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European Medicines Agency

Final Programming Document 2021-2023

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

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Foreword

I am extremely pleased, as new Executive Director, to introduce the EMA single programming document, which provides an overview of the Agency's activities in the upcoming years.

Overall, our future multi-annual planning, alongside fostering scientific excellence in the evaluation and supervision of medicines, will be driven by the implementation of the new the European Medicines Agencies Network Strategy and Regulatory Science Strategy. These documents cover the period 2020-2025 and have been conceived, developed and approved in consultation with our stakeholders. These strategies provide us with a strategic direction helping EMA together with the Network to collectively tackle current and future challenges more effectively and seize the opportunities that new science, new technology and better data present.

The coming years, and especially 2021, will again be exceptional for EMA, as the impact of the COVID-19 pandemic will continue to present challenges to the Agency. EMA will pursue its effort to evaluate and supervise rapidly emerging medical innovations that give access to safe and effective treatments and vaccines against the virus.

Communication will represent a major task for EMA. Communicating effectively about the benefits and the risks of products for COVID-19, in particular on the safety of vaccines, will play a fundamental role. EMA is committed to listening to people's concerns and to turning science-based decisions into high-quality information that meet citizens' needs. The Agency will cooperate closely with other key actors including the European Centre for Disease Prevention and Control, the European Commission and the national competent authorities.

The COVID-19 pandemic has demonstrated that international collaboration is not just an opportunity but a global necessity as treatments and vaccines are common goods. Over the next five years EMA and the EMRN will invest even more in this transversal activity, to confirm the EU supportive, engaged and openly collaborative leadership on delivering safe, effective and high quality medicines to the EU and beyond.

Another challenge, which goes beyond the response to COVID-19, is represented by shortages, access, and availability of medical products. EMA will work with the Member States, the Commission, the Parliament, other EU Agencies and patients and healthcare professionals to find ways to improve access and availability, which are today a daily issue across all therapeutic areas. We firmly believe that there's no value in medicine innovation if it does not reach the patient or animal in need of it.

Antimicrobial resistance will be another priority area of work for the Agency, to preserve the effectiveness of the currently available antibiotics and to support the development of new products. A big step to achieve these goals will be represented by the implementation of the New Veterinary Legislation.

The final focus for EMA will be the integration of digital technologies into the regulatory framework, the exploitation of data from healthcare to complement clinical trials as a source of evidence in our benefit risk decision-making, and the use of advanced data analysis techniques including artificial intelligence to improve our work. Digital technologies, healthcare data and advanced analytics present opportunities throughout the product lifecycle, medicines development, through authorisation to post-authorisation monitoring of medicines and the conduct of independent studies.

Over the last few years EMA has consistently demonstrated resilience and agility in coping with extraordinary circumstances. Now, following the COVID-19 public health crisis, the Agency is again called on to rise to the challenge: strengthening its role and expanding its tasks. The mandate extension

proposed by the Commission will entail even greater responsibilities and we are honoured that our competence, delivery and hard work are acknowledged.

Rest assured that EMA and its staff is ready to take on these new challenges and opportunities and will continue to contribute through its expertise and dedication to the benefit of public and animal health in the European Union.

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
ATD	Access to documents
ATMP	Advanced-therapy medicinal product
BCP	Business continuity plan and public health threat plan
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
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
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	Scientific committees of the Agency
DCP	Decentralised procedure
DIMSIS II	Development, implementation and maintenance support of information systems
DoI	Declaration of interests

Term/abbreviation	Definition
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
EMA	European Medicines Agency
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
ERA	Environmental risk assessment
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 NTC	EU Network training centre
EU-IN	EU innovation network
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
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

Term/abbreviation	Definition
ICMRA	International coalition of medicines regulatory authorities
ICSR	Individual case-safety report
ICT	Information and communication technologies
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
NVR	New veterinary regulation
NUI	Non-urgent information
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

Term/abbreviation	Definition
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma master file
PPHOVA	Pilot project on harmonisation of old veterinary antimicrobials
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
R&D	Research and development
RFI	Request for information
RWD	Real world data
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
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
TF	Task Force
TF AAM	EMA/HMA joint task force on availability of authorised medicines for human and veterinary use
TGA	Therapeutic Goods Administration, Australia
TOPRA	The Organisation for Professionals in Regulatory Affairs
UEMO	European Union of General Practitioners
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 EU legislation relating to medicinal products.

The Community codes for veterinary and human medicines are set out in Directive 2001/82/EC 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).

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 2019, 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 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 on-going professional development of every member of the Agency.

Part I: General context

The 2021-2024 planning exercise is influenced by major events happening in 2020 which had a direct impact on the work of the Agency and whose effect is still under materialisation. As a result, in 2021 the multi-annual objectives will be subject to an even closer monitoring to ensure the timely adaptation to this rapidly evolving scenario. Among those factors, it is worth noting the following:

BCP approach to COVID-19 pandemic and impact on agency activity in 2020 and upcoming years. Following the outbreak of the COVID-19 global pandemic in the European Union in Q1 2020, the Agency invoked its business continuity and public health threat plan (BCP), and established an ad hoc governance structure to manage the crisis. EMA priority was to operate as long as possible under a "business as usual" scenario focussing on any COVID-19 related activity in terms of 1) coordinating all activities of the scientific Committees on scientific aspects of the crisis related to management of medicinal products, 2) liaising with developers to provide scientific contribution to new drugs/vaccines development 3) coordinating the actions required to manage the risk of shortages of centrally authorised products (CAP) and 4) providing enhanced coordination of the EU regulatory network to ensure the least possible impact on time and quality of evaluation and supervision of medicines. The Agency was also ready to speed up Committees procedures for COVID-19 related products ensuring the highest level of quality while continuing the evaluation and supervision of non COVID-19 related medicines. Following an EC proposal, the Agency has exceptionally been granted 40 additional Temporary Agent staff positions for 2021 and 2022 only to support the EMA response to the COVID-19 pandemic.

EMA, in close collaboration with ECDC, EC and Member States is ensuring a robust monitoring of the COVID-19 vaccines. 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. Building on the foundational work initiated in 2020, through the EMA funded ACCESS consortium and the EMA funded bridging vaccine safety study initiated in late 2020, EMA will commission a large European vaccine safety study to run through 2021-2022 to both prospectively evaluate the safety of COVID-19 vaccines and to assess any emerging vaccine safety signals during this period.

