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Foreword

I am proud to present the new EMA single programming document, which summarises the activities and objectives of the Agency for the period 2022-25.

In 2022, EMA expects to continue to still face significant workload related to the ongoing COVID-19 pandemic. The Agency and its scientific committees will provide advice on new medicines under development, and will evaluate the quality, safety and efficacy of vaccines and therapeutics targeting the SARS-CoV-2 virus. EMA will collaborate closely with ECDC, EC and Member States to monitor the situation across the EU and adapt our collective regulatory efforts to tackle the pandemic. In this context, the Agency remains committed to communicating effectively about the benefits and risks of products for COVID-19, particularly on the safety of vaccines. Transparency remains key to reinforcing trust in regulatory decisions, and EMA will continue the exceptional efforts put in place last year to maximise transparency of its regulatory activities on vaccines and therapeutics for COVID-19.

The Agency will build on its international collaboration activities, as the COVID-19 pandemic has reaffirmed the need for increasing convergence, harmonisation and work-sharing on a global scale, in particular by contributing to the strategic work of the International Coalition of Medicines Regulatory Authorities (ICMRA), currently chaired by the EMA.

While EMA is committed to fostering scientific excellence in medicines evaluation and supervision, the driver of our multi-annual work plan remains - in the wider context of the European Union Pharmaceutical Strategy - the implementation of the European Medicines Agencies Network and the Regulatory Science Strategies to 2025. These strategies developed jointly by the EMA and the national competent authorities outline the network's approach to tackling current and future challenges in the areas of availability and accessibility of medicines, data analytics, innovation, supply chain and overall sustainability.

Another area of focus for the Agency in the coming years is the implementation of new legislation. 2022 marks the entry into force of the new regulation on veterinary medicinal products, the long-awaited Clinical Trial Regulation and parts of the Agency's extended mandate. These important milestones will have a significant impact on business processes, scientific procedures and IT systems, but will also empower the Agency, in close collaboration with the network, to tackle outstanding challenges in the areas of supporting innovation, managing shortages, access and availability of medicinal products and of antimicrobial resistance.

To cope with longer planning horizons and to ensure the necessary level of accountability in delivering programmes and projects, the Agency will reconfigure the governance of its information management activities, adopting the Agile methodology. With this new approach EMA, aims at capitalising on the lessons learned from previous programmes, to enhance the synchronisation of deliverables while allowing sufficient space for the introduction of innovation and best practices in its operations.

In the context of the implementation of the clinical trial regulation, 2022 will also see the go-live of the Clinical Trials Information System. This provides an opportunity to transform and accelerate the European approach to supporting clinical development and facilitating impactful large scale multinational clinical trials. This transformation will be complemented by integrating digital technologies into the regulatory framework through a new data strategy and the delivery of DARWIN EU, as a sustainable platform to better access and analyse healthcare data from across the Union to support regulatory decision-making on medicines. Lastly, through the implementation of its cyber

security strategy, EMA will work to enhance its IT security systems to ensure that information assets are appropriately and consistently protected.

Despite the exceptional circumstances the Agency has faced over recent years, the organisation has demonstrated its capacity to adapt to a constantly evolving environment while maintaining the highest possible quality standards of its operations. However, the COVID-19 related workload comes in addition to a significant and cumulative increase in the medicinal products portfolio. This ever-increasing workload needs to be addressed by additional allocation of resources to the Agency and the European Medicines Regulatory Network, to ensure that we can deliver our mission to protect public and animal health in the EU. The Agency will continue to engage with its partners, including the European Commission and budgetary authority on this important resourcing and sustainability issue.

As we move forward in these challenging times, the EMA, its staff with the support of the European medicines network remain committed to continuing to make a significant contribution to ensuring the protection of public and animal health across the EU.

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
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 trial information system
CTTI	Clinical trials transformation initiative
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	Scientific committees of the Agency

Term/abbreviation	Definition
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
GVP	Good pharmacovigilance practice

Term/abbreviation	Definition
GxP	Good practice (e.g., laboratory, clinical, manufacturing etc)
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
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
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
NRG	Name review group established by CHMP
NTWP	Novel Therapies and Technologies Working Party
NUI	Non-urgent information
NVR	New veterinary regulation

Term/abbreviation	Definition
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
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
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
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

Term/abbreviation	Definition
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
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 the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of applicable EU legislation.

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

In 2010, a package of legislation was adopted whose main aim 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, the new legislation governing veterinary medicinal products and repealing Directive 2001/82/EC was adopted. This new Veterinary Medicines Regulation (Regulation (EU) 2019/6) will modernise the existing rules on the authorisation and use of veterinary medicines in the European Union (EU) when it becomes applicable on 28 January 2022. It contains new measures for increasing the availability and safety of veterinary medicines and enhances EU action against antimicrobial resistance. The Agency is working closely with the European Commission, in particular with regards to the preparation of implementing and delegated acts, and other EU partners in preparation for the implementation of the new Regulation.

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 at the international level.

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 the 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 of our partners, stakeholders and colleagues.

We promote the well-being, motivation and ongoing professional development of every member of the Agency.

Part I: General context

The 2022-2025 planning exercise continues to be impacted by the Covid-19 pandemic. Implementation of the 2022 work programme will remain subject to close monitoring to ensure the timely adaptation to a pandemic scenario that could rapidly evolve, and also in view of the finalisation of the EC draft legal proposal for the extension of the Agency's mandate. In this context it is worth noting:

COVID-19 pandemic and impact on Agency. The Agency is still facing a significant level of workload that could be further exacerbated by possible unforeseeable developments of the pandemic. Therefore, EMA priority remains to operate as long as possible under a "business as usual" scenario focussing on any COVID-19 related activity while ensuring the highest level of quality in the evaluation and supervision of non-COVID-19 related medicines. In addressing this workload, EMA still benefits from the 40 additional Temporary Agent staff positions which were exceptionally granted for 2021 and 2022. In consideration of the fact that the workload generated by the response to the COVID-19 pandemic (e.g. in post-authorisation activities) will extend beyond 2022, the termination of the 40 additional TAs posts will significantly impact the Agency's capacity to deliver on these activities.

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, enhanced signal detection from reports of suspected Adverse Drug Reactions in EudraVigilance and commissioning of observational vaccine safety studies. Through the EMA-funded ACCESS consortium and the EMA-funded bridging vaccine safety study initiated in late 2020, EMA commissioned a large European vaccine safety study running throughout 2022 to both prospectively evaluate the safety of COVID-19 vaccines and to assess any emerging vaccine safety signals during this period.

The priority of the Agency towards staff, delegates and contractors remains the reduction of the risk of infection, however, EMA will initiate a pilot to restart face-to-face meetings of its Committees as well as to reintroduce a minimum weekly presence in the office for the Agency's staff. The pilot will represent a first step in view of establishing a new way of working.

Extension of EMA's mandate. On 11 November 2020 the European Commission put forward a set of proposals to strengthen the EU's health security framework, and to reinforce the crisis preparedness and response role of key EU agencies, including EMA.

The proposed Regulation builds on experience from the COVID-19 pandemic and puts several of the structures and processes that EMA had established during the current and previous pandemics into EU legislation. The Regulation will complement and further develop the core tasks already given to the Agency in its founding Regulation, notably to provide scientific advice to medicine developers, including on clinical trial protocols, and to carry out 'rolling reviews' to help speed up assessing the quality, safety and efficacy of medicinal products in crisis situations.

Specifically, the proposal covers four important areas:

- Improving EU crisis-management
- Ensuring the supply of medicinal products
- Improving access to and sharing of health data
- Strengthening the EU's role in global health

The European Commission aims to 'fix' shortcomings highlighted by the current COVID-19 crisis. The objective is to provide a stronger legal basis and framework for the Union to act more rapidly, and trigger EU preparedness and response measures in times of crisis.

If the draft legal proposal were to remain unchanged, and after the legislative process is completed, the Agency's crisis coordination role and structures will be formalised and strengthened.

In this role, the Agency will continue its cooperation with the European Centre for Disease Prevention and Control (ECDC) and Member States in the EMA Pandemic Task Force (ETF) and the Executive Steering Group on Shortages (including EU SPOC and i-SPOC).

Moreover, the role of EMA and the ETF for treatments and vaccines will be reinforced to ensure safe, rapid approval and post-authorisation monitoring, including:

- In pre-marketing-authorisation assessments supporting national emergency use authorisation (EUA) decisions
- For assessing protocols for clinical trials in times of crisis
- To ensure that data can be requested from the industry for early assessment and dialogue (to support rolling reviews)
- To strengthen the collection of (real-world) evidence on safety and effectiveness of vaccines, including from public-health authorities.

Following the publication of the EC legal proposal, EMA drafted a high-level roadmap with the required activities and deliverables to be implemented within the periods set out by the proposal. Preparation for implementation is ongoing in 3 workstreams (shortages of medicines and medical devices; medicinal products for health emergencies; medical device expert panels). A communication plan to inform the Agency’s stakeholders and provide the necessary guidance about how the new tasks will be implemented is being prepared. In order to ensure a lean implementation, the different tasks set out in the legal proposal have been assigned to existing organisational entities, without the establishment of new governance structures. In addition, the Agency has executed the necessary recruitment for 2021, in accordance with the additional staffing posts granted by the European Commission to take on the additional tasks.

EU commission Pharma Strategy. The Agency has contributed to the implementation of the EU Pharmaceutical Strategy by supporting the EC in the discussion with the Members States, notably in the context of the EC Pharmaceutical Committee as regards options for revising the basic pharmaceutical legislation. This support included the attendance of experts in relevant pharmaceutical workshops and feedback on technical aspects of the operation of the centralised procedure for marketing authorisation. In addition, EMA has provided technical feedback for the impact assessment for the preparation of other legislative proposals such as the revision of the regulations of orphan and paediatric medicines, fees payable to the Agency and the EU Health Data Space. Feedback was also provided to the EC for the revision of the legislative framework on blood, tissues and cells.

Part II: Multi-annual programming 2022–2024

1 Multi-annual work programme

The multi-annual EMA programming 2022-2024 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 organized based on the 6 EMANS focus areas and covers also and non-product related public health tasks (e.g. communication, international cooperation, etc.).
3. **Programmes and projects**: this block covers programmes and projects, and development activities aiming at enhancing efficiency and effectiveness of the current operations.

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

PILLAR 1:

Human Medicines: A single entity dealing with all operational aspects related to human medicines was established in March 2020, with the responsibility for the oversight of human medicines throughout their lifecycle, from evidence generation planning to interfacing with health care systems. 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 supports the EU medicines regulatory network to produce patient-centred high-quality outputs to ensure patient trust. The challenges and workload for 2022 are still marked by the COVID-19 pandemic: in fact in addition to processing in a timely manner COVID-19 related applications, post-authorisation activities will generate additional workload which will come on top of the overall growing trend (around 6%) of non-COVID-19 medicines applications from year to year. Furthermore, the Division is required to manage the implementation of the process for managing the presence of nitrosamines in medicinal products, also approved at HMA (for centralised and nationally authorised products), which will add workload stress until 2023. The investment in information management programmes continues to be pivotal to handle the anticipated increase in applications over the coming years. This becomes even more relevant considering the loss of the 40 additional Temporary Agents which were exceptionally granted only for 2021 and 2022 to cope with the additional workload required to effectively respond to the COVID-19 public health crisis. The construction of an integrated environment supported by more advanced digital tools will secure the realisation of the efficiency gains and set the foundation towards integrated knowledge management envisaged in the Future Proofing of the Agency. Increasing efficiency and attention to prioritisation of activities will be necessary to make progress in regulatory science by implementing the strategy.

Veterinary Medicines: In the current planning cycle, the Veterinary Medicines Division is entering a new phase marked by the implementation of Regulation (EU) 2019/6 (Veterinary Regulation), which will have an impact in terms of business processes, scientific procedures and IT systems. The division prepared a seamless transition to the new set of rules which will be effective as of 28 January 2022. The division will face an expected growth in workload related to CAPs procedures and 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 will also entail 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 will become even more central. Another key objective is represented by the deployment, 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:

In the wider context of the EU pharmaceutical strategy to 2025, which is the overarching policy initiative setting the direction of future EU pharmaceutical policy, the Agency elected the network strategy 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 represents also 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).

A prudent line has been adopted, and the Agency identified the key actions achievable with the available resources, building on available synergies with the Network. The remaining set of actions might restart, subject to a phased approach. A rolling review of the Agency's capacity will grant the deployment of additional resources as they become available and, consequently their potential activation.

An overview of objectives which have currently not been prioritised is available in section 2.5 of this document. Actions clustered under those objectives might start once a reassuring level of predictability over the upcoming challenges and workload is reached.

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 and 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 priorities. Further communication activities to increase the visibility of EMA's proactive role international level.

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 and information on the EMA website on COVID-19 vaccines and regular interactions with ECDC and NITAGs. EMA will also keep providing high-quality responses to the unprecedented volume of public requests being received. This is due to the increased visibility the Agency has experienced over recent years and public interest in COVID-19 vaccines and therapeutics which remains high. 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 (EMAN) and in the Agency MAWPs. Requests to access documents (ATD) also continue to increase in number and complexity. The access to document process will be reviewed in 2022 to enable continued management of access to document with limited impact on resources. To support COVID-19 related activities the access to document team additional measures have been introduced to manage incoming requests (limited number of documents requested per request and a system of queueing) to better manage workflow and processing 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 enhanced collaboration with Health Canada.

PILLAR 3 (Programmes and Projects):

As regard Programmes and Projects, 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 Agency programmes and projects portfolio, thus the Clinical Trials, the Veterinary Regulation and Data Integration will account for almost half of the Agency portfolio effort in terms of resources (financial and human) for next 2 years;
- The digitalisation of the Regulatory Business Process optimisation (RBOP) is of paramount importance to allow the Agency and its stakeholders to increase their efficiency and to optimise resources utilisation. A particular focus will be placed on the integration with external stakeholders in view of bringing about a seamless platform for the Network. The RBOP programme focuses in particular in delivering improved business processes in the next 5 years leveraging digitalisation.
- Data Analytics is another key programme aiming at 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;
- 2022 will also be marked by the go-live of the Clinical Trial and the Veterinary Regulation systems, whereas Regulatory Business Process optimisation and the Data Analytics programmes 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 100FTEs on annual basis for the next 5 years.

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

BUSINESS SERVICES:

ADMINISTRATION AND CORPORATE MANAGEMENT DIVISION

Global demographic and technological trends are a major and inevitable change factor, therefore the Administration division is continuously rethinking and reinventing its processes to adjust to and benefit from the rapidly evolving working environment. In this new planning cycle, the objective of the Division is to continuously improve its services for the business areas enabling efficient and effective delivery of the core tasks of the Agency. Essential for this purpose is a holistic view covering processes, ways of working and technology, together with strategic planning which balances reality and ambitions with the Agency capacity and ensures an appropriate degree of flexibility. As a result, EMA staff will remain the focus area for the division by embedding the ongoing initiatives in the performance and development domain, updating the human resource strategy in a broad sense and facilitating efficient use of the agency resources.

The strategy of the Division aims therefore at bringing together the following 4 dimensions:

- **Employee lifecycle**: EMA views its staff as the key asset of its organization, hence significant transformation took place in this domain over the last years, including recruitment and onboarding processes, as well as the development and imminent implementation of the new competency framework. A comprehensive update of the human resources strategy is taking place aiming, among other objectives, at constantly developing the workforce and allowing proper allocation of resources

- **Resourcing the organization**: this dimension focuses on ensuring the optimization of the resources available. This entails maintaining a high level of budget implementation and optimised use of funds to enable more activities and projects. Another aspect of this dimension is the focus on strategic projects to ensure the long-term financial sustainability of the Agency and the network, and future-readiness. In addition to this, centralization of procurement support and coordination of contract management practices will increase outsourcing support to the organization. One of the flagship projects of this dimension is the introduction of a SAFe/Agile methodology in the context of the implementation of the new telematics and programme governance at EMA
- **Short- and long-range planning:** the objective of this dimension will be further improving the effective strategic planning and resource management support to the Agency leading to a constant optimization of resources. This will be achieved by improving the data and processes to support the decision-making through the timely and robust monitoring of the activities. This entails process revision, data quality enhancement and increased deployment of business intelligence
- **Corporate oversight measures and operational excellence:** the Division will implement the results of the ongoing review of the risk management process to elevate the risk management to the top level of the organisation and ensure effective management of constantly evolving risks. In addition to this, process reviews in the financial domain will continue to augment system interoperability and master data management.

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 for the Network providing high-quality services and enabling a connected, interoperable medicines regulatory platform for partners and stakeholders.

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

- **Operational Excellence and Information Security** as the foundation 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 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 the 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 recognised quality standards.
- **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-in-class, standard technologies where possible. 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 transforming legacy to secure and cost-efficient cloud infrastructure. We will collaborate with stakeholders to enable the interoperability of data and business processes.

- **Maximising customer success:** We aim to enable the success of the European Medicines Agencies 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. We aspire to become a trusted partner for our stakeholders' information service needs and want to play an integral part in achieving EMAN'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.

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 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	**Environment and oceans** *Europe's seas, oceans, and environment are a source of natural and economic wealth for Europe. We must preserve and protect them to ensure that they continue sustaining us in the future.* *European Green Deal priorities include* • *protecting our biodiversity and ecosystems* • *reducing air, water and soil pollution*	**FA 4: Antimicrobial resistance and other emerging health threats**	**S.G. 4.3**	EMA contributes to the implementation of this priority and policy through the 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

	• *moving towards a circular economy* • *improving waste management* • *ensuring the sustainability of our blue economy and fisheries sectors*			
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 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*	**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

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 here below will be spanned over the multi-annual strategy timeframe (2020-2025) will find an implementation via annual actions.

Focus Areas 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 to 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 in order 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, evaluation through to access for beneficial medicines (innovative and follow-on) through collaboration between	Develop better scientific evidence which serves different decisionmakers along the decision chain (regulators, HTA bodies, payers), including evidence to support post-licensing follow-up of medicinal products thereby stimulating a life-cycle approach to evidence generation and the possibility to adjust decisions based on new evidence
	Clear and enhanced communication to patients, health care 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 represents real patient access to newly authorised medicinal products in different markets
	Foster alignment of national implementation of compassionate use programmes in order 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 Areas 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 rollout of such analysis
	Establish collaborations 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, etc.)
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 Areas 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 Areas 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 medicines regulation.
	Foster more robust surveillance systems in the EU for both antibacterial agents´ consumption and emergence of resistance in veterinary and human medicine in order to foster analyses of the potential relationships between antimicrobial consumption and AMR and of co-selection of AMR by use of biocides and feed additives
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 medicine 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, ring-fence resources and refine preparedness approaches
	Engage with stakeholders to minimise the risks of antiparasitic resistance

Focus Areas 5: Supply chain challenges

Strategic Goal	Objectives
	Improve and inter-link 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 in order to harmonise approaches to regulatory inspections procedures to address requirements and challenges of APIs, medicinal products, excipients, new technologies and continuous manufacturing
	Promote a more tailored supervision of API manufacturers through assessment and inspection of their API development and risk management practices in technology transfer; increase supervision of sites that produce medicinal products for a significant number of EEA markets or very significant numbers of products, with dedicated cooperative supervision between 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 Areas 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 medicines 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 the 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 2022 - 2024

2.1 Overview of the past and current situation

Overview

In 2021 the total budget (revenues and expenditure), as adopted by the EMA Management Board on 17 December 2020, amounted to €385,919,000. On the revenue side, this included €330,409,000 in fee revenues and contributions from the EU budget totalling €55,448,000. On the expenditure side, this included €128,126,000 in Title I: staff expenditure, €56,175,000 in Title II: infrastructure and operating/IT expenditure, and €176,226,000 in Title III: operational expenditure.

On 7 October 2021, an amending budget was adopted, decreasing the initial budget by €6,691,000, to a total of €379,228,00. The amending budget included an increase in fee income of €8,948,000, while the EU contributions were decreased by €17,811,000 because the Agency did not require the full amount of appropriations available in 2021 for implementing the activities related to the extended mandate. This amount will instead be made available for the Agency in 2022 and 2023.

