers through assessment and inspection of their API development and risk management practices in technology transfer	Review Annex 15 of the GMP guideline on Qualification and Validation to investigate potential extension of scope to APIs Support PIC/s in the revision of the PICs aide memoire "Evaluating management of quality risks at GMP facilities" for reference to development of APIs and identification of impurities”	2023	2025	Reinforced supervision of API manufacturers
5.2	Increase supervision of sites that produce medicinal products for a significant number of EEA markets or very significant numbers of products, with dedicated	Improve the exchange of information among MRA and PIC/s partners through international programmes, such as the API International Programme and PICs and ICMRA	20232	2023	Reinforced supervision of manufacturers

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	cooperative supervision between MS and strategic international partners.	initiatives on hybrid inspections, in order to increase collaboration on reliance and hybrid inspections as needed			
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
6.2	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 learnt communicated
6.2 (ECP 2)	Draw lessons from COVID-19 evaluations by applying regulatory agility while maintaining high standards for quality, safety, and efficacy with an aim to reduce assessment time Develop simplifications/reductions of post-authorisation procedures Increase sustainability and availability of expertise in the European Network by matching expertise with the	Regulatory innovations and flexibilities to accelerate the availability of medicines are identified, and where feasible, are progressed for implementation	2022	2023	Analysis completed and, where feasible, implementation is planned and progressed

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	existing product pipeline and ensuring adequately trained experts to perform the assessment Invest in accelerated approval pathways to target unmet medical needs and where the Agency provides enhanced support for development under the Priority Medicines (PRIME) scheme				
	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 Develop a training curriculum on medical devices for scientific staff with experience on medicinal products to increase medical device expertise at the Agency	Experienced gained to establish scientific advice for medical devices Reinforced competencies on medical devices	2023	2024	Pilot concluded Training curriculum on medical devices is prepared

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 the cornerstone of the Agency's work in the area of veterinary medicines. The fact that about 75 per cent[11] 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 challenges for the year 2023 will be:

- Continue working on the follow-up activities related to the implementation of Regulation (EU) 2019/6 (Veterinary Regulation) which became effective on 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.

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 CVMP, CMDv and the veterinary working parties; for general details on these activities, please refer to section 1.7 Committees and working parties.

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

[11] 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 workforce available in 2023 for the division is currently foreseen at 65 staff (41 TAs, 18 CAs, 6 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**	
		2021	**2022**	**2023**	**2024**
Emerging therapies and technologies	Innovation Task Force briefing requests (Vet)	6	5	5	5

		Results	Expected results	Forecasts	
		2021	2022	2023	2024
Scientific advice	Scientific advice requests received	23	30	23	24
Limited markets	Requests for classification as limited market under article 4(29) and eligibility under article 23	3	25	20	20

Performance indicators

		Results	Expected results	Targets	
		2021	2022	2023	2024
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	
		2021	**2022**	**2023**	**2024**
Initial evaluation	Initial evaluation applications	9	27	24	24
Establishment of MRLs	New MRL applications	0	2	2	2
	MRL extension and modification applications	3	2	2	2
	MRL extrapolations	0	1	1	1
	Art 10, Biocides	0	0	0	0
	Review of draft Codex MRLs	0	5	0	5

Performance indicators

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
Initial evaluation	Initial procedures completed within legal timeframes	100%	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**	
		2021	**2022**	**2023**	**2024**
Variations requiring assessment[12]	Variations requiring assessment, of which[13]	n/a	175	195	213
	Variations level 1	n/a	3	3	3
	Variations level 2	n/a	50	55	60
	Variations level 3	n/a	72	71	78
	Variations level 4	n/a	50	60	65
Maintenance activities	Transfers of marketing authorisations	8	5	5	5

[12] For an explanation of the different Variation Levels, please refer to the *Explanatory note on general fees payable to the European Medicines Agency* (https://www.ema.europa.eu/en/human-regulatory/overview/fees-payable-european-medicines-agency)
[13] New indicators introduced following Regulation (EU) 2019/6.

Performance indicators

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
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	
		2021	**2022**	**2023**	**2024**
Arbitration procedures	Arbitrations and Community referral procedures initiated	0	4	6	6

Performance indicators

		Results	Expected results	Targets	
		2021	2022	2023	2024
Referrals	Referral procedures managed within the legal timelines	100%	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 authorisation safety studies, coordination of safety communication, development, and maintenance of good pharmacovigilance practices.

Workload indicators

		Results	Expected results	Forecasts	
		2021	2022	2023	2024
Pharmacovigilance activities	Total AERs, of which:	80,709	75,000	75,000	80,000
	Adverse-event reports (AERs) for CAPs	43,334	37,500	37,500	40,000
	Adverse-event reports (AERs) for NAPs	37,365	37,500	37,500	40,000

Performance indicators

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
Pharmacovigilance activities	AERs for CAPs monitored within the established timelines	96%	95%	95%	95%

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 (EudraVigilance Veterinary – EVVet3), 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.

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-proof technical standards for novel veterinary therapies, particularly biologicals	Guidance for novel therapies and biologicals developed	2020	2023	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	2023	Impact analysis presented to CVMP
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 (or 2024)	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	2023	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	2023	Better understanding of distribution of incidence of AEs Use of incidence distribution to identify clusters

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
3.1 (ECP 1)	Establish stakeholder expert groups for different food-producing species to access actual-use data of products in the field, both off and on label	Expert group established with mandate and objectives	2021	2023	Increase of available data on actual use Better data quality on actual use
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)	Expand the current data-collection system to include other antimicrobials	Collection of data expanded to include all antimicrobials	2021	2023	EMA report to include all antimicrobials as foreseen in Annex 1-4 of Commission Delegated Regulation (EU) 2021/578
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

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
					Fifth JIACRA report developed via the new process
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 Article 15 of the Commission Delegated Regulation (EU) 2021/578	2021	2025	First EMA report on use data
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
4.1 (ECP 1)	Adjust the methodology for analysis of antimicrobial data, by considering approaches developed internationally	Analyse international approaches and integrate, where possible, in methodology	2021	2023	Methodology revised/updated, guidance on Denominators and Indicators published
4.1 (ECP 1)	Define requirements for harmonised sales and use data collection for antimicrobial medicinal products used in animals	Define new requirements and develop guidance on new requirements based on Commission Delegated Regulation (EU) 2021/578 and Commission Implementing Regulation (EU) 2022/209	2022	2023	ASU protocols and templates developed
4.1 (ECP 1)	Inform policy decisions via enhanced cooperation with European institutions (EFSA, ECDC) to collate data on antimicrobial use with	Policy decisions based on the outputs from JIACRA reports	2020	2025	Recommendations in JIACRA reports

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	information on AMR in animals, humans, and food				
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
4.2	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 (EPC 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	
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 Start	Timeframe End	Performance indicator
4.3 (ECP 3)	Enhance 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 the 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	2023	Vaccine B/R assessment targeted per type of vaccine following guidance established
4 (additional RSS recommendation)	Develop appropriate and proportionate guidance to maximise opportunities offered by Regulation (EU) 2019/6 for promoting availability of vaccines (vaccine antigen master	Guidance developed and implemented	2020	2025	Increase of applications for vaccines

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	files, vaccine platform technology master files and multi-strain dossiers)				
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 record of participation to international fora concerning antiparasitic resistance Take away points communicated
4 (additional RSS recommendation)	Promote responsible use of antiparasitic VMPs in the EU	Awareness events and enhanced dissemination of information	2020	2025	Better use of antiparasitic VMPs for the purpose of reducing antiparasitic resistance
6.1	Prepare for and implement Veterinary Medicines Regulation	Prioritised guidance, processes, and IT systems in place, in time for implementation; monitor implementation from 2022	2020	2025	Submission and evaluation of procedures under 2019/6
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 approaches 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
2 (ECP 2)	Coordinate and implement the Veterinary Big Data Strategy by analysing the landscape of	Compilation of a Veterinary data sources catalogue and metadata analysis	2023	2025 and beyond	Veterinary data sources catalogue and metadata analysis completed

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	veterinary data, engaging stakeholders, and providing training	Define and implement the Big Data Strategy workplan Hold events, workshops, and training to engage and communicate with stakeholders			Veterinary Big Data workplan is approved and planned solutions implemented Vet Big Data Team and Veterinary Data Hub established; stakeholders' forum and ad-hoc meetings are organised, and training modules developed
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. *Activity subject to resources' availability, see the Negative Priorities paragraph*	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	2025 and beyond	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. 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.

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

- Lead the Agency's digital transformation through 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.
- Driving strategic implementation of new legislations in cooperation with all relevant stakeholders, with the Medical Device and In-vitro Diagnostics Regulations being the primary focus. Leading the Agency's (and the Network's) 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.

The workforce available in 2023 for the Task Force is currently foreseen at 24 staff (12 TAs, 11 CAs, 1 SNEs). This figure is subject to constant revision taking into account staff movements (including part-time regime) and workload fluctuation.

Pillar 2 – Public health activities

Digital and analytics solutions

Analytics Centre of Excellence (ACE): ACE is a digital toolbox experimentation hub in which the Agency experiments and boosts capacity to experiment with new technologies in analytics, such as artificial intelligence (AI) and machine learning in connection with the business-process design, automation, information, and knowledge management.

Digital Innovation Lab (DigiLab): DigiLab is a framework established in 2021, designed to accelerate digital transformation at the Agency by delivering 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.

Change Management Centre of Expertise (CoE): The Centre of Expertise has been established and will be further developed with the aim to build and grow change management capabilities of staff across the Agency and, in the future, also for the Network.

EU Network Training Centre (EU NTC): 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.

Digital Academy: The Digital Academy aims to build digital literacy, capability, and capacity at EMA through the development of a digital knowledge-sharing academy, capitalising on the experience of the EU Network Training Centre (EU NTC), with future expansion to the EMRN.

Medical Devices Regulation (MDR)/*In Vitro* Devices Regulation (IVDR) implementation: For the MDR, the Task Force is setting up a consultation procedure and developing the relevant internal and external guidance and supporting material for medical devices composed of systemically absorbed substances (SAS) and is continuing the implementation of MDR Art. 117 for drug-device combinations (DDC). For IVDR, the Task Force is optimising the consultation procedure on companion diagnostics (CDx) and updates relevant internal/external guidance and supporting material (forms, templates, etc). The Task Force is also coordinating a medical device training/curriculum regarding the interplay with pharmaceuticals in the framework of the EU NTC network for both MDR and IVDR.

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.

SAFe/Agile transformation, Value Streams and Portfolio Board: 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. Two of the Value Streams, Product Lifecycle Management (PLM) and Monitoring (MON), are led by the Task Force. PLM brings together products that deliver capabilities to authorise and manage the lifecycle of medicines and medical devices, while MON delivers capabilities to monitor the availability and safety of products. Going forward,

the Head of Task Force will also take on the role of Portfolio Board chair, which will reinforce the Task Force's position in ensuring oversight of digital transformation at EMA.

Area of work	Key action	Expected benefit
Analytics Centre of Excellence	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	• Leverage innovative technologies in analytics, including artificial intelligence (AI), robotics, machine learning and others • The areas of process design, automation, information, and knowledge-management at EMA are improved • Decision support is improved using analytics on EMA data assets • Cross-Agency work is carried out in an Agile way, in close collaboration with the business and end-users • 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)	Set of services to discover, experiment, and develop digital solutions that have the potential to support core business and enable its strategies	• Management of the innovation idea portfolio is supported and centralised • Scalable emerging technologies applicable to concrete business cases that may change the way EMA works are piloted and enabled
Change management	Operationalise and develop EMA's Change Management Centre of Expertise (CoE) further, to build and grow change management capabilities	• Agency's staff (and in the future also Network's staff) benefit from increased change management capabilities

	of staff across the Agency and in the future also for the Network	
EU Network Training Centre	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 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)
Digital Academy	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	• Digital skills crucial for our successful digital transformation are identified and defined, new skills are tracked and added when necessary • There is wide awareness of digital skills and understanding of their potential application at EMA and in the Network

	• Building awareness around these skills and their importance for EMA and the network • Creating, maintaining, and growing collections of learning offers to further develop these skills and encouraging staff to explore skills of interest to them Provide these collections to EMA and Network staff through a single platform which acts as entry point to the content	• 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
Implementation of the EU Regulation on medical devices and on in vitro diagnostic medical devices	MDR: Set up a consultation procedure and develop relevant internal / external guidance and supporting material for medical devices composed of systemically absorbed substances (SAS) Continue the implementation of MDR Art. 117 for drug-device combinations (DDC) IVDR: Optimise the consultation procedure on companion diagnostics (CDx) and update relevant internal / external guidance and supporting material (forms, templates, etc.) MDR / IVDR: Develop a medical device training / curriculum regarding the interplay with pharmaceuticals in the framework of the EU NTC network	• MDR: Efficient implementation of consultation procedure initiated by notified bodies on medical devices with SAS • IVDR: Efficient implementation of consultation procedure initiated by notified bodies regarding CDx • MDR/IVDR: Build knowledge and harmonise operational practices across the EU regulators' network

Transformation / Optimisation of Submissions and Regulatory Processes	Coordinate and support the eSubmissions portfolio, linking to the Agile portfolio as required to deliver improved systems and processes Implement eCTD v4.0. (Portfolio project launched in 2022 and transitioning to Agile)	• 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

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2021	**2022**	**2023**	**2024**
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	77	60	60	60
	Number of reimbursed training events to the EU Network	0	5	12	12
	Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	15	14	10	10

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**		**Performance indicator**
			Start	**End**	
	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	2022	2025	Number of Digital Academy trainings accessed Number of trainings completed Number of hits on the platform participation to events

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		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			positive survey feedback
	Modernise the delivery of scientific advice at central and national level by developing Network skills and processes: support future-proofing of EMA and the Network by developing regulatory capacity through the EU NTC Develop a future state learning delivery model and landscape that serves new and existing audiences, in co-creation with the EU-NTC	Develop a future state learning delivery model and landscape that serves new and existing audiences, in co creation with the EU-NTC	2022	2025	Number of new external audiences with access to certain EU NTC courses Number of KPIs linked to business needs, with reporting and tracking set up Social learning set up for a number of courses
2.2 (ECP 2)	Establish a digital innovation lab to explore, pilot and develop solutions and processes across the drug regulation spectrum that leverage novel digital technology and artificial intelligence, to support increase in efficiency and regulatory decision-making	Build pragmatic and innovative solutions for new and existing EMA business needs, using data analytics and experimentation with new emerging technologies	2021	2025	Number of new and relevant emerging technologies being experimented with Number of innovative ideas started Number of solutions successfully piloted Number of processes reengineered for efficiency

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
2.2 (ECP 2)	Establish an EU collaboration on AI to support regulatory decision making with the relevant 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
2.3	Develop capacity and expertise across the regulatory network through curriculum development and knowledge-sharing initiatives on data science, digital technologies, and artificial intelligence-related solutions, products and endpoints, and their applications in the regulatory system	Develop a future state learning delivery model and landscape that serves new and existing audiences, in co creation with the EU-NTC			Number of new external audiences with access to certain EU NTC courses Number of new KPIs linked to business needs, with reporting and tracking set up Social learning set up for a number of courses
3.4	Develop the integrated evaluation pathways in cooperation with medical device authorities and notified bodies Strengthen coordination between relevant actors for the assessment of combinations of medicinal products with medical devices and of companion diagnostics	Design and implement an integrated regulatory pathway for the assessment of medical devices and IVDs intended to be used with medicinal products or support their development Ensure an overall more efficient and consolidated input in the development and management of such products	2022	2025	Number of workshops held Relevant guidance developed

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. While doing so, the Task Force operates or supports the core business activities of EMA. This includes:

- the operation of the human EudraVigilance database of suspected adverse drug reactions;
- analysis of medicinal product data to enable core processes in pharmacovigilance;
- provision of real-world evidence to core processes, including expertise to scientific advice and study results and interpretation to committees;
- provision of biostatistics advice to core processes, including to scientific advice and to committees;
- scientific coordination of methodological advice and study methods development;
- management of the Clinical Trials Information System (CTIS).