Overall the purpose of the BCP plan was reducing the risk of infection of staff, delegates and contractors by containing the spread of the virus; safeguarding core activities by ring-fencing resources to deal with COVID-19 related workload. The Agency's overarching goal is to expedite the development of effective measures to fight and prevent the spread of COVID-19 and to ensure that the assessment and monitoring of medicines are not disrupted so that patients in Europe continue to have access to high quality, safe and effective medicines during the pandemic. While it is still not possible to foresee the full impact of this pandemic, it will undoubtedly be substantial and multifaceted. Whereas the consequences of Brexit severely impacted only the operations of the Agency (i.e. execution of the physical relocation and retaining staff to ensure Agency's ability to deliver its core activities), the COVID-19 crisis has transformed the landscape which the Agency operates in. Specifically, the COVID-19 pandemic has affected the whole European Medicines Regulatory Network (EMRN) – National Competent Authorities (NCA), EMA and the Commission. As a result, EMA had to react to the impact of the pandemic both in terms of the impact on the Agency itself and of the impact on the Network.
Extension on EMA's mandate. On 11 November 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. The establishment of this framework for the activities to be

deployed by the Agency in preparation for and during public health emergencies should enhance the Union's capacity to react quickly, efficiently, and in a coordinated manner to such emergencies.

The envisaged approach is based on strong preparedness, to be achieved with the development of common tools and agreed methods for monitoring, reporting and data collection. The proposed Regulation builds on experience from the COVID-19 pandemic so far and on ad hoc solutions set up over the last months as well as the management of previous major events in the context of the established incident management plan. The proposed Regulation will complement and further develop the core tasks already given to the Agency in its founding Regulation, notably to provide scientific advice and to assess the quality, safety and efficacy of medicinal products as part of their authorisation process.

- The general objectives of the EC proposal are to:
    1. ensure a high level of human health protection by strengthening the Union’s ability to manage and respond to public health emergencies, which have an impact on medicinal products and medical devices;
    2. contribute to ensuring the smooth functioning of the internal market for such products during public health emergencies.
- The specific objectives of the EC proposal are to:
    1. monitor and mitigate potential and actual shortages of medicinal products and medical devices considered as critical in order to address a given public health emergency or, for medicinal products, other major events which may have a serious impact on public health;
    2. ensure timely development of high quality, safe and efficacious medicinal products with a particular focus on addressing a given public health emergency;
    3. ensure smooth functioning of expert panels for the assessment of some high-risk medical devices and avail of essential advice in crisis preparedness and management with regard to the use of medical devices.
- The European Medicines Agency's mandate will therefore be reinforced so that it can facilitate a coordinated Union-level response to health crises by:
    - monitoring and mitigating the risk of shortages of critical medicines and medical devices
    - providing scientific advice on medicines which may have the potential to treat, prevent or diagnose the diseases causing those crises
    - coordinating studies to monitor the effectiveness and safety of vaccines
    - coordinating clinical trials.

EU commission Pharma Strategy. The Agency has contributed to the EU Pharmaceutical Strategy by drafting an overarching paper which builds on recommendations included in both the EMA Regulatory Science Strategy to 2025 and in the draft European medicines agencies network strategy to 2025. The document provides suggestions to promote innovation and accommodate emerging science, further promote patient access to medicines and affordability, address key bottlenecks for developing orphan and paediatric medicines, new antimicrobials. In addition to this, the paper puts forwards proposals to embrace digital transformation and build the necessary digital infrastructure in the network, optimise regulatory frameworks and processes, improve the oversight of pharmaceutical quality and manufacturing, monitor and prevent shortages and ensure sustainable resources for EMA and the network to implement all relevant actions.

In 2021 the Agency, on the basis of the evolution of the approval process of the EC proposal by the budgetary authority will need to start the preparation for the implementation and amend the 2021 work programme accordingly.

EMANS and RSS. The European Medicines Agencies Network Strategy (EMANS) to 2025 and the new Regulatory Science Strategy (RSS) have been finalised and validated in 2020.
The European Medicines Agencies **Network strategy to 2025**, devised by EMA and Heads of Medicines Agencies (HMA), identifies shared challenges, goals and priorities, to give strategic direction to the work of the European medicines regulatory network. Guided by this strategic approach, the network aims to collectively tackle current and future challenges more effectively. Sets out how the network intends to continue enabling the supply of safe and effective medicines in the face of developments in science, medicine, digital technologies, globalisation and emerging health threats. The network strategy outlines six priority areas in line with the European Commission's roadmap for a Pharmaceutical strategy for Europe: (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, with transversal international activities. Recent developments linked to the COVID-19 pandemic fed into the strategy's development. Further lessons from the pandemic will continue to inform future reviews of the strategy and subsequent work plans. Development of the strategy also took account of feedback received from stakeholders, following a public consultation, including from patient, consumer and healthcare-professional organisations, industry, academia and veterinary stakeholders.
The **Regulatory Science to 2025 strategy** is a plan for advancing EMA's engagement with regulatory science over the next five years, covering both human and veterinary medicines. The strategy aims to build a more adaptive regulatory system that will encourage innovation in human and veterinary medicine.

As science and technology advance and bring potential new treatments and diagnostic tools, regulatory science must advance in tandem so that these can be correctly, rigorously and efficiently assessed. It follows that the EU network must have access to the best and most up-to-date scientific data, methodologies and tools available on which to base decisions.

The RSS identifies 5 strategic goals for such engagement: (1) Catalysing integration of science and technology (2) Driving collaborative evidence generation (3) Advancing patient-centred access (4) Addressing emerging health threats (5) Leveraging research and innovation; it proposes core recommendations and underlying actions that would need to be taken to support these, which have been prepared in collaboration with our many stakeholders.

RSS has been fully aligned with EMANS and its implementation will therefore contribute to the overall goals set by the Network.

Completion of the relocation from London to Amsterdam. In 2020 the Agency completed its two-stage relocation following the Brexit with its final transfer from the temporary premises in Amsterdam Sloterdijk to its permanent location in Amsterdam Zuidas. The move has been carried out successfully by transferring and maintaining operational IT systems, without significant disruption to the Agency’s day-to-day activities and minimising its impact on the staff.

Court Ruling on screening of the Declaration of Interest. The Judgment of the General Court in Case T-594/18, *Pharma Mar v Commission* annulled the Commission Decision to refuse the marketing authorisation for the medicinal product Aplidin, having identified a conflict of interest of two external experts involved in the Scientific Advisory Group (SAG) supporting the Committee for Medicinal

Products for Human Use (CHMP) scientific assessment of that product, after a first negative opinion and during the ensuing re-examination phase.

It is the Agency's view that the General Court misinterpreted EMA's 2016 Policy on handling of competing interests of scientific committees' members. and experts. The Agency submits that it applied said Policy correctly with regard to the two external experts and that, therefore, they could legitimately join the SAG's activities in accordance with the Policy.

The Agency will review the Judgment to determine its impact on the way competing interests for experts are handled and revise the Policy as required. It is noted, however, that the interpretation of the Policy followed in the Judgment may have a detrimental impact on the proper functioning of the Agency, and by analogy also on the National Competent Authorities, e.g. the exclusion of experts leading to a shortage of experts with in-depth expertise and a risk for decreasing the robustness of the scientific assessment of medicinal products.

New Executive director: After reaching the end of his second mandate, on 15 November Guido Rasi has left EMA. He has been replaced by Emer Cooke as new Executive Director of the Agency.