The staffing ceilings in 2021 were 657 temporary agents (TA), 226 contract agents and 30 national experts on secondment, this level of staffing was determined after additional 14 TA posts were not granted by the budgetary authority, however, 40 additional time-bound TA posts were exceptionally granted for 2021 and 2022. Throughout the year, the Agency operated an occupancy rate close to 100%.

2.2 Outlook for the years 2022 - 2024

New tasks

On 11 November 2020, the EC put forward a proposal to extend the Agency's mandate (see also information in Part I General context). Following the publication of the EC legal proposal, EMA started to prepare for its implementation which has a significant impact on the resources of the Agency.

With regard to human resources, the current proposal includes 21 TAs and 8 CAs granted in 2021, growing to a total of 30 TAs and 10 CAs by 2024. In 2021 the Agency executed all the foreseen recruitment to ensure proactive preparedness in view of the final adoption of the legal text.

As for financial resources, the draft proposal includes €27.79M EU contribution for 2021 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 a big part in line with the increasing number of authorised Centrally Authorised Products (hence, more fee-funded post-authorisation monitoring and maintenance 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. On average, the product portfolio increases by 100 new products each year.

Fee income and associated workload have grown by 64% 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.

Despite a 64% increase in fee income and associated workload, EMA will have less establishment plan staff posts in 2022 than in 2014 (596 versus 599, when we exclude Extended Mandate staffing for new tasks, and the 40 2-year short-term TA posts for COVID-related workload which EMA has been requested by the EC to surrender by 2023). The COVID-19 workload alone continues to consume around 70 to 80 FTEs across the Agency, while post-authorisation activities will continue beyond the 2023 timeline.

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, and as supported by EMA's Management Board, 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 Trial 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 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 2022-2024

Financial resources

An increase in revenue generated by scientific applications is assumed in 2022 and 2023. The total revenue from fees in 2022 will amount to €357.7 million, an increase of 18.8 million (5.3%) compared to the amended 2021 budget.

In 2023 the total revenue from fees is expected to reach €373.8 million due to a continued increase in the number of submissions of scientific advice applications.

In 2024 and 2024 the increasing trend is expected to slow down at respectively €381 million and €389 million, based on conservative projections of the impact of the new fee regulation, expected to come into force in 2024. EU contributions are set to stabilise in line with the new multi-annual financial framework, at €35 million, after a spike in 2022, when compared with the amended 2021 budget, it will increase from €37.6 million to €55.2 million. Of this increase €14 million are linked to activities under the Agency's 'extended mandate', and were 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 2022 when they will be consumed. In 2023 the EU contributions are set to €50.15 million including the contribution for the extended mandate.

The orphan medicinal products contribution in the draft budget 2022- and preliminary draft budget 2023 reflects the amount proposed in the EU budget.

Neither the draft budget 2022 nor the preliminary draft budget 2023 include provisions for any exceptional costs related to the Agency's former headquarters in London.

Some impact of the restrictions introduced to manage the pandemic is expected to continue into Q1 and Q2 of 2022, resulting in lower meeting expenditure and staff duty travel.

The expenditure related to the running and maintenance of the EMA building in Amsterdam has now stabilised, with mainly annual price revisions and inflation adjustments. Communications activities are expected to remain stable, compared to 2021, and Business consultancy related to review of business processes and various (IT) projects will increase, with more projects as well as activities related to processes and re-organisation foreseen in 2022.

Expenditure on rapporteurs will increase as a consequence of the higher number of scientific applications expected.

Expenditure related to scientific studies and services will increase further, with DARWIN receiving funding totalling €12 million in 2022, and COVID-19 related studies are expected to continue at a high level.

IT project development is expected to continue to increase, due to an increased need to deliver extensive projects such as those linked to the delivery of the extended mandate, implementation of clinical trials legislation and implementation of the new veterinary legislation. This level of expenditure is expected to continue for the period 2022-2024 due to the modernisation of the core scientific EMA IT platforms.

Human resources

The draft budget 2022 includes the 40 time-limited (2 years) TA posts awarded by the EC to cope with the extra workload linked to the response of the COVID-19 pandemic, and 5 TA posts linked to the Extended mandate new tasks.

Should the EC proposal to extend the EMA mandate be further amended, the currently included establishment plan (see annex IV) would be modified to reflect the latest changes (at present the establishment plan includes as of 2022, 26 TAs and 10 CAs growing to a total of 30 TAs and 10 CAs in 2024).

For the 2023 preliminary draft budget, the Agency will request 20 additional TA posts (excluding any additional extended mandate staffing requirements), to be utilised as follow:

- 11 additional TAs for workload linked to the (non-COVID) growing product portfolio;
- 3 TA posts for Veterinary Medicines workload;
- 1 TA post to support data protection activities;
- 1 TA post to support the International activities;
- 2 TAs posts to support the go-live phase of CTIS activities;
- 2 TAs to support the CTTI (Clinical Trials Transformation Initiative).

The Agency will also request the extension of the 40 time-limited TAs for 3 additional years.

The need and justification for additional staff driven by increased fee-related workload have been described in detail in the previous section on the growth of existing tasks, where the Agency is requesting 11 posts from 2023. Outlined below is further detailed justification for each of the requests for additional establishment plan posts.

- In 2021 the Agency had been granted 40 2 year time-bound TAs, however while these posts are available for two years only, the Agency also needs to deliver the subsequent post-authorisation work on vaccines and therapeutics as well as on pharmacovigilance activities in terms of the monitoring of the safety and efficacy of these medicines. Activities and workload that will extend far beyond a two-year horizon. The Agency is therefore requesting the extension of these posts for an additional 3 years to cope with the workload.
- In 2020 partial additional human and financial resources have been granted to EMA to prepare for the implementation of the new EU Veterinary legislation, which comes into application in early 2022, however, these did not meet the Agency’s initial request and needs. The implementation will entail remarkable efforts on the side of the Agency to meet the requirements of the new legislation. For this reason, the Agency requires the 3 TA posts requested.

- The Agency has an obligation to devote adequate resources to data protection activities. The volume of activities requires almost 4 FTEs and in the context of progressive digitalisation of information and access to data sources as well as due to legislative requirements and factors such as growing digitalisation of the Agency and the Network, which require that data management is fully compliant with the EU regulation this workload will further increase. However, the agency's requests to resource increased workload in numerous areas have not been supported by the Commission, and the Agency remains unable to appoint sufficient resources to cope with significant and increased workload in this area. The fulfilment of this task will require the allocation of skilled resources as soon as made available to the Agency. A request for 1 TA post to that effect is once again included in the resourcing requests for 2023.
- In the context of the COVID-19 pandemic, the Agency international activities have seen a further increase in interaction with international partners, a collaboration that is due to remain at intense levels beyond the resolution of the current crisis. Therefore, in order to deliver on this set of activities, the Agency is once again putting forward a resource request of 1 TA post that should be permanently allocated in the establishment plan.
- In order to fulfil the recommendation, put forward by the EMRN strategy to 2025 to foster innovation in clinical trials and make the EU competitive for the conduct of clinical trials the Agency started the Clinical Trials Transformation Initiatives. CTTI aims at:
    - reducing administrative burden
    - increasing set up speed especially for large multistate clinical trials
    - conduct impactful large scale multinational clinical trials by leveraging data and information to better monitor trial safety.
        - For this activity, the Agency has put forward a request for 2 TA posts, in addition to 2 TA posts required to support the CTIS implementation.

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 64% 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. However, EMA will have less establishment plan staff posts in 2022 than in 2014 (596 versus 599, when we exclude Extended Mandate staffing for new tasks, and the 40 2-year short-term TA posts for COVID-related workload which EMA has been requested by the EC to surrender by 2023). 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, especially those most 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 telematics and programme governance at EMA. The objective of this project 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 constant evolving environment the Agency is embracing Digital Transformation to ensure a proper response. In 2020, in the context of the Future Proofing programme, 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.

EMA is managing to absorb some of the growing activities, both fee-related and 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 on short-term 'interim' contracts and contractors.

This is not sustainable in the longer term and is not in the best interest of enabling the Agency to contribute to a robust and sustainable European Health Union. Already, because of staff capacity constraints, the Agency is unable to fully carry out the required scope of its objectives. Some activities linked to objectives (described in detail in the table below) such as improving EU-level horizon scanning, tackling falsified medicines and strengthening supply chains, expanding Benefit/Risk assessment communication, reducing testing in animals through 3R implementation, and aspects of clinical data publication have had to be deprioritised.

The table below illustrates the public health objectives which have currently not been prioritised by the Agency for 2022 and 2023 due to lack of staff capacity.

In accordance with the Agency multi-annual planning structure, the actions are clustered as follows:

Focus Area	Objectives
Availability and accessibility of medicines	• Foster alignment of national implementation of compassionate use programmes in order to promote equity in access for patients during late-stage development and improved utilisation of data from such programmes to support later decision making • New metrics for accessibility of medicines that better represents real patient access to newly authorised medicinal products in different markets • Reinforce patient relevance in evidence generation

Data analytics, digital tools and digital transformation	• Establish collaborations with external stakeholders (including patients, academia, NGOs and industry) and with international regulatory authorities on Big Data initiatives • Ensure data are managed and analysed within a secure and ethical governance framework
Innovation	• 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. • 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 • Develop network-led partnerships with academic/research centres to undertake research in strategic areas of regulatory science • 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 • Update Environmental Risk Assessments in line with the latest scientific knowledge • Support the development and implementation of a repurposing framework
Supply-chain challenges	• Tackle falsified medicines; prevent the presence of falsified medicines in the supply chain by strengthening inspections of manufacturers' application of safety features and of the repository systems. • Promote 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. 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
Sustainability of the network and operational excellence	• Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products • Expand benefit-risk assessment and communication

Part III: Work programme 2022

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 driver and challenges are provided as follows:

- 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 continued extra focus on 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
    - Progress the digitalisation of core regulatory processes through extending IRIS to incorporate additional regulatory and scientific procedures, improve the support to Committees and put in operation the expert panels on medical devices and in vitro diagnostic devices as well as establishing a new operating model for working parties. Strengthen the Agency's ability for efficient safety monitoring of medicines through the use of data analytics and by modernising underpinning information systems
- Veterinary Medicines Division:
    - Implement the Regulation (EU) 2019/6 (Veterinary Regulation) as of 28 January 2022 and continue working on the follow-up activities: 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 in 2022
    - 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.
- Information Management Division
    - 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
    - A modernisation mindset: focusing strategically on innovating IT capabilities and transforming how EMA delivers IT to our customers
    - Maximising customer success: enabling the success of the European Medicines Agencies Network and maximise business impact through customer focus.
- Administration Division:
    - Supporting staff management and development and launching the competency framework to facilitate the 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 the administrative processes, including the domains of 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, procurements 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:
  - 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.
- Clinical Studies and Manufacturing (TCS) Task Force:
  - 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 on the application of the GDPR in clinical research, in particular for secondary use of health data and preparation for the application of the Clinical Trials Regulation (see also Pillar 3) through the development of the Clinical Trial Information System

- Support the agency strategy on vaccines and therapeutics for the prevention and treatment of COVID19 in response to the COVID19 pandemic. Lead the Agency's COVID-19 ETF and its activities in developing requirements for an evaluation of evidence supporting the development and authorisation of vaccines and therapeutics for the treatment and prevention of COVID-19 infection and disease. Start to build on the lessons learned from this pandemic in the evolution of its future strategy the in management of biological health threats and vaccine strategy, including where resource permits on antimicrobial resistance
- Extended EMA Mandate: The HTV team will work to implement the provisions of the regulation extending EMA's Mandate for the articles which apply to the operation of the ETF
- Evolution of novel manufacturing approaches and new strategies to support the application of GMP in the context of global supply chains and of new manufacturing approaches and novel medicines. Work with international partners on digitalised and remote inspections with ICMRA.

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 under the new legislation, or to solve disagreements between two or more Member States[1].

The three main drivers for 2022 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 continued extra focus on 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
- Progress the digitalisation of core regulatory processes through extending IRIS to incorporate additional regulatory and scientific procedures, improve the support to Committees and put in operation the expert panels on medical devices and in vitro diagnostic devices as well as establishing a new operating model for working parties. Strengthen the Agency's ability for efficient safety monitoring of medicines through the use of data analytics and by modernising underpinning information systems.

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. More details on the activities are provided in the following subsections.

The workforce available in 2022 for the Division is currently foreseen at 374 staff (268 TAs, 92 CAs, 14 SNEs). This figure is subject to constant revision to consider staff movements (including part-time regime) and workload fluctuation.

[1] Reference: *1.4. Referrals*

Pillar 1 - Product related activities

1.1 Pre-authorisation activities

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

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

Supporting the development of PRIority MEdicines. PRIME is a scheme launched in March 2016 designed to reinforce scientific and regulatory support to new medicines addressing a major public health needs 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 a number of 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, the 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**
		2020	**2021**	**2022**
Scientific advice and protocol assistance (non-exhaustive list)	**Total scientific-advice and protocol-assistance requests**	**784**	**826**	**885**
	Parallel scientific advice with international regulators requests	4	4	4
	Joint scientific advice with HTA bodies requests	2	4	3
	Scientific advice for PRIME products	37	40	42
	Protocol assistance	143	146	154
	Novel technologies qualification advice/opinions	15	19	21
Supporting the development of PRIority MEdicines	PRIME eligibility requests received	69	55	55
Orphan medicinal product designation and related maintenance procedures	Applications for orphan medicinal product designation	235	250	280

		Results	Expected results	Forecasts
		2020	**2021**	**2022**
Development of medicines for children	Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	735	764	801
Classification and certification of advanced therapy medicinal products (ATMPs)	Requests for classification of ATMPs	74	70	60

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, in particular for personalised medicines. 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 an individual patient. 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 takes into account updated dossier requirements for a medicinal product with an integrated medical device.

Workload indicators

		Results	Expected results	Forecasts
		2020	**2021**	**2022**
Scientific assessment of medicines submitted for centralised marketing authorisation	New non-orphan medicinal products	43	68	61
	New orphan medicinal products	34	28	28
	Similar biological products	12	13	15
	Generic, hybrid and abridged products	24	23	26
	Scientific opinions for non-EU markets (Art 58)	0	3	1
	Paediatric-use marketing authorisations	0	1	1
	Number of granted requests for accelerated assessment	12	10	12
	ATMP marketing application authorisation requests received [1]	6	9	8
	COVID-19 related product applications received[2]	6[3]	9[4]	11[5]

[1] New indicator introduced in 2021 work programme
[2] New indicator introduced in 2021 work programme
[3] Of which 1 therapeutic, 1 immunomodulator, 4 vaccines
[4] Of which 2 immunomodulators EoI, 3 therapeutics, 5 vaccines
[5] Of which 10 vaccines including 3 Booster vaccines (variations of exciting MAs), and 1 Immunomodulators

Performance indicators

		Results	**Expected results**	**Targets**
		2020	**2021**	**2022**
Scientific assessment of medicines submitted for centralised marketing authorisation	Average assessment time for new active substances and biosimilars	192	205	205
	Average clock-stop for new active substances and biosimilars	166	180	180
	% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	50%	60%	60%
	% of initial marketing authorisation applications that had received centralised scientific advice	70%	80%	80%

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**
		2020	**2021**	**2022**
Variations to marketing authorisations	Type-IA variations	3,989	4,046	4,078
	Type-IB variations	2,675	2,888	3,016
	Type-II variations	1,274	1,243	1,245
Line extensions of marketing authorisations	Line-extensions of marketing authorisations	35	32	38
Maintenance activities	Renewal applications	99	84	75
	Annual reassessment applications	24	29	31
	Transfer of marketing authorisation applications	36	60	60

		Results	Expected results	Forecasts
		2020	2021	2022
	Article 61(3) applications	211	300	200
	Post Authorisation Measure data submissions	990	900	925
	Plasma Master File Annual update and variation applications	28	25	25

Performance indicators

		Results	Expected results	Targets
		2020	2021	2022
Maintenance activities	Average assessment time for variations that include extension of indication	167	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
		2020	**2021**	**2022**
Referrals	Pharmacovigilance referrals started	2	5	6
	Non-pharmacovigilance referrals started	6	10	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 on the basis of 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**
		2020	**2021**	**2022**
Pharmacovigilance	Number of signals peer-reviewed by EMA	1,888	1,900	1,800
	Number of ICSRs for CAPs (reports received)	n/a[1]	2.75M	1.5M-2.5M
	Number of signals assessed by PRAC (validated by EMA)	39	50	40
	PSURs (standalone CAPs only) started	525	570	560
	PSUSAs started	304	327	358
	Number of imposed PASS protocol procedures started	4	6	6
	Number of imposed PASS result procedures started	4	9	8

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:

[1] New indicator introduced in 2021 Work Programme.

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, in order 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, at IPRP and ICMRA.

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.

Workload indicators

		Results	**Expected results**	**Forecasts**
		2020	**2021**	**2022**
Coordination of inspections	GMP inspections	130	160	270
	GLP inspections	0	1	1
	GCP inspections	59	40	87
	Pharmacovigilance inspections	16	15	10
	PMF inspections	40	76	54
Quality defects	Notifications of suspected quality defects	170	250	250
Sampling and testing programme	Medicinal products included in the sampling and testing programme	81	94	81
Certificates	Standard certificate requests received	3,115	3,585	3,641
	Urgent certificate requests received	1,647	1,654	1,737
Parallel distribution	Parallel distribution initial notifications received	3,172	2,800	2,900
	Parallel distribution annual updates received	11,624[1]	5,000	4,160

[1] The figure includes a backlog of annual updates received in 2018 and 2019.

Performance indicators

		Results	Expected results	Targets
		2020	**2021**	**2022**
Certificates	Standard certificates issued within established timelines (30 working days)	80%	90%	90%
	Average days to issue standard certificate	23.6	15	15
	Urgent certificates issued within established timelines (2 working days)	98%	98%	98%
Parallel distribution	Parallel distribution initial notifications checked for compliance within the established timeline	90%	90%	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 on a monthly basis, 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 public website. Transfer of the 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
		2020	**2021**	**2022**
Meeting management	Number of reimbursed meetings	52	91	420
	Committee meetings	75	38	75[1]
	Trainings[2]	4	2	22
	Workshops	2	2	13
	Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	112	49	310
	Number of virtual meetings/connections (audio-, video- and web-conferences)	5,409	6,400	6,500
	Number of reimbursed delegates	1,003	0	8,500
	Number of non-reimbursed delegates	60	7,129	1,500
Herbal medicinal products	Herbal monographs, new	3	3[3]	5
	Herbal monographs, reviewed[4]	14	20	22
	Herbal monographs, revised	8	2	6
	EU herbal List entries	1	0	1

[1] In 2022 committee meetings will be held physically and remotely.
[2] Includes EU Network training centre meetings.
[3] Not included: two new public statements finalising the assessment of two substances that did not lead to the establishment of a monograph
[4] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published

Performance indicators

		Results	Expected results	Targets
		2020	**2021**	**2022**
Meeting management	Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings.	100%	100%	100%

Pillar 2 – Public health activities

Beyond product-related activities described under pillar 1, the Human Medicines Division's priority is 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.