TDA liaises strongly with the Network to progress the EMRN strategy pillar on transformation to data-driven regulation. It provides leadership and programme management to the Big Data Steering Group (BDSG) and seeks to engage with stakeholders at national and international level. To progress the transformation to data-driven regulation, TDA leads key projects and initiatives, including DARWIN EU, committee pilots using real world evidence, Clinical Trials Raw Data, Network Data Quality Framework, AI guidance development, development of catalogues for real-world data, biostatistics and observational studies, and training curricula in data science and real-world evidence. TDA also supports the Big Data strategy for veterinary medicines.

The Task Force coordinates and supports the cross-Agency initiative to improve data governance. This includes the coordination of a cross-Agency Data Board and leading on an Agency data strategy, data standardisation strategy, and data governance framework. TDA also leads on the review of BDSG and EU Network Data Board (EUNDB) mandates.

The Task Force drives EMA Data Protection activities and ensures compliance with the European Union Data Protection Regulation by providing advice on all data protection related matters at the Agency and additional support through training for the Network.

TDA manages and leads the further development of the Clinical Trials Information System (CTIS) which is the information management, workflow, and registry for the Clinical Trials Regulation (CTR). It also operates the EUDRACT database for clinical trial registration under the Clinical Trials Directive (CTD). In this context, TDA works closely with users of CTIS, including the Member States and clinical trial sponsors, thereby supporting the operation of the CTR and CTD.

TDA manages Accelerating Clinical Trials in the EU (ACT EU), an HMA/EC/EMA co-led initiative to transform the European clinical trials landscape. The initiative aims to optimise the environment for clinical research in Europe, whilst maintaining high-level participant protection, data robustness and

transparency. ACT EU is structured in 10 priority actions (PAs) and TDA works closely with representatives from the European Commission and the Clinical Trials Coordination Group to coordinate matrix working across EMA and the EMRN to deliver this transformation agenda.

TDA contributes to the transition to SAFe/Agile methodology in the context of the implementation of the new programme governance at EMA and provides leadership for the Research and Development value stream.

In close collaboration with the DigiLab, the Task Force will lead on experimentation with healthcare data for decision-making for medicines regulation.

The annual work plan of the Task Force is guided by the following drivers:

- Emerging importance and development in the data field, acknowledging the European Data Strategy and related legal proposals, including the European Health Data Space
- 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 establish and operate a vaccine monitoring platform (for the conduct of observational studies on vaccine use, safety and effectiveness)
- Innovation 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 preparation for the application of the CTR (see also Pillar 3) through the maintenance and development of CTIS.

The workforce available in 2023 for the Task Force is currently foreseen at 68 staff (39 TAs, 15 CAs, 14 SNEs). This figure is subject to constant revision taking into account staff movements (including part-time regime) and workload fluctuation.

Pillar 2 – Public health activities

Data Analytics Workstream

The Data Analytics workstream supports decisions on medicines made by EMA Scientific Committees, by providing and analysing observational real-world data (RWD) and providing real-world evidence (RWE) on their utilisation, safety and effectiveness.

The team provides RWE advice, including methodological advice on data sources and disease registries, study designs and analytical methods. It also,

performs rapid data analytics for Committees in databases available in-house and through contracts with academic service providers. It has established DARWIN-EU, aiming to build and access a federated network of real-world data partners in Europe. The workstream develops tools and learning material to support the use of valid and reliable real-world evidence (RWE), including the IHD rapid data analytic software and the Big Data pharmacoepidemiology training curriculum. It provides RWE support to public health emergencies by leveraging existing resources in Europe (this includes [COVID-19] vaccine utilisation, safety, and effectiveness) by developing the Vaccine Monitoring Platform and by providing an overall coordination of framework contracts and the ENCePP network. The team develops good practice for statistical and epidemiological methods applicable to the workstream's activities and across EMA and collaborates with the Digital Business Transformation Task Force (TDT) to ensure the provision of artificial intelligence (AI) advice service to the Agency. It influences and leverages EU and international initiatives.

Area of work	Key action	Expected benefit
Safety and effectiveness monitoring	• Establish a monitoring system in the post-authorisation safety and effectiveness monitoring of vaccines, in collaboration with ECDC	• Safety and effectiveness of vaccines are adequately monitored and measured to allow timely regulatory decision-making to protect public health and reassure health care professionals and the public on the effectiveness of the regulatory system

Methodology workstream

The Methodology Workstream provides expert advice 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. It works closely 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). It provides strategic and scientific input to the Methodology Working Party (MWP) activities, including drafting groups and product-related topics, and coordinates its activities in partnership with EMA artificial intelligence, pharmacokinetics, modelling, and RWE functions. Hand in hand with CTCG representatives, the team leads or supports three ACT EU priority actions with a focus on methodologies (implementation of guidelines and convergence of regulatory needs between clinical trial application and authorisation) and on training (delivery of the Big Data biostatistics and clinical trials curricula). The workstream actively interacts with EMA external stakeholders at scientific events and fosters regulatory science research, including with academia.

Healthcare Data Workstream

The Healthcare Data Workstream supports decisions on medicines made by EMA Scientific Committees by collecting, managing, providing and analysing EudraVigilance data and by producing the electronic Reaction Monitoring Reports (eRMRs), essential to perform signal detection activities (pharmacovigilance). The team designs safety monitoring analyses of COVID-19 vaccines and is also responsible for the EudraVigilance system and related stakeholder training, as well as expert advice to stakeholder queries raised via askEMA and the EMA Service Desk. The team maintains the ADR Report website. The workstream conducts data analyses on medicinal product information collected in the Art57 Medicinal Product Dictionary to support computation of PhV Fees and supports the definition of the scope of PSUR, referral procedures, and the maintenance of the EURD List, and contributes to the work on establishing medicine shortages reporting to ensure compliance with EMA's extended mandate. The team collects metadata information on Real World Data sources on behalf of the EU Medicine Regulatory Network to improve data discoverability. The workstream drives the development of the EU Data Quality Framework for EU medicines regulation to measure and improve the quality of data used in regulatory processes. It coordinates EU regulatory involvement in international data standardisation activities within ICH, ISO, and HL7, and assists with the development of implementation guides for data standards and the use of terminologies. It collaborates with IM Division to implement ISO IDMP via SPOR, in particular for its integration with Art57, EudraVigilance and PhV fees computation system.

Clinical Trials Workstream

The Clinical Trials workstream drives, in collaboration with the Information Management Division, the operation and IT delivery of the Clinical Trials Information System (CTIS) - a cornerstone of the Clinical Trials Regulation (CTR). The team works closely with the product owners to manage and prioritise requirements and bugs, tests bug fixes and new functionalities prior to deployment. It updates and publishes release notes along with lists of known issues and suggested workarounds.
At the same time, the workstream proactively supports sponsors with their submitted trial applications by providing advice to the queries raised via the EMA Service Desk and askEMA. Core change management activities include publishing of training materials and regular trainings organised as part of a continuous change management process. The team actively cooperates and supports various clinical trials bodies established by the HMA and the European Commission, such as CTCG, CTAG and CTEG. The workstream also leads the finalisation and publication of relevant guidance documents, including guidance on the protection of personal data and commercially confidential information in CTIS. Regarding the still applicable Clinical Trials Directive and its IT system - EudraCT - the team provides operational support to the stakeholders and addresses questions raised via askEMA.

Workload indicators

	Results	Expected results	Forecasts	
	2021	**2022**	**2023**	**2024**
Number of MLM ICSRs created	9193	8010	9000	9000
Number of healthcare data sets to which EMA access and therefore its committees can integrate analyses into assessments	3	6	8	8

Performance indicators

	Results	Expected results	Targets	
	2021	**2022**	**2023**	**2024**
Number of individual reaction-monitoring reports supplied to the Member States according to the agreed timelines and data quality indicators	91%	97%	95%	95%

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

MAWP Strategic Goal (EC policy/action)	**Action**	**Expected result**	**Timeframe**		**Performance indicator**
			Start	**End**	
2.1 (ECP 2)	Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis Real World Interrogation Network -DARWIN EU)	DARWIN EU Coordination Centre established EU regulatory network routine access to RWE established	2020	2023	16 studies performed by DARWIN EU in 2023

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Build a business case with stakeholders and secure funding to establish and maintain a secure EU data platform that supports better decision-making on medicines, by informing those decisions with robust evidence from healthcare	DARWIN EU pilot with EHDS initiated Processes for EMA oversight of DARWIN EU activities in place, including review of all deliverables and DARWIN EU outputs			10 additional Data partners onboarded in 2023 (giving a total of 20 data sources)
2.4 (ECP 2)	EMA business processes to identify the need for RWE and to deliver that evidence into the regulatory decision making	Process established to identify the committees' needs and feed RWE in their decision-making processes for prioritising analytical requests established Processes for the drafting and review of study protocols and study reports Processes for choice of analytical strategy depending on research question and committees' needs (in-house analysis, use of framework contracts, feeding into DARWIN EU) Users' training on utilisation of IHD and analytical templates	2022	2023	At least one pilot study has been performed with CAT, PDCO, COMP, CHMP and SAWP Committees Training of IHD users has been performed across Divisions and Task Forces By Q4 2023, processes established with all Committees with RWE provision 40 (incl. 16 through DARWIN EU) studies performed in 2023
	Support EMA operations and Committees with advice and epidemiological expertise on: - methods for RWE collection, analysis, and reporting in the fields of health care and medicinal products evaluation	Guideline on evidentiary standards, methodological aspects, formats, and contents of RWE used for regulatory purposes Templates and checklists for feasibility analyses on appropriateness of RWE data sources used in regulatory decision-making	2023	2025	Availability of templates on format and content of RWE submitted for regulatory purposes Tracking table of SAWP, pre-submission and PRIME meetings is up to date, with information on advice and decisions

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	- 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	(e.g., registries and electronic health care records) Participation and contribution to SAWP, pre-submission, PRIME, and other relevant meetings where RWE is addressed			100% of SAWP, pre-submission and PRIME meetings with RWE discussion are attended Process to screen marketing authorisation applications and extension of indication applications including main/supportive RWE and pilot for automation using natural language processes are established
	To pilot the use of AI to increase efficiency to extract information from EMA documents and real-world data, including development of good practices and training	Report on lessons learnt from the test Paper on methods developed and published Application to extract and communicate data extracted from SmPCs, other documents, and RWD Reflection paper on gaps in guidance on use of AI and on how to validate AI-based algorithms in healthcare and medicine AI glossary	2023	2025	Test on 100 documents finalised 2 research projects initiated 1 application developed 1 scientific paper published 2 reports developed (incl. AI glossary) 1 draft reflection paper initiated

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Establishment of a monitoring system in the post-authorisation safety and effectiveness monitoring of vaccines	Core infrastructure for prioritisation, launch and supervision of vaccine studies Establish and operate working arrangements with ECDC Identification of EU networks with capacity to perform representative and reliable studies Identification of the need for studies Management of public calls and monitoring of funded studies Results of studies that are publicly available and made available to EU decision-makers	2022	2023	Secretariat appointed and sustainable Conduct of studies under the VMP starts in 2022 50% of project milestones achieved in 2022 Joint advisory board meets twice annually
2.1 (ECP 2)	Enable data discoverability; the final output will be to interlinked public catalogues - one of EU RW data sources, the other of EU observational studies. This will be built on the RW metadata list and replace the ENCePP resources database and EU PAS register Identify key meta-data for regulatory decision-making on the choice of data	MINERVA final study report (EMA/2017/09/PE/16) Design and delivery of a Catalogue of Observational Studies Design and delivery of a Catalogue of Real-World Data sources	2021	2024	ENCePP resource database and the current EU PAS register replaced Data Quality Framework for data used in the regulatory context delivered A contract to maintain the Metadata Repository is signed

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	source, strengthen the current ENCePP resources database to signpost to the most appropriate data, and promote the use of the FAIR principles (Findable, Accessible, Interoperable and Reusable)				
	Resolve the current difficulties that PhV Office and HCD teams are experiencing with the tools used for Signal Detection and ICSR data analysis, and future-proof EV based on data security SPOR and cloud technology	Replacement of the current EV analytics system and integration with EMA systems (SPOR) to increase performance, security, usability and reduce maintenance costs	2021	2024	Reduce number of FTEs required to prepare the eRMR Improved performances for running reports on ADR data Agree revised Access Policy by the end of 2023
	Implement the Clinical Trials Safety Monitoring Implementing regulation	Deliver IT tools and processes described in Art. 11 of the IR of the Clinical Trials Regulation	2021	2023	Implementation of IT systems to support cooperation in safety assessment in the context of the clinical trials Enhancements post go-live Permanent solutions implemented before the end of the transition period (Q4 2024)
	Strengthen the EU Network on methodology and RWE in committee advice and assessment Develop Big Data learning initiative with a view to developing guidelines and processes that learn from applications	Embed identification of submissions with complex methodological and RWE aspects into EMA forecast and tracking processes Establish a systematic lessons-learnt process for challenging methodological regulatory procedures	2021	2025	One overarching work plan for the MWP published in Q1 2023 Delivery of guidelines as planned and outlined in the MWP workplan

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	Work with international partners to develop roadmap and guidance	Fully integrate RWE and AI as key expertise in the methodology domain Start a European Specialised Expert Community (ESEC) Prioritise RWE topics that need guidance development			International cluster meetings on methodological aspects, including RWE held with support of ESECs
	Collaborate with international initiatives on Big Data Support the development of guidelines at international multilateral fora, a data standardisation strategy delivered through standards bodies, and bilateral collaboration and sharing of best practice with international partners	Standardise clinical study protocols and reports and enable data exchange	2021	2024	Close collaboration with ICH M11 on development of logical model for clinical study protocols Develop the logical model for clinical study protocols and reports and interact with SDOs Reflection paper to ICH on the development of a suite of RWE guidelines
2.1 (ECP 2)	Build capacity and capability to receive, store, manage, and analyse raw data	Determine the regulatory and public health benefit of access to raw data	2021	2026	Reach approximately half of the intended 10 'raw data' pilot procedures by end 2023 Presentation to CHMP of interim pilot findings in Q4 2023 Establish a 'Network community on Raw Data' by Q1 2023
	Support an initiative with the EC and HMA to transform CT in Europe, including	Establish EMA support to ACT EU Engage external stakeholders and lay foundations for a multi-stakeholder platform			Establish Network governance support by early Q3 2022

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	modernisation of CT design and good clinical practice Strengthen EU-level governance of CT; leverage data on CT to support regulatory decision-making	Develop business case for CT data analytics Establish a roadmap for methodologies guidance Adopt a plan for GCP modernisation implementation Deliver CT training curriculum with links to universities and SMEs Develop RACI matrix for network governance groups Launch a scheme to support large multinational CTs One stop-shop for academic sponsors			Multi-stakeholder workshop Q2 2023 Develop research agenda and business case for CT data analytics by Q2 2023 Establish a roadmap for methodologies guidance by Q4 2023 Adopt a plan for GCP modernisation by Q4 2022

3.3. Regulatory Science and Innovation (TRS)

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

- Advance support to innovation through enhanced first-contact functionalities within the Innovation Task Force, Business Pipeline, SME Office, and academic liaison.
- Develop horizon-scanning and outreach capabilities of EU-IN, SME Office and the academic liaison, and expand business analysis and forecasting to deliver enhanced quality outputs to the Agency and the EU network.
- Leverage collaborations between academia and network scientists to prepare for engagement with Horizon Europe and IHI; define EMA's regulatory science research agenda and enable the exchange of knowledge and expertise.

- Deliver the reinforced EMA mandate to facilitate a coordinated EU-level response to health crises by monitoring and mitigating the risk of shortages of critical medicines and medical devices.