Part II: Multi-annual programming 2021–2023

1) Multi-annual work programme

The multi-annual EMA programming 2021-2024 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 Division: 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 2021 are significantly marked by the COVID-19 pandemic. The year 2021 will be characterised by the need to process in a timely manner according to the Agency's standards all COVID-19 related applications. In addition to this, the overall trend shows a constant growth (around 7%) of non-COVID-19 medicines applications from year to year. It is expected that the evolution of the development of medicines to prevent or treat COVID-19 will lead to a workload peak in the first half of 2021 for the approval of COVID vaccines/ therapeutics and a long-term workload increase in the area of safety and post-authorisation once these medicines are approved. This will severely impact the ability of the Human Medicines Division to support the implementation of the EMANS and RSS in 2021. In addition, the expected increase in authorisations of new medicines will result, in the medium to long term, in a growth of post authorisation procedures, which will further stretch the capacity of the division. 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 will be critical to adapt to the anticipated increase in applications over the coming years. The construction of an integrated environment supported by more advanced digital tools will secure the realisation of the efficiency gains and sets 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 Division: In the current planning cycle, the Veterinary Medicines Division is entering a new phase marked by the preparation and 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 is making efforts to achieve a seamless transition to the new set of rules which will be effective as of 28 January 2022. The division will have not only to respond to a growth in workload related to CAPs and new methodologies for pharmacovigilance surveillance, but also to the need to update all the necessary guidance and processes in time for 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 deployment by January 2022 and subsequent management and maintenance of the new or updated IT systems necessary for implementing Regulation (EU) 2019/6: Union Product Database, EVVet3 and integration of veterinary procedures in IRIS.

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

PILLAR 2:

The 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 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). The timeline of their implementation is highly affected by the prioritisation of the workload related to COVID-19 related medicines. The additional 40 posts for temporary staff awarded for 2021 and 2022 will help to cope with the first workload peak concerning applications of COVID-19 related vaccines and therapeutics. Yet, it can be envisaged a second workload peak coming at a later

stage, probably as of 2022 onwards, which would be mainly centred around the post-authorisation procedures. At present, the required effort for the latter is not quantifiable, although a notable impact on the capacity of the Agency to contribute to pillar 2 is presumable.

A prudent line has been adopted, and the Agency identified the key actions achievable with the available resources, approximately one third of the total covering all 6 focus areas, which will start already 2021, whereas the remaining set of actions have been classified on a 2 tier priority scale subject to a phased approach. A rolling review of the Agency capacity will grant the deployment of additional resources as they become available and, consequently the potential activation of additional actions from tier 1 in the second half of 2021. An overview of objectives for which actions might start once a reassuring level of predictability over the upcoming challenges and workload is reached, is available in section 2.5 of this document.

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 current collaborations with existing confidentiality arrangements, 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, starting with Brazil, as well as the expansion of the Mutual Recognition Agreement with the US FDA (Veterinary products, vaccines, etc). Alongside with the promotion of Parallel Scientific Advice and fellowships, The Agency will engage in a new project (OPEN) to allow participation of non-EU authorities in CHMP for COVID-19. Currently EMA is actively participating in several International Organisations (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 scientific training are among the Agency priorities. Further communication activities to increase EMA visibility and leadership at international level.

Communication and transparency

EMA is committed to providing 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. We recognise that transparency is key to reinforcing trust in regulatory decisions, and are taking exceptional measures to maximise the transparency of its regulatory activities on treatments and vaccines for COVID-19 that are approved or are under evaluation. In parallel, access to documents requests continue to increase in number and complexity and the process will be reviewed in 2021-22 to enable continued management of ATD with existing resource. Clinical Data Publication (CDP) will remain on hold whilst business continuity measures are in place, with the exception of COVID-19 medicines. Once BCP is lifted a strategy will be agreed for resourcing and relaunch of CDP, with enhanced collaboration with Health Canada and other international partners. To support COVID-19 related activities the ATD team will have reduced capacity in 2021 and measures will be introduced to manage incoming requests (with a maximum of 2 documents per request and limit of 5 requests per requester at a time). This will improve processing time and provide for more consistency of service.

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 and the technology innovations will be the second driver for the Agency portfolio in order to be able to cope with the increase of demands especially in the 2020 pandemic context. The Agency needs more and modern tools to increase its efficiency and to optimise its 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. As a result, an increased effort will be put in better supporting the Agency regulatory business process by modernising and bringing new tools in the next 5 years.
- Data Analytics is the 3rd driver, in order to strengthen the promotion and protection of public health by supporting decisions on medicines with evidence derived from robust and standardised data;
- The 2022 horizon will be the sight for the Clinical Trial and the Veterinary Regulation systems to be fully operational, where the 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 comprised between 60 and 70 FTEs 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 rethinking and reinventing its function to a rapidly evolving working environment. The objective of the Division in this new planning cycle is to confirm is position as business enabler in the delivery of the core tasks of the Agency, while strengthening is advisory role by proving tailored data for the decision-making process. Essential for this purpose is a holistic view covering processes, ways of working and organizational design, together with a strategic planning which balances reality and ambitions according to the Agency capacity and ensures an appropriate degree of flexibility. As a result, another key driver would be the focus on EMA staff: Administration Division intends to further bridge silos across organizational entities, maximise value and reward the already available resources and expertise.

The strategy of the Division aims therefore at bringing together the following 3 dimensions

- Decision-making: constant optimization of resource will be achieved by creating a solid platform matching data and processes to support the decision-making process by granting timely and robust monitoring of the activities. This entails process revision, data quality enhancement and increased deployment of business intelligence.
- Leaner financial governance: to cope with the new fee regulation which will affect also the veterinary medicines, the Agency needs to display a higher degree of agility, therefore system interoperability needs to be augmented as well as master data management. The implementation of the related actions will increase the risk management capabilities of the Agency.
- Employee lifecycle: EMA acknowledge its staff as the key asset of its organization, hence the transformation of the HR function to consider the employee lifecycle. This translates into a human resources strategy aiming at constantly developing the workforce and allowing proper

allocation of resources. The objective will be pursued by the development of the competences, improvement of the career path and introducing agile working methods.

INFORMATION MANAGEMENT DIVISION

Information Management underpins everything we do, whether it is receiving, validating and processing regulatory submission content, assessing the safety and efficacy of medicines throughout their lifecycle or communicating on public health issues. Information Management is about connecting our data, processes and analytics to overcome organisational silos.

Over the next 5 years, the goal for Information Management at the EMA is to become a catalyst for transforming scientific assessment and regulatory decision-making in close collaboration with its Task Forces and Divisions. Ultimately, we need to move towards an integrated regulatory platform that enables seamless collaboration and information sharing across the European Medicines Regulatory Network connecting industry, regulatory agencies and the public.