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	2023	Better communication on biosimilars and better guidance
1.1 (ECP 1, ECP4)	• Support the STAMP scientific advice pilot for repurposing established medicines	• A number of prioritised established medicines are enlisted in the pilot	2021	2022	A number of candidate products have been enrolled to receive scientific advice

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe		Performance indicator
			Start	End	
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 payer's representative, to explore potential scope and feasibility	• Scientific evidence for marketing authorisation is serving different decision-makers	2022	2023	• Scientific evidence for marketing authorisation is better serving different decision-makers
1.2 (ECP 1)	• Provide updated guidance for key regulatory outputs (assessment reports, labelling) to enhance usefulness for down-stream decision makers • Conduct product-specific reviews with HTA assessors at time of licensing/launch for products of mutual interest and review the experience: perform debriefings of payers on regulatory outcomes	• Stakeholder communication about regulatory assessment is enhanced	2022	2023	• Increased interactions between EMA and HTA and payers • Better guidance
3.1 (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 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	• Better interaction between developers and academia; Better guidance • Increased international harmonisation
3.1 (ECP 1)	• Develop guidance on information required to implement decentralised manufacturing and batch release for ATMPs • Deliver tailored engagement with academics and the community of ATMP developers • Strengthen support to development of ATMPs	• Increased support to the integration of scientific and technological progress in the development of ATMPs	2022	2023	• Better support for the development, manufacturing and accessibility of ATMPs
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	• Reinforced responsibility for product quality by	2022	2023	• Effectiveness and efficiency of GMP inspections in the

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	recognition agreement to other medicines, and implement recognition of FDA's third country inspections for products already in scope of US MRA	harmonising and reinforcing guidance			context of globalisation of pharmaceutical manufacturing
5.4 (ECP 4)	• Develop guidance for MAH's to undertake a risk assessment of supply chain and have a 'resilience plan' including shortage prevention and management • Start a pilot for key medicines including training	• Promoted supply chain resilience and reliability of supply of APIs and medicinal products	2022	2023	• Pilot launched in 2023
6.2 (ECP 2)	• Undertake pilots applying quantitative benefit-risk assessment for initial marketing authorisations and select and pilot communication tools for quantitative benefit-risk assessment	• Improved benefit/risk communication	2022	2023	• Several pilots are concluded, and lessons learned communicated
6.2 (ECP 2)	• Draw lessons from COVID-19 evaluations • Develop simplifications/reductions of post-authorisation procedures • Review of the scientific advice offering to provide more agility • Analyse experiences gained to allow exceptions to the use of paper Package leaflets	• 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

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
Meeting secretariat improvement	Implementation of a new operating model for working parties, of the support to medical devices expert panels (EMA extended mandate), and meeting secretariat operating improvements	2021	2022	• Establishment of a new governance for working parties per domains (quality, safety, efficacy, methodology) • Develop and implement the prioritised portfolio of activities and new operating model for expert groups • Implement the support for the medical device expert panels; Introduce improvements in the meeting secretariat to manage the new operating model

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[1] 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 2022 will be:

- Implement the Regulation (EU) 2019/6 (Veterinary Regulation) as of 28 January 2022 and continue working on the follow-up activities: 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.

The 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 the 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 workforce available in 2022 for the Division is currently foreseen at 61 staff (42 TAs, 16CAs, 3 SNEs). This figure is subject to constant revision to take into account staff movements (including part-time regime) and workload fluctuation.

[1] 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'

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. In order to facilitate the 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 the 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**
		2020	**2021**	**2022**
Emerging therapies and technologies	Innovation Task Force briefing requests (Vet)	5	5	5
Scientific advice	Scientific advice requests received	31	22	22

		Results	Expected results	Forecasts
		2020	2021	2022
Products for minor uses and minor species (MUMS)/limited markets[1]	Requests for classification as MUMS/limited market, of which	29	25	n/a
	Re-classification requests	4	5	n/a
Limited markets	Requests for classification as limited market under article 4(29) and eligibility under article 23	n/a	n/a	20

Performance indicators

		Results	Expected results	Targets
		2020	2021	2022
Scientific advice	Scientific advice procedures completed within set timeframes	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 publishes a European public assessment report (EPAR).

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

[1] As of 28 January 2022, the legislative requirement for limited markets are changing therefore the classification issued under the EMA policy 0075 are not valid anymore and a new classification from is to be submitted and evaluated.

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**
		2020	**2021**	**2022**
Initial evaluation	Initial evaluation applications	15	11	32
Establishment of MRLs	New MRL applications	1	2	2
	MRL extension and modification applications	1	2	2
	MRL extrapolations	0	0	1
	Art 10, Biocides	0	0	0
	Review of draft Codex MRLs	3	0	5

Performance indicators

		Results	**Expected results**	**Targets**
		2020	**2021**	**2022**
Initial evaluation	Initial procedures completed within legal timeframes	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 years 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**
		2020	**2021**	**2022**
Variations to marketing authorisations	Variations applications, of which:	637	649	n/a[1]
	Type I A variations	380	366	n/a[1]
	Type I B variations	195	205	n/a[1]
	Type II variations	62	78	n/a[1]
Extensions of marketing authorisation	Line extensions of marketing authorisations	2	3	n/a[1]
Maintenance activities	Transfers of marketing authorisations	9	8	5

[1] Regulation (EU) 2019/6 defines post-authorisation variations differently from currently applicable rules, therefore detailed forecast was not possible at the time of drafting.

Performance indicators

		Results	Expected results	Targets
		2020	2021	2022
Maintenance activities	Post-authorisation applications evaluated within the legal timeframes	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 disagreement 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
		2020	2021	2022
Arbitration procedures	Arbitrations and Community referral procedures initiated	3	3	6

Performance indicators

		Results	Expected results	Targets
		2020	2021	2022
Referrals	Referral procedures managed within the legal timelines	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 takes action 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
		2020	2021	2022
Pharmacovigilance activities	Periodic safety-update reports (PSURs)	160	160	n/a[1]
	Total AERs, of which:	66,901	75,000	75,000
	Adverse-event reports (AERs) for CAPs	30,297	37,500	37,500

[1] PSUR for veterinary medicinal products will be no longer required as of 2022.

		Results	Expected results	Forecasts
		2020	2021	2022
	Adverse-event reports (AERs) for NAPs	36,604	37,500	37,500

Performance indicators

		Results	Expected results	Targets
		2020	2021	2022
Pharmacovigilance activities	PSURs evaluated within the established timeline	98%	90%	n/a[1]
	AERs for CAPs monitored within the established timelines	97%	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 Start	Timeframe End	Performance indicator
3.1 (ECP 1)	• Produce further guidance to implement the annex to the new veterinary legislation (Regulation (EU) 2019/6) that defines proportionate and future-proofed technical standards for novel veterinary therapies, particularly biologicals	• Guidance for novel therapies and biologicals developed	2020	2022	• Increase of innovative veterinary products applications • Better quality of dossier submitted
3.1 (ECP 1)	• Engage with EU and international risk assessment bodies with a view to aligning methodology for estimating consumer exposure to residues, including dual-use substances	• Analysis of existing models Evaluation of finding and recommendation on harmonised approach	2020	2022	• Recommendation sent to EC
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	2022	• Better understanding of distribution of incidence of AEs • Use of incidence distribution to identify clusters
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	2022	• Increase of available data on actual use

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
					• Better data quality on actual use
3.1 (ECP 1)	• Improve communication of veterinary pharmacovigilance to the general public	• Establish PhV communication framework	2020	2022	• Increased and better communication published/disseminated on PhV topics
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)	• Develop further guidance on when the use of persistent, bio accumulative and toxic substances in animals can be justified	• PBT guidance developed and published	2021	2023	• Improved justifications in dossier for PBT substances
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 current ESVAC system to include other antimicrobials	• Collection of data expanded to include all antimicrobials	2021	2023	• ESVAC report to include all antimicrobials

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
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 and implement new process for JIACRA report to be led by EMA and CVMP in cooperation with EU MSs	2021	2023	• 5th JIACRA report developed via the new process
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	2025	• Methodology revised/updated
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	2020	2023	• New requirements applied and guidance finalised
4.1 (ECP 1)	• Inform policy decisions via enhanced cooperation with European institutions (EFSA, ECDC) to collate data on antimicrobial use with information on AMR in animals, humans and food	• Actively participating to policy development	2020	2025	• Policy includes vision from EMA
4.1 (ECP 1)	• Participate in international initiatives to reduce the risk of AMR	• Actively participating in international fora	2020	2025	• Track records of participation to International fora regarding AMR
4.3 (ECP 3)	• Update existing guidelines, and initiate new guidance as needed	• Develop 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	2020	2022	• CHMP conclusions on H medicines based on V paper

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
4.3 (ECP 3)	• Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms	• Framework developed • Communication with stakeholders	2020	2025	• Framework established and in use • Increase of alternative products submission
4.3 (ECP 3)	• Enhance the promotion of the responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion	• Guidance development • Communication with stakeholders	2020	2025	• Guidance published • Awareness raised in the Network
4.3 (ECP 3)	• Provide scientific and regulatory support to encourage development of veterinary antimicrobials and alternatives, to fill therapeutic gaps, without adversely impacting public health	• Guidance development	2021	2025	• Awareness raised in the Network • Increase of alternative products submission
4.3 (ECP 3)	• Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and their alternatives	• Cooperation at EU and International level for events • Common approach agreed	2021	2025	• Awareness raised in the Network • Increase of alternative products submission
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	2022	• Vaccine B/R assessment targeted per type of vaccine following guidance established
4 (additional RSS recommendation)	• Develop a regulatory framework for authorisation, under exceptional circumstances, of vaccines for emerging health threats and benefit-risk monitoring post-approval	• Guidance developed and implemented	2021	2022	• Exceptional circumstances products submitted
4 (additional RSS recommendation)	• Develop appropriate and proportionate guidance to maximise opportunities offered by Regulation (EU) 2019/6 for promoting availability of vaccines	• 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
	(vaccine antigen master 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 records of participation to International for a concerning antiparasitic resistance • Take away points communicated
4 (additional RSS recommendation)	• Promote responsible use of antiparasitics in the EU	• Awareness events and enhanced dissemination of information	2020	2025	• Better use of antiparasitics (decrease of AERs)
6.1	• Prepare for and implement Veterinary Medicines Regulation	• Prioritised guidance, processes and IT systems in place, in time for implementation and from 2022 monitor implementation	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 approach and guidance	2021	2025	• Consistent decisions taken for B/R assessment of veterinary products
6.2 (ECP 2)	• Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies	• Analysis of current methodologies, development of harmonised approach and guidance • Enhanced communication with stakeholders	2021	2025	• Consistent high-quality output from EMA • Increased publication of relevant information for stakeholders

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
EVVet3 - Union Pharmacovigilance Database / EudraVigilance Veterinary v3.0	• The EVVet3 project aims to provide a "Union veterinary pharmacovigilance system", by bringing the database in line with the requirements of Regulation (EU) 2019/6 and the Commission implementing regulation (EU) 2021/1281 on good pharmacovigilance practice by 28 January 2022 and on delivering possible improvements beyond that date as well as the VICH guidelines relating to pharmacovigilance reporting	2017	2023	• Go-live (Q1/2022) • Development of additional data quality functionalities • Improvements to all EVVet3 components
UPD - Union Product Database [continues]	• Providing a Union Product Database system regarding Veterinary products according to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018	Q1 2020	Q3 2022	• Go-live (Q1/2022) • Improvements to all UPD components
ASU - Collection of Antimicrobials Sales and Use Data [new]	• The Collection of Antimicrobial Sales and Use data (ASU) project collects information on how antimicrobial medicines are used in animals across the European Union (EU)	Q1 2021	2023	• Development of functionalities to collect sales, use and population data • Development of reporting functionality for use data

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
	• The objective obtains reliable data for input into risk profiling and risk assessment regarding antimicrobial resistance and for setting risk management priorities regarding AMR			
MWD - Union Manufacturers and Wholesale Distributors Database	• The EudraGMDP database is the Community database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates	2021	Q2 2022	• Go-live (Q1/2022) • Development of change to the GDP module • Enhanced search functionality

3. Task forces

The European Medicines Agency (EMA) has four 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 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 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.

The workforce available in 2022 for the Task Force is currently foreseen at 17 staff (13 TAs, 4 CAs). This figure is subject to constant revision to take 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. Operationalise and further develop EMA's Change Management Centre of Expertise (CoE) 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). Delivering a learning and knowledge sharing ecosystem for the European Medicines Regulatory Network (EMRN) to build scientific and regulatory expertise and gradually expanding EU NTC training to wider audiences outside of the EMRN.

Digital Academy. Building 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.

Business and regulatory intelligence. This encompasses the implementation of ongoing (medical devices and in vitro diagnostics regulations, veterinary legislation) and future legislative initiatives, and extends to the assessment of performance and soundness of the operation of the current legislative framework. The Task Force will oversee designing policies and will set up governance frameworks to support a high standard of quality in EMA decision-making.

Transformation / Optimisation of Submissions and Regulatory Processes. 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.

Area of work	Key action	Expected benefit
ACE	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 through the use of 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	Set of services to discover, experiment and develop digital solutions that have the potential to support core business and enable the strategies	• The management of the innovation idea portfolio is supported and centralised • Scalable emerging technologies applicable to concrete business cases that may change the way the 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 of staff across the Agency and in the future also for the Network.	• Agency's staff (and in the future also Network's staff) benefit from increased change management capabilities
EU NTC	Support futureproofing of EMA and the Network by developing regulatory capacity through the EU NTC	• Access to EU NTC training is extended to external audiences

Digital Academy	Develop a digital skills framework for EMA and lead on digital capability building	• Digital Skills framework for EMA is validated and introductory training on topics in the digital skills framework are available. • Introductory training content is delivered through a platform that acts as entry point • An agency-wide awareness campaign on the digital skills framework is delivered
Business and regulatory intelligence	• Implemented in-vitro diagnostics regulation • Provide additional guidance on Medical Device Regulation implementation for medicinal products used in combination with devices	• EMA is operationally ready for future legislative initiatives. Go live of in-vitro diagnostics opinions from May 2022
Transformation / Optimisation of Submissions and Regulatory Processes	• Ongoing coordination and support of the eSubmissions portfolio • Implementation of eCTD v4.0. (Portfolio project to be launched in 2022)	• EMA is prepared for adoption of the eCTD v4.0 standard

Workload indicators

		Results	**Expected results**	**Forecasts**
		2020	**2021**	**2022**
EU Network Training Centre (EU NTC	New scientific, regulatory and telematics curricula developed	2	2	2
	Number of training events advertised to the EU Network	46	40	40
	Number of reimbursed training events to the EU Network	1	12	12

		Results	Expected results	Forecasts
		2020	2021	2022
	Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	7	10	10

Performance indicators

		Results	Expected results	Targets
		2020	2021	2022
EU Network Training Centre (EU NTC	Number of users registered to the EU NTC Learning Management System	5,290	5400	n/a[1]
	Number of NCA experts registered to the EU NTC Learning Management System	4,297	4500	n/a[1]

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

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
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	• 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

[1] Indicator to be reformulated as of 2022.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	increases in efficiency and regulatory decision-making				• Number of innovative ideas started • Number of solutions successfully piloted • Number of processes reengineered for efficiency
2.2 (ECP 2)	• Establish an EU collaboration on AI to support regulatory decision making with the relevant Agencies in the EU Network	• Use of trustworthy and human-centric artificial intelligence for increased collaboration amongst EU Agencies and Member States (Develop and promote AI community) whilst seeking efficiency gains and demonstrating the overall added-value and contribution of EU agencies and Members States to the EU AI Strategy	2021	2025	• Number of meeting 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 EUNTC	2021	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 courses

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
3.4	• Develop the integrated evaluation pathways in cooperation with medical device authorities and notified bodies. Strengthen the 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 (drug device combinations), In Vitro Diagnostics and borderline products	2021	2023	• Two workshops held by end of 2022 • 80% of the relevant guidance to be developed
3.4	• Identify and enable access to the best expertise across Europe and internationally	• Map all current working groups (i.e. at EMA, HMA/CAMD, NCA, EC) working on medical devices and in vitro diagnostic where there is a connection to medicinal products and identifying common tasks/topics • Establish a more formal link between the current groups and the experts at the NCA's facilitating systematic interaction	2021	2023	• Mapping across WGs/EMA activities (Q2 2022) • Establishment of a list of experts and group with a thematic expertise (Q3-Q4 2022)

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe Start	Project timeframe End	Deliverables 2022
ECTD4: Implementation and adoption of eCTD v4.0 standard	• The project aims at implementing the next generation standard defining the message for exchanging regulatory submission information electronically between	2021	2025	• Impact analysis and pre-implementation activities including review tool options in preparation for the implementation of eCTD v4.0 specification at the EMA (and the EU regulatory network)

	applicants and Regulatory Authorities			
IRIS: Platform to support regulatory business processes of the Agency	• The IRIS platform will provide a single space for applicants and EMA to submit requests, communicate, share information and deliver documents concerning regulatory and scientific procedures	2019	2025	• DADI forms (eAF replacement) • Inspections • Variations process • Marketing status • Supply chain
Other Digital Business Transformation initiatives	• Bringing about innovative digital tools for the Agency	2021	2025	• Implementation of Analytics Centre of Excellence (ACE) / Digital Innovation Lab projects. • Chatbot • Extended Reality / Virtual Reality • EU Network Training Centre (EU NTC) enhancements and expansion to new audiences • Development of Change Management Centre of Expertise • Launch of EMA Digital Academy

3.2. Data Analytics and Methods (TDA)

The Data Analytics and Methods Task Force will contribute to the Agency's mission by building capability and capacity in the analysis of data and in study methods that will, over time, be embedded within the core operations of the Agency and support delivery of the data and analytics objectives of the Network Strategy to 2025. While doing so, the Task Force will support the Agency's methodology, data management and data-analytics services throughout the lifecycle of medicinal products. In addition, the Task Force includes clinical trials leadership including for the delivery and operation of the Clinical Trials Information System.

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

- 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 the development of the Clinical Trial Information System.

The workforce available in 2022 for the Task Force is currently foreseen at 62 staff (42 TAs, 11 CAs, 9 SNEs). This figure is subject to constant revision to take into account staff movements (including part-time regime) and workload fluctuation.

Pillar 2 – Public health activities

Data Analytics Workstream

The Data Analytics workstream supports the Agency's committees and working parties with real-world evidence (RWE) for decision-making and in assessing the impact of regulatory decisions through targeted data analyses. This covers RWE support to public health emergencies. Manages contracts with academic service providers for studies, including RWE studies. Leads capacity-building in methodology, data science and analytics for EMA and the EU network (including through EU-NTC). The team collaborates with the Digital Business Transformation Task Force (TDT) to ensure the provision of an artificial intelligence (AI) advice service to the Agency. Influence and leverage EU and international initiatives.

Methodology workstream

The Methodology Workstream provides expert advice on study design and the availability and suitability of existing data sources and provides an analytics advice service to the Agency and support to the EU Network. The team is responsible for piloting the analyses of patient-level data from clinical trials and progressing work on meta-data in lifecycle regulatory submissions.

Healthcare Data Workstream

The Healthcare Data Workstream covers activities related to the EudraVigilance Data Management and the Medical Literature Monitoring service. Maintains a public inventory of healthcare data sources for the EU regulatory network and provide EMA's position on the validity of those data sources for specific regulatory use-cases. The team leads and coordinates EU regulatory efforts in data standardisation, including in industry submissions and real-world data. Coordinates and develops guidelines in data standards, terminologies, data management, etc., and participates in guideline development at an international level. Furthermore, as a continuation to the work done in 2021, the Agency will be supporting NCAs during 2022 in performing some processing of COVID Vaccine-related ICSRs in the wider context of the vaccination campaigns and to support the monitoring of vaccine safety.

Clinical Trials Workstream

The Clinical Trials workstream is responsible for the preparation for the application of the Clinical Trials Regulation through the development of the Clinical Trials Information System (CTIS) and the preparation and deployment of user-support mechanisms, including training materials and activities, change-management processes and user help, both pre- and post go-live, of the system; operational support of EudraCT, development of personal-data protection approaches for the CTIS.