The workforce available in 2023 for the Task Force is currently foreseen at 33 staff (19 TAs, 8 CAs, 6 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Pillar 2 – Public health activities

Area of work	Key action	Expected benefit
SME Office Workstream Addresses the unique needs of micro, small, and medium-sized enterprises	• Delivering operational business of the SME Office • Initial qualifications and renewals • Translations • SME briefing meetings • Response to queries • Organisation of workshops/trainings	• Addressing the specific needs of smaller pharmaceutical companies, with the aim of promoting innovation and development of new human and veterinary medicines
Research and Innovation 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 companies • Reports to Committees • Develop and deliver the EU-IN action plan, including horizon scanning, repurposing, borderline classification, scientific advice 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 by addressing gaps in early regulatory support to innovation, making the regulatory support available at national and EU level more visible and attractive to innovators from an early stage

Research and Innovation 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 warn the system of upcoming submissions • Organisation and conduct of Business Pipeline meetings • Expand business analysis and forecasting to deliver enhanced quality outputs to the Agency and the EU network	• Enables accurate budgeting and identification of the most appropriate resources and scientific expertise needed, and to facilitate internal operations
Research and Innovation Workstream *Horizon scanning* Identifies future innovations and trends in a comprehensive and systematic manner to allow appropriate response and enable innovations to reach the market	• Develop the horizon-scanning and outreach capabilities of EU-IN and SME Office, also in collaboration with ICMRA • 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	• Allows the network to respond appropriately and enable innovations to reach the market with minimal developmental, legal, regulatory, process, or procurement bottlenecks • Creation and implementation of systems to inform on trends in science and technology which could challenge the regulatory system
Research and Innovation 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	• 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	• 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

regulatory science research projects	• 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	• 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) • 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	• 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 • Enhanced monitoring system for medicines used for treating COVID-19 patients • Continuous monitoring of supply chains • Guidelines for EU Member States • Guidance for companies

	• International collaboration on shortages-related strategic topics and shortages case-management at the level of the Global Regulatory Shortage Network	
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	
		2021	**2022**	**2023**	**2024**
Research and innovation: innovation and emerging therapies	Innovation Task Force briefing meetings	36	35	35	40
	Innovation Task Force consultation: CHMP opinion requests according to Regulation (EC) No 726/2004 Art. 57 and MDR Art. 4 / IVDR Art. 3[14]	0	2	4	4
Research and innovation: business and analysis forecasting	Business Pipeline briefing meetings[15]	15	21	18	20
SME Office	Regulatory assistance, including SME briefing meetings[16]	180	183	183	192
	Requests for SME qualification	504	516	516	541
	Requests for SME status renewal	1,293	1,260	1,260	1,323

Performance indicators

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
SME Office	Satisfaction level of SMEs	98%	80%	80%	80%

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

[14] Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), applying to 2021 onwards for MDR and 2022 onwards for IVDR.
[15] New indicator introduced in work programme 2021
[16] New indicator introduced in work programme 2021

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
1.1 (ECP 1, ECP4)	Improve further the collaboration with international partners on shortages at the level of ICMRA and the Global Regulators Working Group, including in the area of supply disruptions due to manufacturing quality issues	Established framework for collaboration with international regulators	2021	2025	Framework for collaboration adopted by 2025 Defined actions to take
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
3.3	Identify, in consultation with research institutions, academia and other relevant stakeholders, fundamental research and associated training/education topics in strategic areas of regulatory science relevant to patients	Topics for network training identified and communicated to 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

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
1.1 (ECP 1, ECP4)	Improve monitoring of shortages and enhance communication of supply problems to EU citizens, their representatives, and HCPs	Enhanced communication of supply problems to stakeholders to facilitate mediating action	2022	2023	Consultancy report finalised Workshop/awareness session reports

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, approaches, and other activities that take place across the lifecycle of the product and in 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.

For the year to come, health crises (COVID-19 and Nitrosamines), an extension of US MRA, supply chain, Article 58, promoting reliance on scientific outputs of the EMA scientific committees, implementing the OPEN initiative, support to priority countries, capacity building (including IPA training) and scientific training, and providing the secretariat for the International Coalition of Medicines Regulatory Authorities (ICMRA) are driving the work programme.

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, like the new veterinary legislation or the new medical devices legislation. 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 2023-24 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 and of the orphan and paediatric regulations, 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 review periods 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, with the long-term commitment of being climate neutral by 2050, and with the EC commitment of leading by example (see also Annex VI).

The **Information Security Office** develops and implements the Agency's information security strategy, by implementing the administrative and technical controls to ensure that information assets are appropriately and consistently protected, in order to reduce the Agency's risks to an acceptable level. Specifically, Information Security works in the areas of governance, technology security and risk management. As part of the implementation of its cyber security strategy, the Information Security Office will focus in 2023 on the establishment of a security awareness programme and on the set up of the Security Operation Centre. These activities contribute to the overall objective of strengthening the Agency's security position.

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 2023 for the Advisory functions is currently foreseen at 58 staff (45 TAs, 10 CAs, 3 SNE). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Pillar 2 – Public health activities and Business Services

Workload indicators

		Results	Expected Results	Forecasts	
		2021	2022	2023	2024
International Affairs[17]	Number of product-related interactions with international stakeholders – including requests for information and requests for documents	n/a	n/a	130	130
	Number of participations in external forums	n/a	n/a	60	60
	Number of external participants in training organised by International Affairs	n/a	n/a	150	150
	Number of visits to EMA / fellowships organised by International Affairs	n/a	n/a	10	10

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

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
1.1 (ECP 1, ECP4)	ICMRA secretariat, including COVID-19 response	Continue demonstrating leadership of and secretariat to ICMRA: regulatory convergence and in particular, vaccine safety monitoring collaboration Regulatory communication Provide strategic directions for enhanced collaboration, improved communication and approaches to jointly address common challenges	2022	2025	Number of TCs Number of Executive Committee meetings Number of key public statements Number of workshops

[17] New workload indicators starting in 2023.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
1.1 (ECP 1, ECP4)	ICMRA workstream leadership and contribution	1- Track and Trace (T&T) (currently on hold pending Executive Committee decision) 2- Pregnancy and Lactation (P&L) 3- Pharmaceutical Quality Knowledge Management System (PQKMS) 4- (Public Health Emergency Clinical Trials Working Group)	2020	Continuous	Number of TCs Number of collaborative workstreams meetings
1.1 5.5 (ECP 1, ECP4)	Nitrosamines	Participation in Nitrosamines International Steering Group (NISG)	2018	Continuous	Regulatory actions Information exchanged
1.1 5.5 (ECP 1, ECP4)	Extension of US MRA	Extension to vaccines and plasma-derived products and veterinary medicines	2019	Continuous	Support to the extension
1.2 (ECP 1)	Fostering reliance on EMA scientific outputs: EU-M4all	Provide scientific opinions on high-priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU) in collaboration with WHO Support to developers and promotion of parallel art 58 and centralised submissions	N/A	Continuous	Number of parallel submissions Number of Article 58 opinions and new approvals
1.2 (ECP 1)	Fostering reliance on EMA scientific outputs: Collaborative registration and other reliance pathways	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	Continuous	Continuous	Number of new products ongoing with the CRP with contribution from International Affairs
6.1	Provide assistance to candidate countries (IPA), to align their standards and practices with those established in the European Union, and to	Facilitate EU integration to EU candidate countries and Potential candidate countries Increased visibility of EMA	2020	2024 (For	Number of trainings organised Meeting with contact points arranged

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	further foster their integration process, in particular via scientific and regulatory training activities	Training on acquis Communautaire of candidate and accessing countries		IPA II)	
6.5	OPEN project	Active collaboration of selected regulatory authorities in CHMP and European Task Force for COVID-19 vaccines and therapeutics; extension of the OPEN model to other therapeutic areas	2021	Continuous	Number of experts Number of procedures
5.1	Promote increased international cooperation in the area of supply chain security, in particular through efforts to coordinate and integrate initiatives at the level of ICMRA	Assure product supply chain and data integrity	Continuous	Continuous	Support the efforts to promote increased international cooperation
6.1	Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU	Support training and capacity building of non-EU regulators	2017	Continuous	Participation of EU network members to trainings organised
6.1	Re-start of the international awareness sessions for regulators	Increase the awareness of the EU system through dedicated sessions	2020	Continuous	Number of sessions organised Number of participants
6.1	Collaboration in the establishment of the African Medicines Agency (AMA)	Capacity building and regulatory system strengthening at continental, regional and national levels through provision of adequate guidance, and other support as needed, as part of wider EU engagement strategy	Continuous	Continuous	Capacity building through provision of adequate guidance and support
6.2 (ECP2)	Full implementation of the EU-DPR and monitoring of compliance for exchange with international partners	In the initial implementation phase, assistance and guidance to Internal Controllers regarding data protection obligations (update existing and develop new records, privacy statements, DPIA reports, joint controllership agreements; adopt instruments for	2019	Continuous	Number of shared redacted documents Update of the guidance

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		international data transfers; conclude appropriate contracts with data processors) Following the first implementation phase, as necessary, update and adopt further annexes to 0055-2020 Internal Guidance of Personal Data Protection. Update, develop and deliver data protection trainings on request or upon own initiative			
	Anti-Tuberculosis Medicines Project	Collaboration with WHO to support child-friendly TB medicines Approve anti-TB medicines for unmet medical needs in the EU	2021	Continuous	Number of TB products application Number of meetings with companies
	International Cooperation Platform (IntCoP)	Strengthen exchange of information and coordination, fostering a harmonised EU approach to international cooperation on medicines between national competent authorities, DG SANTE/the European Commission and EMA, through a dedicated communication and discussion channel	2022	continuous	Number of meetings organised regarding information sharing on international activities of common interest
3.2 (ECP 1)	Promote the inclusion of neglected populations, such as pregnant and lactating women, the elderly, and those of diverse ethnicity in clinical trials	Use the revision of ICH E8 and E6 to remove barriers and to encourage the inclusion of neglected populations in clinical trials	2020	2024	For 2022 - Agreement of Step 2 at ICH for ICH E6 GCP (objectives and Annex 1)
4.2 (ECP 1)	Foster development of POC diagnostics for human and veterinary use	Inclusion of diagnostics in the discussion on a new business model on the antibacterial agent	2022	2025	Workshop with stakeholders in 2022

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
4.2 (ECP 1)	Define approaches for review of data with international regulators	Build on the experience acquired with COVID-19 to establish the approach for future emergencies	2021	2025	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	2025	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	2025	Studies of safety and effectiveness of vaccines

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, improving understanding and awareness of EMA's role and work. It facilitates engagement and dialogue with the European medicines regulatory network and those 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 2023 are:

- COVID-19: coordination of the Agency's response, communication, stakeholder engagement, and enhanced transparency measures to support the Agency's response to the pandemic. 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 the extension of EMA's mandate will be other key focus areas.

- The implementation of the framework strategy for communication and engagement 2021-2025: this aims to establish optimised crisis-communication processes, leverage progress in digitalisation and review, and adapt operations to ensure sustainability and responsiveness. Also, the development and implementation of a strategy for the restart of clinical data publication (beyond COVID-19), once BCP measures are lifted.
- 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).

The workforce available in 2023 for the Division is currently foreseen at 84 staff (53 TAs, 27 CAs, 4 SNEs). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Pillar 2 – Public health activities

Interactions with partners. To deliver its mission, the Agency collaborates with national competent authorities in Europe, the European Commission, other EU institutions and EU agencies, and health technology assessment (HTA) bodies. These interactions range from exchange of information, qualification of novel methodologies with HTA bodies, and collaboration on guideline and standards development, to capacity-building, providing scientific expertise in the evaluation processes, cooperation on inspections, and other areas.

Area of work	Key action	Expected benefit
Interaction with EU partners	Continue collaboration with communication counterparts within EC/ECDC/HERA and HCIN, to share information and update on communication plans	Aligned and streamlined approach to communication across EU
Interaction with national competent authorities	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
Interaction with international partners	Coordination of International Coalition of Medicines Regulatory Authorities (ICMRA) communications	Increase the visibility of international collaboration of regulatory authorities

Stakeholder interactions with patients, healthcare professionals, industry organisations and academia. The interactions involving patients and healthcare professionals range from information and consultation to participation in the scientific activities of the Agency and its committees, and review of information

intended for the public. The Agency is also developing its collaboration with academia, with a particular focus on innovation in medicines, such as qualification of biomarkers and new methodologies. EMA also aims to continue building and maintaining trusted relationships with international media and to strengthen the EMA brand to further increase the Agency's reach and European citizens' awareness of the Agency's work for the benefit of the patient.

Area of work	Key action	Expected benefit
Stakeholder interactions	Identify suitable experts (patients and HCPs) and support their involvement in cross-Agency procedures throughout the lifecycle of medicines	Input from patients, healthcare professionals, academia, and the general public throughout the regulatory lifecycle of medicines
	Further develop external engagement and communications to raise awareness of EMA's work and promote trust and confidence in the EU regulatory system	Network of stakeholder organisations and individuals is maintained and expanded for interaction, enhanced dialogue with patients, consumers, healthcare professional organisations and industry associations
	Maintain and foster the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) as a platform for dialogue and exchange	The platforms for interaction with key stakeholder groups are optimised and maintained
	Review and update the approach to Industry Standing Group, based on experience	
	Manage the Early Notification system	Consistent messaging across EU is promoted through coordination of key information within the EU Network

Communication and transparency. The Agency places high importance on the transparency, openness, and efficiency of its interactions with partners and stakeholders. The Agency 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 important subject matters and developments, including lay-language summaries on medicines and regulatory outcomes. This information is also shared within the European regulatory network in advance of publication to ensure that consistent messages on medicines are available to citizens across the EU. In addition to the activities described above, public access to

documents and information is provided in accordance with Regulation (EC) No 1049/2001, and the number of requests for access to documents and information is continuously increasing.

Area of work	Key action	Expected benefit
Communication and transparency	Develop, maintain up-to-date and communicate high-quality product-related information, including on emerging issues	Patients, HCP, and general public recognise EMA as a trusted source of information
	Provide stakeholders and partners with consistent, high-quality, timely, targeted information when answering queries	Patients and healthcare professionals receive clarification from EMA on specific topics of interest
	Maintain the provision of cross-Agency services, including Information Centre support to the work of scientific staff and experts, guidance on corporate identity, as well as media and communication training for EMA staff	Relevant knowledge resources and communication-related services available at all times
	Streamline the cross-Agency approach to scientific publications	Streamlined process for publications
	Coordinate and manage requests for access to documents, third-party interaction, and data entry	Access to Documents (ATDs) requests are processed in line with Policy 0043 and Regulation (EC) No 1049/2001
	Continue work on automation processes for requests for information and access to documents from third parties through ACE tools	Increased efficiency of ATD, RFI and CDP
	General coordination of Clinical data publication and development and implementation of a strategy for CDP re-launch beyond COVID-19	Increased transparency by providing access to clinical documents supporting EMA decisions on CAPs

	Assessment of proposed CCI redaction and anonymisation / PPD redaction proposals in post-authorisation publication EPARs, RMPs, ARs and other documents for publication	Increased transparency while ensuring protection of PPD and CCI

Specific activities:

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 produces a wide variety of communication materials including press releases, infographics, videos distributed via a range of channels, with its corporate website, ema.europa.eu, as the main channel. 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 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.

Area of work	Key action	Expected benefit
Communication activities	Planning of communication activities and campaigns	Maximise public health impact of communication
	Provide and maintain timely, accurate, trustworthy, and high-quality information on EMA’s activities and their benefits to stakeholders, partners, and European citizens through the most appropriate communication channels	Access to information for EMA's publics is ensured
	Support research into and development of optimised communication tools and user testing of the Agency’s communication materials	Relevant, timely and targeted information for EMA stakeholders

	Develop and cultivate positive and constructive relations with the media	Enhanced interaction with media to facilitate access to information
	Review, update and maintain EMA's branding and corporate identity guideline	Promote visibility of corporate identity
	Manage and further develop EMA's social media activities	Expand outreach to broader targeted audience
	Social listening through media monitoring and social media monitoring Explore options for a more proactive approach to countering misinformation	Better and earlier awareness of mis- and/or disinformation, enabling tailored counter-information/transparency Enhanced understanding of stakeholders; future strategy development is improved through the collection of insights
	Provide up-to-date guidance on the corporate website and on other EMA websites	Promote understanding of EMA staff of the way the Agency uses, governs, and maintains all its websites for the benefit of their users

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.