How can this be achieved:

- **Streamline IM Governance:** There is a need to simplify our governance structures for both EMA and the Network and move towards a portfolio management approach focused on maximising value across the enterprise, aligning demand across stakeholders and providing focus and stability for the technical teams. The objective is to secure business sponsorship, bridge the gap between Business-IT and empower product teams to make decisions at the solution level by appropriate delegation of authority.
- **Reshape the delivery of IT and expand our change capacity to help EMA deliver:** New project methodologies and new ways of Business-IT alignment can help ramp-up output. The adoption of agile methodologies across the organisation and use of shared technologies (preferably Software as a Service) delivered through scalable platform contracts that create economies of scale, will accelerate delivery and step-change the quality of IT solutions.
- **Drive the modernisation of the IT landscape:** There needs to be a strong focus and continuous investment for the coming years into cleaning up and re-platforming 25 years of legacy by moving towards a common set of standard technologies and shared information services. We also need to further invest into self-service capabilities and automating IT in the areas of testing, deployment and security.

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).Not all the objectives mentioned here below will find an implementation via annual action as of 2021.

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 decision makers 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

Goal	Objectives
2.1) Enable access to and analysis of routine healthcare data, analysis of individual patient data from clinical trials, and promote standardisation of targeted data	Deliver a sustainable platform to access and analyse healthcare data from across the EU (DARWIN EU)
	Pilot the analysis of individual patient data from clinical trials in initial marketing authorisation assessments with a view to a targeted roll out of such analysis.
	Establish 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

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

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	Modernise SmPC of old antibiotics for human and veterinary use,
	Define 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 investigation of medicinal products during emergencies
Additional RSS recommendations	Promote and support 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

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

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
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 2021 - 2023

2.1 Overview of the past and current situation

Overview

In 2020 the total budget (revenues and expenditure), as adopted by the EMA Management Board on 19 December 2019, amounted to €358,071,000. On the revenue side this included €306,773,000 in fee revenues and contributions from the EU budget totalling €51,025,000budget. On the expenditure side this included €119,738,000 in Title I: staff expenditure, €83,646,000 in Title II: infrastructure and operating/IT expenditure, and €154,687,000 in Title III: operational expenditure.

On 16 September 2020 an amending budget was adopted, increasing the initial budget by €11,678,000, to a total of €369,649,000. The amending budget included on the revenue side the 2018 surplus of 13.8 million and an increase in fee income of €3.8 million, while the EU contributions were decreased by €5.9 million. The matching expenditure appropriations were mainly earmarked for IT investments, scientific studies (including COVID-19 related) and rapporteur payments. The staffing ceilings in 2020 were 596 temporary agents (TA), 228 contract agents and 33 national experts on secondment, this level of staffing was determined after additional 14 TA posts were not granted by the budgetary authority. Throughout the year, the Agency operated an occupancy rate close to 100%.

It should be noted that the Agency was required to reduce the number of establishment plan posts by 5% between 2014 and 2018, with a requirement for an additional 5% reduction to create an Agencies-wide redeployment pool, meaning an overall reduction of 10% on like-for-like tasks. At the same time, fee-related workload (as reflected by increased fee income but excluding new pharmacovigilance fees and adjusted for inflation) increased by more than 30% compared to 2014 and is expected to continue to increase in 2021. The fee-related workload continues to grow every year as the portfolio of products increases, but the 10% establishment plan cuts remain in place with no new posts earmarked for this workload were granted for 2019 or 2020.The 2021 budget reflects the activities described in the 2021 work programme developed under the assumption that several activities will be severely impacted by the continuation of the COVID-19 pandemic which already in 2020 triggered the BCP status. This set of assumptions will be constantly monitored throughout 2021, allowing the deployment of resources if they become available. The impact on public health activities is more severe than during the BCP invoked by the Agency's relocation because it is mostly concentrated on staff working in the scientific domain. Considering the staffing evolution in the last few years it is evident that all activities will need to be carefully prioritised.

2.2 Outlook for the years 2021 - 2023

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). Should the proposal be approved by the relevant institutions, EMA tasks would then be significantly expanded to cover monitoring and mitigation of the risk of shortages of critical medicines and medical devices; provision of scientific advice on medicines which may have the potential to treat, prevent or diagnose the diseases causing those crises; coordination of the studies to monitor the effectiveness and safety of vaccines; coordination of critical trials.

The current proposal might have a significant impact on the resources of the Agency since for 2021 it foresees 21 TAs and 8 CAs growing to a total of 30 TAs and 10 CAs in 2024. The EU contribution foreseen in 2021 is 27.79M decreasing to 15.3 in 2024 as a stable subsidy after the bulk of investment is realised in the first 3 years of the initial implementation.

Growth of existing tasks

There has been a constant growth in the fee-related workload over the last years. Two effects are driving this growth: i) a steady increase of initial application; ii) a subsequent development of the post-authorisation portfolio. The Agency has been able to cope with this trend by reprioritising work in not-application related areas. Therefore, for 2022 EMA will request additional 20 TAs and 2CAs. These posts are meant to become permanently part of the establishment plan and are linked to the growing product portfolio, Veterinary Medicines workload, support to data protection activities; support to EMA International activities, support to the go live phase of CTIS activities, support to the preparation for ongoing *DARWIN/Data Analytics activities*.

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.

The Agency's has an obligation to devote adequate resources to data protection activities. In 2019, more than 3.5 FTE were working for the implementation of the EU DPR and 3.78 FTE were estimated for 2020. Activities in this area are increasing due to legislative requirements and factors such as growing digitalisation of the Agency and the Network requiring to ensure that data management is fully compliant with the EU regulation. 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 to that effect is once again included in the resourcing requests.

To strengthen and support the EMA response to the COVID-19 pandemic, the Agency has exceptionally been granted 40 additional Temporary Agent staff positions for 2021 and 2022 only. The Agency will utilise the additional capacity and competencies from these resources to help meet the exceptional challenge to European and global public health, reinforcing ongoing work in the areas of therapeutic response to COVID-19 medicines and vaccines; supporting coordination of EU responses to COVID-19 related medicines shortages/supply chain issues; for pro-active clinical data publication of COVID-19 related medicines and vaccines in the interest of full transparency in the public domain; and for meeting the unprecedented demand for public health information and communication arising from a broad array of stakeholders and the general public.

These posts have been granted for two years only, but the Agency also needs to prepare for the subsequent post-authorisation work on vaccines and therapeutics. Pharmacovigilance activities in terms of the monitoring of the safety and efficacy of these medicines will also be of paramount importance. These activities and workload will extend far beyond a two-year horizon. The Agency will therefore apply a strategic approach to the allocation and utilisation of these time-limited resources, aiming to ensure the competencies and capacity of the organisation, supported by modernised and digitalised systems and processes, are sufficient not just to the immediate short-term issues but also with the longer-term workload. This work will also take into account the workload implications of the preparation and implementation EMA's extended mandate, which is currently going through the legislative process at the level of the EU institutions.