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 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
Clinical Trials	• Clinical Trials Transformation Initiative	• Make the EU competitive for the conduct of clinical trials especially for large multistate clinical trials

		• Enable conduct of large scale multinational clinical trials to be impactful based on excellent methodological advice • Leverage data and information to better monitor trial safety and for public health benefit • Strengthen the leadership and coordination

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)	• Data Analytics and Real World • Interrogation Network (DARWIN EU) • Deliver a sustainable platform to access and analyse healthcare data from across the EU. Establish and maintain a secure EU data platform that supports better decision-making on medicines by informing those decisions with robust evidence from healthcare	• Data Analytics and Real World • Interrogation Network (DARWIN EU) established and operational	2020	2023	• 50% of project milestones achieved in 2022 (current project plan) • 10 number of studies performed by contractor in 2022 • 16 number of studies performed by contractor in 2023 • 10 Data partners onboarded in 2022 and 10 additional Data partners onboarded in 2023

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
2.1 (ECP 2)	• Submission of Raw Data in Regulatory Submissions • Build capability and capacity to receive, store, manage and analyse raw data	• Determine the regulatory and public health benefit of analysis of raw data	2021	2023	• Agreement with CHMP of a protocol for a pilot of IPD from CT by Q1 2022 • 70% of project milestones achieved in 2022 (current project plan)
2.1 (ECP 2)	• Data standardisation in medicines regulation across the lifecycle of a medicine: • Develop a data standardisation strategy, drive standardisation of regulatory submissions across the lifecycle of a medicine, search the unstructured data stored at the Agency, collaborate with worldwide standards data organisations	• Enable effective interrogation of scientific information across the lifecycle of medicines and for multiple types of users within and across regulatory procedures. Drive up the quality of data submitted to EMA through the use of standards	2021	2022	• Publish Data Standardisation Strategy in Q1 2022 • Establish EMA data board Q1 2022 • Mandate of the EU NDB and BDSG reviewed Q1 2023 • Start collaboration with ICH M11 on development of logical model for clinical study protocols and reports • Develop a logical model for clinical study protocols and reports Initiate work on FHIR messaging

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
					Produce final report for Advanced Analytics Scientific Advice pilot
2.1 (ECP 2)	• Metadata, Data Quality Framework and Catalogues Project: • Enable data discoverability. Identify key meta-data for regulatory decision-making on the choice of data 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). Upgrade the current EU PAS database to support the registration and transparency for observational studies	• Data discoverability enabled for the Network	2021	2023	• ENCePP and EUPAS upgraded and maintained based on agreed metadata for RWD • Delivered a Data Quality Framework for data used in the regulatory context
2.2 (ECP2, ECP4)	• Strengthen EU Network on methodology and RWE in committee advice and assessment • Develop Big Data learning initiative where submissions on complex methodology and RWE are forecast and tracked, work with international partners on RWE to develop roadmap and guidance, drive the creation of guidance documents in the methodological area, drive the creation of the Methodology Working Party	• Improved preparedness of the EU Network for applications with RWE and complex methodology. Systematic learnings from submissions with RWE and complex methodology. Published roadmap for collaboration with international partners. The Methodology Working Party is	2021	2025	• Deliver an overarching 2022 work plan for the Methodology Working Party. At least one European Specialised Expert Community (ESEC) meeting in 2022 • Workshop with international regulators on RWE topics

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		operational and publish a workplan for methodology guidelines.			
2.1 (ECP 2)	• RWE process and analysis • EMA business processes to identify the need for RWE and to deliver that evidence into the regulatory decision making	• Enable better regulatory decision making through the provision of the high-quality RWE	2020	2022	• At least one pilot study has been performed with CAT, PDCO, COMP, CHMP and SAWP Committees • Training of EMA users on in-house RWD analysis has been performed across Divisions and Task Forces • By Q4 2023 processes established with all committees with RWE provision • 20 (10 through DARWIN EU) number of studies performed by contractor in 2022 • 40 (16 through DARWIN EU) number of studies performed by contractor in 2023

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
3.2 (ECP 1)	• Establish a multi-stakeholder, neutral, platform, to enable new approaches to clinical studies and to position the EU as a preferred location for innovative clinical research	• Establish a framework, mandate and objectives for a multi-stakeholder platform for discussion of new approaches for Clinical Studies	2021	2025	• 2022 - Outline Framework, Mandate and Objectives established and published. 2022 - Two workshops to initiate platform
3.2 (ECP 1)	• Work with stakeholders, the EU Medicines Regulatory Network and the European Commission to promote and facilitate the conduct of complex clinical trials and other innovative clinical trial designs	• Using the multi-stakeholder framework from 3.2.1.11 develop action plan and workstreams on complex clinical trials	2021	2025	• 2022 - Action and workstreams for complex clinical trials established
3.2 (ECP 1)	• Promote increased information sharing on clinical trial design, conduct, results and best practices. Build on this information and the multi-stakeholder platforms to enable further education, training and sharing of best practice in order to accelerate innovative change	• Using the multi-stakeholder framework from 3.2.1.11. Promote awareness of and use of public information on clinical trials	2022	2024	• 2022 - Publish paper on availability and methods for use of public information on clinical trials

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe Start	Project timeframe End	Deliverables 2022
- Lifecycle Regulatory Submission Metadata	• Identify relevant data sources and by defining and standardising the structure of the information (i.e.	2021	2023	• Establish a framework and operating model for data standards

	defining the 'metadata' and supported through relevant standards), the scientific information will become more accessible			• Develop conceptual model for clinical study protocols and reports • Scientific Advice advanced Analytics pilot: present report/demo UI • Launch contracts for Standards Specification; Implementation of FHIR resources; Implementation of Fast Healthcare Interoperability Resources (FHIR) tools; Implementation & Change Management
- Lifecycle Regulatory Submission Raw Data	• Report on review of experience with IPD at EMA and other international regulatory agencies and develop protocol for IPD	2021	2024	• Initiate stepwise implementation • Initiate communication and training in accordance with plans
- Real-world Metadata, Quality Framework and Catalogues	• Conduct external studies to identify data sources of real-world data, define and collect metadata and deliver a data quality framework.	2021	2025	• Adoption of the metadata list and guide • Development of data sources and studies catalogue • Development and adoption of data quality framework for regulatory purposes
- Observational Studies Rapid Analytics	• Increase the amount of real-world evidence and real-time evidence analysis in committee decision making	2020	2022	• Finalise proof of concepts with PDCO and COMP and pilot with SAWP • Start pilots with CAT, CHMP, COMP and PDCO • Finalise awareness and training material • Finalise change management • IHD software training for H-Division champions • Databases accessible in-house in OMOP common data model
- Observational Studies DARWIN EU	• Establish a network of data, expertise, and services to support better decision-making by EMA and NCA scientific committees on the benefits and risks of products via rapid access and analysis and increased reliability, validity and	2021	2025	• 1st year of establishment of the DARWIN EU coordination centre • Coordination centre set-up, inc. operational processes and governance • Establish connectivity with European Health Data Space (EHDS) and existing Data Permit Authorities • First catalogue of standard data analyses available • Start recruiting and onboarding the data partners

	representativeness of EU health data			• Start running pilot studies to support EMA committees • Pilot with EHDS • Prepare EMA to be ready as a node • Training and change management
- Signal and Safety Analytics	• Increase saleability and efficiency in processing of signals & safety data	2021	2023	• Collection of IT and business requirements for the design of the new EudraVigilance data analysis system (EVDAS) platform/ electronic Reaction Monitoring Reports (eRMR) solution/ADR website • Design of the new systems and identification of possible gaps • Start implementation of the new solutions • Analysis of potential future needed work
CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database, renamed including a merger with SUSAR)	• The project aims at delivering Clinical Trials Information System (CTIS) to support the harmonisation of the assessment and supervision processes for clinical trials throughout the EU	Q3 2014	2023	• Go Live 31 January 2022 • Finalise implementation of post go live release(s) • Final acceptance of post-go-live release and business change management • Continued communications, training programme and related documentation • Planning and development for further post-go-live release(s) in 2023
Safety Implementation Regulation - cooperation in safety assessment (CTIS scope extension)	• Implementation of IT systems to support cooperation in safety assessment in the context of the clinical trials	Q3 2021	2023	• Go Live 31 January 2022 • Finalise implementation of post go live release(s) • Final acceptance of post-go-live release and business change management • Continued communications, training programme and related documentation • Planning and development for further post-go-live release(s)

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 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 so as 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 2022 for the Task Force is currently foreseen at 25 staff (14 TAs, 7 CAs, 4 SNEs). This figure is subject to constant revision to take 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	• 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-	• Allows the network to respond appropriately and enable innovations to reach the market with minimal developmental, legal, regulatory, process or procurement bottlenecks

	matter experts across the product-development lifecycle	
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 regulatory science research projects	• Execute the agency-wide plan for interactions with academia. (1) to support governance and oversight of interactions with externally funded research and networks; (2) identify academic disciplines/research topics; (3) support the establishment of staff-exchange programmes and placements; (4) create academia-targeted materials to promote existing regulatory tools; (5) set up a communication strategy • Continue support to IMI2's closing projects, and plan and coordinate engagement with Horizon Europe and IHI • Disseminate EMA's regulatory science research needs, develop stakeholder consultation and update and review mechanisms • Coordinate the conduct and/or commissioning of impact-assessment studies	• Delivers the Agency's Academic Matrix Action Plan with particular focus on 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
Supply and availability of medicines and devices workstream Delivering the reinforced EMA mandate so as 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	• Key operational structures established as foreseen within the adopted legislation • Short to medium term tactical IT solutions delivered through 2022 • Scoping of the EU-level platform addressing supply of medicines delivered in 2022-2023

	• Coordination of required actions for Covid-19 related shortages of CAPs and high-impact medicines used in intensive care setting for Covid-19 patients (CAPs and NAPs) • Coordination of the activities of the EU SPOC Network (single points of contact in NCAs for shortages) • Coordination of the activities of the i-SPOC system (single points of contact in industry for shortages) • Coordination of the implementation of the EMANS to 2025 in the area of availability of medicines • Co-chairmanship and secretariat of the HMA/EMA Task Force on the Availability of authorised medicines • International collaboration on shortages-related strategic topics and shortages case-management at the level of the Global Regulatory Shortage Network	

Workload indicators

		Results	**Expected results**	**Forecasts**
		2020	**2021**	**2022**
	Innovation Task Force briefing meetings	30	35	35

		Results	Expected results	Forecasts
		2020	**2021**	**2022**
Research and innovation: innovation and emerging therapies	Innovation Task Force Art 57 CHMP opinion requests	0	3	4
Research and innovation: business and analysis forecasting	Business Pipeline briefing meetings[1]	20	18	18
SME Office	Regulatory assistance, including SME briefing meetings[2]	232	223	183
	Requests for SME qualification	518	532	516
	Requests for SME status renewal	1,205	1,362	1,260

Performance indicators

		Results	Expected results	Targets
		2020	**2021**	**2022**
SME Office	Satisfaction level of SMEs	89%	80%	80%

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

[1] New indicator introduced in work programme 2021
[2] 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	• 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
	expertise and provide continuous training through the EU Network Training Centre				
1.1 (ECP 1, ECP4)	• Review of the mandate of EMA to include the activities of the EU Executive steering group, the iSPOC, and the EU SPOC Network	• Fulfilment of the requirements established by EMA's extended mandate for availability of medicines	2021	2022	• Key operational structures established 20 days post legislation adoption
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

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe Start	Project timeframe End	Deliverables 2022
EUMSD database	To support development of functional specifications for the EUMSD database, together with a plan for the implementation of national IT systems, and consultation with stakeholders	2022	2022	• EUMSD database functional specifications developed
Digital workspace (TRIP)	To use a Digital workspace for capturing, filtering and scientifically assessing HS signals by users from the Horizon Scanning team (TRS) and by	2022	2022	• Provision of data sources for the Digital workspace (internal and - external sources), regularly updated, enable data analytics activities

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
	Regulatory Observatory members (experts across the Agency, and eventually the EMRN)			• Provide the user facing workspace and underlying system for manual curation of horizon scanning signals and topics • Provide automatically updated topic insights • Prepare for additional automated signal assessment
EMA's Regulatory Science Observatory	To support review of TRS operations with a view to optimise, create synergies and efficiencies leading to fulfilling our mandate as a EMA's Regulatory Science Observatory. Operations to review include the Business Pipeline, Horizon Scanning, Innovation Task Force as well as Academia and SME liaisons	2022	2023	• Review of the Innovation Task Force, Business Pipeline and Horizon Scanning operations
Shortages (new mandate)	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 in order to ensure availability of critical medicines in the EU/EEA by supporting increase of production capacity to meet demand	2021	2025	• Monitoring supply and demand for critical medicines list and critical medical devices lists • Reception of shortages notifications and supply data from MAHs for critical medicines and from industry bodies for critical medical devices • Reception of demand data from EU SPOC for critical lists • Matching /analyse supply and demand data to mitigate shortages • Aggregated data analysis and reporting capabilities on forecasts of demand in combination with epidemiological data from ECDC • Contact management for MAHs iSPOC contact data for all medicinal products portfolio and for industry bodies contact data for all medical devices portfolio

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
				• Monitoring of events that can lead to shortages reported by EU SPOC • Case management capabilities • Provide analysis capabilities to evaluate the impact of the event on the supply and availability of medicines • Streamline the various channels that shortages are reported

3.4. Clinical Studies and Manufacturing (TCS)

The Clinical Studies and Manufacturing task force develops and guides EMA's strategy at European Union and global level to support the facilitation of clinical studies, manufacturing and the management of biological health threats and vaccine strategy.

The main drivers for the 2022 annual work programme are:

- 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 on the application of the GDPR in clinical research, in particular for secondary use of health data and preparation for the application of the Clinical Trials Regulation (see also Pillar 3) through the development of the Clinical Trial Information System.
- Support the agency strategy on vaccines and therapeutics for the prevention and treatment of COVID-19 in response to the COVID-19 pandemic. Lead the Agency's COVID-19 ETF and its activities in developing requirements and evaluation of evidence supporting the development and authorisation of vaccines and therapeutics for the treatment and prevention of COVID-19 infection and disease. Start to build on the lessons learned from this pandemic in the evolution of its future strategy in the management of biological health threats and vaccine strategy, including where resource permits on antimicrobial resistance.
- Extended EMA Mandate: The HTV team will work to implement the provisions of the regulation extending EMA's Mandate for the articles which apply to the operation of the ETF.
- Evolution of novel manufacturing approaches and new strategies to support the application of GMP in the context of global supply chains and of new manufacturing approaches and novel medicines. Work with international partners on digitalised and remote inspections with ICMRA.

The workforce available in 2022 for the Task Force is currently foreseen at 16 staff (10 TAs, 5 CAs, 1 SNE). This figure is subject to constant revision to take into account staff movements (including part-time regime) and workload fluctuation.

Pillar 2 – Public health activities

Biological Health Threats and Vaccine Strategy Workstream

COVID-19 response: The Biological Health Threats and Vaccine Strategy team lead the agency's strategic response in supporting the development and evaluation of vaccines and therapeutics for the treatment and prevention of COVID-19 infection and relation disease. The team chair and coordinate the activities of the EMA Task Force on COVID-19 (COVID-19 ETF) and its role in scientific advice and rolling review and evaluation of marketing application dossiers for therapeutics and vaccines.

Extended EMA Mandate: The HTV team will work to implement the provisions of the regulation extending EMA's Mandate for the articles which apply to the operation of the ETF.

Antimicrobial resistance and availability of anti-infective treatment options: The Agency cooperates with European and international partners, including the EC, other European agencies (e.g., ECDC and EFSA), WHO, ICH, TATFAR and others, in exploring opportunities for new and effective anti-infective treatment options and other important initiatives to overcome the problem of antimicrobial resistance. Work in this field is done in regard to both human and veterinary medicines.

Public health threat preparedness. The 2009 influenza pandemic led to a review of the cross-European strategy for pandemic preparedness. In 2016 the Agency reviewed its pandemic preparedness plan and transformed it into a wider-ranging preparedness plan for emerging health threats. The Agency continuously works, in collaboration with NCAs, the EC and ECDC, to implement improvement actions to ensure a high level of coordinated cross-European preparedness to act upon public health threats. The evolution of the activity is linked to the approval of the activity for the extension of EMA mandate. This requires intensive international collaboration within ICMRA or directly and formally or informally with our regulatory partners with which we have confidentiality arrangements.

Manufacturing Strategy: Leadership of the EU GMDP Inspectors Working Group. Evolution of novel manufacturing approaches and new strategies to support the application of GMP in the context of global supply chains and of new manufacturing approaches and novel medicines. These activities are closely linked to those of the inspection and quality offices in H Division. In order to answer key challenges including whether we collectively make best use of resources for ensuring GXP compliance at global level, or are prepared for challenges in manufacturing and operation of the supply chain? There will be a lesson learned exercise regarding remote and digitalised GMP/GCP inspections.

Area of work	Key action	Expected benefit
Manufacturing Strategy	Develop and provide input into GMP and manufacturing topics at EU level, through the GMDP IWG and in collaboration with H-Division in areas such as: 1. PQKMS (including post-approval change management) 2. Novel Manufacturing 3. Inspections	Input into GMP and manufacturing topics at EU level is provided by the: 1. Reflection paper on PQKMS to form basis of network engagement and EU position 2. & 3. Concept papers to support the review of the general pharmaceutical legislation

Manufacturing Strategy	Develop and provide input into GMP and manufacturing topics at EU level, through the GMDP IWG and in collaboration with H-Division in areas such as: 1. vulnerabilities of the supply chain (structured dialogue) 2. Pharmaceuticals in the environment	The Agency is involved in the reflection on Phase 1 supply chain vulnerabilities exercise and next steps when confirmed by the EC
Manufacturing Strategy	Develop and provide input at international level into GMP and manufacturing topics, through ICMRA and in collaboration with H-Division in areas such as, PQKMS (including post-approval change management) regulatory flexibilities (RAFS) and inspection reliance and hybrid inspection	1. Regulatory flexibilities and sustainability reflection paper by end Q1 2022 2. Hybrid Inspection pilot to be designed end Q1 2022 and pilot concluded end 2022
Management of Declared Public Health Emergency	Operate the ETF during COVID-19 public health emergency	ETF operates in accordance with the health threat plan and ETF mandate
AMR	Develop and implement the AMR EMA strategy	The pipeline for anti-microbials to tackle AMR is improved

In addition to the above, the Clinical Studies and Manufacturing Task Force plans to undertake and progress the following additional activities:

MAWP Strategic Goal (EC policy/action)	**Action**	**Expected result**	**Timeframe**		**Performance indicator**
			Start	**End**	
3.2 (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	KPI for 2022 Agreement of Step 2 at ICH for ICH E6 GCP (objectives and Annex 1)

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
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	Agreement of Step 2 at ICH for ICH E6 GCP (objectives and Annex 1)
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	1. 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 new business model on the antibacterial agent	2022	2025	Workshop with stakeholders in 2022
4.6	• Define approaches for review of data with international regulator	• Build on the experience acquired with COVID 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

4. Advisory functions (International Affairs, Internal Audit, Legal Department, Institutional and Policy Department, Information Security)

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, support to priority countries, capacity building (including IPA training) and scientific training 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 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 related to anti-fraud issues. The tasks of the Legal Department include also 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** covers activities related to the Agency's interactions with the EU institutions, in particular the European Commission, the European Parliament, the Council and other EU agencies. This includes the monitoring of relevant pharmaceutical and health-related EU policy initiatives and coordinating EMA's input during the legislative procedure for new pharmaceutical legislation. The department is also responsible for the organisation of EMA's management board and for EMA's interactions with the Heads of national Medicines Agencies (HMA). The department also coordinates the development and revision of EMA policies and monitors their implementation. Furthermore, the department is responsible for the coordination of the Agency's environmental management activities (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 the 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 2022 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 workforce available in 2022 for the Advisory functions is currently foreseen at 46 staff (32 TAs, 13 CAs, 1 SNE). This figure is subject to constant revision to take 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**
		2020	**2021**	**2022**
International Affairs	Interactions with FDA	644	700	700
	Interactions with MHLW/PMDA	132	150	200
	Interactions with Health Canada	224	200	200
	Interactions with any other stakeholders	866	700	700
	Number of information and/or document exchanges	988	900	900
	Number of teleconferences organised (including OPEN, but excluding ICMRA)	235	150	150
	ICMRA executive committee and full membership teleconferences	52	10	14
	International stakeholders' visits (fellowships, experts, observers)	1	0	5
	Organisation of International awareness sessions	0	0	2