Area of work	Key action	Expected benefit
Crisis Management	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
	Conduct lessons learnt exercise for experiences from dealing with the COVID-19 pandemic	Improvements in response and effectiveness of measures in case of future crises
	Complete a review of various frameworks in place at EMA for crisis response in different areas	Streamlining, harmonisation and rationalisation of the crisis response processes

	Review and improve crisis communication processes based on lessons learnt from COVID-19	EMA's ability to communicate effectively during a crisis is reinforced

Workload indicators

		Results	**Expected results**	**Forecasts**	
		2021	**2022**	**2023**	**2024**
Stakeholder interaction	Number of cases of patient/consumer engagement in EMA (medicines-related) activities	485	570	500	550
	Number of cases of healthcare professionals' engagement in EMA (medicines-related) activities	202	300	300	300
	Number of professional membership organisation events attended by participating Agency staff	27	36	25	25
	Number of sessions with Agency representatives	138	158	120	120
	Number of messages circulated via the Early Notification System	1,206	500	500	500
	Number of EMA communications pro-actively sent to stakeholders	182	190	200	200
Communication activities	Number of EPAR summaries and EPAR summaries updates published	239	200	250	300

		Results	Expected results	Forecasts	
		2021	**2022**	**2023**	**2024**
	Number of summaries of orphan designation published	167	150	150	150
Information and transparency	Access to documents, requests received	710	750	750	750
	Access to documents, documents released	1136	1,500	2,000	2,000
	Requests for information received	12500	10,000	10,000	10,000
	Clinical Data Publication (CDP), Procedures published[18]	11	41	45	45
	Clinical Data Publication (CDP), Documents published[19]	215	690	750	750
Communication activities	Number of documents published on EMA website	6,712	7,500	7,500	7,500
	Number of pages published and updated on the EMA website	3,064	3,500	3,500	3,500
	Number of press releases and news items published	220	170	140	120
	Number of press briefings conducted	19	15	10	10
	Number of social media posts published	975	900	1,300	1,300
	Completed requests for interviews and comments by media representatives	5,000	1,800	1,500	1,200
	Number of reports, brochures, leaflets laid out or printed, social media visuals	989	800	800	800

[18] numbers based on publications solely linked to Covid-19 related medicinal products. Depending on strategy to relaunch CDP post-BCP, the numbers in 2023 and 2024 may be higher.

[19] numbers based on publications solely linked to Covid-19 related medicinal products. Depending on strategy to relaunch CDP post-BCP, the numbers in 2023 and 2024 may be higher

Performance indicators

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
Stakeholder interactions	Satisfaction level of patient and consumer organisations	93%	n/a	90%	n/a
	Satisfaction level of Healthcare Professionals organisations	94%	n/a	85%	n/a
Information and transparency	Triage of incoming requests received via AskEMA within set timelines	100%[20]	100%	100%	100%
	Response to ATD within set timelines	92%	90%	90%	90%
	Response to RFI within set timelines (for EMA)	85%	95%	95%	95%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	81%	75%	75%	75%
	Satisfaction level of partners/stakeholders with EMA communications as per the 'EMA perception survey for communication'	n/a[21]	80%	n/a	80%
Communication activities	Average rating given to pages on the corporate website during the year	3.6	3.0	3.6	3.6

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

[20] New indicator introduced in 2021 Work Programme.
[21] Survey carried out every 2 years.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
1 RSS	Design communication campaigns in collaboration with relevant stakeholders to proactively approach key public-health areas (e.g., vaccines) Improve communication for patients, healthcare professionals and other stakeholders, including HTAs and payers Enhance professional outreach through scientific publications and conferences	Delivery of communication campaigns on key topics, with focus on COVID-19	2020	2025	Communication campaigns on key topics delivered (CTIS/CTR, AMR, etc.) Strategic plan for stakeholder engagement finalised Consolidated EMA approach to scientific publications agreed Three 'Key facts' documents on COVID-19 vaccines developed and published Periodic update of lines to take on COVID-19 vaccines Timely response to open access requests High-priority scientific publications coordinated and published

6. Information Management Division

Information Management underpins everything we do and is a key enabler for moving towards EMA's vision to become an all-digital, modern, efficient, and data-driven Agency of the future. To cope with emerging business needs and new legislative requirements, 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 transition legacy systems to a secure and data-protection compliant cloud-native enterprise architecture. The goal is to become a digital hub, providing high-quality data and information services by enabling a connected, interoperable medicines regulatory platform for the Network and its stakeholders.

On this journey, we will focus on the following pillars for success:

- **Maximising customer success**: We aim to enable success of the European Medicines Regulatory Network and maximise business impact through customer focus. We operate in a diverse internal and external stakeholder landscape which requires a well-coordinated demand management process, so Information Management can fully contribute to the success of each stakeholder. Our aim is to be recognised as a trusted partner for our stakeholders' information service needs, and to play an integral part in achieving EMRN's mission. We will enable this by having customer-focused, multidisciplinary teams with the right level of business understanding and technology expertise, demonstrating a customer-centric, can-do, and agile attitude delivering business value incrementally and quickly.
- **A modernisation mindset**: We will strategically focus on innovating IT capabilities and transforming how we deliver IT to our customers. We will introduce and foster best-in-class technology ecosystems, leveraging best-of-breed, standard technologies where possible, adapting our processes to the strengths of the technologies. We will provide opportunities for staff to grow and be proficient in emerging technologies and empower them to recommend the right technologies for the right use cases. We will continue the journey to bring data together and make it actionable. We will enable the re-design of key business processes by migrating to strategic platforms and transform legacy to secure and cost-efficient cloud infrastructure. We will collaborate with stakeholders to enable interoperability of data and business processes.
- **Operational Excellence and Information Security** are the foundations for well-run IT operations. We will continuously enhance information security and data protection compliance and will assess progress based on best practices and frameworks. We work to enhance performance and responsiveness of our systems. We will apply a risk-based approach to ensure focus where it is needed the most first, and leverage cloud-enabled services to enhance security monitoring and threat protection using latest technologies supported by Artificial Intelligence and Machine Learning. We will meet customers' expectations through Service Level Agreements that are fit for purpose and provide services in accordance with Procurement functions. The Division will pursue a flexible, scalable IT sourcing contract portfolio that covers the breadth of skills and profiles required to optimise delivery and address growing business demands. This is achieved by establishing capability-based IT sourcing contracts that incentivise vendors to provide high-quality products efficiently and drive continuous improvement. The planning function will be further matured to coordinate and manage these contracts.

We will work closely with HPAC (Health Policy Agencies Collaboration) to identify areas of collaboration and synergies for the delivery of technology and information management programmes across the EU health agencies. The objective of this collaboration is to ensure interoperable digital services for implementing EU-wide policies, enable data sharing and reuse of technologies.

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.
- **Integrated Programme Management Services** ensure strategic alignment with EMA's business objectives and facilitate the delivery and maintenance of information-management systems through collaboration, communication, and coordination within the I-Division and other enabling functions, such as Procurement and Purchase Standards (A-FI-PPS), Information Security (AF-INS) and the Portfolio Office (A-SG-PFO). We provide integrated programme management for I-Division initiatives, including budget and acquisition planning, strategy development, data standards development and enterprise architecture. We are also responsible for managing relationships with the network of EU regulators, the pharmaceutical industry and other international regulators related to information-management topics.
- **Network Portfolio governance** has replaced Telematics as part of the Agile transformation of EMA. The decision for an Agile transformation was endorsed by the Management Board in June 2021 and is being implemented at the Agency in a phased approach since autumn 2021. With the new Agile governance and way of working, external stakeholders are engaged through Agile ceremonies, either directly (for example System Demos) or through representatives acting as their delegates. Summaries of the ceremonies can be accessed on the EMA's corporate website.

The workforce available in 2023 for the Division is currently foreseen at 105 staff (77 TAs, 25 CAs, 3 SNEs) This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Workload indicators

		Results	Expected results	Forecasts	
		2021	**2022**	**2023**	**2024**
Network Portfolio	Number of information services/IT systems provided by EMA	25	28	28	28
	Number of Epics[22]	n/a	26	34	40

Performance indicators

		Results	Expected results	Targets	
		2021	**2022**	**2023**	**2024**
Network Portfolio	Satisfaction of EMA internal and external users	95.8%	80%	80%	80%
	Availability of IT systems and corporate website	99%	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 the proper governance to ensure effective functioning for 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, the budget, personnel, rules and regulations on finances, audit and accounting.

The key drivers for the annual work programme are:

[22] New indicator introduced in the context of the EMA Agile Transformation.

- Supporting staff management and development and embedding the recently launched competency framework to facilitate performance management, including the appraisal process and staff development, and act as a foundation for further staff-related initiatives. Launching the revised strategy for human resources and working through the multi-annual implementation plan; focus on staff wellbeing measures.
- Enhancing the administrative processes, including the domains of planning and resourcing of the Agency (workforce planning aspects), procurement (centralised support, vendor management, market research, tools facilitating procurement processes), quality of data for more automated reporting, accounts receivable processes and tools, and managing associated master data.
- Efficiently and effectively filling the positions granted by the budgetary authority.
- Efficiently and effectively managing additional budgeting, procurement and contracting stemming from the extension of the Agency's mandate, scientific studies, information technology portfolio. Running the recently implemented administrative processes (procurement, payments, support systems) associated with medical device expert panels.
- Working with the Institutions to support the revision of the Fee regulation.
- 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.

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.

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

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

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 environmental management activities of the Agency.

Programme management: The Portfolio Office ensures the Network Portfolio is managed according to the Agency's standard methodology and governance arrangements, and monitors, controls, and reports on the progress of the portfolio. It supports EMA's Portfolio Board in ensuring that delivery is done in line with the strategy and meets customer expectations.

The workforce available in 2023 for the Division is currently foreseen at 159 staff (122 TAs, 34 CAs, 3 SNE). This figure is subject to constant revision, taking into account staff movements (including part-time regime) and workload fluctuation.

Performance indicators

		Results	**Expected results**	**Target**	
		2021	**2022**	**2023**	**2024**
Human Resources	Posts on the Agency establishment plan filled	98%	100%	100%	100%
	Average time to run selection procedures from vacancy notice to establishment of reserve list	65% < 3 months	100%< 3 months	100% average < 3 months	100% average < 3 months
Planning and Monitoring	Revenue appropriations implemented	99.87%	97%	97%	97%
	Expenditure appropriations implemented	96.38%	95%	95%	95%
	Payments against appropriations carried over from year N-1	92.87%	95%	95%	95%
	The maximum rate of carryover to year N+1, of total commitments within the title				

		Results	Expected results	Target	
		2021	**2022**	**2023**	**2024**
	Title 1	5.75%	10%	10%	10%
	Title 2	24.31%	20%	20%	20%
	Title 3	37.59%	30%	30%	30%
Finance (part 1)	Payments made within 30 days' time	96.6%	98%	98%	98%
	Receivable overdue for more than 30 days (including provision for bad debts)	2.89%	<10%	<10%	<10%
	Balance sheet volume (as proxy for treasury mgmt., accounts receivable/payable transactions, audits, financial analysis, and reporting) (in million EUR)	335	395	400	405

Forecast activity

		Results	Expected results	Forecast	
		2021	**2022**	**2023**	**2024**
Human Resources	Total TA staff recruited against vacant posts	70	50	50	50
	Staff turnover rate (staff leaving against total no. of staff TA & CA)	5.10%	5%	5%	5%
	Total TA, CA, END at the Agency	875	879	930	950

		Results	Expected results	Forecast	
		2021	**2022**	**2023**	**2024**
	Onboarding of staff (TAs, CAs, ENDs)	65	70	75	75
	Staff entitlements management	880	850	950	950
Finance (part 2)	Procurement procedures implemented	63	48	56	46
	Contracts under management (excluding expert contracts)	352	354	364	360
	Financial transactions initiated (in thousands)	10	10.1	14	15
	Financial Transactions verified (in thousands)	18.6	17.1	24.1	25
	Invoices issued (as proxy for workload linked to registering and processing applications, solving questions of fee interpretation and invoicing) (in thousands)	40.8	50	50	50

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	Implement the revised human resource and talent management strategy	The HR strategy will consolidate practices into a coherent system and practices and will lead to continuously-improving approaches in domains of staff wellbeing, leadership and management, talent management and culture Staff engagement survey carried out in Q1 2023	2021	2024	The new strategy adopted The implementation plan delivered The prioritised activities for 2023 implemented
6.2	Implement the new competency management framework	A number of other deliverables will be proposed for prioritisation under the Agile HR approach (e.g., career paths, career coaching, 360 evaluations), but given the organisational capacity to uptake new practices, the implementation is expected to extend over a number of years	2020	2024	The 2022 staff appraisal system applies the new competency framework Prioritisation of further actions carried out under the strategy for human resources
6.4	Potential replacement of the human resource management and financial systems, taking into account the discontinuation of support for the current system by vendors	Gradual replacement of the financial and HR system in line with the future project plan	2023	tbc	Implementation of the project plan once confirmed

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
6.4	Implement the Agency's new intranet and migrate or develop related content	New intranet implemented. Content is gradually rolled out, taking into account business capacity	2021	2023	New intranet launched and used by staff Migration completed in 2023
6.4	Further develop procurement and contract management practices and implement a procurement tool	A tool supporting procurement processes implemented Further modules developed by DG Budget implemented	2020	2023	Further modules implemented
6.3	New Fee Regulation: optimisation and review of revenue and expenditure process	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	2022	Implementation of the Fee Regulation following mandatory deadlines
6.3	Improve efficiency of certain administrative processes	Identified improvement in the accounts receivable and customer data management processes implemented	2021	2023	Identified process improvements implemented

8. Pillar III Network Portfolio

Following the implementation during 2022 of the SAFe Agile methodology, the Agency has migrated all of its former programmes and projects into the new governance. To reflect this change, the 2023 Single Programming Document no longer includes a separate Annex XIV with programmes and projects. Instead, all activities falling under Pillar III have been centralised in this new chapter.

The implementation of the new methodology has led to the creation of five different 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:

- Product Lifecycle Management Value Stream (PLM VS) objective is to enhance capabilities to authorise and manage lifecycle of medicines and medical devices
- Research and Development Management Value Stream (R&D VS) objective is to enhance capabilities to foster R&D and generate scientific evidence
- Monitoring Value Stream (MON VS) objective is to enhance capabilities to monitor availability and safety of products
- Managing the Agency Value Stream (MTA VS) objective is to enhance capabilities to manage the Agency and coordinate and support the network
- Technology Lifecycle Management and Information Security Value Stream (TLM & IS VS) objective is to enhance capabilities to manage information technology and security

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 2023, to be reviewed during quarterly Programme Increment planning ceremonies. The planned deliverables for 2024 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 2024, based on the progress made in 2023.

Note: The budget figures for 2023 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.