2.3 Resource programming for the years 2021-2023

Financial resources

A considerable increase in revenue generated by scientific applications is assumed in 2021 and 2022.The total revenue from fees in 2021 will amount to €330 million, an increase of 19 million (6.7%) compared to the amended 2020 budget. In 2022 the total revenue from fees will reach €351 million due to continuation of the increase in submission of scientific applications. In 2023 and 2024 the increasing trend is expected to slow down at respectively €359 million and €369 million. Following the completion of the relocation process (which was supported by ad hoc related EU funding) and net of the financing associated to the proposal for EMA mandate extension, the EU contributions are set to decrease in line with new multi-annual financial framework (which at the moment of drafting this document has not been officially adopted yet). The EU financing in 2021 (excluding OMP) is expected at €12.5M and as from 2022 onwards, at €8.73 million. The orphan medicinal products contribution in the draft budget 2021 reflects the amount in the EU budget. The financing foreseen in the proposed mandate extension is peaking at €27.8M in 2021, decreasing to 15.3 as from 2024. The full contribution of €55.45M should be available as soon as the proposal will be approved by the EU institutions. Neither the draft budget 2021 nor preliminary draft budget 2022 include provisions for exceptional costs related to the Agency's former headquarters in London. Some impact of the restrictions introduced to manage the pandemic is expected in Q1 of 2021, resulting in lower meeting expenditure and staff duty travel. The expenditure related to the running and maintenance of the EMA building in Amsterdam is expected to stabilise, after a couple of years with high expenditure caused by the Agency's move to the Netherlands. Communications activities are expected return to a more normal level, resulting in higher expenditure.

Business consultancy related to review of business processes and various (IT) projects will result in the 2020 level of expenditure continuing into 2021.Expenditure on rapporteurs will increase as a consequence of the higher number of scientific applications expected. Expenditure related to scientific studies and data analytics initiatives, already increasing in 2020, is expected to continue at a higher level, caused by the expected need for more studies related to COVID-19. IT project development is expected to continue at the higher level seen in 2020, thanks to an increased capacity to deliver projects. This level of expenditure is expected to continue for the period 2021-2024 due to revamping of the EMA IT platforms. As from 2023 the maintenance costs will begin to reduce thanks the consolidation of the technologies deployed.

Following the approval of the EMA mandate extension in 2021, the Agency will perform a revision of the Activity Based Budget (ABB) to properly included the tasks and activities deriving from the EC proposal.

Human resources

The draft budget 2021 covers the increase of 40 time-bound TAs awarded by the EC to cope with the extra workload linked to the response of the COVID-19 pandemic. For the 2022 preliminary draft budget, the Agency will request 11 additional TAs for workload linked to the growing product portfolio as well as 9TAs and 2CAs (3 TAs for Veterinary Medicines workload, 1 TA post to support data protection activities; 1 TA post to support the International activities; 1 TA and 2 CAs to support the go live phase of CTIS activities; 3 TAs to support preparation for ongoing *DARWIN/Data Analytics activities*).

Should the EC proposal to extend the EMA mandate be further amended, the currently included establishment plan (see annex) would be modified to reflect the latest changes (at present the establishment plan includes as of 2021, 21 TAs and 8 CAs growing to a total of 30 TAs and 10 CAs in 2024).

2.4 Strategy for achieving efficiency gains

In the last 5 years the Agency recorded an increase of application driven activities of more than 30%, 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, during the same period EMA has been obliged to reduce the baseline establishment plan staff numbers by 10% and had to deal with the loss of staff due to the relocation from London. In this period the Agency has clearly demonstrated significant productivity gains and more efficient ways of working. The impact of the COVID-19 pandemic increased the pressure on a limited number of staff mostly involved in scientific activities as reflected in the BCP approach taken in 2020.

Considering the challenges identified for the upcoming years EMA will further develop its efficiency gains strategy mainly following two dimensions: a) process improvement; b) digitalisation.

Process improvement: following the Future Proofing exercise drivers, the Agency is currently focussing on process review to complete the integration of the Human Medicines division activities. The objective of the exercise is twofold, the first is the revision of the activities to improve efficiency and to support a time and capacity model; the second is the preparation of optimised processes to be transferred to the Iris Platform. The long-term view is to apply the same framework to the other Agency processes.

Digitalisation: in a constant evolving environment the Agency is asked to embrace the 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. This work encompasses several activities key to digitalisation of EMA services:

- Creation of the Analytics Centre of Excellence (ACE), a cross-Agency initiative with the aim of exploring how analytics - including artificial intelligence, machine learning and robotics – can be used to build pragmatic solutions for existing EMA business needs. ACE aims to make improvements in the areas of process design, automation, information and knowledge-management, deliver user-friendly solutions that improve efficiency and have tangible beneficial impact on processes. As an example, projects include automated recognition of personal data in documents, re-engineering the procurement process and using AI to identify inconsistencies between submission data in documents and databases.

- Establishment of a Digital Change Workstream to drive complex, digital change initiatives that impact on EMA's strategy, operational structure and operations in relation to the European medicines regulatory network, its partners and stakeholders.

- 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.

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/decrease of existing tasks

Following the approach outlined under pillar 2 at the beginning of the multi-annual programming section, the set of actions that are not immediately starting in 2021 are grouped according to a 2-tier priority level.

This system for identifying reduced priority actions is driven by the EU's public health priority to respond to the COVID-19 pandemic and to manage the presence of nitrosamines in medicinal products (for centralised and nationally authorised products). Given that the capacity to deliver of the Agency had already been put under pressure in the previous years, as noted during the Brexit BCP period, this situation could be further exacerbated by the current health crisis whose outcome is still unpredictable.

Tier 1 covers actions that might be activated already in the second half of 2021 following a rolling review of the Agency capacity.

Tier 2 includes actions that might start after the activation of tier 1 actions, in case of sufficient resources available.

The implementation of EMA's health threats plan, ring-fencing of resources, and refinement of preparedness approaches will be initiated only following a lesson learned review at the end of the current COVID-19 crisis.

As regards antimicrobial resistance, the support to the development of new antibacterial agents and their alternatives will progress at an incremental pace according to the available resources.

The support to innovative approaches to the development/approval and post-authorisation monitoring of vaccines will focus on COVID-19 vaccines.

De-prioritisation of actions linked to the focus area of the supply chain challenges does not affect COVID-19 related products.

Finally, actions on scientific guidelines development, support to working parties and training/workshop for stakeholders might be reprioritised during 2021.

In accordance to the Agency multi-annual planning structure, the actions are clustered as follows .