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)	• COVID-19 and ICMRA secretariat	• Continue demonstrating leadership of ICMRA: regulatory convergence and in particular, vaccine safety monitoring collaboration • Regulatory communication	2020	2025 (assuming re-election as ICMRA chair)	• Collaborative projects undertaken • Statements released • Technical workshops organised
1.1 5.5 (ECP 1, ECP4)	• Nitrosamines	• Participation in Nitrosamines International Steering Group (NISG)	2018	2024	• Regulatory actions • Information exchanged
1.1 5.5 (ECP 1, ECP4)	• Extension of US MRA	• Extension to vaccines and plasma-derived products, and vet medicines	2020	2023	• Full capability of the EU, NCAs and FDA
1.2 (ECP 1)	• Article 58 – EU-M4all	• Support to developers and promotion of parallel art 58 and centralised submissions	2021	Ongoing	• Number of parallel submissions • Number of art 58 opinions and NRA approvals
1.2 (ECP 1)	• Reliance on scientific output of EMA committees	• Promote reliance on scientific output of EMA committees by non-EU regulators, in particular through WHO facilitated pathways	2021	Continuous	• Number of NRA approvals or regulatory actions based on reliance on EMA assessments • Number of WHO Prequalifications, Emergencies Use

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
					Listings and other regulatory actions based on reliance on EMA assessments
6.5	• Develop International collaboration and reliance including through Confidentiality Arrangements in accordance with defined priorities	• Update existing and putting in place new confidentiality arrangements on the basis of prioritisation	2019	Ongoing	• Number of new (permanent and ad-hoc) or revised confidentiality arrangements
6.1	• Capacity building • Provide assistance to candidate countries (IPA), to align their standards and practices with those established in the European Union, and to further foster their integration process	• Increased visibility of EMA • Training on acquis Communautaire of candidate and accessing countries	2020	2024	• Awareness sessions per year • Successful IPA training (complete and positive evaluations)
5.2	• Supply chain	• Work with project on shortages, on API with priority countries • China project on API	2021	Ongoing	• Active contribution to shortages global approach • Development of the shortage project
5.2	• Support to priority countries	• India and Russia joining PIC/S and ICH, GMP and GCP improved compliance	2021	2024	• Membership gained

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
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	2022	• Number of authorities and number of medicines with participation in evaluation • Qualitative and quantitative data from 2021-22 survey of ongoing procedures
1.1 (ECP 1, ECP4)	• Active participation in WHO activities, international fora and communication to stakeholders, including but not limited to ICDRA, DIA, ICH, IPRP	• Promote convergence of global standards and contribution to international fora	2016	Ongoing	• Number of participations
5.3	• Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries	• Improve application of equivalent standards of good manufacturing and clinical practices throughout the world	Ongoing	Ongoing	• Number of observed inspections
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	• Progress in the quality management system project at ICMRA
6.1	• Increase the number of opportunities for non-EU regulators, in particular from candidate and	• Support training and capacity building of non-EU regulators	2016	Continuous	• Maintenance of updated training calendar

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
	potential candidate countries, to participate in scientific and regulatory training activities[1]				• Increase participation of non-EU regulators in EU NTC
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	• Trainings delivered to non-EU regulators
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 awareness sessions
6.1	• Collaborating with EC/EMA to develop a joint long-term strategy for targeted and effective training programs on pharmaceutical GMP/GCP in China and India	• Capacity building through training	2020	Continuous	• Trainings delivered
1.1 (ECP 1, ECP4)	• ICMRA secretariat management, including operational and financial contribution to bi-annual ICMRA meetings	• Communication	01 Oct 2019	Mid-2025 (depending on re-election of EMA as ICMRA chair	• Executive Committee meetings organised • Plenary meetings organised • Policy Teleconferences organised • (Financial contribution indicator suspended

[1] Including contributing to the IPA activities of the European Commission (Instrument for Pre-accession Assistance) and a virtual meeting/training related to IPA will be organised in Q1 2021.

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
					due to no face-to-face meetings)
1.1 (ECP 1, ECP4)	Communication of information, answer to queries, internal coordination. Monitoring of the matrix of the tracking of interactions. Organisation of cluster meetings, teleconferences and preparations of visits, missions' preparation, support to FDA, Health Canada, PMDA and other international partners, fellowships and expert visits. Selected redaction of documents	• Support to the International Affairs Division and its specific activities	Ongoing	Ongoing	• Number of interactions with different international counterparts as per internal tracking categories
5.2	Support EU and EU/MRA team meetings	• Reliance and supply chain integrity	Ongoing	Ongoing	• Number of meetings
6.1	Collaboration in the establishment of the African Medicines Agency (AMA)	• Capacity building through providing adequate guidance, and other support as needed as part of wider EU engagement strategy	Ongoing	Ongoing	• Delivery against programme to be agreed with EC and relevant stakeholders
6.2 (ECP2)	Full Implementation of the EU-DPR and monitoring of compliance	• 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 international data	2019	2025	• Full implementation achieved

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		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			

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, which improves 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 main drivers for 2022 are:

- COVID-19 - communication, stakeholder engagement and enhanced transparency measures to support the Agency's response to the pandemic will continue to be a priority in 2021. 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 a framework strategy for communication and engagement 2021-2025 that aims to establish optimised crisis-communication processes, leverage progress in digitalisation and review and adapt operations to ensure sustainability and responsiveness. Also, a strategy for the restart of clinical data publication, once BCP measures are lifted will be developed.
- 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 2022 for the Division is currently foreseen at 83 staff (53 TAs, 23 CAs, 1 SNEs). This figure is subject to constant revision to take into account staff movements (including part-time regime) and workload fluctuation.

Pillar 2 – Public health activities

Interactions with partners. In order 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 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 the 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 medicine's lifecycle	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
	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 in order 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 senior managers as needed	Relevant knowledge resources and communication-related services available at all times.
	Streamline the cross-Agency approach to scientific publications	Streamlined process for publications.
	Activities on coordinating and managing 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"
	Automating triaging and assigning requests for information or all access to documents from third parties through ACE tools	Increased efficiency of ATD, RFI and CDP.
	General coordination of Clinical data publication	Increased transparency by providing access to clinical documents supporting EMA decisions on CAPs for Covid-19 products

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

Specific activities:

Communication activities. The Agency's communication activities aim at supporting 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 for example press releases, infographics, videos distributed via a range of channels with its corporate website, ema.europa.eu, as the main channel. The role of EMA in the European and global response to the COVID-19 pandemic, increased awareness of the Agency's work and resulted in an unprecedented number of interview and information requests from European and international media. These include not only media outlets that are specialised on medicine regulation and development in the pharma industry but also high-reach media that target the general public such as news agencies and international print media. The Agency fosters productive relationships with the media, both general and specialist, through the provision of press materials, the organisation of media interviews and timely response to journalists' queries. To meet the massive information need from the media 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 in order to become aware at an early stage of dis- and misinformation and to take appropriate action. The Agency has 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 the information for EMA's publics is ensured
	Review of the Agency 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
	Manage and further develop EMA's social media activities	Expand outreach to broader targeted audience
	Review, update and maintain EMA's branding and corporate identity guideline	Promote visibility of corporate identity
	Social listening through media monitoring and social media monitoring	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 understand the way the Agency uses, governs and maintains all its websites for the benefit of their users
	Review and improve crisis communication processes	EMA's ability to communicate effectively during a crisis is reinforced

Workload indicators

		Results	**Expected results**	**Forecasts**
		2020	**2021**	**2022**
Stakeholder interaction	Number of cases of patient/consumer engagement in EMA (medicines-related) activities	594	600	650
	Number of cases of healthcare professionals' engagement in EMA (medicines-related) activities	127	200	200
	Number of messages circulated via 'Early Notification System'	612	1100	440
	Number of EMA communications pro-actively sent to stakeholders	178	200	175

		Results	Expected results	Forecasts
		2020	**2021**	**2022**
Communication activities	Number of EPAR summaries and EPAR summaries updates published	297	250	300
	Number of summaries of orphan designation published	154	120	120
Information and transparency	Access to documents, requests received	597	650	750
	Access to documents, documents released	904	1300	2,000
	Requests for information received	7,062	11,000	10,000
Communication activities	Number of documents published on EMA website	5,963	7,500	7,500
	Number of pages published and updated on EMA website	2,511	3,500	3,500
	Number of press releases and news items published	217	170	170
	Numbers of press briefings conducted	3	19	20
	Numbers of social media posts published	484	1,000	1200
	Completed requests for interviews and comments by media representatives	1,770	5,000	3,000
	Number of reports, brochures, leaflets laid out or printed, social media visuals	357	500	500

Performance indicators

		Results	**Expected results**	**Targets**
		2020	**2021**	**2022**
Stakeholders interactions	Satisfaction level of patient and consumer organisations	n/a[1]	90%	n/a[1]
	Satisfaction level of Healthcare Professionals organisations	n/a[21]	90%	n/a[1]
Information and transparency	Triage of incoming requests received via AskEMA within set timelines	n/a[3]	100%	100%
	Response to ATD within set timelines	90%	90%	90%
	Response to RFI within set timelines (for EMA)	82%	95%	95%
	Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	83%	80%	80%
Stakeholders interactions	Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"	78%	n/a[1]	80%
Communication activities	Average rating given to pages on corporate website during the year	3.4	3.4	3.5

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

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

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 to key public-health areas (e.g. vaccines) • Improve communications for patients, healthcare professionals and other stakeholders including HTAs and payers • Enhance professional outreach through scientific publications & conferences	• Delivery of communication campaigns on key topics, with focus on COVID-19	2020	2025	• Strategic plan for stakeholder engagement drafted • Consolidated EMA approach to scientific publications agreed • 3 Key facts documents on COVID-19 vaccines developed and published • By-weekly lines to take on COVID-19 vaccines • Timely response to open access requests • High-priority scientific publications coordinated and published

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe Start	Project timeframe End	Deliverables 2022
ePI pilot	This e-PI pilot project for human medicines (CAPs and NAPs) will provide the initial building blocks towards creation of electronic product information (summary of product characteristics, package leaflet and labelling) for EU medicines. Product	2022	2023	• Delivery and implementation of electronic Product Information (ePI) pilot

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
	information is currently only provided in PDF format			
European Medicines web portal	Providing a unified and harmonised web-portal giving access to information on medicinal products	2022	2023	• There are common elements with the Union Product Database project from the VMP-Reg programme supporting some of the future developments, as well interdependencies with SPM&S and e-PI projects

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 for the Network providing high-quality services and enabling a connected, interoperable medicines regulatory platform for partners and stakeholders.

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

- **Operational Excellence and Information Security** as the foundation 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 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 recognised quality standards.

- **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-in-class, standard technologies where possible. 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.

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.

- **Maximising customer success**: We aim to enable success of the European Medicines Agencies 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. We aspire to become a trusted partner for our stakeholders' information service needs and want to play an integral part in achieving EMAN'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.

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** build strategic client relationships and stimulate, shape and align business demand from partners and stakeholder groups for IT products and services. We ensure that the potential business value from those products and services is captured, optimised and recognised. We also make sure that business strategies fully leverage IT capabilities and that the portfolio of IT products and services enables business strategies. A key focus is to align requirements to common capabilities.
- **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.
- **Core Services** provide foundational infrastructure services and high-productivity collaboration tools to EMA staff and Network users. We provide services across both technology and data services, onboard and manage cloud services, and run the Agency's data management services for all core regulatory data.
- **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.
- **Telematics activities are undergoing transformation.** Telematic secretariat that looks after organising Telematics activities (i.e.: organising meetings, enabling communication between IT directors in NCAs, monitoring Telematics inbox, maintaining the Telematics website) will change the way this activity is reported in 2022. The Telematics governance is undergoing a very impactful agile transformation and soon, this activity will no longer be called Telematics.

The workforce available in 2022 for the Division is currently foreseen at 96 staff (74 TAs, 21 CAs, 1 SNE). This figure is subject to constant revision to take into account staff movements (including part-time regime) and workload fluctuation.

	Workload indicators	Results	Expected results	Forecasts
		2020	2021	2022
Telematics	Number of Telematics information services provided by EMA	25	26	28
	Number of ongoing Telematics IT projects where EMA is the delivery organisation	5	10	7
	Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	8	12	6

Performance indicators

		Results	Expected results	Targets
		2020	2021	2022
Telematics	Satisfaction of EMA internal and external users	92.8%	80%	80%
	Availability of Telematics/corporate IT systems and corporate website	98.2%	98%	98%

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
DREAM Replacement Agency Document: Management system end of lifecycle and need to be replaced	The objective is to replace the Agency Document Management System, which is at end of lifecycle with a modern, flexible, collaborative	2021	2023	• Develop the functional and technical design of the future solution • Plan the migration process
Data Centre 2.0	Impact assessment of moving the Agency data centre to a cloud system	2022	2023	• Plan and impact assessment on how to move to a cloud-based data centre solution

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
Security Awareness Integration of Critical Systems Identity Management PKI Infrastructure Data Sharing	Reinforce the Information security of the Agency IT systems	Q1 2022	2024	• Implementation of Security Awareness program • Multifactor Authentication on Critical Systems • Implement portal-based solution for data sharing • Implementation of Zero Trust architecture
External User Journey	Facilitate the external users to get access to Agency systems in a secure way	Q4 2021	2022	• Redesign the Agency's Identity and Access Management (IAM) platform to improve self-registration of external users
SPM&S Substances and products management services EU SRS	Implementation of ISO Identification of Medicinal Products standards to apply interoperability and consistency to the information shared across the regulatory authorities within the EU and internationally and hand over of the European Substance Registration System to the Agency I-DIV	2017	2024	• Art 57 migration • Product Management Services (PMS) Application Programming Interface • SIAMED & Art 57 integration/feedback loop • EU scientific substance information system (EU SRS) handover

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 and rules and regulations on finances, audit and accounting.

The key drivers for the annual work programme are:

- Supporting staff management and development and launching the competency framework to facilitate the performance management, including the appraisal process, and staff development, and act as a 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 the administrative processes, including the domains of 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, procurements 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.

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 maintain 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 offsite archives, as well as catering. The service contributes also to the environmental management activities.

Programme management: The Portfolio Office ensures the programmes and projects are 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 the programmes and projects in the Agency's portfolio are delivered in line with the strategy and meet customer expectations.

The workforce available in 2022 for the Division is currently foreseen at 155 staff (120 TAs, 34 CAs, 1 SNE). This figure is subject to constant revision to take into account staff movements (including part-time regime) and workload fluctuation.

Performance indicators/Forecast activity

		Results	**Expected results**	**Targets/ Forecast**
		2020	**2021**	**2022**
Human Resources	Posts on the Agency establishment plan filled	100%	99%	100%
	Total TA staff recruited against vacant posts	51	90	50
	Staff turnover rate (staff leaving against total no. of staff TA & CA)	4.81%	6%	7%
	Average time to run selection procedures from vacancy notice to establishment of reserve list	88% < 3 months	100%< 3 months	average < 3 months

		Results	Expected results	Targets/ Forecast
		2020	**2021**	**2022**
Planning and Monitoring	Revenue appropriations implemented	104.30%	97%	97%
	Expenditure appropriations implemented	98.83%	97%	95%
	Payments against appropriations carried over from year N-1	95.49%	97%	95%
	The maximum rate of carryover to year N+1, of total commitments within the title			
	Title 1	4.62%	1%	10%
	Title 2	20.71%	15%	20%
	Title 3	31%	25%	30%
Finance	Payments made within 30 days' time	96%	97%	98%
	Receivable overdue for more than 30 days (including provision for bad debts)	6%	6%	<10%

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	• Develop and implement a framework for integrated planning and monitoring activities	• Finalisation of the Human Medicines Division business processes and full implementation of the time & capacity model	2021	2022	• 100% of the processes mapped and covered
6.2	• Implement the revised human resource and talent management strategy (HR strategy)	• The HR strategy will consolidate practices into 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 Q4 2022	2021	2023	• The new strategy adopted. • The implementation plan delivered. • The prioritised activities for 2022 and 2023 implemented
6.2	• Implement the new competency management framework	• Implementing the competency framework (behavioural and technical competencies); revised role descriptions with embedded competency profiles and proficiency levels of competencies leading to higher effectiveness, contributing to job satisfaction and development opportunities • A number of other deliverables will be proposed for prioritisation under the Agile HR approach (e.g. career paths, career coaching, 360 evaluations), but	2020	2024	• The 2022 staff appraisal system applies the new competency framework • Prioritisation of further actions carried out

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		given the organisational capacity to uptake the new practices, the implementation is expected to extend over a number of years			
6.4	• The potential replacement of the human resource management and the financial systems taking into account the discontinuation of the support for the current system by vendors	• Gradual replacement of the financial and HR system in line with the future project plan.	2023 tbc	tbc	• Implementation of the project plan once confirmed
6.4	• Implement the Agency's new intranet and migrate or develop related content	• The new intranet implemented. Content is gradually rolled out taking into account the business capacity	2021	2022	• The new intranet launched and used by staff
6.4	• Further develop the procurement and contract management practices and implement the procurement tool	• The procurement and contract management process are further improved with the further developed vendor management and market research capabilities • A tool supporting procurement processes implemented	2020	2022	• The aforementioned policies revised • The procurement tool implemented
6.4	• Implement the revised risk management process	• The new process adopted and implemented • The tool facilitating risk management implemented	2021	2022	• The 2022 risk register delivered applying the revised process
6.2	• Implement the project governance in line with Agile development approach	• The Agile portfolio office implemented in line with the implementation of the Agile governance and taking into	2021	2022	• The portfolio office supports the Agile product development

MAWP Strategic Goal (EC policy/action)	Action	Expected result	Timeframe Start	Timeframe End	Performance indicator
		account lessons learned from the ongoing pilots			
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 the sustainability of the agency and the European Medicines Regulatory Network	2021	2022	• Implementation of the Fee Regulation following the mandatory deadlines
6.3	Improve efficiency of certain administrative processes	• The identified improvement in the accounts receivable and customer data management processes implemented	2021	2022	• The identified process improvements implemented
6.3	Implement the administrative aspects of the extended mandate	• The processes to manage procurement and payment processes in relation to the medical device expert panels are implemented	2022	2022	• The new processes are implemented

Pillar 3 – Programmes and projects

Admin transformation is a comprehensive change, which covers changes to processes, technology, organisation and ways of working in the areas of strategy and resource planning, workforce management, finance, travel and meetings management, process improvement and automation. The transformation is part of a multi annual journey of ensuring the delivery of state-of-the-art administrative services, which was started in 2018, and significantly slowed down during the relocation and pandemic emergencies.

This transformation encompasses a variety of programmes, projects, process improvement and enhancements, which are called change initiatives, and aim at providing a better service to the organisation and its staff members by modernising processes and tools which our organisation uses in staff management, finance and planning areas as well as promote an open culture and more agile ways of working.