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Budget 2023 (M€)
Product Lifecycle Management Value Stream (PLM VS)					**17.6**
Electronic Applications Form (Product Lifecycle Management Portal) *(Formerly DADI)*		2021	2024	– Human Variations Form – Human + Vet Marketing Authorisation Application (MAA) – Vet Variation Form – Renewals – Product User Interface (for viewing, submitting and correcting product data)	

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Budget 2023 (M€)
Regulatory Procedure Management for PLM		2022	2024	– Process Core (Variations, Transfers, Art 61.3) – PSURs, post-authorisation measures – MAA + additional functionality	
Electronic Product Information (ePI)		2022	2023	– Authoring Portal – Publishing and Consuming – Pilot planning	
Expert Panels for Medical Devices (EXPAMED)	– Regulation (EU) 2022/123 of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices	2022	2023	– Procedure Management – Collaboration Enablement	
Medicinal Product Management System (PMS)	– Regulation 726/2004, art.57(2) - Regulation (EC) 520/2012, art.25 and 26 - Clinical trials reg. 536/2014, art.8193) - Pharmacovigilance 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	– XEVMPD Integration (Data migration/transformation into ISO IDMP format) – IDMP Implementation (Data migration/transformation into ISO IDMP format) – XEVMPD Integration (Feedback Loop – capabilities to ensure XEVMPD and PMS are fully synchronised) – FHIR Ingestor (Capabilities to import IDMP compliant product data to PMS) – IDMP compliance (Capabilities to validate ISO 11615 compliance)	
eCTD4 (eSubmissions incl. EURS/CR)		2021	2026	– eCTD v4.0 preparation and implementation	
Veterinary Union Product Database (UPD)		2021	--	– Union Product Database (UPD)	
Research and Development Management Value Stream (R&D VS)					**14.7**

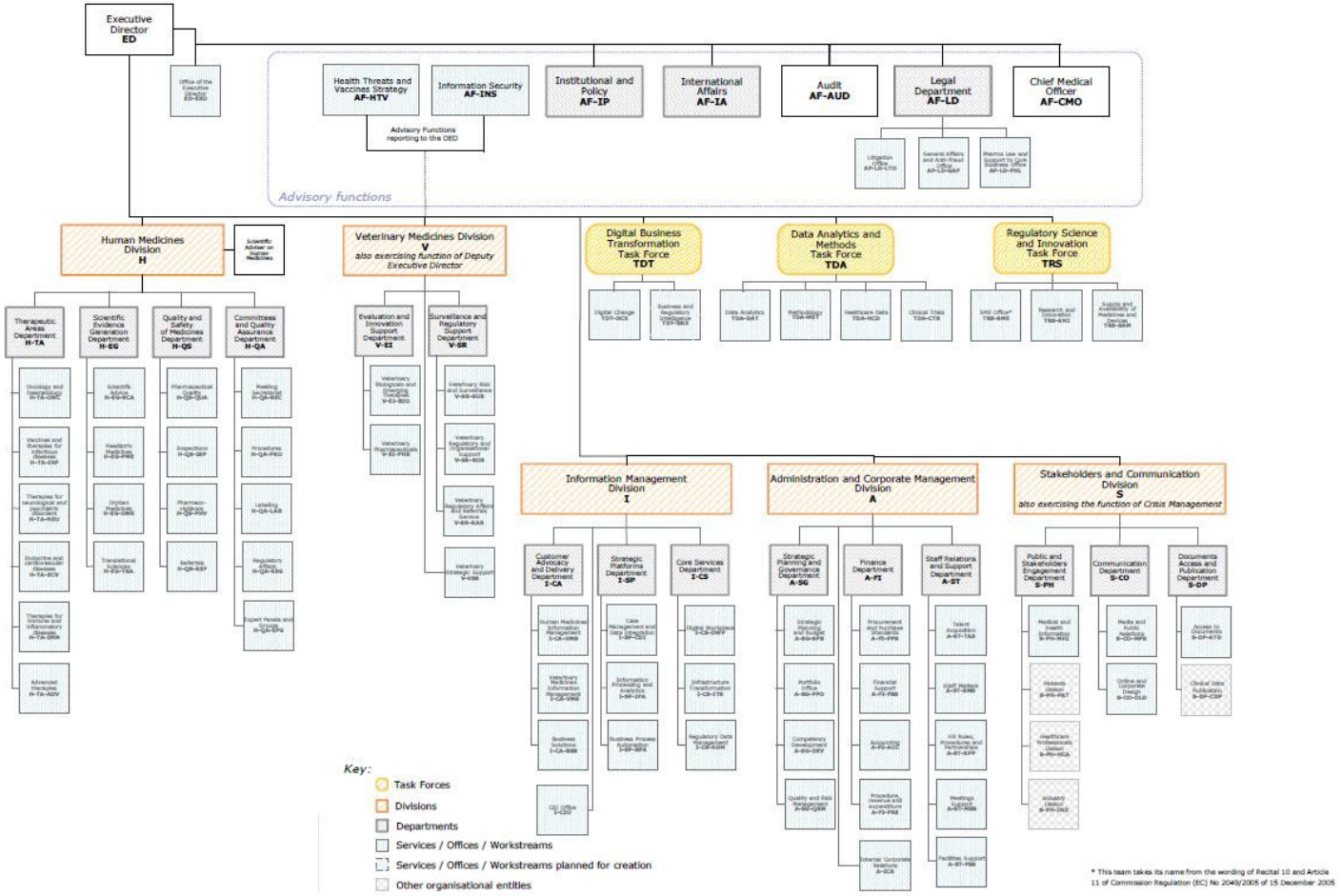
Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Budget 2023 (M€)
Clinical Trials Information System (CTIS)	– Regulation (EC) 536/2014, art.80-82 – Art. 11(3) of Implementing Regulation to Regulation (EC) 536/2014	2014	tbc	– After go-live version for January 2023	
Regulatory Procedure Management for R&D				– Pipeline (tbc): PRIME, Paediatrics, SA for Medical Devices	
Lifecycle Regulatory Submission Metadata (LRSM)		2020	2023	– Scientific Explorer (regulatory documents search tool) – Clinical trial Study Protocol/Results conceptual data model	
T.R.I.P. (Horizon Scanning)		2023	2023	– Platform to support horizon scanning capability (identify futures innovations and trends earlier to support development)	
Real World Metadata & Studies catalogue		2021	2025	– Catalogue of real-world evidence data sources and studies	
Monitoring Value Stream (MON VS)					**13.2**
European Shortages Monitoring Platform (ESMP)	– Regulation (EU) 2022/123	2022	2023	– Monitoring of events in preparation for major crisis or Public Health Emergency (PHE) – Monitoring of Critical Medicines during PHE/ME – Support the work of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	
Medical Devices Shortages	– Regulation (EU) 2022/123	2022	2023	– IT implementation medical devices shortages	
Inspections and Parallel Distribution				– Inspections – Parallel Distribution	
Union Pharmacovigilance Database (UPhD, formerly EVVet3)	– Regulation (EC) 726/2004, art.57(d) – Regulation (EU) 2019/6; associated implementing acts	2017	2023	– UPhD MVP completion and improvements	

Value Stream/Products	Legal basis (if applicable)	Start date	End date	Deliverables (Epics) 2023	Budget 2023 (M€)
Antimicrobial Sales & Use (ASU)		2021	2023	– Transfer reporting functionalities for sales data from existing ESVAC	
Signal and Safety Analytics (SSA)		2022	2024	– Conclude implementation of the new solutions – Implement change management plan	
Managing the Agency Value Stream (MTA VS)					**8.8**
Expert Database replacement		2022	2023	– Expert Database replacement	
Admin Data Quality		2022	2023	– Admin data quality management	
SAP Finance replacement		2023	2025	– Start implementation of selected solution	
SAP HR replacement		2023	2025	– SAP HR on-premise migration	
New Fee Regulation		Q4/2022		– Analysis and impact assessment	
E-procurement		Q4/2022	2023	– E-procurement suite	
EU Network Training Centre (EU NTC)		Q4/2022	2023	– EU NTC website	
Technology Lifecycle Management and Information Security Value Stream (TLM & IS VS)					**18.2**
Information Security		2022	2024	– Cyber and Information Security enhancements – Operational Security enhancements – Application Security enhancements	
Data Centre 2.0		2022	2023	– Migration from data centre to cloud provider	

Annexes

Annex I Organisational chart

Data valid on 01/01/2023



Annex II: Resource allocation per activity 2023

Activity-based budget 2023

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	**279**	**112**	**67,201**	**35,275**	**6,731**	**150,979**	**7,010**	**267,196**	**58%**
1.1 Pre-authorisation activities	82	30	20,292	6,346	3,191	27,863	57	57,749	13%
1.2 Initial evaluation activities	52	16	11,406	3,363	613	15,784	1,003	32,168	7%
1.3 Post-authorisation activities	76	27	19,049	14,640	222	94,071	1,885	129,868	28%
1.4 Referrals	7	2	1,238	416	213	-	258	2,125	0%
1.5 Pharmacovigilance activities	43	26	7,937	8,472	1,232	13,261	3,798	34,699	8%
1.6 Other specialized areas and activities	20	13	7,279	2,039	1,261	-	9	10,587	2%
2 Evaluation activities for veterinary medicines	**39**	**18**	**12,490**	**7,509**	**1,731**	**6,306**	**614**	**28,649**	**6%**
2.1 Pre-authorisation activities	2	1	1,427	627	164	364	3	2,585	1%
2.2 Initial evaluation activities	8	3	1,610	517	387	1,417	233	4,164	1%
2.3 Post-authorisation activities	10	2	3,456	1,431	79	1,949	208	7,123	2%
2.4 Arbitrations and Referrals	1	1	191	73	97	-	156	517	0%
2.5 Pharmacovigilance activities	8	5	2,400	3,906	482	2,575	14	9,379	2%
2.6 Other specialized areas and activities	11	7	3,406	953	521	-	-	4,880	1%
3 Horizontal activities and other areas	**219**	**87**	**50,045**	**42,380**	**7,153**	**6,064**	**13,030**	**118,671**	**26%**
3.1 Committee coordination	54	21	12,547	8,772	3,381	-	1,420	26,120	6%
3.2 Inspection and Compliance	29	18	5,523	2,634	853	6,064	30	15,103	3%
3.3 Partners and Stakeholders	27	7	6,456	1,766	1,369	-	461	10,052	2%
3.3a Transparency and access to documents	18	10	4,781	1,743	-	-	-	6,524	1%
3.3b Information	42	17	9,111	6,928	450	-	195	16,684	4%
3.4 International activities	12	3	3,200	839	521	-	-	4,561	1%
3.5 Information Management (incl. EU Telematics)	36	10	8,427	19,698	579	-	10,924	39,628	9%
4 Corporate Governance and Support activities	**145**	**30**	**28,648**	**14,284**	**548**	**-**	**6**	**43,487**	**9%**
4.1 Governance, quality management and internal audit	24	7	6,136	1,596	548	-	-	8,280	2%
4.2 Finance	29	9	5,754	2,978	-	-	6	8,738	2%
4.3 Information technology	24	5	5,094	3,565	-	-	-	8,659	2%
4.4 Human resources	56	9	9,972	5,495	-	-	-	15,467	3%
4.5 Infrastructure services	11	1	1,693	650	-	-	-	2,344	1%
Total	**682**	**248**	**158,385**	**99,449**	**16,162**	**163,348**	**20,659**	**458,003**	**100%**

FTEs are calculated as follows:	FTEs
Temporary Agents	682
Contract Agents	203
Seconded National Experts	45
Total Staff	**930**

Annex III: Financial resources 2023 - 2025

Table 1 – Revenue

General revenues

Revenues	2022	2023	2024	2025
	Revenue estimated by the agency	Budget forecast	Budget forecast	Budget forecast
EU contribution	€ 49,679,960	€ 50,027,000	€ 34,997,000	€ 34,996,000
Other revenue	€ 365,182,650	€ 407,976,000	€ 446,114,000	€ 455,036,000
PROVISIONAL REVENUE				
Total revenue	**€ 414,862,610**	**€ 458,003,000**	**€ 481,111,000**	**€ 490,032,000**

General Revenues							
REVENUES	Executed 2021[1]	Estimated by the agency 2022[2]	2023		VAR 2023/2022 (%)	Forecast 2024	Forecast 2025
			Agency request	Budget forecast			
1 Revenue from services rendered	€ 341,640,284	€ 364,882,044	€ 407,609,000	€ 407,609,000	11.71%	€ 445,756,000	€ 454,854,000
2 EU and EEA contribution	€ 37,636,730	€ 49,679,960	€ 50,027,000	€ 50,027,000	0.70%	€ 34,997,000	€ 34,996,000
- of which special contribution for orphan medicinal products	€ 12,187,155	€ 12,895,240	€ 14,411,000	€ 14,411,000	11.75%	€ 14,411,000	€ 14,378,000
- of which assigned revenues deriving from previous years' surpluses	€ 0	€ 4,368,321	€ 24,983,000	€ 24,983,000	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'
- of which EEA/EFTA (excluding Switzerland)	€ 0	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.
- of which Candidate Countries	€ 0	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.
4 Other contributions	€ 0	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.
- of which delegation agreement, ad hoc grants	€ 0	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.
5 Administrative operations	€ 0	€ 55,129	€ 27,000	€ 27,000	-51.02%	€ 18,000	€ 77,000
- 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
6 Revenues from services rendered against payment	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
7 Correction of budgetary imbalances	€ 0	€ 0	€ 0	€ 0	p.m.	p.m.	p.m.
9 Miscellaneous revenue	€ 2,878,523	€ 245,477	€ 340,000	€ 340,000	n/a	€ 340,000	€ 105,000
TOTAL REVENUES	**€ 382,155,537**	**€ 414,862,609.76**	**€ 458,003,000**	**€ 458,003,000**	10.40%	**€ 481,111,000**	**€ 490,032,000**

1) Data as per final 2021 accounts
2) Data updated in accordance with the provisional outturn

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

REVENUES	2022	2023	2024	2025
	Budget forecast	Budget forecast	Budget forecast	Budget forecast
TOTAL REVENUES	€ 750,000	€ 0	€ 0	€ 0

REVENUES	General Revenues						
	Executed 2021[1]	Estimated by the agency[2] 2022	2023		VAR 2023/2022 (%)	Forecast 2024	Forecast 2025
			Agency request	Budget forecast			
ADDITIONAL EU FUNDING STEMMING FROM GRANTS (FFR Art.7)	€ 25,415	€ 750,000		€ 0	-100.00%	€ 0	p.m
ADDITIONAL EU FUNDING STEMMING FROM CONTRIBUTION AGREEMENTS (FFR Art.7)	-	-	-	-	*n/a*	-	-
ADDITIONAL EU FUNDING STEMMING FROM SERVICE LEVEL AGREEMENTS (FFR Art. 43.2)	-	-	-	-	*n/a*	-	-
TOTAL	€ 25,415	€ 750,000	€ 0	€ 0	-100%	€ 0	€ 0

1) Data as per final accounts 2021

2) Data updated in accordance with the provisional outturn

Table 2 – Expenditure

Expenditure	2021 [1]		2022		2023		2024		2025	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1 - Staff expenditure	€ 125,481,673	€ 125,481,673	€ 138,841,910	€ 138,841,910	€ 158,385,000	€ 158,385,000	€ 161,297,000	€ 161,297,000	€ 164,523,000	€ 164,523,000
Title 2 - Infrastracture and operating expenditure	€ 47,758,405	€ 47,758,405	€ 52,245,279	€ 52,245,279	€ 72,741,000	€ 72,741,000	€ 72,290,000	€ 72,290,000	€ 73,737,000	€ 73,737,000
Title 3 - Operational expenditure	€ 192,250,624	€ 192,250,624	€ 217,237,648	€ 217,237,648	€ 226,877,000	€ 226,877,000	€ 247,524,000	€ 247,524,000	€ 251,772,000	€ 251,772,000
Title 9 - Provisional appropriations			€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 365,490,701**	**€ 365,490,701**	**€ 408,324,837**	**€ 408,324,837**	**€ 458,003,000**	**€ 458,003,000**	**€ 481,111,000**	**€ 481,111,000**	**€ 490,032,000**	**€ 490,032,000**

1) Data as per final 2021 accounts

Expenditure	2021			2022			2023			2024			2025		
	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	€ 68,418,177	€ 57,063,495	€ 125,481,673	69,774,615	69,067,295	€ 138,841,910	€ 80,114,687	€ 78,270,313	€ 158,385,000	€ 81,586,050	€ 79,710,950	€ 161,297,000	€ 83,217,801	€ 81,305,199	€ 164,523,000
Title 2 - Infrastracture and operating expenditure	€ 26,712,450	€ 21,045,955	€ 47,758,405	25,329,830	26,915,449	€ 52,245,279	€ 32,328,546	€ 40,412,454	€ 72,741,000	€ 31,840,005	€ 40,449,995	€ 72,290,000	€ 32,477,334	€ 41,259,666	€ 73,737,000
Title 3 - Operational expenditure	€ 172,117,311	€ 20,133,312	€ 192,250,624	194,235,776	23,001,872	€ 217,237,648	€ 199,953,331	€ 26,923,669	€ 226,877,000	€ 218,514,273	€ 29,009,727	€ 247,524,000	€ 222,264,409	€ 29,507,591	€ 251,772,000
Title 9 - Provisional appropriations	€ 0	€ 0	€ 0	€ 0		€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 267,247,938**	**€ 98,242,762**	**€ 365,490,701**	**€ 289,340,221**	**€ 118,984,616**	**€ 408,324,837**	**€ 312,396,564**	**€ 145,606,436**	**€ 458,003,000**	**€ 331,940,328**	**€ 149,170,672**	**€ 481,111,000**	**€ 337,959,544**	**€ 152,072,456**	**€ 490,032,000**
% of total expenditure	**73%**	**27%**	**100%**	**71%**	**29%**	**100%**	**68%**	**32%**	**100%**	**69%**	**31%**	**100%**	**69%**	**31%**	**100%**
* Full-time Equivalent	509	348	**857**	478	408	**886**	478	408	**886**	476	407	**883**	484	414	**898**
% of total FTEs	59%	41%	**100%**	54%	46%	**100%**	54%	46%	**100%**	54%	46%	**100%**	54%	46%	**100%**