FOCUS AREA	TIER 1	TIER 2
Availability and accessibility of medicines	Develop new and improved communication and engagement channels and methods to reach out to stakeholders Improve coordination of information and actions, including implementation of best practices, both for EU regulatory authorities, stakeholders and international partners Increase transparency on availability/launch to facilitate targeted regulatory actions and communication with patients, HC professionals and HTA bodies.	Contribute to HTA's preparedness and downstream decision making for innovative medicines Bridge from evaluation to access through collaboration with payers Reinforce patient relevance in evidence generation Promote the availability and support uptake of biosimilars in healthcare systems
Data analytics, digital tools and digital transformation	Exploit digital technology and artificial intelligence in decision making 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.)	Modernise the delivery of scientific advice at central and national level by developing Network skills and processes
Innovation	Apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines Transform the regulatory framework for innovative veterinary medicines through to support innovation and implementation of veterinary medicines regulation Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance Identify and enable access to the best expertise across Europe and internationally Develop the regulatory framework for emerging clinical data generation Reinforce and further embed application of the 3Rs principles	Support the development and implementation of a repurposing framework Support developments in precision medicine/ biomarkers and 'omics' Support translation of advanced therapy medicinal products (ATMPs) into patient treatments Expand the PRIME scheme Facilitate the implementation of novel manufacturing technologies Develop understanding of/ and regulatory response to/ nanotechnology and new materials in pharmaceuticals Diversify and integrate the provision of regulatory advice along the development continuum

	Develop network-led partnerships with academic/research centres to undertake research in strategic areas of regulatory science Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions Update Environmental Risk Assessments in line with the latest scientific knowledge	Leverage non-clinical models and 3Rs principles Invest in special populations initiatives
Antimicrobial resistance and other emerging health threats	Coordinate network activities to improve data collection on antimicrobial use in animals Continue to support development of new antibacterial agents and their alternatives Engage with stakeholders to minimise the risks of antiparasitic resistance Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches Promote and support development of veterinary vaccines Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines Adapt use and sales data reporting to new legislative requirements for veterinary medicine, spread knowledge and ensure better access to data in line with NVR requirements Modernise SmPC of old antibiotics for human and veterinary use Define a roadmap for Point Of Care (POC) diagnostics to support the development of improved diagnostic tests 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 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	Continue to promote the responsible use of antimicrobials and their alternatives Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines 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 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

	Foster development of new antimicrobials including new antibacterials for human use, define regulatory pathways for phages and other innovative products in human and veterinary medicine and engage with relevant stakeholders to effectively discuss the issue Refine regulatory activities in inter-epidemics periods to increase preparedness and harmonise regulatory framework and approaches for investigation of medicinal products during emergencies	
Supply-chain challenges	Promote global cooperation to anticipate and address supply problems	Improve and inter-link information in current/existing databases to provide supply chain compliance overview 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 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. 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 2021

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:
    - The top priority and challenge in 2021 will be the processing in a timely manner according to the Agency's standards all COVID-19 related applications in addition to the management of the presence of nitrosamines in medicinal products in accordance with the CHMP art 5(3) Scientific Opinion and the HMA approved process, in the context of the growing trend of non-COVID-19 medicines applications.
    - The implementation of the network strategy priority areas and objectives relevant for human medicines will be primarily delivered through the Agency's other divisions and task forces, yet constant monitoring of the division's workload and human resources will be carried out to assess the feasibility of a phased support to other divisions/task forces as of Q2 2021
    - The investment in information management programmes, such as IRIS, robotics and use of advanced analytics, and continuous improvement in regulatory procedures will be critical to adapt to the anticipated increase in applications in 2021 and beyond.
- Veterinary Medicines Division:
    - The main priority of the Division remains to advance the preparation for the implementation of the Regulation (EU) 2019/6 (Veterinary Regulation): technical and scientific advice to the EC, IT systems, change management, processes and guidance.
    - Continue to support core business activities optimising the use of resources and maintaining timeliness and quality of outputs.
    - Ensure stakeholders and network transition into Regulation (EU) 2019/6
- Stakeholders and Communication Division:
    - COVID-19 and the Agency's response to the pandemic will continue to be a priority for communication, stakeholder engagement and enhanced transparency measures 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 next 5-year framework strategy for communication will be finalised., together with a strategy for restart of clinical data publication once BCP measures are lifted. EMA will continue to ensure that the patient voice is systematically incorporated throughout medicine development and evaluation, and enhance its interaction with healthcare professionals, industry stakeholders and academia
- Information Management Division
    - Deliver the initial operating capabilities required to support key legislative programmes for Clinical Trials and Veterinary Medicines

- Accelerate the modernisation of the Agency's and the Network's regulatory systems
- Assess the impact of new EMA mandates on the Information Systems landscape and establish implementation plan

- Administration Division:
  - Efficiently and effectively filling the positions granted by the budgetary authority to manage COVID-19 workload
  - Efficiently and effectively managing additional budget, staffing and procurements stemming from the extension of the mandate
  - Fostering integrated planning and talent management processes and practices.
  - Supporting the staff management and development and launch first parts of the performance and development programme; completing the development and transition into the implementation of the competency framework
  - Enhancement of the administrative processes, including the domains of procurement, finance and budget, accounts; human resource management; planning and monitoring; programme management; risk management.
- International affairs:
  - Support and develop our international activities for COVID-19 medicines development, evaluation and safety monitoring, in our regular meetings, clusters and ad-hoc discussions, through ICMRA and in the OPEN project. Continue support to priority countries (China, India), global supply chain, and WHO with in particular EU-M4all. Promote the extension of US MRA to veterinary medicines and vaccines, and establish a new relationship with the UK as third country.
- 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 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 data 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
- Data Analytics and Methods (TDA) Task Force:
  - Need to deliver EU Network Strategy to 2025 objectives to transform to data-driven medicines regulation
  - Opportunity to leverage real world evidence as a complement to randomised controlled trials

- Move by stakeholders to novel clinical trial designs

- 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 exchange of knowledge and expertise.

- Clinical Studies and Manufacturing (TCS) Task Force:
  - Preparation for the application of the Clinical Trials Regulation through development of the Clinical Trial Information System and user support for that. Innovation in the conduct of clinical trials through the renovation of GCP, development of multi-stakeholder discussions on clinical trial innovation, the application of the GDPR in clinical research, in particular for secondary use of health data.
  - 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 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 the in management of biological health threats and vaccine strategy.
  - 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.

1. Human Medicines Division

The European Medicines Agency supports and facilitates 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 main drivers for 2021 are:

- Facilitate the development of medicines to prevent or treat COVID-19, evaluating their benefit-risk to support their authorisation, and monitoring their safety and performance once placed on the market;
- Manage of the presence of nitrosamines in medicinal products in accordance with the CHMP art 5(3) Scientific Opinion and the HMA approved process;
- Assure the quality of the continuous assessment of the benefit-risk of medicines throughout their lifecycle;
- Catalyse the use of innovative approaches for the development and authorisation of innovative treatments addressing the needs of patients.

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 2021 for the Division is currently foreseen at 355 staff (262 TAs, 79 CAs, 14 SNEs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

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 a number of activities and incentives offered to companies prior to submitting an application for

[1] Reference: *1.4. Referrals*

marketing authorisation. The assistance and support is 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.