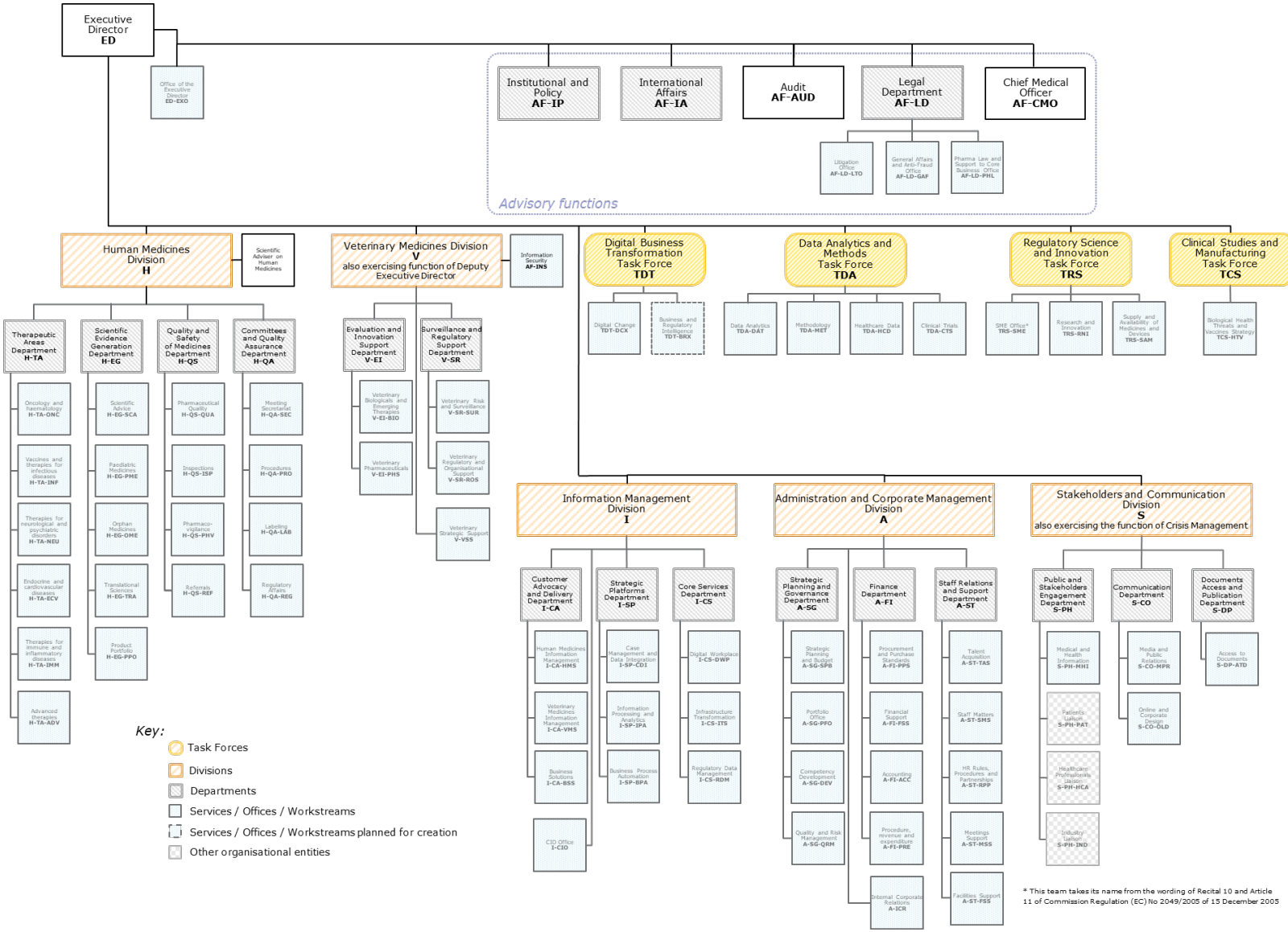
Significant improvements were introduced in the previous years and further needs are in the pipeline. However, taking into account resource constraints and associated challenges, the activities in 2022 will be limited to the completion of the already ongoing projects/initiatives, requirements of the new legislation and assessing the need to replace outdated system as outlined in the previous section.

Project title	Long term objective	Project timeframe		Deliverables 2022
		Start	End	
Optimisation of the Administration supporting tools	Providing modern digital tools to support administration processes, increasing efficiency of processes, staff (as customers) satisfaction with improved services and reducing manual work	2021	2024	• New fee regulation • Intranet • Risk Management • Procure2Pay • Onboarding V2.0
SAP Finance	Replacement of the Agency financial IT system due to its end of life	2021	2025	• Solution analysis and selection of replacement for SAP Finance

Annexes

Annex I: Organisation chart

(data as of 31/12/2021)



Annex II: Resource allocation per activity 2022

Activity Based Budget 2022

Work programme activities	STAFF (FTEs)		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		
Evaluation activities for human medicines	**269**	**106**	**58,837**	**21,297**	**6,104**	**136,043**	**6,619**	**228,900**	**55%**
Pre-authorisation activities	68	35	17,258	5,387	3,574	24,029	28	50,276	12%
Initial evaluation activities	59	15	11,725	3,505	681	17,031	1,525	34,468	8%
Post-authorisation activities	71	23	13,704	6,558	130	80,584	1,915	102,890	25%
Referrals	8	1	1,307	459	76	-	337	2,179	1%
Pharmacovigilance activities	37	23	8,594	3,196	1,133	14,399	2,805	30,126	7%
Other specialized areas and activities	27	10	6,249	2,192	510	-	9	8,960	2%
Evaluation activities for veterinary medicines	**31**	**18**	**7,517**	**10,861**	**1,528**	**6,504**	**603**	**27,013**	**6%**
Pre-authorisation activities	2	0	282	99	136	287	1	804	0%
Initial evaluation activities	8	2	1,371	491	351	2,441	294	4,948	1%
Post-authorisation activities	12	4	2,131	848	88	3,776	179	7,021	2%
Arbitrations and Referrals	0	1	159	66	108	-	122	455	0%
Pharmacovigilance activities	5	3	1,157	469	193	-	7	1,825	0%
Other specialized areas and activities	4	8	2,418	8,889	653	-	-	11,960	3%
Public health activities and other areas	**208**	**79**	**43,130**	**45,501**	**7,447**	**4,168**	**24,951**	**125,196**	**30%**
Committee coordination	46	15	8,270	12,980	2,401	-	14,000	37,651	9%
Inspection and Compliance	26	17	5,621	2,178	1,012	4,168	250	13,229	3%
Partners and Stakeholders	20	7	5,270	1,645	2,425	-	703	10,043	2%
Transparency and access to documents	19	11	4,173	1,826	-	-	-	5,999	1%
Information	39	16	7,745	7,165	685	-	299	15,893	4%
International activities	11	4	2,953	707	299	-	-	3,959	1%
Information Management (incl. EU Telematics)	48	10	9,099	18,999	624	-	9,700	38,422	9%
Corporate Governance and Support activities	**141**	**34**	**25,686**	**10,103**	**567**	**-**	**6**	**36,362**	**9%**
Governance, quality management and internal audit	21	8	5,117	1,482	567	-	-	7,166	2%
Finance	33	9	5,473	2,353	-	-	6	7,832	2%
Information technology	30	5	5,704	2,091	-	-	-	7,796	2%
Human resources	47	11	7,938	3,682	-	-	-	11,620	3%
Infrastructure services	10	0	1,453	496	-	-	-	1,949	0%
Total	**649**	**237**	**135,169**	**87,761**	**15,646**	**146,715**	**32,180**	**417,471**	**100%**

FTEs are calculated as follows:	FTEs
Temporary Agents	662
Estimated vacancy rate Temporary Agents (2%)	-13
Temporary Agents	649
Contract Agents (203 FTEs business as usual + 20 Brexit related)	223
Seconded National Experts	30
Estimated vacancy rate Contract Agents (6%)	-16
Contract Agents and Seconded National Experts	237
Total Staff	**886**

Annex III: Financial Resources 2022 - 2024

Table 1 – Revenue

General Revenues

Revenues	2021	2022	2023	2024
	Revenue estimated by the agency	Budget forecast	Budget forecast	Budget forecast
EU contribution	€ 55,448,000	€ 55,231,000	€ 50,145,000	€ 34,853,000
Other revenue	€ 330,471,000	€ 362,240,000	€ 373,979,000	€ 381,459,000
PROVISIONAL REVENUE				
Total revenue	**€ 385,919,000**	**€ 417,471,000**	**€ 424,124,000**	**€ 416,312,000**

REVENUES	General Revenues						
	Executed 2020[1]	Estimated by the agency 2021[2]	2022		VAR 2022/2021 (%)	Forecast 2023	Forecast 2024
			agency request	budget forecast			
1 Revenue from services rendered	€ 316,888,819	€ 341,638,052	€ 357,702,000	€ 357,702,000	4.70%	€ 373,800,000	€ 381,277,000
2 EU and EEA contribution	€ 58,880,754	€ 37,636,730	€ 55,231,000	€ 55,231,000	46.75%	€ 50,145,000	€ 34,853,000
- of which special contribution for orphan medicinal products	€ 11,374,395	€ 12,187,155	€ 14,378,000	€ 14,378,000	17.98%	€ 14,351,000	€ 14,378,000
- of which assigned revenues deriving from previous years' surpluses	€ 13,802,754	€ 0	€ 4,369,000	€ 4,369,000	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	€ 3,039	€ 65,000	€ 65,000	2039.02%	€ 75,000	€ 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	€ 4,369,000	€ 4,369,000	p.m.	p.m.	p.m.
9 Miscellaneous revenue	€ 476,450	€ 2,878,523	€ 104,000	€ 104,000	n/a	€ 104,000	€ 105,000
TOTAL REVENUES	**€ 376,246,023**	**€ 382,156,344**	**€ 417,471,000**	**€ 417,471,000**	9.24%	**€ 424,124,000**	**€ 416,312,000**

1) Data as per final accounts 2020

2) Data as per provisional 2021 accounts

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

REVENUES	2021	2022	2023	2024
	Budget forecast	Budget forecast	Budget forecast	Budget forecast
TOTAL REVENUES	€ 25,415	€ 1,500,000	€ 0	€ 0

REVENUES	General Revenues						
	Executed 2020[1]	Estimated by the agency[1] 2021	2022		VAR 2022/2021 (%)	Forecast 2023	Forecast 2024
			agency request	budget forecast			
ADDITIONAL EU FUNDING STEMMING FROM GRANTS (FFR Art.7)	€ 254,919	€ 25,415	€ 1,500,000	€ 1,500,000	5802.03%	p.m	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	€ 254,919	€ 25,415	€ 1,500,000	€ 1,500,000	5802%	€ 0	€ 0

1) Data as per final accounts 2020

2) Data as per provisional 2021 accounts

Table 2 – Expenditure

Expenditure	2020 [1]		2021 [2]		2022		2023		2024	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1 - Staff expenditure	€ 114,634,112	€ 114,634,112	€ 125,481,673	€ 125,481,673	€ 135,169,000	€ 135,169,000	€ 140,724,000	€ 140,724,000	€ 139,039,000	€ 139,039,000
Title 2 - Infrastracture and operating expenditure	€ 82,926,883	€ 82,926,883	€ 47,758,405	€ 47,758,405	€ 58,523,000	€ 58,523,000	€ 61,610,000	€ 61,610,000	€ 62,843,000	€ 62,843,000
Title 3 - Operational expenditure	€ 167,872,236	€ 167,872,236	€ 192,250,624	€ 192,250,624	€ 223,779,000	€ 223,779,000	€ 221,790,000	€ 221,790,000	€ 214,430,000	€ 214,430,000
Title 9 - Provisional appropriations			€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 365,433,232**	**€ 365,433,232**	**€ 365,490,701**	**€ 365,490,701**	**€ 417,471,000**	**€ 417,471,000**	**€ 424,124,000**	**€ 424,124,000**	**€ 416,312,000**	**€ 416,312,000**

1) Data as per final 2020 accounts

2) Data as per provisional 2021 accounts

Expenditure	2020			2021			2022			2023			2024		
	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	€ 66,991,315	€ 47,642,797	€ 114,634,112	€ 68,418,177	€ 57,063,495	€ 125,481,673	€ 67,921,506	€ 67,247,494	€ 135,169,000	€ 70,608,860	€ 70,115,140	€ 140,724,000	€ 69,763,404	€ 69,275,596	€ 139,039,000
Title 2 - Infrastracture and operating expenditure	€ 43,760,469	€ 39,166,414	€ 82,926,883	€ 26,712,450	€ 21,045,955	€ 47,758,405	€ 24,445,263	€ 34,077,737	€ 58,523,000	€ 27,729,081	€ 33,880,919	€ 61,610,000	€ 28,284,023	€ 34,558,977	€ 62,843,000
Title 3 - Operational expenditure	€ 152,581,955	€ 15,290,281	€ 167,872,236	€ 172,117,311	€ 20,133,312	€ 192,250,624	€ 170,001,857	€ 53,777,143	€ 223,779,000	€ 175,906,384	€ 45,883,616	€ 221,790,000	€ 170,069,011	€ 44,360,989	€ 214,430,000
Title 9 - Provisional appropriations	€ 0	€ 0	€ 0	€ 0		€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 263,333,739**	**€ 102,099,493**	**€ 365,433,232**	**€ 267,247,938**	**€ 98,242,762**	**€ 365,490,701**	**€ 262,368,626**	**€ 155,102,374**	**€ 417,471,000**	**€ 274,244,325**	**€ 149,879,675**	**€ 424,124,000**	**€ 268,116,438**	**€ 148,195,562**	**€ 416,312,000**
% of total expenditure	**72%**	**28%**	**100%**	**73%**	**27%**	**100%**	**63%**	**37%**	**100%**	**65%**	**35%**	**100%**	**64%**	**36%**	**100%**
* Full-time Equivalent	509	348	**857**	498	400	**898**	478	408	**886**	476	407	**883**	484	414	**898**
% of total FTEs	59%	41%	**100%**	55%	45%	**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 2020[1]	Estimated by the Agency, 2021[2]	Draft budget 2022		VAR 2022/2021 (%)	Forecast 2023	Forecast 2024
			Agency request	Budget forecast			
Title 1 - Staff Expenditure							
11 Staff holding a post provided for in the list of posts	104,979,006	106,812,414	€ 115,028,000	€ 115,028,000	7.69%	€ 123,036,000	€ 125,497,000
- of which establishment plan posts							
- of which external personnel							
12 Expenditure relating to staff recruitment	199,235	211,242	€ 300,000	€ 300,000	42.02%	€ 300,000	€ 306,000
13 Duty travel expenses and incidental expenditure	137,782	24,508	€ 650,000	€ 650,000	2552.16%	€ 850,000	€ 867,000
14 Socio-medical infrastructure	1,695,263	1,646,279	€ 2,385,000	€ 2,385,000	44.87%	€ 2,278,000	€ 2,324,000
15 Staff training	555,731	648,765	€ 1,090,000	€ 1,090,000	68.01%	€ 915,000	€ 933,000
16 External services	7,000,918	16,084,186	€ 15,571,000	€ 15,571,000	-3.19%	€ 13,190,000	€ 8,954,000
17 Receptions and events	66,176	54,279	€ 145,000	€ 145,000	167.14%	€ 155,000	€ 158,000
Total Title 1	**€ 114,634,112**	**€ 125,481,673**	**€ 135,169,000**	**€ 135,169,000**	7.72%	**€ 140,724,000**	**€ 139,039,000**
Title 2 - Infrastructure and operating expenditure							
20 Investment in immovable property, renting of buildings and associated costs	41,541,362	14,813,190	€ 15,694,000	€ 15,694,000	5.95%	€ 15,505,000	€ 15,815,000
21 Corporate information and communication technology	32,334,229	26,268,794	€ 32,858,000	€ 32,858,000	25.08%	€ 36,339,000	€ 37,066,000
22 Movable property and associated costs	1,221,641	588,233	€ 632,000	€ 632,000	7.44%	€ 640,000	€ 653,000
23 Current administrative expenditure	886,940	1,025,312	€ 1,674,000	€ 1,674,000	63.27%	€ 1,796,000	€ 1,832,000
24 Postal and delivery services	35,404	31,098	€ 56,000	€ 56,000	80.08%	€ 57,000	€ 58,000
25 Other meetings	269,686	342,248	€ 320,000	€ 320,000	-6.50%	€ 325,000	€ 332,000
26 Restaurant and catering	1,703,201	601,622	€ 1,288,000	€ 1,288,000	114.09%	€ 1,306,000	€ 1,332,000
27 Information and publishing	1,240,950	2,027,511	€ 2,510,000	€ 2,510,000	23.80%	€ 2,898,000	€ 2,956,000
28 Business consultancy and audit services	3,693,470	2,060,396	€ 3,491,000	€ 3,491,000	69.43%	€ 2,744,000	€ 2,799,000
Total Title 2	**€ 82,926,883**	**47,758,405**	**€ 58,523,000**	**€ 58,523,000**	**22.54%**	**€ 61,610,000**	**€ 62,843,000**
Title 3 - Operational expenditure							
300 Meetings	1,309,092	143,394	€ 6,174,000	€ 6,174,000	4205.61%	€ 8,549,000	€ 8,720,000
301 Evaluation of medicinal products	133,570,796	143,175,359	€ 146,715,000	€ 146,715,000	2.47%	€ 150,001,000	€ 153,001,000
302 Translations	5,046,746	4,772,548	€ 5,480,000	€ 5,480,000	14.82%	€ 5,117,000	€ 5,219,000
303 Scientific studies and services	7,490,376	14,706,874	€ 26,700,000	€ 26,700,000	81.55%	€ 22,550,000	€ 17,001,000
31 Expenditure on business related IT projects	20,455,227	29,452,448	€ 38,710,000	€ 38,710,000	31.43%	€ 35,573,000	€ 30,489,000
Total Title 3	**€ 167,872,236**	**192,250,624**	**€ 223,779,000**	**€ 223,779,000**	**16.40%**	**€ 221,790,000**	**€ 214,430,000**
900 Provisional appropriations	€ 0	0	€ 0	€ 0	0.00%	€ 0	€ 0
Total Title 9	**€ 0**	**0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**
TOTAL EXPENDITURE	**€ 365,433,232**	**365,490,701**	**€ 417,471,000**	**€ 417,471,000**	**14.22%**	**€ 424,124,000**	**€ 416,312,000**

1) Data as per final accounts 2020

2) Data as per provisional 2021 accounts

EXPENDITURE	Payment appropriations						
	Executed budget 2020[1]	Estimated by the Agency, 2021[2]	Draft budget 2022		VAR 2022/2021 (%)	Forecast 2023	Forecast 2024
			Agency request	Budget forecast			
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- of which external personnel							
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13 Duty travel expenses and incidental expenditure	137,782	24,508	€ 650,000	€ 650,000	2552.16%	€ 850,000	€ 867,000
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15 Staff training	555,731	648,765	€ 1,090,000	€ 1,090,000	68.01%	€ 915,000	€ 933,000
16 External services	7,000,918	16,084,186	€ 15,571,000	€ 15,571,000	-3.19%	€ 13,190,000	€ 8,954,000
17 Receptions and events	66,176	54,279	€ 145,000	€ 145,000	167.14%	€ 155,000	€ 158,000
Total Title 1	**€ 114,634,112**	**€ 125,481,673**	**€ 135,169,000**	**€ 135,169,000**	7.72%	**€ 140,724,000**	**€ 139,039,000**
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22 Movable property and associated costs	1,221,641	588,233	€ 632,000	€ 632,000	7.44%	€ 640,000	€ 653,000
23 Current administrative expenditure	886,940	1,025,312	€ 1,674,000	€ 1,674,000	63.27%	€ 1,796,000	€ 1,832,000
24 Postal and delivery services	35,404	31,098	€ 56,000	€ 56,000	80.08%	€ 57,000	€ 58,000
25 Other meetings	269,686	342,248	€ 320,000	€ 320,000	-6.50%	€ 325,000	€ 332,000
26 Restaurant and catering	1,703,201	601,622	€ 1,288,000	€ 1,288,000	114.09%	€ 1,306,000	€ 1,332,000
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28 Business consultancy and audit services	3,693,470	2,060,396	€ 3,491,000	€ 3,491,000	69.43%	€ 2,744,000	€ 2,799,000
Total Title 2	**€ 82,926,883**	**47,758,405**	**€ 58,523,000**	**€ 58,523,000**	**22.54%**	**€ 61,610,000**	**€ 62,843,000**
Title 3 - Operational expenditure							
300 Meetings	1,309,092	143,394	€ 6,174,000	€ 6,174,000	4205.61%	€ 8,549,000	€ 8,720,000
301 Evaluation of medicinal products	133,570,796	143,175,359	€ 146,715,000	€ 146,715,000	2.47%	€ 150,001,000	€ 153,001,000
302 Translations	5,046,746	4,772,548	€ 5,480,000	€ 5,480,000	14.82%	€ 5,117,000	€ 5,219,000
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31 Expenditure on business related IT projects	20,455,227	29,452,448	€ 38,710,000	€ 38,710,000	31.43%	€ 35,573,000	€ 30,489,000
Total Title 3	**€ 167,872,236**	**192,250,624**	**€ 223,779,000**	**€ 223,779,000**	**16.40%**	**€ 221,790,000**	**€ 214,430,000**
900 Provisional appropriations	€ 0	0	€ 0	€ 0	0.00%	€ 0	€ 0
Total Title 9	**€ 0**	**0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**	**€ 0**
TOTAL EXPENDITURE	**€ 365,433,232**	**365,490,701**	**€ 417,471,000**	**€ 417,471,000**	**14.22%**	**€ 424,124,000**	**€ 416,312,000**

1) Data as per final accounts 2020

2) Data as per provisional 2021 accounts

Table 3 –Budget outturn and cancellation of appropriations 2017-2020

Budget outturn	2017	2018	2019	2020[1)]
Revenue actually received (+)	€ 317,360,425.30	€ 317,081,125.07	€ 339,889,499.26	€ 376,246,022.54
Payments made (-)	-€ 253,807,515.04	-€ 253,281,077.77	-€ 292,769,994.74	-€ 290,132,295.87
Carry-over of appropriations (-)	-€ 54,017,070.70	-€ 54,821,802.27	-€ 59,150,354.42	-€ 75,300,936.06
Cancellation of appropriations carried over (+)	€ 4,350,907.86	€ 4,982,084.89	€ 2,744,268.82	€ 2,423,908.71
Adjustment for carry over of assigned revenue appropriations from previous year (+)	€ 0.00	€ 0.00	€ 0.00	€ 0.00
Exchange rate differences (+/-)	€ 581,555.58	-€ 159,476.48	€ 1,003,466.80	-€ 585,264.08
Adjustment for negative balance from previous year (-)	€ 0.00	€ 0.00	€ 0.00	-€ 8,283,114.28
Total	**€ 14,468,303.00**	**€ 13,800,853.44**	**-€ 8,283,114.28**	**€ 4,368,320.96**

1) Data as per final 2020 accounts

The financial outturn for 2021, a surplus of approx. EUR 25.0 million, representing 6.13% of total revenue collected, i.e. EUR 407.6 million, cf. the draft budget outturn for all fund sources (C1, C11, R0 and CL), was caused by higher income from fees, exchange rate gains, and unused and cancelled expenditure 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 3.19% lower than final appropriations, which is considered a good result;

Title II, infrastructure and operating expenditure

- final expenditure was 11.91% lower than final appropriations, with surpluses resulting from changes made to project plans, , legal costs not incurred and some savings from the the effects of the COVID-19 pandemic;

Title III, operational expenditure

- final expenditure was 1.61% lower than final appropriations, with main surpluses stemming from lower commitments for rapporteurs (driven by types of scientific applications submitted) and lower expenditure on scientific studies (demand driven, so difficult to predict).