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

EXPENDITURE	Commitment appropriations						
	Executed budget 2021[1]	Estimated by the Agency, 2022[2]	Draft budget 2023		VAR 2023/2022 (%)	Forecast 2024	Forecast 2025
			Agency request	Budget forecast			
Title 1 - Staff Expenditure							
11 Staff holding a post provided for in the list of posts	106,812,414	117,411,847	€ 132,958,000	€ 132,958,000	13.24%	€ 138,062,000	€ 140,823,000
- of which establishment plan posts							
- of which external personnel							
12 Expenditure relating to staff recruitment	211,242	202,880	€ 200,000	€ 200,000	-1.42%	€ 300,000	€ 306,000
13 Duty travel expenses and incidental expenditure	24,508	388,680	€ 676,000	€ 676,000	73.92%	€ 693,000	€ 707,000
14 Socio-medical infrastructure	1,646,279	2,433,756	€ 2,874,000	€ 2,874,000	18.09%	€ 2,733,000	€ 2,788,000
15 Staff training	648,765	1,011,818	€ 1,135,000	€ 1,135,000	12.17%	€ 1,140,000	€ 1,163,000
16 External services	16,084,186	17,301,239	€ 20,405,000	€ 20,405,000	17.94%	€ 18,216,000	€ 18,580,000
17 Receptions and events	54,279	91,691	€ 137,000	€ 137,000	49.42%	€ 153,000	€ 156,000
Total Title 1	**€ 125,481,673**	**€ 138,841,910**	**€ 158,385,000**	**€ 158,385,000**	14.08%	**€ 161,297,000**	**€ 164,523,000**
Title 2 - Infrastructure and operating expenditure							
20 Investment in immovable property, renting of buildings and associated costs	14,813,190	14,880,714	€ 16,808,000	€ 16,808,000	12.95%	€ 16,483,000	€ 16,813,000
21 Corporate information and communication technology	26,268,794	30,449,340	€ 45,717,000	€ 45,717,000	50.14%	€ 48,867,000	€ 49,844,000
22 Movable property and associated costs	588,233	581,136	€ 643,000	€ 643,000	10.65%	€ 660,000	€ 673,000
23 Current administrative expenditure	1,025,312	1,333,674	€ 1,437,000	€ 1,437,000	7.75%	€ 1,482,000	€ 1,512,000
24 Postal and delivery services	31,098	19,636	€ 31,000	€ 31,000	57.88%	€ 33,000	€ 34,000
25 Other meetings	342,248	165,255	€ 87,000	€ 87,000	-47.35%	€ 93,000	€ 95,000
26 Restaurant and catering	601,622	1,023,101	€ 1,245,000	€ 1,245,000	21.69%	€ 1,282,000	€ 1,308,000
27 Information and publishing	2,027,511	1,807,772	€ 1,403,000	€ 1,403,000	-22.39%	€ 1,460,000	€ 1,489,000
28 Business consultancy and audit services	2,060,396	1,984,652	€ 5,370,000	€ 5,370,000	170.58%	€ 1,930,000	€ 1,969,000
Total Title 2	**€ 47,758,405**	**52,245,279**	**€ 72,741,000**	**€ 72,741,000**	**39.23%**	**€ 72,290,000**	**€ 73,737,000**
Title 3 - Operational expenditure							
300 Meetings	143,394	2,193,316	€ 5,468,000	€ 5,468,000	149.30%	€ 5,394,000	€ 5,502,000
301 Evaluation of medicinal products	143,175,359	145,993,812	€ 163,348,000	€ 163,348,000	11.89%	€ 178,635,000	€ 182,208,000
302 Translations	4,772,548	4,072,491	€ 4,245,000	€ 4,245,000	4.24%	€ 4,656,000	€ 4,749,000
303 Scientific studies and services	14,706,874	27,604,840	€ 16,414,000	€ 16,414,000	-40.54%	€ 24,239,000	€ 24,724,000
31 Expenditure on business related IT projects	29,452,448	37,373,189	€ 37,402,000	€ 37,402,000	0.08%	€ 34,600,000	€ 34,589,000
Total Title 3	**€ 192,250,624**	**217,237,648**	**€ 226,877,000**	**€ 226,877,000**	**4.44%**	**€ 247,524,000**	**€ 251,772,000**
900 Provisional appropriations	€ 0	0	€ 0	€ 0	0.00%	€ 0	€ 0
Total Title 9	**€ 0**	**0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**
TOTAL EXPENDITURE	**€ 365,490,701**	**408,324,837**	**€ 458,003,000**	**€ 458,003,000**	**12.17%**	**€ 481,111,000**	**€ 490,032,000**

1) Data as per final accounts 2021

2) Data updated in accordance with the provisional outturn

EXPENDITURE	Payment appropriations						
	Executed budget 2021[1]	Estimated by the Agency, 2022[2]	Draft budget 2023		VAR 2023/2022 (%)	Forecast 2024	Forecast 2025
			Agency request	Budget forecast			
Title 1 - Staff Expenditure							
11 Staff holding a post provided for in the list of posts	106,812,414	117,411,847	€ 132,958,000	€ 132,958,000	13.24%	€ 138,062,000	€ 140,823,000
- of which establishment plan posts							
- of which external personnel							
12 Expenditure relating to staff recruitment	211,242	202,880	€ 200,000	€ 200,000	-1.42%	€ 300,000	€ 306,000
13 Duty travel expenses and incidental expenditure	24,508	388,680	€ 676,000	€ 676,000	73.92%	€ 693,000	€ 707,000
14 Socio-medical infrastructure	1,646,279	2,433,756	€ 2,874,000	€ 2,874,000	18.09%	€ 2,733,000	€ 2,788,000
15 Staff training	648,765	1,011,818	€ 1,135,000	€ 1,135,000	12.17%	€ 1,140,000	€ 1,163,000
16 External services	16,084,186	17,301,239	€ 20,405,000	€ 20,405,000	17.94%	€ 18,216,000	€ 18,580,000
17 Receptions and events	54,279	91,691	€ 137,000	€ 137,000	49.42%	€ 153,000	€ 156,000
Total Title 1	**€ 125,481,673**	**€ 138,841,910**	**€ 158,385,000**	**€ 158,385,000**	14.08%	**€ 161,297,000**	**€ 164,523,000**
Title 2 - Infrastructure and operating expenditure							
20 Investment in immovable property, renting of buildings and associated costs	14,813,190	14,880,714	€ 16,808,000	€ 16,808,000	12.95%	€ 16,483,000	€ 16,813,000
21 Corporate information and communication technology	26,268,794	30,449,340	€ 45,717,000	€ 45,717,000	50.14%	€ 48,867,000	€ 49,844,000
22 Movable property and associated costs	588,233	581,136	€ 643,000	€ 643,000	10.65%	€ 660,000	€ 673,000
23 Current administrative expenditure	1,025,312	1,333,674	€ 1,437,000	€ 1,437,000	7.75%	€ 1,482,000	€ 1,512,000
24 Postal and delivery services	31,098	19,636	€ 31,000	€ 31,000	57.88%	€ 33,000	€ 34,000
25 Other meetings	342,248	165,255	€ 87,000	€ 87,000	-47.35%	€ 93,000	€ 95,000
26 Restaurant and catering	601,622	1,023,101	€ 1,245,000	€ 1,245,000	21.69%	€ 1,282,000	€ 1,308,000
27 Information and publishing	2,027,511	1,807,772	€ 1,403,000	€ 1,403,000	-22.39%	€ 1,460,000	€ 1,489,000
28 Business consultancy and audit services	2,060,396	1,984,652	€ 5,370,000	€ 5,370,000	170.58%	€ 1,930,000	€ 1,969,000
Total Title 2	**€ 47,758,405**	**52,245,279**	**€ 72,741,000**	**€ 72,741,000**	**39.23%**	**€ 72,290,000**	**€ 73,737,000**
Title 3 - Operational expenditure							
300 Meetings	143,394	2,193,316	€ 5,468,000	€ 5,468,000	149.30%	€ 5,394,000	€ 5,502,000
301 Evaluation of medicinal products	143,175,359	145,993,812	€ 163,348,000	€ 163,348,000	11.89%	€ 178,635,000	€ 182,208,000
302 Translations	4,772,548	4,072,491	€ 4,245,000	€ 4,245,000	4.24%	€ 4,656,000	€ 4,749,000
303 Scientific studies and services	14,706,874	27,604,840	€ 16,414,000	€ 16,414,000	-40.54%	€ 24,239,000	€ 24,724,000
31 Expenditure on business related IT projects	29,452,448	37,373,189	€ 37,402,000	€ 37,402,000	0.08%	€ 34,600,000	€ 34,589,000
Total Title 3	**€ 192,250,624**	**217,237,648**	**€ 226,877,000**	**€ 226,877,000**	**4.44%**	**€ 247,524,000**	**€ 251,772,000**
900 Provisional appropriations	€ 0	0	€ 0	€ 0	0.00%	€ 0	€ 0
Total Title 9	**€ 0**	**0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**
TOTAL EXPENDITURE	**€ 365,490,701**	**408,324,837**	**€ 458,003,000**	**€ 458,003,000**	**12.17%**	**€ 481,111,000**	**€ 490,032,000**

1) Data as per final accounts 2021

2) Data updated in accordance with the provisional outturn

Table 3 –Budget outturn and cancellation of appropriations 2018-2021

Budget outturn		2018	2019	2020	2021[1)]
Revenue actually received (+)	€ 317,360,425.30	€ 317,081,125.07	€ 339,889,499.26	€ 376,246,022.54	€ 382,156,343.70
Payments made (-)	-€ 253,807,515.04	-€ 253,281,077.77	-€ 292,769,994.74	-€ 290,132,295.87	-€ 274,400,002.19
Carry-over of appropriations (-)	-€ 54,017,070.70	-€ 54,821,802.27	-€ 59,150,354.42	-€ 75,300,936.06	-€ 91,090,698.54
Cancellation of appropriations carried over (+)	€ 4,350,907.86	€ 4,982,084.89	€ 2,744,268.82	€ 2,423,908.71	€ 5,372,131.21
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 0.00	€ 0.00	€ 0.00	€ 0.00	€ 0.00
Exchange rate differences (+/-)	€ 581,555.58	-€ 159,476.48	€ 1,003,466.80	-€ 585,264.08	€ 2,944,406.68
Adjustment for negative balance from previous year (-)	€ 0.00	€ 0.00	€ 0.00	-€ 8,283,114.28	€ 0.00
Total	**€ 14,468,303.00**	**€ 13,800,853.44**	**-€ 8,283,114.28**	**€ 4,368,320.96**	**€ 24,982,180.86**

1) Data as per final 2021 accounts

The financial outturn for 2022, a surplus of approx. EUR 10.5 million, representing 2.40% of total revenue collected, i.e. EUR 435.9 million, cf. the draft budget outturn for all fund sources (C1, C11, R0 and CL), was caused by lower income from fees, partially offset by cancelled expenditure appropriations and adjustment for carry-over of assigned revenue appropriations.
The Agency's adopted budget consists of non-differentiated appropriations only, so no distinction is made between commitment and payment appropriations:

Title I, expenditure

- final expenditure was 1.57% lower than final appropriations, which is considered a good result;

Title II, infrastructure and operating expenditure

- final expenditure was 4.17% lower than final appropriations, with surpluses resulting from changes made to fitting-out project plans, savings on IT support and maintenance and lower expenditure on financial charges;

Title III, operational expenditure

- final expenditure was 3.17% lower than final appropriations, with main surpluses stemming from lower commitments for rapporteurs and translations (matching lower fee income) and lower expenditure on IT projects.

The agency managed to comply with the indicative ceiling for the amounts carried forward (C1 to C8) for title I (indicative ceiling of 10%), where 4.34% of committed appropriations were carried forward to 2023. For title II (indicative ceiling of 20%), 26.38% of committed appropriations wer carried forward to 2023. The main contributors were IT budget lines (CH21) and business consultancy. For title III (indicative ceiling of 30%), 40.06% of committed appropriations were carried forward. The main contributors were Art. 301, rapporteurs, BL3030, scientific studies and BL3105, 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.

Annex IV: Human Resources - Quantitative

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

- A. Statutory staff and SNEs

Staff	2021			2022			2023	2024	2025	2026
ESTABLISHMENT PLAN POSTS	**Authorised Budget**	**Actually filled as of 31/12/2021**	**Occupancy rate %**	**Authorised Budget**	**Actually filled as of 31/12/2022**	**Occupancy rate %**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**
Administrators (AD)	472	459	97%	477	473	99%	497	517	525	525
Assistants (AST)	185	185	100%	185	185	100%	185	185	185	185
Assistants/Secretaries (AST/SC)	0	0	0%	0	0	0%	0	0	0	0
TOTAL ESTABLISHMENT PLAN POSTS	**657**	**644**	**98%**	**662**	**658**	**99%**	**682**	**702**	**710**	**710**
EXTERNAL STAFF	**FTE corresponding to the authorised budget**	**Executed FTE as of 31/12/2021**	**Execution Rate %**	**FTE corresponding to the authorised budget**	**Executed FTE as of 31/12/2022**	**Execution Rate %**	**FTE corresponding to the authorised budget**	**Envisaged FTE**	**Envisaged FTE**	**Envisaged FTE**
Contract Agents (CA)	226	205	91%	223	192	86%	203	203	203	203
Seconded National Experts (SNE)	30	26	87%	30	25	83%	45	45	45	45
TOTAL EXTERNAL STAFF	256	231	90%	253	217	86%	248	248	248	248
TOTAL STAFF	**913**	**875**	**96%**	**915**	**875**	**96%**	**930**	**950**	**958**	**958**

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

Human Resources	2022	2023	2024	2025
	FTE	Envisaged FTE	Envisaged FTE	Envisaged FTE
Contract Agents (CA)	1.01	1.01	1.01	0.81
Seconded National Experts (SNE)				
TOTAL	1.01	1.01	1.01	0.81

- C. Other human resources
    - Structural service providers

	Actually in place as of 31/12/2021
Security	23
IT service desk	17
IT maintenance and support 'time&means' contracts only	2
Reception[1]	5
Building maintenance[2]	n/a
Cleaning	28
Catering	18
Reprographics and mail services	7
1) Security 24/7 service	
2) Building maintenance: included in the rental package	

    - Interim workers

	Total FTEs in year 2021
Number	70

Table 2 – Multi-annual staff policy plan 2021, 2022, 2023, 2024, 2025

Function group and grade	2021				2022				2023		2024		2025	
	Authorised budget		Actually filled as of 31/12/2021		Authorised budget		Actually filled as of 31/12/2022		Envisaged		Envisaged		Envisaged	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16		0		0		0		0		0		0		0
AD 15		3		2		3		0		3		3		3
AD 14		9		9		10		9		12		12		12
AD 13		13		11		13		13		12		12		13
AD 12		45		42		50		50		57		61		64
AD 11		51		49		52		52		49		50		51
AD 10		51		47		50		50		53		57		61
AD 9		55		54		62		62		66		82		98
AD 8		71		71		77		77		87		82		71
AD 7		94		94		97		97		89		90		90
AD 6		65		65		60		60		67		68		62
AD 5		15		15		3		3		0		0		0
AD TOTAL	**0**	**472**		**459**	**0**	**477**		**473**	**0**	**495**	**0**	**517**	**0**	**525**
AST 11		2		2		2		2		2		3		3
AST 10		7		7		7		7		7		7		7
AST 9		9		9		10		10		10		10		11
AST 8		10		10		13		13		14		15		16
AST 7		19		19		19		19		25		29		33
AST 6		20		20		26		26		31		35		46
AST 5		38		38		43		43		43		49		48
AST 4		46		46		42		42		43		32		16
AST 3		32		32		23		23		12		5		5
AST 2		2		2		0		0		0		0		0
AST 1		0		0		0		0		0		0		0
AST TOTAL	**0**	**185**		**185**	**0**	**185**		**185**	**0**	**187**	**0**	**185**	**0**	**185**
AST/SC1														
AST/SC2														
AST/SC3														
AST/SC4														
AST/SC5														
AST/SC6														
AST/SC TOTAL	**0**	**0**	**0**		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
GRAND TOTAL	**0**	**657**	**0**	**644**	**0**	**662**	**0**	**658**	**0**	**682**	**0**	**702**	**0**	**710**