Designation of orphan medicines 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 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		Forecasts
	2019	2020	2021
Parallel scientific advice with international regulators requests	2	4	4
Joint scientific advice with HTA bodies requests	20	2	4
Scientific advice for PRIME products	26	37	40
Protocol assistance	137	143	132
Novel technologies qualification advice/opinions	16	15	19
PRIME eligibility requests received	60	69	55
Orphan medicines applications	233	235	250
Submitted applications on the amendment of an existing orphan designation	1	0	2
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	671	735	670
Finalised procedures for compliance check on PIPs	94	97	80
Requests for classification of ATMPs	70	74	70

Performance indicators

	Results		Targets
	2019	2020	2021
Scientific advice/protocol assistance procedures completed within regulatory timeframes	100%	100%	100%
PRIME eligibility requests assessed within regulatory timeframe	100%	100%	100%
Orphan designation opinions delivered within the legal timeframe	100%	100%	100%
PDCO opinions sent to applicants within legal timelines	99.5%	100%	99%

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. Personalised medicine approaches are increasingly being used as an integrated package of tailor-made healthcare solutions comprising elements of pharmaceuticals (personalised medicines, advanced therapy medicinal products) and devices that address in an optimal 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 evaluation of a large amount of data relating to quality, safety and efficacy of a medicine. Scientific guidelines are developed to guide applicants with regards to the requirements for demonstrating quality, safety and efficacy of a medicine.

The scientific review on which a committee’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, also provides opinions to Notified Bodies on companion diagnostics.

Workload indicators

	Results		Forecasts
	2019	2020	2021
New non-orphan medicinal products	33	43	46
New orphan medicinal products	27	34	29
Similar biological products	13	12	15
Generic, hybrid and abridged products	29	24	25
Scientific opinions for non-EU markets (Art 58)	0	0	3

	Results		Forecasts
	2019	2020	2021
Paediatric-use marketing authorisations	0	0	1
Number of granted requests for accelerated assessment	13	12	10
Reviews on the maintenance of the orphan designation criteria at MAA stage	40	35	30
ATMPs applications requests received[1]	3	6	12
COVID-19 related product applications received[2]	n/a	6[3]	9[4]
Companion diagnostics opinions[5]	n/a	n/a	10

Performance indicators

	Results		Targets
	2019	2020	2021
Applications evaluated within legal timeframes	100%	100%	100%
Average assessment time for new active substances and biosimilars	192.8	192	205
Average clock-stop for new active substances and biosimilars	178.1	166	180
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	43%	50%	60%
% of initial marketing authorisation applications that had received centralised scientific advice	68%	70%	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.

[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 immonomodulators, 3 therapeutics, 4 vaccines
[5] New indicator introduced in 2021 work programme

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		Forecasts
	2019	2020	2021
Type-IA variations	3,886	3,989	4,038
Type-IB variations	2,425	2,675	2,536
Type-II variations	1,123	1,274	1,222
Line-extensions of marketing authorisations	27	35	25
PASS scientific advice through SAWP	3	1	1
Renewal applications	107	99	87
Annual reassessment applications	25	24	29
Transfer of marketing authorisation applications	63	36	60
Article 61(3) applications	286	211	300
Post Authorisation Measure data submissions	776	990	900
Plasma Master File Annual update and variation applications	17	28	29

Performance indicators

	Results		Targets
	2019	2020	2021
Post-authorisation applications evaluated within the legal timeframes	99%	99%	99%
Average assessment time for variations that include extension of indication	165	167	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 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		Forecasts
	2019	2020	2021
Pharmacovigilance referrals started	8	2	8
Non-pharmacovigilance referrals started	7	6	8

Performance indicators

	Results		Targets
	2019	2020	2021
Referral procedures managed within the legal timelines	100%	100%	100%

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		Forecasts
	2019	2020	2021
Number of signals peer-reviewed by EMA	1,806	1,888	1,900
Number of ICSRs for CAPs (reports received)	n/a[1]	n/a[1]	1,660,000
Number of signals assessed by PRAC (validated by EMA)	50	39	50
PSURs (standalone CAPs only) started	554	525	569
PSUSAs started	246	304	327
Number of imposed PASS protocol procedures started	12	4	6
Number of imposed PASS result procedures started	3	4	5
Number of notifications of withdrawn products received	462	510	400

[1] New indicator introduced in 2021 Work Programme.

Performance indicators

	Results		Targets
	2019	2020	2021
Periodic Safety Update Reports (PSURs standalone CAPs only) assessed within the legal timeframe	100%	100%	100%
Periodic Safety Assessment Reports (PSUSAs result procedures) assessed within the legal timeframe	100%	95%	95%
Protocols and reports for non-interventional imposed post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%
PRAC recommendations on signals and translation of labelling changes in EU languages published	100%	100%	100%

1.6 Inspections and compliance

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

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

Harmonisation of inspection standards and practices. The Agency contributes to the harmonisation of inspection standards and practices within the European Union and with international partner authorities including PIC/S, ICH and ICMRA.

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

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

Certificates. The Agency issues electronic certificates of medicinal products, in accordance with WHO requirements, 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 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		Forecasts
	2019	2020	2021
GMP inspections	386	130	50
GLP inspections	0	0	1
GCP inspections	137	59	90
Pharmacovigilance inspections	9	16	16
PMF inspections	111	40	20
Notifications of suspected quality defects	175	170	250
Notifications of GMP non-compliances[1]	19	10	20
Medicinal products included in the sampling and testing programme	67	81	88

[1] Previously: "Other GMP inspections related notifications

	Results		Forecasts
	2019	2020	2021
Standard certificate requests received	2,565	3,115	3,720
Urgent certificate requests received	2,399	1,647	1,485
Parallel distribution initial notifications received	2,468	3,172	2,450
Parallel distribution notifications of bulk changes received	12	10	10
Parallel distribution annual updates received	4,270	11,624[1]	5,500

Performance indicators

	Results		Targets
	2019	2020	2021
Inspections conducted within established regulatory timeframes	100%	100%	100%
Standard certificates issued within established timelines (30 working days)	28%	80%	90%
Average days to issue standard certificate	59.6	23.6	10
Urgent certificates issued within established timelines (2 working days)	97%	98%	100%
Parallel distribution initial notifications checked for compliance within the established timeline	37%	90%	90%
Impact of GCP confidentiality arrangements: Additional GCP inspections addressed through information exchange on inspections carried out by international partners	42%	38%	35%

1.7 Committees and working parties

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:

[1] Includes parallel distribution notifications of change

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 implementation of the EMA regulatory science strategy. Regarding its coordination role, it ensures there is sufficient coordination between the committees, to increase the robustness and predictability of the outcomes of benefit-risk assessments, by having consistent standards set for the development of medicines across the whole product lifecycle.