The agency managed to comply broadly with the ceilings/KPIs for the amounts carried forward (C1 to C8): title I (10%), title II (20%) and title III (30%), with the following percentages achieved for the automatic carry-forward: title I: 5.75%, title II: 24.31%, title III: 37.59%. Higher amounts related to IT, scientific studies and data management contributed to higher carry-forward on titles II and III.

Annex IV: Human Resources - Quantitative

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

- A Statutory staff and SNE

Staff	Year 2020			2021			2022	2023	2024	2025
ESTABLISHMENT PLAN POSTS	**Authorised Budget**	**Actually filled as of 31/12/2020**	**Occupancy rate %**	**Authorised Budget**	**Actually filled as of 31/12/2021**	**Occupancy rate %**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**
Administrators (AD)	395	395	100.0%	472	459	97%	477	497	510	521
Assistants (AST)	201	201	100.0%	185	185	100%	185	185	187	187
Assistants/Secretaries (AST/SC)	0	0	N/a	0	0	0%	0	0	0	0
TOTAL ESTABLISHMENT PLAN POSTS	**596**	**596**	**100.0%**	**657**	**644**	**98%**	**662**	**682**	**697**	**708**
EXTERNAL STAFF	**FTE corresponding to the authorised budget**	**Executed FTE as of 31/12/2020[1]**	**Execution Rate %**	**FTE corresponding to the authorised budget**	**Executed FTE as of 31/12/2021[1]**	**Execution Rate %**	**FTE corresponding to the authorised budget**	**Envisaged FTE**	**Envisaged FTE**	**Envisaged FTE**
Contract Agents (CA)	228	199	87.2%	226	205	91%	223	203	203	203
Seconded National Experts (SNE)	30	28	93.2%	30	26	87%	30	30	30	30
TOTAL EXTERNAL STAFF	258	227	87.9%	256	231	90%	253	233	233	233
TOTAL STAFF	**854**	**823**	**96.4%**	**913**	**875**	**96%**	**915**	**915**	**930**	**941**

1) 117 CAs finances by fees, 81,7 by EU contribution, 0,3 by grants.

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

Human Resources	2021	2022	2023	2024
	Envisaged FTE	**Envisaged FTE**	**Envisaged FTE**	**Envisaged FTE**
Contract Agents (CA)	1.41	1.01	1.01	1.01
Seconded National Experts (SNE)				
TOTAL	1.41	1.01	1.01	1.01

- C. Other Human Resources

- Structural service providers

	Actually in place as of 31/12/2020
Security	20
IT service desk	16
IT maintenance and support 'time&means' contracts only	22
Reception[1]	8
Building maintenance[2]	0
Cleaning	15
Catering	16
Reprographics and mail services	4

1) Security 24/7 service

2) Building maintenance: included in the rental package

- Interim workers

	Total FTEs in year 2020
Number	23

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

Function group and grade	2020				2021				2022		2023		2024		2025	
	Authorised budget		Actually filled as of 31/12/2020		Authorised budget		Actually filled as of 31/12/2021		Authorised budget		Envisaged		Envisaged		Envisaged	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16		0		0		0		0		0		0		0		0
AD 15		3		3		3		2		3		3		3		3
AD 14		8		8		9		9		10		12		14		16
AD 13		12		12		13		11		13		12		11		10
AD 12		44		44		45		42		50		57		64		71
AD 11		47		47		51		49		52		49		46		43
AD 10		44		44		51		47		50		53		56		59
AD 9		46		46		55		54		62		66		70		74
AD 8		66		66		71		71		77		87		96		104
AD 7		76		76		94		94		97		89		81		73
AD 6		46		46		65		65		60		67		68		68
AD 5		3		3		15		15		3		2		1		0
AD TOTAL	**0**	**395**	**0**	**395**	**0**	**472**		**459**	**0**	**477**	**0**	**497**	**0**	**510**	**0**	**521**
AST 11		2		2		2		2		2		2		2		2
AST 10		7		7		7		7		7		7		7		7
AST 9		8		8		9		9		10		10		10		10
AST 8		19		19		10		10		13		14		15		16
AST 7		15		15		19		19		19		25		31		50
AST 6		15		15		20		20		26		31		49		41
AST 5		39		39		38		38		43		43		30		30
AST 4		52		52		46		46		42		43		31		19
AST 3		44		44		32		32		23		10		12		12
AST 2		0		0		2		2		0		0		0		0
AST 1		0		0		0		0		0		0		0		0
AST TOTAL	**0**	**201**	**0**	**201**	**0**	**185**		**185**	**0**	**185**	**0**	**185**	**0**	**187**	**0**	**187**
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**	**0**
GRAND TOTAL	**0**	**596**	**0**	**596**	**0**	**657**		**644**	**0**	**662**	**0**	**682**	**0**	**697**	**0**	**708**

The medicine industry is developing a high number of products in reaction to the COVID-19 pandemic. The European Medicines Agency (EMA) will have to evaluate and authorise the medicines and vaccines currently under development, which are proposed to be brought to the market. This creates a temporary peak in EMA's scientific work as well as its coordinating role. A two-year temporary staff reinforcement of 40 temporary agents is thus warranted as of 2021. The financial impact will be covered through other revenue (fees and charges) and will not have an impact on the Union contribution

External Personnel

Contract agents

Contract agents	FTE corresponding to the authorised budget 2020	Executed FTE as of 31/12/2020	Headcount as of 31/12/2020	FTE corresponding to the authorised budget 2021	Executed FTE as of 31/12/2021	Headcount as of 31/12/2021[2]	FTE corresponding to the authorised budget 2022	FTE corresponding to the authorised budget 2023	FTE corresponding to the authorised budget 2024	FTE corresponding to the authorised budget 2025
Function Group IV	52	78	76	110	89	90	122	122	122	122
Function Group III	131	62	62	81	72	94	81	81	81	81
Function Group II	10	28	26	10	18	0	0	0	0	0
Function Group I	0	0	0	0	0	0	0	0	0	0
Additional CA[1]	35	31	33	25	21	22	20	0	0	0
TOTAL	**228**	**199**	**197**	**226**	**200**	**206**	**223**	**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 2020	Executed FTE as of 31/12/2020	Headcount as of 31/12/2020	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	FTE corresponding to the authorised budget 2023	FTE corresponding to the authorised budget 2024	FTE corresponding to the authorised budget 2025
Total	30	28	31	30	26	28	30	30	30	30

Table 3 – Recruitment forecasts 2022 (N+1) following retirement/mobility or new requested posts

Job title in the Agency	Type of contract (Official, TA or CA)		TA/Official		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)	
Scientific Specialist		Extended mandate	AD06-AD08	AD06	
Scientific Officer		Extended mandate			FGIV
Budget Specialist	Retirement		AD06	AD06	
Head of Workstream	Retirement		AD06 and above	AD08	
Scientific Specialist	Retirement		AD06	AD06	
Medical Devices Senior Specialist		Extended Mandate	AD08 – AD10	AD08	

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

EMA recruited three staff members through the inter-agency mobility in 2021.

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							
	2017	2018	2019	2020	2021	2022 [1]	Actual average over 5 years	Average over 5 years (According to decision C(2015)9563)
AD05	5.39	2.29	4.23	2.27	2.21		4.1	2.8
AD06	3.46	3.34	4.96	3.47	2.81		3.7	2.8
AD07	4.14	3.05	3.61	4.37	4.81		4	2.8
AD08	4.59	3.52	4	4.96	3.25		4	3
AD09	5.31	4.55	5.09	5	4.62		4.9	4
AD10	5.37	5.43	2.97	4.71	5.2		4.9	4
AD11	8	5.62	3	6.33	8		6.6	4
AD12	5.97	7.2	7.1	10	2.84		6.8	6.7
AD13	6.22	6.55		6	9.5		7.6	6.7
AST1	4.73	5.45	5.24				5.2	3
AST2	4.13	3.61	5.43	3	4.28		4.1	3
AST3	3.8	3.36	3.41	4.73	3.89		3.8	3
AST4	4.3	3.24	5.43	3.33	4.91		4.1	3
AST5		3.97	5.66	4	5.2		4.5	4
AST6	3.89	4.55	7	7.75	5.14		5.6	4
AST7	5.33	5.54	4.5	7.5	11		6.8	4
AST8	4	0	2	5	0		3.8	4
AST9	0	0	0	6.83	0		6.83	N/A
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 2022								

Table 2 -Reclassification of contract staff

Function Group	Grade	Staff in activity at 1.01.2019	How many staff members were reclassified in 2020	Average number of years in grade of reclassified staff members 2020	How many staff members were reclassified in 2021	Average number of years in grade of reclassified staff members 2021	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	6	1	2.16	3	2.35	Between 5 and 7 years
	15	21	1	3	4	3	Between 4 and 6 years
	14	28	4	3.37	5	2.73	Between 3 and 5 years
	13	11	3	2.29	3	3.74	Between 3 and 5 years
CA III	11	0	0	0	0	0	Between 6 and 10 years
	10	9	0	0	4	2.5	Between 5 and 7 years
	9	32	2	2	6	2.63	Between 4 and 6 years
	8	9	1	2	3	2.54	Between 3 and 5 years
CA II	6	19	3	3.33	0	0	Between 6 and 10 years
	5	26	10	3.24	1	3.29	Between 5 and 7 years
	4	4	1	6.21	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 31/12/2020 statutory staff (only officials, AT and AC)

		2020							
		Official		Temporary		Contract Agents		Grand Total	
		Staff	%	Staff	%	Staff	%	Staff	%
Female	Administrator level	0	N/a	182	30%	70	36%	252	31%
	Assistant level (AST & AST/SC)	0	N/a	203	34%	81	41%	284	35%
	Total	**0**	**0**	**385**	**64%**	**151**	**77%**	**536**	**67%**
Male	Administrator level	0	N/a	187	31%	24	12%	211	26%
	Assistant level (AST & AST/SC)	0	N/a	33	5%	22	11%	55	7%
	Total	**0**	**0**	**220**	**36%**	**46**	**23%**	**266**	**33%**
Grand Total		**0**	**0**	**605**	**100%**	**197**	**100%**	**802**	**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

	2016		2020	
	Number	%	Number	%
Female Managers	**14**	**47%**	**10**	**38%**
Male Managers	**16**	**53%**	**16**	**62%**

D. Geographical balance

Table 1 - Data on 31/12/2020 - statutory staff only (officials, AT and AC)

Nationality	2020					
	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	6	1%	4	1%	10	1%
Belgium	20	4%	2	1%	22	3%
Bulgaria	9	2%	13	4%	22	3%
Croatia	6	1%	1	0%	7	1%
Cyprus	0	0%	2	1%	2	0%
Czech Republic	2	0%	16	5%	18	2%
Denmark	6	1%	5	1%	11	1%
Estonia	2	0%	7	2%	9	1%
Finland	4	1%	5	1%	9	1%
France	64	14%	28	8%	92	11%
Germany	35	8%	20	6%	55	7%
Greece	36	8%	19	6%	55	7%
Hungary	11	2%	15	4%	26	3%
Ireland	17	4%	3	1%	20	2%
Italy	63	14%	40	12%	103	13%
Latvia	3	1%	6	2%	9	1%
Lithuania	4	1%	12	4%	16	2%
Luxembourg	0	0%	0	0%	0	0%
Malta	0	0%	0	0%	0	0%
Netherlands	8	2%	4	1%	12	1%
Norway	1	0%	1	0%	2	0%
Poland	13	3%	36	11%	49	6%
Portugal	27	6%	13	4%	40	5%
Romania	18	4%	12	4%	30	4%
Slovakia	5	1%	17	5%	22	3%
Slovenia	1	0%	1	0%	2	0%
Spain	65	14%	36	11%	101	13%
Sweden	6	1%	6	2%	12	1%
United Kingdom	31	7%	15	4%	46	6%
Other	0	0%	0	0%	0	0%
TOTAL	463	100%	339	100%	802	100%

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

Most represented nationality	2016		2020	
	Number	%	Number	%
Italian	91	12.5%	103	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: Environment management

EMA's environmental management activities were reinitiated in January 2021 in line with the Agency's Environmental Policy[24], Environmental Roadmap 2020 to 2024 and the updated mandate for the EMA Green Group.

The EMA Environmental Management System (EMS) manual was updated and subject to external review by procured environmental consultants during the second half of 2021 in preparation for performing an internal audit of EMA's EMS in 2022 as the next step towards obtaining the EU Eco-Management and Audit Scheme (EMAS) registration, targeted to be in place within the environmental roadmap period 2020 to 2024.

As part of the review of EMA's EMS the Agency is changing the method used to calculating its carbon footprint from DEFRA[25] to using the Greenhouse Gas (GHG) protocol[26], scope 1, 2 and 3.

Based on the updated method the emissions from the Agency's activities in the following areas will continue to be monitored in 2022:

Scope 1: Direct emissions

- Fugitive emissions from air-conditioning
- Fugitive emissions from water consumption

Scope 2: Indirect emissions

- Purchased electricity
- Purchased heat and steam

Scope 3: Upstream activities (activities in italics to be considered for future monitoring)

- Purchased goods and services
- Waste generated in operations
- Business travel
- Employee commuting.

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.

For the preparation of objectives, targets and actions for 2022 improvements in procured services, receipt of more granular data from emissions and other operational improvements serve as a foundation.

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 life cycle 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.

[24] POLICY 78: Environmental Policy (europa.eu)
[25] UK Department for Environment, Food and Rural Affairs environmental data platform
[26] Greenhouse Gas Protocol – global standard widely used for greenhouse gas accounting and reporting

To support reaching the long-term targets, the following applies:

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 achieved. Actions targeted to directly support the objective	Replacement scheme of IT equipment such as lap-tops and small electricity for further energy efficiency
	Material efficiency: "EMA drives material efficiency in line with good practices"	Monitor the consumption of materials used (paper, plastic) to reduce or maintain levels during the pandemic	Promote reduced use of single-use materials along "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	Reduce non-recyclable waste along "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 short haul travel and the ratio of air versus train travel Measure emissions from commuting and purchased goods & services with high environmental impact
Indirect	Environmental effects of medicines for human and veterinary use (ERA)	As included in the single programming document (SPD) 2022-2025 with an objective to update Environmental Risk Assessments (ERA) in line with the latest scientific knowledge with a target to reach a harmonised approach on ERA	Actions as included in the SPD 2022-2025 to provide scientific support to the European Commission and the EU network to ensure that an adequate Environmental Risk Assessment for medicines, in line with the "One Health" approach is applied to ERA

Overarching actions include:

- Further introduce green criteria in the Agency procurements during 2022 in line with the prepared EMA 0061-2021 Internal guidance on Green Public Procurement
- Introduce the option for offsetting the carbon footprint with emissions certificate in the highest impacting goods and services procured during 2022
- Perform an internal environmental audit of the whole EMA EMS.

For 2022 a number of key performance indicators are set to support the monitoring of the identified environmental objectives, targets and actions.

Key Performance indicators	2020 outcome	2021 expected	2022 forecast
Number of contracts with Green criteria/Green helpdesk involvement	2	2	3
Include option for offsetting carbon emissions in procured contracts	0	0	1
Monitor the rate of non-recyclable waste out of total waste with a target to reduce	36%	45%	45%
Monitor the share of short haul air travel with a target to reduce for the benefit of train travel where possible	10.83% (out of total travel) 98,5% (out of short haul travel	N/A*	10% (/total travel) 91% (/short haul travel)
Monitor the share of train travel as part of total travel with a target to increase	0,17% (out of total travel) 1,5% (out of short haul travel)	N/A*	1% (/total travel 9% (/short haul travel)
Monitor virtual participation in meetings, trainings and other business activities for the reduction of carbon emissions	75%**	98.5%**	TBD**
Total Tonnes CO2 emissions	809	349	TBD**

* due to the Covid-19 pandemic very limited amounts of travel took place in 2021

** the outcome of virtual meetings is a result of specific measures made during the Covid-19 pandemic. Expected outcome 2021 values are based on the assumption that virtual meetings will remain throughout the year due to the Covid-19 pandemic. The forecast values for 2022 are based on a pilot with scientific meetings resuming with 50% performed face-to-face and 50% virtual meetings once the pandemic situation so allows, after which a decision will be made for the long term plan with consideration to the updated rules of procedure of each committee27. The forecast of total share of virtual meetings and as a result, emissions from travel may be confirmed once these decisions are in place.

The EMA will continue to track and monitor the consumption and carbon footprint from occupying the premises at Domenico Scarlattilaan 6 in Amsterdam Zuidas as well as the carbon emissions from delegate and staff travel as performance indicators with the following forecast for 2022:

Performance indicator	2020 outcome	2021 expected*	2022 forecast*
Energy, kW	1.131.079	1.748.233	2.160.000
Renewable energy, % (carbon neutral)	100%	100%	100%
Water, M3	3.955	3.366	4.500
Office paper consumption, n sheets	906.046	872.446	1.744.892
Waste total, kg	69.035	55.777	111.556
- paper, kg	13.165	7.706	15.412
- plastic, kg	1.044	1.289	2.579
- glass, kg	1.554	1.037	2.075
- food, kg	26.875	18.639	37.278
- confidential (paper), kg	1.690	1.730	3.461

[27] Rules of procedure of EMA's scientific committees and management board, to allow for virtual meetings also during non-emergency situations

- non-recyclable, kg	24.707	25.376	50.751
Purchased heat and steam	5.263	6.000	7.050
TCO2e from building	283,4	327,1	438
TCO2e from travel	525,7	22,3**	TBD***
TCO2e total	809,1	349,3	TBD***

* The expected outcome 2021 and forecast 2022 for building consumption is based on an average daily occupancy of 450 people in Q4, 2021 and throughout 2022

** The expected carbon emissions from travel in 2021 is a result of the Covid-19 pandemic with very little travelling taking place and meetings being conducted virtually

*** The carbon emissions from travel for the forecast 2022 will be based on the result from a pilot with resumed scientific committee meetings with 50% performed face-to-face and 50% virtual meetings after which a long-term plan will be made. On average for the years 2012 to 2017 the CO2 from delegate travel was 2452 Tonnes annually based on an average of 7.773 delegates.

The EMA building has a net lettable area of 33,100 Sqm and 1300 workstations.