External personnel

Contract agents

Contract agents	FTE corresponding to the authorised budget 2021	Executed FTE as of 31/12/2021	Headcount as of 31/12/2021	FTE corresponding to the authorised budget 2022	Executed FTE as of 31/12/2022	Headcount as of 31/12/2022	Envisaged FTE 2023	Envisaged FTE 2024	Envisaged FTE 2025
Function Group IV	110	89	90	122	94	107	122	125	128
Function Group III	81	72	94	81	89	91	81	78	75
Function Group II	10	18	0	0	1	1	0	0	0
Function Group I	0	0	0	0	0	0	0	0	0
Additional CA[1]	25	21	22	20	8	8	0	0	0
TOTAL	**226**	**200**	**206**	**223**	**192**	**207**	**203**	**203**	**203**

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

Seconded National Experts

Seconded National Experts	FTE corresponding to the authorised budget 2021	Executed FTE as of 31/12/2021	Headcount as of 31/12/2021	FTE corresponding to the authorised budget 2022	Executed FTE as of 31/12/2022	Headcount as of 31/12/2022	Envisaged FTE 2023	Envisaged FTE 2024	Envisaged FTE 2025
Total	30	26	28	30	25	30	45	45	45

Table 3 – Recruitment forecasts 2023 (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 Coordinator/Assistant			AST3 and above	AST3	FGIII
Communication Senior Specialist			AD08 and above	AD08	
EMA Liaison Officer at FDA			AD08 and above		
Head of Audit			AD09 and above	AD09	
Head of Service (ATD)			AD06 and above		
Liaison Coordinator			AST3 and above	AST3	

Liaison Senior Specialist			AD08 and above	AD08	
Policy Senior Specialist			AD06 and above	AD06	
Security coordinator			AST3 and above	AST3	
Scientific Advisor			AD12 and above	AD12	
Pharmacoepidemiology Specialist			AD06 and above	AD06	
Biostats Specialist			AD06 and above	AD06	
Computer Scientist					FGIV
EU NTC Senior Specialist			AD08 and above	AD08	
Project Management Specialist			AD06 and above	AD06	
Project Officer (Digital Lab)					FGIV

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

Annex V: Human Resources - Qualitative

A. Recruitment policy

Implementing rules in place:

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

B. Appraisal and reclassification/promotions

Implementing rules in place:

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

Table 1 - Reclassification of TA/promotion of officials

Grades	Average seniority in the grade among reclassified staff							
	2018	2019	2020	2021	2022	2023 [1]	Actual average over 5 years	Average over 5 years (According to decision C(2015)9563)
AD05	2.29	4.23	2.27	2.21	2.00		3.2	2.8
AD06	3.34	4.96	3.47	2.81	3.13		3.6	2.8
AD07	3.05	3.61	4.37	4.81	3.23		3.8	2.8
AD08	3.52	4	4.96	3.25	3.93		3.9	3
AD09	4.55	5.09	5	4.62	3.33		4.5	4
AD10	5.43	2.97	4.71	5.2	4.95		4.8	4
AD11	5.62	3	6.33	8	2.92		5.9	4
AD12	7.2	7.1	10	2.84			6.6	6.7
AD13	6.55		6	9.5			7.9	6.7
AST1	5.45	5.24					5.3	3
AST2	3.61	5.43	3	4.28	3.12		3.9	3
AST3	3.36	3.41	4.73	3.89	3.53		3.7	3
AST4	3.24	5.43	3.33	4.91	3.72		4	3
AST5	3.97	5.66	4	5.2	3.75		4.4	4
AST6	4.55	7	7.75	5.14	3.50		5.1	4
AST7	5.54	4.5	7.5	11	3.00		6.2	4
AST8	0	2	5	0	3.00		3.3	4
AST10 (Senior assistant)	0	0	0	0	0		0	5
AST/SC1	N/A	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	N/A	5
AST/SC3	N/A	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	N/A	6.7
AST/SC5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	8.3

1) To be updated in Sept 2023

Table 2 -Reclassification of contract staff

Function Group	Grade	Staff in activity at 1.01.2020	How many staff members were reclassified in 2021	Average number of years in grade of reclassified staff members 2021	How many staff members were reclassified in 2022	Average number of years in grade of reclassified staff members 2022	Average number of years in grade of reclassified staff members according to Decision C(2015)9561
CA IV	17	1	0	0	0	0	Between 6 and 10 years
	16	10	3	2.35	0	0	Between 5 and 7 years
	15	15	4	3	1	2	Between 4 and 6 years
	14	44	5	2.73	5	2.91	Between 3 and 5 years
	13	29	3	3.74	1	2.54	Between 3 and 5 years
CA III	11	1	0	0	1	0	Between 6 and 10 years
	10	15	4	2.5	4	3.34	Between 5 and 7 years
	9	39	6	2.63	4	2.79	Between 4 and 6 years
	8	16	3	2.54	2	2.98	Between 3 and 5 years
CA II	6	10	0	0	0	0	Between 6 and 10 years
	5	17	1	3.29	0	0	Between 5 and 7 years
	4	2	0	0	0	0	Between 3 and 5 years
CA I	2	0	0	0	0	0	Between 6 and 10 years
	1	0	0	0	0	0	Between 3 and 5 years

C. Gender representation

Table 1 - Data on 31/12/2021 statutory staff (only officials, TA and CA)

		2021							
		Official		Temporary		Contract Agents		Grand Total	
		Staff	%	Staff	%	Staff	%	Staff	%
Female	Administrator level	0	N/a	204	32%	69	33%	273	32%
	Assistant level (AST & AST/SC)	0	N/a	205	32%	84	41%	289	34%
	Total	**0**	**0**	**409**	**64%**	**153**	**74%**	**562**	**66%**
Male	Administrator level	0	N/a	201	31%	29	14%	230	27%
	Assistant level (AST & AST/SC)	0	N/a	34	5%	24	12%	58	7%
	Total	**0**	**0**	**235**	**36%**	**53**	**26%**	**288**	**34%**
Grand Total		**0**	**0**	**644**	**100%**	**206**	**100%**	**850**	**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

	2017		2021	
	Number	%	Number	%
Female Managers	**13**	**45%**	**11**	**39%**
Male Managers	**16**	**55%**	**17**	**61%**

D. Geographical balance

Table 1 - Data on 31/12/2021 - statutory staff only (officials, TA and CA)

Nationality	2021					
	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%	4	1%	11	1%
Belgium	21	4%	2	1%	23	3%
Bulgaria	10	2%	13	4%	23	3%
Croatia	7	1%	3	1%	10	1%
Cyprus	0	0%	2	1%	2	0%
Czech Republic	2	0%	15	4%	17	2%
Denmark	5	1%	5	1%	10	1%
Estonia	2	0%	7	2%	9	1%
Finland	4	1%	5	1%	9	1%
France	66	13%	30	9%	96	11%
Germany	38	8%	18	5%	56	7%
Greece	40	8%	25	7%	65	8%
Hungary	10	2%	17	5%	27	3%
Ireland	18	4%	4	1%	22	3%
Italy	69	14%	43	12%	112	13%
Latvia	1	0%	6	2%	7	1%
Lithuania	4	1%	12	3%	16	2%
Luxembourg	0	0%	0	0%	0	0%
Malta	0	0%	0	0%	0	0%
Netherlands	8	2%	5	1%	13	2%
Norway	2	0%	1	0%	3	0%
Poland	13	3%	33	10%	46	5%
Portugal	34	7%	12	3%	46	5%
Romania	22	4%	10	3%	32	4%
Slovakia	5	1%	17	5%	22	3%
Slovenia	2	0%	2	1%	4	0%
Spain	76	15%	36	10%	112	13%
Sweden	7	1%	6	2%	13	2%
United Kingdom	29	6%	14	4%	43	5%
Other	1	0%	0	0%	1	0%
TOTAL	**503**	**100%**	**347**	**100%**	**850**	**100%**

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

Most represented nationality	2017		2021	
	Number	%	Number	%
Italian	**93**	**13%**	**112**	**13%**

E. Schooling

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

Annex VI. Environmental management

EMA's environmental management activities were pursued in 2022 in line with the Agency's Environmental Policy[23] and the Environmental Roadmap 2020 to 2024.

Following a review of the EMA Environmental Management System (EMS) manual by externally sourced environmental consultants in the second half of 2021, an internal audit is scheduled for the end of 2022 or early 2023, as the next step towards obtaining the EU Eco-Management and Audit Scheme (EMAS) registration. During 2023, the findings of the audit will be worked through with implementation of any improvement actions identified.

The European Union has within its Green Deal set an amended 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. EMA aligns its long-term target with the Green Deal and climate neutrality by the year 2050, with an intermediate target of 55% by the year 2030.

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 considering a lifecycle perspective. 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 and small electricity for further energy efficiency, when technically and financially justifiable
	Material efficiency: "EMA drives material efficiency in line with good practices"	Monitor consumption of materials used (paper, plastic) to reduce or maintain levels during the pandemic	Promote reduced use of single-use materials along a circularity approach Promote paper-less workflows and digitisation
	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 to reduce the non-recyclable waste and hazardous waste	Monitor total waste per FTE and year and manage waste along a circularity approach
	Biodiversity – not relevant due to no further land being taken into use	N/A	N/A
	Emissions: "EMA drives emission reduction, including carbon zero by 2050"	Emissions of greenhouse gases [t] Air emissions [t]	Monitor travel by staff and delegates to align with internal interim mission rules, for a balanced approach between face to face and virtual meetings

[23] POLICY 78: Environmental Policy (europa.eu)

			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) 2022-2025	Actions as included in the SPD 2022-2025

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

- focus on further implementation of green criteria in the Agency procurements during 2023, in line with the prepared EMA 0061-2021 Internal guidance on Green Public Procurement and the support from the Green Criteria Helpdesk Services;
- introduce the option for offsetting the carbon footprint with emissions certificate in the highest impacting goods and services procured during 2023;
- implement improvement actions as identified in the scheduled internal environmental audit.

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 2023, a number of environmental performance indicators are monitored, related to the building occupancy with planned actions to support continuous improvements such as:

- For **energy consumption,** EMA uses 100% electricity from renewable sources at the EMA building since 2021. Heating and cooling are provided through the Amsterdam district systems where the Agency has very limited ability to impact the sourcing.

- For **water efficiency,** sensor taps have been installed in all sanitary facilities.

- Separation of **waste** is supported by provision of separate bins for paper, plastic, food waste and non-recyclables in line with Dutch legislation.

EMA also monitors paper consumption for printing and copying, as well as emissions from refrigeration.

During 2022, interim rules for staff missions and delegate travels were prepared to maintain some of the virtual meeting practices during the pandemic, whilst being sensitive to the need for in-person meetings.

Through the EMA Green Group, several awareness and communication campaigns are planned for 2023 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++.

The environment management performance from office occupancy at the EMA building will continue to be tracked with the calculation of the Agency's CO^2 emissions, with a purpose to report and communicate on an annual basis.

Annex VII: Building policy

#	Building Name and type	Location	SURFACE AREA(in m²)			RENTAL CONTRACT					Host country (grant or support)
			Office space	non-office	Total	RENT (€/year)	Duration of the contract	Type	Breakout clause Y/N	Conditions attached to the breakout clause (if applicable)	
1	EMA premises Amsterdam	Domenico Scarlattilaan, 6 Amsterdam, 1083 HS	22,574	10,837	33,411	10,937,840	20 years 1.5 months from commencement date of 15/11/2019 to 31/12/2039.	Lease agreement with CGREA (NL government 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	10,937,840					

Building projects in planning phase: None

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 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 which will be proposed by the European Commission and ultimately agreed by the European Parliament and Council of the EU. 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 future 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 is under preparation, and the European Commission legal proposal for the revised EMA's fees regulation is planned for the end of 2022.

Project and programme evaluations (also Agile Epics)

The EMA Financial Regulation establishes the requirement for ex ante and retrospective evaluations for programmes, projects, and activities. The evaluation method is currently being adapted to the new

EMA Agile way of working. As a consequence, instead of evaluation of projects, EMA performs evaluation of "Epics" (where "Epic" means a container for a solution initiative, aligned with Portfolio objectives).

Similar to the 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.

The new Agile approach, which has just finalised its experimentation phase through the Agile Transformation Pilot, is currently under finalisation and formalisation, based on experience and lessons learnt from the pilot. Formal documentation is planned to be completed in the upcoming months as part of the finalisation of the Agile framework.

As part of the pilot and similarly to projects, the Epics oversight is under responsibility of two Agency boards: the Executive Board (EXB) and the Portfolio Board (PB). The PB is responsible for approving the start of Epics and monitor their progress throughout the stages in their lifecycle, via 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 a lean business case, simply called Epic. Oversight of progress and steering of the Epic development is provided by PB via reporting through Agile Ceremonies, with escalation to Portfolio 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.

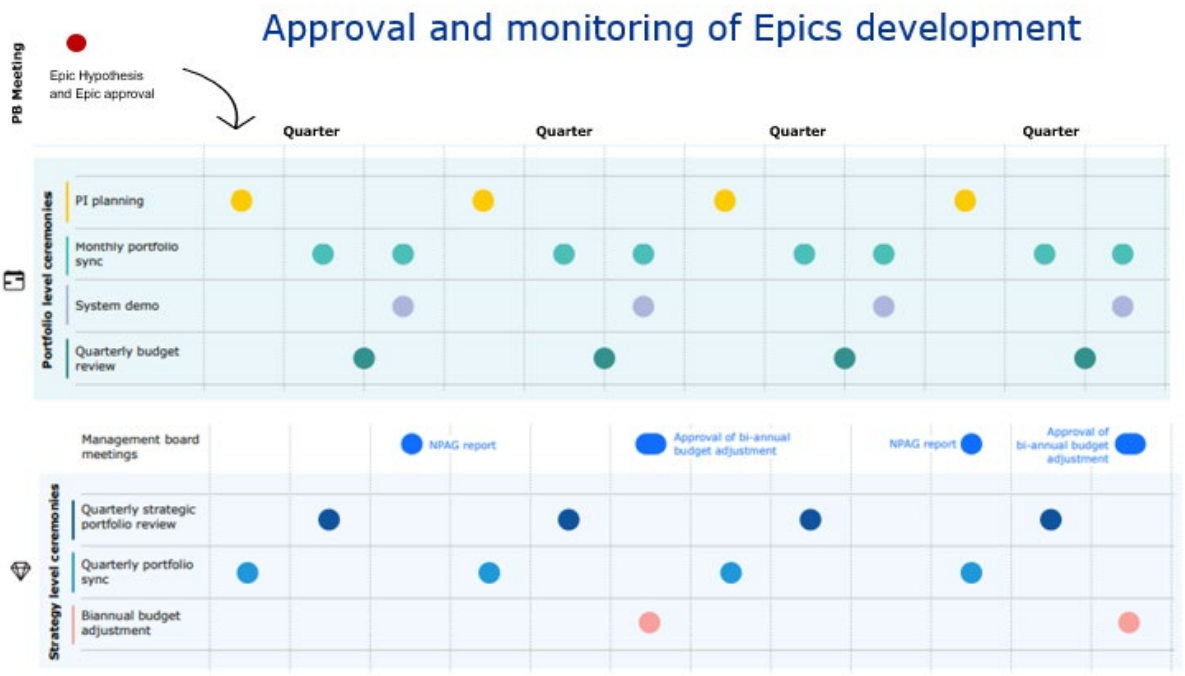
Interim evaluations are conducted by the PB when the status of an Epic is reviewed due to relevant modifications to scope, timeline and/or budget. Whenever the initial cost estimate at the time of Epic approval does not exceed EUR 1 million, but is later exceeded, the PB conducts an interim evaluation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

Epic oversight and evaluations

The picture below illustrates the flow where an Epic is approved and prioritised by the Portfolio Board, then included in scope of a Programme Planning Increment (planning of work to be undertaken from the next quarter). Afterwards, the Epic is continuously reported and monitored thorugh ceremonies, which include quarterly reviews and also quarterly system demos, besides a monthly sync, to ensure timely transparency of progress.



Annex X: Strategy for the organisational management and internal control system[24]

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.

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

- **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[25] model of internal control, and consists of five integrated internal control components, supported by seventeen principles.