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	10,721,000	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	10,721,100					

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 motor cycles; 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

According to Article 86 of the Regulation (EC) No 726/2004: "At least every ten years, the Commission shall publish a general report on the experience acquired as a result of the operation of the procedures laid down in this Regulation,[and] in Chapter 4 of Title III of Directive 2001/83/EC […]." In addition, according to Article 38(2) of the Directive 2001/83/EC: "At least every ten years the Commission shall publish a report on the experience acquired on the basis of the procedures described in this Chapter [Chapter 4 of Title III] and shall propose any amendments which may be necessary to improve those procedures. The Commission shall submit this report to the European Parliament and to the Council." 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.

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.

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 and paediatric regulations. This revision addresses shortcomings identified in a recent evaluation whose results were published by the European Commission on 11 August 2020.

Revision of rules on fees payable to the European Medicines Agency

Based on the outcome of the evaluation of the EMA fee system finalised in 2019, in 2020 the European Commission started to prepare to update the legal framework on EMA fees. The impact assessment of future policy options to update the legal framework on fees is in progress and the European Commission legal proposal for the revised EMA's fees regulation is planned for mid-2022.

Project and programme evaluations

The EMA Financial Regulation and Implementing Rules establish the requirement for ex ante and retrospective evaluations for programmes, projects and activities. By applying the safeguards foreseen in the EMA programme and project governance and gated procedure, the EMA has adopted a proportionate approach to evaluations and avoided burdening the system with additional levels of evaluation, control and reporting.

Project oversight is the responsibility of two Agency boards: the Executive Board (EXB) and the Portfolio Board (PB). The PB is responsible for approving projects throughout the stages in their

lifecycle. In exceptional circumstances, as defined in the PB's terms of reference, the PB may refer approvals or other project issues to the EXB for resolution.

The project procedure foresees approval of a project idea at Gate 1, approval of a preliminary business case at Gate 2 prior to the start of a project, approval of a final business case at Gate 3, and finally approval of project closure. An approval at Gate 4, which is optional, has been introduced as a check of business readiness prior to closure, primarily for larger projects, particularly those delivering complex IT solutions.

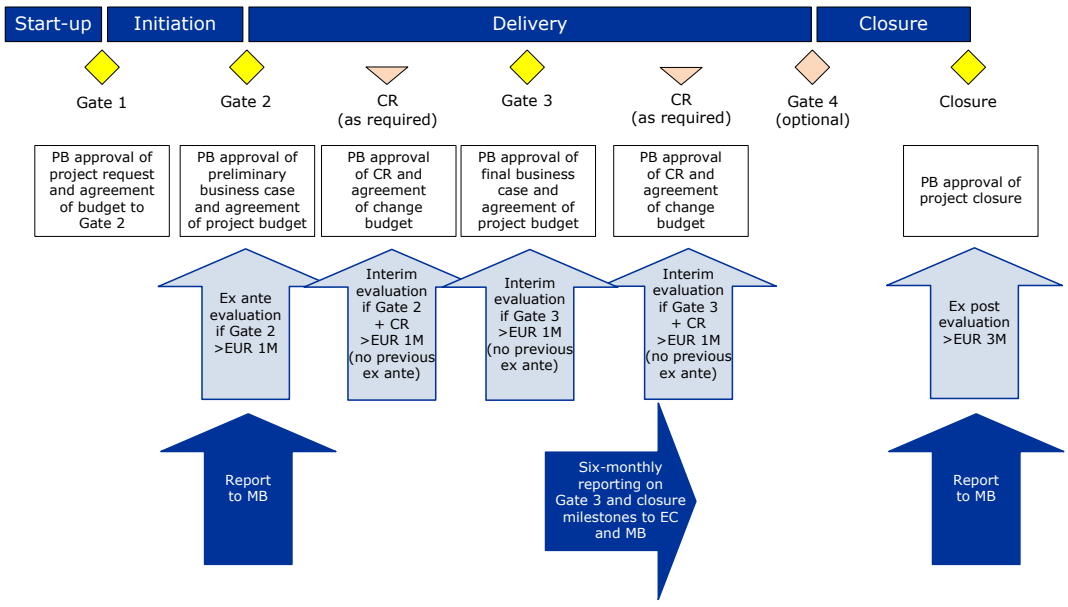
Ex ante evaluations are conducted at Gate 2 of the project procedure on the basis of the preliminary business cases (including cost estimates), before projects and budget expenditure are formally initiated. When the total project costs estimated at Gate 2 exceed EUR 1 million, the evaluation is conducted by the PB against the criteria laid down in Article 11(1) of the Implementing rules. The follow-up actions, i.e. Gate 3 and project closure planned milestones, are identified.

Retrospective evaluations are conducted at project closure when a project is being formally closed. When actual costs at project closure exceed EUR 3 million, the evaluation is conducted by the PB against the criteria laid down in Article 11(3) of the Implementing rules.

Interim evaluations are conducted in regular project reporting to the PB and EXB where the status of projects is reviewed and in more detail at Gate 3 when the final business case is assessed and approved. Modifications to project scope, timelines and budget are evaluated and controlled by way of project change requests that are subject to PB approval. Whenever the initial cost estimate at Gate 2 does not exceed EUR 1 million but is later exceeded at Gate 3, or as a result of a project change request, the PB conducts an interim evaluation against the criteria laid down in Article 11(1) of the Implementing rules.

The results of ex ante and retrospective evaluations for projects that exceed the cost thresholds are sent to the Management Board in a six-monthly overview, with annexed business cases and closure reports. Follow-up actions to ex ante evaluations are reported twice a year to the Commission and regularly to the Management Board. Therefore, the status of Gate 3 and project closure milestones is reported in the six-monthly overview.

Project oversight and evaluations:



Annex X: Strategy for the organisational management and internal control system[28]

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

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

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

Internal controls are aimed toward achievement of several objectives:

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

EMA internal control framework is based on the COSO[29] 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 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 operations; Internal Control Coordinator and IQM and planning coordinators across the Agency, that help to coordinate internal control activities throughout the organisation; and

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

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

In order 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, taking into account risks to the achievement of objectives and reducing them to acceptable levels through cost-effective controls.

Components

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

- **Internal control framework** (ICF) is the umbrella for all the 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, so as to prevent errors and irregularities before the authorization 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 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 organization such as mismanagement, corruption, fraud, without jeopardizing 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 adopted by the EMA Management Board in March 2017.
- **Conflict of interest**: in order 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 EMA Management Board, scientific committee members and experts, EMA staff and candidates, as well as consultants and contractors.
- **Data protection**: in order to fulfil its tasks and mission, the Agency handles on a daily basis 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[30]					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	Prioritisation and Risk Evaluation of	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

[30] For ongoing agreements, please provide the requested general information. For expected agreements, please provide the information available. When the information is not known, put "not known".

				Initiative 2 Joint Undertaking	Medicines in the EnviRonment	Number of SNEs/FTE	0	0	0	0	0
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 Analyzing Patient-Reported Outcomes and Quality of Life endpoints	Amount	18,000	18,000	18,000	18,000	18,000
						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	36 months as of 01/01/2020	European Union	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	Tbc /2021	EUR 1.5 million	Tbc / 24 months as of 01/01/2022	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
Total contribution agreements						Amount	0	835,000	835,000	84,919	-
						Number of Cas/FTE	tbc	tbc	tbc	tbc	-
						Number of SNEs/FTE	0	0	0	0	0
Service-level agreements											
						Amount	-	-	-	-	-

EMA does not provide services for other EU entities, hence has no corresponding service level agreements	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 have pointed to a need to develop synergies through communication, collaboration and cooperation 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 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 optimize 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 the 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).[31]

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

[31] 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 as well.

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 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 provide together an active and constructive co-operation in the field of GMP. PIC/S' mission is "to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products." EMA is 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 mean 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:

- 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 etc.). 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[32] 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).

[32] 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: Procurement plan

Procurement plan 2022

Procurement Title	Type of contract	Type of procedure	Contract value	Initiation of Procurement	Start date of new contract
DARWIN EU Network Programme	**Direct** service contract	Competitive procedure with negotiation	52,000,000	Q2/2021	Q1/2022
204 X contracts - 2022 - CEI for experts on medical devices	Service contract	Call for expression of interest	€ 2.000.000	T.b.d.	03/03/2022
Emerging technologies	Framework service contract	Open tender	€ 20.000.000	01/01/2022	01/10/2022
RoC - New Mandate - MDM Development	Service contract	Re-opening of competition	€ 3.500.000	01/01/2022	01/04/2022
RoC - New Mandate - Microsoft - Case Management Dev	Service contract	Re-opening of competition	€ 4.000.000	01/02/2022	01/04/2022
RoC - New Mandate - MS Data Analytics Dev + BI@Admin	Service contract	Re-opening of competition	€ 2.500.000	01/12/2021	01/04/2022
ROC02 - Bayesian methods study (Lot 3)	Service contract	Re-opening of competition	€ 350.000	30/09/2022	31/03/2022
ROC04 - RMM Communication study (Lot 4)	Service contract	Re-opening of competition	€ 250.000	30/09/2022	31/03/2022
ROC07 - COVID vaccines effectiveness (Lot 5)	T.b.d.	Re-opening of competition	€ 750.000	30/09/2022	15/12/2021
ROC - 3 x pre-clinical study (Lot 1) placeholder (2022 yearly estimate)	T.b.d.	Re-opening of competition	T.b.d.	30/09/2022	31/12/2022
ROC - 3 x vet study (Lot 2) placeholder (2022 yearly estimate)	T.b.d.	Re-opening of competition	T.b.d.	28/02/2022	31/12/2022
ROC - 3 x statistical research (Lot 3) placeholder (2022 yearly estimate)	T.b.d.	Re-opening of competition	T.b.d.	24/10/2022	31/12/2022
ROC - 2 x qualitative study (Lot 4) placeholder (2022 yearly estimate)	T.b.d.	Re-opening of competition	T.b.d.	30/09/2023	31/12/2022
ROC - 10 x pharmacoepi study (Lot 5) placeholder (yearly estimate)	T.b.d.	Re-opening of competition	T.b.d.	30/09/2023	31/12/2022
Quality of medicines studies (re-tender Lot 6, EMA/2020/46/TDA)	T.b.d.	Open tender	€ 3.000.000	30/09/2023	31/12/2022
Management consultancy for Clinical Trials Transformation Initiative	T.b.d.	Re-opening of competition	€ 300.000	31/12/2021	31/03/2022
Standards specification & specification of FHIR resources	Service contract	T.b.d.	€ 250.000	T.b.d.	31/03/2022
Implementation of FHIR resources & tooling	Service contract	Re-opening of competition	€ 500.000	30/06/2022	30/09/2022

Technology Implementation & Change Management	Service contract	T.b.d.	€ 250.000	T.b.d.	30/09/2022
ROC08 Support for the Pilot on receipt of Raw Data (Lot 3)	Service contract	T.b.d.	€ 350.000	T.b.d.	15/04/2022
Design & Implementation Phase 1	Service contract	T.b.d.	€ 1.000.000	T.b.d.	29/05/2022
PROVISIONAL - Virtual reality	T.b.d.	T.b.d.	€ 200.000	T.b.d.	31/03/2022

Annex XIV: Projects

In order to support the Agency's work and achievement of set objectives, several programmes and projects will be undertaken. The table below details the main projects, their timelines and deliverables that the Agency will pursue in 2022-2023. The deliverables for 2023 provide a high-level overview and will be detailed during the preparation of the final work programme 2023.

Note: the budget figures for 2022 show the total estimated cost of the project, including internal and external costs

Programme / Project	Legal basis	Start date	End date	Deliverables 2022	Budget 2022
Information Security Programme					
Security Awareness **Integration of Critical Systems** **Identity Management** **PKI Infrastructure** **Data Sharing** [new]	n/a	Q1 2022	2024	• Implementation of Security Awareness program • Multifactor Authentication on Critical Systems • Implement portal-based solution for data sharing • Implementation of Zero Trust architecture	€ 3,000,000
External User Journey [new]	n/a	Q4 2021	2022	• Redesign the Agency's Identity and Access Management (IAM) platform to improve self-registration of external users	€ 100,000
Clinical Trials Programme					€ 8,503,000
CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database, renamed including a merger with SUSAR) [continues]	- Regulation (EC) 536/2014, art.80-82	Q3 2014	2023	• Go Live 31 January 2022 • Finalise implementation of post go live release(s) • Final acceptance of post-go-live release and business change management • Continued communications, training programme and related documentation • Planning and development for further post-go-live release(s) in 2023 •	*(included in CT Programme figure)*

Programme / Project	Legal basis	Start date	End date	Deliverables 2022	Budget 2022
Safety Implementation Regulation - cooperation in safety assessment (CTIS scope extension) [new]	Art. 11(3) of Implementing Regulation (pending adoption) to Regulation (EC) 536/2014	Q3 2021	2023	• Go-live 31 January 2022 • Continued communications, training programme and related documentation • Planning and development of safety-related functionalities in CTIS • Planning and development for further post-go-live release(s)	*(included in CT Programme figure)*
New Veterinary Medicine Regulation Programme - VMP-Reg					€ 400,000
EVVet3 - Union Pharmacovigilance Database / EudraVigilance Veterinary v3.0 [continues]	- Regulation (EC) 726/2004, art.57(d) - Regulation (EU) 2019/6; associated implementing acts	2017	2023	• Go-live Q1/2022 • Development of additional data quality functionalities • Improvements to all EVVet3 components •	€ 3,620,000
UPD - Union Product Database [continues]	- Regulation (EU) 2019/6; associated implementing act	2020	Q3 2022	• Go-live Q1/2022 • Improvements to all UPD components	€ 4,275,000
ASU - Antimicrobials Sales and Use Data [continues]	- Regulation (EU) 2019/6; associated implementing act and delegated act	2021	2023	• Development of functionalities to collect sales, use and population data • Development of reporting functionality for use data	€ 2,045,000
MWD - Union Manufacturers and Wholesale Distributors Database [continues]	- Regulation (EU) 2019/6; associated implementing act and delegated act	2021	Q2 2022	• Go-live Q1/2022 • Development of change to the GDP module • Enhanced search functionality	€ 235,000
Regulatory and Lifecycle Business Processes					€ 14,150,000
EMA extended mandate implementation - Monitoring and mitigating shortages of critical medicinal products and management of major events - Monitoring and mitigating shortages of critical medical devices - Medicinal Products with the potential to address public health emergencies (PHE) - Support of medical device expert panels	*- Regulation COM(2020) 725 (proposal of 11 Nov 2020 on reinforced role for EMA, under discussion in EP and Council, expected adoption date Q1 2022)*	2022	2023	• MAH iSPOC contact management for all authorised human medicines • Critical medicines shortages reporting and monitoring • Streamlining medicines shortages reporting and monitoring • Critical medical devices shortages reporting and monitoring v1	*(included in the above total)*

Programme / Project	Legal basis	Start date	End date	Deliverables 2022	Budget 2022
[new]	***Disclaimer:*** *the Agency will revise its IT portfolio roadmap following the finalisation of the legislative process*			• Expert management for medical devices v1 • Management of expert panels for medical devices v1 • Electronic submissions for the Emergency Task Force and collaboration capabilities v1	
SPMS - Substances and products management services (SPM&S) [continues] - EU SRS [new]	- Regulation 726/2004, art.57(2) - Regulation (EC) 520/2012, art.25 and 26 - Clinical trials reg. 536/2014, art.8193) - Pharmacovig. fees reg. 658/2014, art.7 Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	2017	2024	• Art 57 migration • PMS API • SIAMED & Art 57 integration/feedback loop • EU SRS handover	*(included in the above total)*
IRIS Platform to support regulatory business processes of the Agency [continues]	n/a	2019	2025	• DADI forms (eAF replacement) • Inspections • Variations process • Marketing status • Supply chain	*(included in the above total)*
ePI pilot [new]	n/a	2022	2023	• Delivery and implementation of electronic Product Information (ePI) pilot	€ 1,015,000 (€ 750,000 from EU4Health, € 265,000 staff costs)
European Medicines web portal *[possible restart in 2022 depending on resource and budget availability]*	*- Regulation (EC) 726/2004* *- Regulation (EC) 1235/2010, art.26*	*2022*	*2023*	• There are common elements with the Union Product Database project from the VMP-Reg programme supporting some of the future developments, as well interdependencies with SPM&S and e-PI projects.	*TBD*

Programme / Project	Legal basis	Start date	End date	Deliverables 2022	Budget 2022
Replacement of Document Management System (DREAM replacement)	n/a	2021	2023	• Develop the functional and technical design of the future solution • Plan the migration process	€ 557,000
Data Centre 2.0	n/a	2022	2023	• Plan and impact assessment on how to move to a cloud-based data centre solution	€ 765,000
SAP Finance	n/a	2021	2025	• Solution analysis and selection of replacement for SAP Finance	€ 232,000
Optimisation of the Administration supporting tools [continues]	n/a	2019	2024	• New fee regulation • Intranet • Risk Management • Procure2Pay • Onboarding V2.0	€ 1,345,000
Digital Workspace TRIP *[possible start in 2022 depending on resource and budget availability]*	*n/a*	*2022*	*2023*	• Provide programmatic access to specified internal and external data sources (medicines, development, assessment, pipelines, scientific and grey literature etc.) needed for horizon scanning • Provide large-scale access and mining solution (eg. data lake) for one selected internal data source • Pilot data governance capabilities incl. asset mapping, data lineage and classification, sensitive data management	*€ 550,000*
Digital Business Transformation					
eCTD4: Implementation and adoption of eCTD v4.0 standard [restart]	n/a	Q4 2021	2023	• Impact analysis and pre-implementation activities including review tool options in preparation for the implementation of eCTD v4.0 specification at the EMA (and the EU regulatory network)	€ 365,000
Other Digital Business Transformation initiatives		2021	2025	• Implementation of Analytics Centre of Excellence (ACE) / Digital Innovation Lab projects	€ 1,430,000

Programme / Project	Legal basis	Start date	End date	Deliverables 2022	Budget 2022
				• Chatbot • Extended Reality / Virtual Reality • EU Network Training Centre (EU NTC) enhancements and expansion to new audiences • Development of Change Management Centre of Expertise • Launch of EMA Digital Academy	
Data Analytics Programme					€20,190,000
Lifecycle Regulatory Submissions Raw Data	n/a	2021	2024	• Initiate stepwise implementation • Initiate communication and training in accordance with plans	*(included above in the DA programme figure)*
Lifecycle Regulatory Submissions Meta Data	n/a	2020	2023	• Establish a framework and operating model for data standards • Develop conceptual model for clinical study protocols and reports • Scientific Advice advanced Analytics pilot: present report/demo UI • Launch contracts for Standards Specification; Implementation of FHIR resources; Implementation of FHIR tools; Implementation & Change Management	*(included above in the DA programme figure)*
Observational Studies DARWIN EU ** Real-world Metadata and Rapid Analytics merged with DARWIN into one project in November 2021*	n/a	2021	2025	• 1st year of establishment of the DARWIN EU coordination centre • Coordination centre set-up, incl.. operational processes and governance • Establish connectivity with European Health Data Space (EHDS) and existing Data Permit Authorities • First catalogue of standard data analyses available • Start recruiting and onboarding the data partners	*(included above in the DA programme figure)*

Programme / Project	Legal basis	Start date	End date	Deliverables 2022	Budget 2022
				• Start running pilot studies to support EMA committees • Pilot with EHDS • Prepare EMA to be ready as a node • Training and change management	
*Real-world Metadata, Quality Framework and Catalogues **	n/a	2021	2025	• Adoption of the metadata list and guide • Development of data sources and studies catalogue • Development and adoption of data quality framework for regulatory purposes	*(included above in the DA programme figure)*
*Observational Studies Rapid Analytics **	n/a	2020	2022	• Finalise proof of concepts with PDCO and COMP and pilot with SAWP • Start pilots with CAT, CHMP, COMP and PDCO • Finalise awareness and training material Finalise change management • IHD software training for H-Division champions • Databases accessible in-house in OMOP common data model	*(included above in the DA programme figure)*
Signal and Safety Analytics	n/a	2021	2023	• Collection of IT and business requirements for the design of the new EVDAS platform/eRMR solution/ADR website • Design of the new systems and identification of possible gaps • Start implementation of the new solutions • Analysis of potential future needed work	*(included above)*