Organisational management

Internal control governance, roles, and responsibilities

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

EMA management structures and bodies

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

Delegation of powers and responsibilities

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

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.

[25] Committee of Sponsoring Organizations of the Treadway Commission (COSO) Internal Control - Integrated Framework, June 2017

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**, including gated approval process, ex-ante and retroactive evaluations, and periodic reporting, are implemented to ensure appropriate checks on project alignment with the EMA strategy, priorities and business need, resource consumption and progress in delivery of the intended benefits at various stages of the project lifecycle.
- **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		2021	2022	2023	2024	2025
Grant agreements											
1. STARS	17/07/2019 (EMA's accession)	EUR 6,000	36 months as of 01/01/2019	European Commission, DG Research & Innovation, Health, Administration & Finance	Strengthening training of academia in regulatory sciences and supporting regulatory scientific advice	Amount	2,000	-	-	-	-
						Number of Cas/FTE	0.4	-	-	-	-
						Number of SNEs/FTE	0	0	0	0	0
2. ConcePTION	26/04/2019	EUR 85,000	60 months as of 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	17,000	17,000	-
						Number of CAs/FTE	0.2	0.2	0.2	0.2	-
						Number of SNEs/FTE	0	0	0	0	0
3. PREMIER	29/06/2020	EUR 47,000	72 months as of 01/09/2020	Innovative Medicines Initiative 2 Joint Undertaking	Prioritisation and Risk Evaluation of Medicines in the Environment	Amount	8,000	8,000	8,000	8,000	8,000
						Number of CAs/FTE	0.06	0.06	0.06	0.06	0.06
						Number of SNEs/FTE	0	0	0	0	0
						Amount	18,000	18,000	18,000	18,000	18,000

4. SISAQOL	30/10/2020	EUR 76,800	48 months as of 01/01/2021	Innovative Medicines Initiative 2 Joint Undertaking	Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life endpoints	Number of Cas/FTE	0.75	0.75	0.75	0.75	0.75
						Number of SNEs/FTE	0	0	0	0	0
Total grant agreements						Amount	45,000	43,000	43,000	43,000	26,000
						Number of Cas/FTE	1.41	1.01	1.01	1.01	0.81
						Number of SNEs/FTE	0	0	0	0	0
Contribution agreements											
1. IPA 2020-2022	19/12/2019	EUR 254,919	01/01/2020 to 31/12/2023 (36 months)	European Commission DG NEAR	Participation of candidate countries and potential candidates in EMA trainings and activities	Amount		85,000	85,000	84,919	-
						Number of CAs/FTE	tbc	tbc	tbc	tbc	-
						Number of SNEs/FTE	tbc	tbc	0	0	0
2. ePi	13/04/2022	EUR 1.5 million	13/03/2022 to 31/12/2023	European Commission, DG SANTE/ EU4Health	Development of electronic product information (ePI) for EU medicines	Amount	-	750,000	750,000	0	0
						Number of CAs/FTE	tbc	tbc	tbc	0	0
						Number of SNEs/FTE	0	0	0	0	0
3. MAV+	First quarter 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	n/a	n/a	tbc	tbc	tbc
						Number of CAs/FTE	n/a	n/a	tbc	tbc	tbc
						Number of SNEs/FTE	n/a	n/a	tbc	tbc	tbc
						Amount	0	835,000	835,000	84,919	-

Total contribution agreements	Number of Cas/FTE	tbc	tbc	tbc	tbc	-
	Number of SNEs/FTE	0	0	0	0	0
Service-level agreements						
EMA does not provide services to other EU entities, hence has no corresponding service level agreements	Amount	-	-	-	-	-
	Number of Cas/FTE	-	-	-	-	-
	Number of SNEs/FTE	-	-	-	-	-
Total service-level agreements	Amount	0	0	0	0	0
	Number of Cas/FTE	0	0	0	0	0
	Number of SNEs/FTE	0	0	0	0	0
Total	Amount	45,000	878,000	878,000	127,919	26,000
	Number of Cas/FTE	1.41	1.01	1.01	1.01	0.81
	Number of SNEs/FTE	-	-	-	--	-

Annex XII: Strategy for cooperation with third countries and/or international organisation

Creating successful synergies through communication, scientific and regulatory collaboration, and cooperation for the benefits of patients.

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 a global approach to authorisation and supervision of medicines, as well as capacity building. Excellence in regulatory operations serve patients in the EU and beyond.

The objectives beyond the support include promoting the European approach to scientific excellence in the evaluation and supervision of medicines, and networking arrangements with international regulators.

These objectives will be achieved in collaboration with the EU regulatory network through:

- Collaboration with the Agency's existing international partners, both in bilateral and multilateral activities
- Extending collaboration to new partners according to priorities and resources
- Strengthening internal coordination processes

1. **Background**

Since its creation in 1995 from Regulation 2309/93/EEC, the European Medicines Agency has had an active role in international activities with the responsibility to provide technical and scientific support to international organisations on issues related to the evaluation of medicinal products, as well as an obligation to collaborate with 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, VICH and ICH, and successfully reformed and enlarged in 2015.

The EU enlargement steps in 2004, 2007 and 2013 were supported by preparatory activities in the framework of the Pan-European Regulatory Forum (1999-2004) and are continuing with the Instrument for Pre-Accession (IPA) training to Candidates countries.

The revision of the Agency's founding regulation (Reg (EC) No 726/2004) introduced a more comprehensive recognition of the Agency's international role, in particular through the introduction of Article 58 to address public health needs in non-EU countries, in cooperation with WHO. This article 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.

The growth in international activity mirrors the increasing globalisation of pharmaceutical activities, in particular the growth of clinical trials in countries outside the EU with potential GCP and ethical concerns, of manufacturing of Active Pharmaceuticals Ingredients (API) and finished products, and of increasing illegal activities on counterfeit, spurious and falsified medicines.

The 2009 pandemic flu and now COVID-19 are challenging medicines regulators worldwide and demonstrate once again the benefits of international cooperation and collaboration, and information exchange.

Despite some achievements in international cooperation through data exchange and publications (i.e., WHO Clinical Trials platform, WHO Uppsala Monitoring Centre for pharmacovigilance) the development of compatible IT tools has been limited.

2. Vision

The EMA vision is to continue developing strong and active collaboration with international partners in collaboration with the European Commission. Priorities go to non-EU partners with whom we have confidentiality arrangements and Mutual Recognition Agreements, and priority areas are supply chain integrity, data integrity, shortages, scientific collaboration from early development stage, support to innovative medicines and emerging technologies, pharmacovigilance, and crisis management.

3. Current collaborative activities

Bilateral activities

Confidentiality arrangements (CA)

Formalised confidentiality arrangements were signed between the European Commission, the European Medicines Agency, and the US Food and Drug Administration in 2003. This was followed by detailed implementation plans over the years. Similar arrangements were signed with Health Canada in 2007, with the Japanese MHLW and PMDA (human medicines only) in 2007, with the Australian Therapeutic Goods Association in 2009, with Swissmedic in 2010, with WHO in 2015, and with EDQM in 2019. Most cover human medicines only. A confidentiality arrangement was signed with ANVISA, Brazil, in 2021.

To allow rapid exchanges of information during crisis (nitrosamines) and the COVID-19 pandemic, ad-hoc CAs have been signed between the Agency (only) and other authorities (e.g., Singapore, Korea, Taiwan, UK, and others); these are limited in scope and time. UNICEF is also a potential candidate for such arrangement to facilitate better quality medicines tenders. Other arrangements are expected on the basis of defined priorities.

Confidentiality arrangements are essential tools of collaboration, allowing exchange of meaningful and utile information; they allow better use of resources and should be developed on the basis of prioritisation. This should include the countries (Singapore, Korea, Taiwan, and UK later) with which the EU has frequent and extensive exchanges, as trust has been built over years and an authority is never obliged to exchange confidential information, therefore limiting the risks. Other countries (Cuba, South Africa, etc.) have expressed interest in such CAs as well.

Mutual Recognition Agreements

Mutual recognition agreements (MRAs) between the European Union and third countries allow EU Member States and the MRA partner to mutually recognise conclusions of inspections of manufacturers carried out by the respective inspection services.

The European Union has operational Mutual Recognition Agreements, since 2002, covering the exchange of GMP inspection information with Australia, New Zealand, Canada, Switzerland, Japan and the US FDA.

The Agency is responsible for implementation and operational aspects of these MRAs. MRAs with Australia, New Zealand, Switzerland, Canada, Japan and the US are currently operational, but with slightly different provisions as to scope and applicability. Expansion of the scope to veterinary medicines, vaccines and plasma derived pharmaceuticals is part of current activities with the US FDA. There is a different type of agreement between EU and Israel (ACAA), which allows mutual recognition of products, not limited to pharmaceuticals.

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. This activity is developing slowly but with more and more interest from sponsors.

Participation in EMA Committees work- Access to EMA data

Health Canada, Swissmedic, the occasional fellows, and the US FDA and Japanese MHLW/PMDA Liaison officials attend the CHMP, the CAT or PRAC, on a case-by-case basis as an observer basis. Representatives from these Regulatory Authorities can also attend other Committees, Working Parties/Working Groups to follow discussions on specific topics. These authorities though do not have access to the repositories of EMA, nor to the databases (DREAM, SIAMED, etc.), with the exception of the Paediatric Database of PIPs which is accessible to FDA. Access would have to be on a reciprocal basis.

The OPEN Pilot, introduced in December 2020, allowed for TGA Australia, Health Canada, MHLW/PMDA, Swissmedic and WHO to participate as experts (cf. observer capacity) in the work of the CHMP and ETF for COVID-19 vaccines and therapeutics, although not in the benefit-risk decision making. Proposals to extend the OPEN model to other therapeutic areas are being considered.

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 EMA since 2009.

Multilateral activities

Clusters

Clusters have been established with FDA initially on oncology medicines, rapidly extended to other areas and including other partners with whom a confidentiality arrangement was in place. Clusters have different objectives and compositions. Some are more forum for exchange of information and experience (e.g., patient engagement), others involve scientific discussions of specific medicines (e.g., paediatric, vaccines).[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 a view towards 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

[26] Teixeira T et al. Are the European Medicines Agency, US Food and Drug Administration, and Other International Regulators Talking to Each Other? Clin Pharmacol Therap 2019; https://doi.org/10.1002/cpt.1617

(where there is a CA). In any case, all documents must be redacted to protect personal data. In 2019, there were about 1200 such requests managed by International Affairs.

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

EMA is chairing the ICMRA communication group that is implementing a two-year communication strategy (2021/2022).

Publication of EMA Clinical Data (policy 70): The implementation of the CDP policy has been the occasion of collaboration with Health Canada, which has adopted a similar policy with similar application of personal data redaction (application of DPR). The plan is to look at possibilities 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 gathers Heads of Agencies for human medicines and its objective is to promote convergence and common responses to challenges. ICMRA has been very active on COVID-19, providing the forum and opportunities for rapid collaboration and agreement on regulatory requirements. The European Commission is collaborating with EMA and the EMA Executive Director is currently the chair of ICMRA (2019-2022).

ICMRA allowed for a great degree of alignment and convergence of international regulators in the global COVID-19 pandemic response, in collaboration with WHO. ICMRA allowed regulatory convergence, exchange of information, regulatory agility, and rapid agreements on regulatory requirements for medicines, vaccines and post-approval monitoring of safety for vaccines and therapeutics.

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 (Art 57j, of Reg (EC) No 726/2004). EMA is supporting the involvement of the EU 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 is also supporting IPRP involvement 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 together provide 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 a partner but not a member of PIC/S, supports its activities and participates in the 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 TransAtlantic Task force on Antimicrobial Resistance (TATFAR), the Tri-partite activities with Japan, the OECD (on GCP), etc.

4. **Proposed approaches and priorities**

Supply chain integrity in a global environment for manufacturing creates challenges and justifies the 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

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, trial data integrity, and training.

Collaborating early on development of medicines increases the chances of agreeing regulatory requirements, which in turn increases the chances of uptake by companies, decreases duplicative work, and speeds up development and eventually patient access.

With respect to pharmacovigilance information, international collaboration provides a greater pool of information on which to base decisions and advances in electronic reporting systems which means that these can become very quickly available.

In a similar fashion, helping to ensure that paediatric development studies performed in the context of European legal requirements provides information which facilitates the availability of medicines for children outside our borders is of potential benefit to children worldwide.

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 consistency, and facilitate advances in these areas.

Transparency is also an area of active international collaboration. Either under the confidentiality arrangements or as public information, EMA should continue exchanging information with our international partners. Some of this information is exchanged before publication (under embargo) to facilitate reactive communication by our partners. Furthermore, proactive publication of clinical data supporting Marketing Authorisations is also an area for further international collaboration.

The Agency works actively with WHO in several domains: support to the African Medicines Regulatory Harmonisation, which prepares for the continual African Medicines Agency; AVAREF; training and capacity building; Collaborative Registration, and Joint assessments. It also provides expertise to various standing WHO expert groups including its paediatric regulatory network.

The Agency works with other partners, such the European Department for the Quality of Medicines (EDQM) or European Pharmacopoeia, CIOMS, OECD, Codex and OIE, and is an active member of the International Coalition of Medicines Regulatory Authorities, which it currently chairs.

Two recent crises have demonstrated again the benefits of international collaboration. Nitrosamine impurities in APIs and finished products affected all regions, required information exchange and coordination, and the COVID-19 pandemic is ongoing.

5. **Overall international priorities for the next years (2022-2025)**

Considering the successive reduction in activities due the Agency’s relocation and COVID-19 pandemic response, international activities are prioritised as follows:

- Continue involvement in international management of COVID-19 pandemic response, and nitrosamines crises
- Continue providing answers to queries and requests for exchange of information
- Continue support to Clusters, Parallel Scientific Advice, and other scientific and regulatory interactions
- Develop existing MRA with US FDA to include veterinary medicines, vaccines and plasma derived pharmaceuticals and support to other MRAs

- Continue support to ICMRA as secretariat, and participation in priority projects (e.g., Innovation, Track and Trace, shortages)
- Develop Confidentiality Arrangements with other regulatory and international counterparts on the basis of prioritisation
- Cooperate on activities of mutual interest within the ICH and VICH framework and OIE
- Maintain EMA webpage collecting training opportunities for non-EU partners
- Provide and support training on priority areas (GMP, GCP) for priority countries
- Support activities with countries such as China, India, including bilateral meetings in the context of the Commission's agreements on pharmaceuticals with these countries, with focus on GCP and GMP
- Support preparation for accession of candidate countries to the EU, as part of the IPA. The Agency receives a grant from the European Commission to provide training on the acquis Communautaire, additional engagement is expected to continue into the next IPA III cycle
- Continue collaborative activities with WHO (e.g., vaccines, pandemic, prequalification, guidance). Support reliance on scientific output of EMA committees by non-EU regulators, in particular through WHO facilitated pathways. Support activities on certificates of medicinal products and transition from paper to electronic. Promoting article 58 eligible medicines (incl. vaccines) which are intended to prevent or treat diseases of major public health interest. This activity has had a demonstrated impact[27], despite the low number of opinions so far. Promote allowing parallel submissions of a centralised MA and the Art 58 opinion
- Russia: provide support, but currently low priority for political reasons, except in the context of COVID-19
- Promote 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).

[27] Cavaller-Bellaubi M et al. The European Medicines Agency facilitates access to medicines in low- and middle-income countries. Expert Rev Clin Pharmacol 2020. doi.org/10.1080/17512433.2020.1724782

Annex XIII: Global budgetary envelope reserved for procurements

Introduction

In accordance with Article 72 of the Agency's Financial Regulation[28]

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

As the Agency does not award grants or prizes, the tables below set out the global budgetary envelope reserved 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 11)

[28] EMA/MB/911312/2019)

Operational sourcing by Pillar

Pillar	Indicative 2023 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 3,200,000
Budget line 3000	

Pillar II	Indicative 2023 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 also covers non-productrelated public health tasks (e.g., communication, international cooperation)	EUR 14,600,000
Budget line 3003	
Budget line 3030	

Pillar III	Indicative 2023 Budget
Pillar III (detailed description see Part II, Chapter 1) **Network Portfolio and business services**: this block covers development activities aimed at enhancing efficiency and effectiveness of the current operations	EUR 39,800,000
Budget line 3031	
Budget line 3105	