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

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

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

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

Scientific guideline development. To facilitate the development of medicinal products and guide applicants in their medicines' development planning, the Agency, through its working parties, prepares and reviews guidelines on a variety of scientific topics relevant for the development of medicines. The guidelines take into consideration the latest scientific developments and the knowledge derived from product assessments within the Agency, and contain detailed requirements for the demonstration of quality, safety and efficacy for specific diseases or conditions. They are consulted upon with stakeholders, adopted by the Agency's scientific committees and made available on the Agency's 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		Forecasts
	2019	2020	2021
Number of reimbursed meetings	321	52	512
Committee meetings	76	75	77
Trainings[1]	29	4	33
Workshops	4	2	20
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	212	112	382
Number of virtual meetings (audio-, video- and web-conferences)	3,443	5,409	4,600
Number of reimbursed delegates	6,015	1,003	9,358
Number of non-reimbursed delegates	523	60	1,500
Herbal monographs, new	0	3	4
Herbal monographs, reviewed[2]	13	14	15
Herbal monographs, revised	2	8	4
List entries	0	1	1

Performance indicators

	Results		Targets
	2019	2020	2021
Evaluation of declarations of interests of committee members and alternates prior to their participation in committee meetings.	100%	100%	100%

[1] Includes EU Network training centre meetings.
[2] When after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published

Pillar 2 – Public health activities

The priority for the human medicines division is to respond to the COVID-19 public health crisis, hence in 2021 the implementation of the network strategy priority areas and objectives relevant for human medicines will be primarily delivered through the Agency's other divisions and task forces (see sections below for a detailed description). Constant monitoring of the division's workload and human resources will be deployed to assess the feasibility of a phased support to other divisions/task forces as of Q2 2021.

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

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Support the STAMP scientific advice pilot for repurposing established medicines	1.1	A number of prioritised established medicines are enlisted in the pilot	Q1 2021	Q4 2022	Number of products enlisted in the pilot

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe		Deliverable 2021
		Start	End	
SPM&S - Substances and products management services	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	2017	2024	- Merge for delivery optimisation into the Regulatory Business Process Optimisation Programme (**RBPOP**) in Q2 2020 - Deliver requirements set out in the pharmacovigilance legislation to provide an ISO IDMP compatible substance and product repository, linked to EU-SRS, and messaging format.

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 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 percent[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 on 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 year 2021 will be:

- Advance the preparation for the implementation of the Regulation (EU) 2019/6 (Veterinary Regulation): technical and scientific advice to EC, IT systems, change management, processes and guidance.
- Continue to support core business activities optimising the use of resources and maintaining timeliness and quality of outputs.
- Ensure stakeholders and network transition 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 2021 for the Division is currently foreseen at 61 staff (41 TAs, 18 CAs, 2 SNEs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

[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 development of veterinary medicines. Activities in this area cover the following:

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

Support for authorisation of **products for minor uses and minor species** (MUMS)**/limited markets**. To stimulate development of new veterinary medicines for minor species and/or for rare diseases in major species, the Agency provides support and incentives to applicants submitting applications for products for limited markets.

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 Ad hoc experts group on Veterinary Novel Therapies (ADVENT) 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		Forecasts
	2019	2020	2021
Innovation Task Force briefing requests (Vet)	6	5	5
Scientific advice requests received	21	31	22
Requests for classification as MUMS/limited market, of which	34	29	25
Re-classification requests	9	4	5

Performance indicators

	Results	Expected results	Targets
	2019	2020	2021
Scientific advice procedures completed within set timeframes	95%	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 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		Forecasts
	2019	2020	2021
Initial evaluation applications	23	15	18
New MRL applications	3	1	2
MRL extension and modification applications	4	1	2
MRL extrapolations	0	0	0
Art 10, Biocides	0	0	0
Review of draft Codex MRLs	0	3	0

Performance indicators

	Results		Targets
	2019	2020	2021
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. 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.

Applications for **extensions of marketing authorisation.** These include fundamental changes to the veterinary medicinal product, such as changes to the active substance, changes to the strength or pharmaceutical form, or a change or addition of a food-producing species to the authorisation.

Maintenance activities. These include follow-up on certain obligations that marketing-authorisation holders need to fulfil following the granting of a marketing authorisation. These include reassessment and renewal of marketing authorisations, as well as marketing-authorisation transfers when the legal entity of the marketing-authorisation holder changes.

Workload indicators

	Results		Forecasts
	2019	2020	2021
Variations applications, of which:	568	637	425
Type I A variations	356	380	217
Type I B variations	139	195	145
Type II variations	73	62	63
Line extensions of marketing authorisations	2	2	3
Transfers of marketing authorisations	24	9	5

Performance indicators

	Results		Targets
	2019	2020	2021
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 (e.g. in granting a variation or a marketing authorisation), or when over the years Member States have adopted different decisions for some medicines and discrepancies need to be harmonised.

Referrals are initiated regarding centrally and nationally authorised products to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by Member States, or in cases where there is a Community 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. 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.

Workload indicators

	Results		Forecasts
	2019	2020	2021
Arbitrations and Community referral procedures initiated	9	3	6

Performance indicators

	Results		Targets
	2019	2020	2021
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 as well as management and assessment of periodic safety update reports (PSURs).

Workload indicators

	Results		Forecasts
	2019	2020	2021
Periodic safety-update reports (PSURs)	159	160	160
Total AERs, of which:	70,392	66,901	75,000
Adverse-event reports (AERs) for CAPs	33,656	30,297	37,500
Adverse-event reports (AERs) for NAPs	36,736	36,604	37,500

Performance indicators

	Results		Targets
	2019	2020	2021
PSURs evaluated within the established timeline	96%	98%	90%
AERs for CAPs monitored within the established timelines	95%	97%	95%

Pillar 2 – Public health activities

This area covers EMA activities in the veterinary medicines field, other than routine activities related to 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. In addition, this year main focus of the Agency is on revising its processes and guidance to fit the new provisions and designing and implementing the new IT systems required by the regulation: Union database on veterinary medicinal products (Union product database), Union pharmacovigilance database (EudraVigilance Veterinary) and Union database on manufacturing, import and wholesale distribution

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 treatment of infectious disease 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:

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
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;	3.1	Guidance for novel therapies and biologicals developed	2020	2021	Increase of innovative veterinary products applications Better quality of dossier submitted
Engage with EU and international risk assessment bodies with a view to aligning methodology for estimating consumer exposure to residues, including dual-use substances;	3.1	Analysis of existing models Evaluation of finding and recommendation on harmonised approach	2020	2022	Recommendation sent to EC
Together with stakeholders, develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database;	3.1	Guidance for surveillance and signal detection developed Enhanced communication with the network	2020	2023	Increase of reporting Better quality of reporting
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;	3.1	Methodology established and guidance developed	2020	2022	Better understanding of distribution of incidence of AEs

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
					Use of incidence distribution to identify clusters
Establish stakeholder expert groups for different food-producing species to access actual-use data of products in the field, both off and on label"	3.1	Expert group established with mandate and objectives	2021	2022	Increase of available data on actual-use Better data quality on actual use
Improve communication of veterinary pharmacovigilance to the general public.	3.1	Establish PhV communication framework	2020	2022	Increased and better communication published/disseminated on PhV topics
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;	3 (additional RSS recommendation)	Support EC in the monographs feasibility study	2020	2025	Feasibility study concluded
Develop further guidance on when the use of persistent, bio accumulative and toxic substances in animals can be justified;	3 (additional RSS recommendation)	PBT guidance developed and published	2021	2023	Improved justifications in dossier for PBT substances
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;	3 (additional RSS recommendation)	Establish ERA framework with EU and international partners Harmonised approach on ERA assessment	2021	2025	Increased cooperation between institutions Enhanced flow of information
Provide scientific support to the European Commission and the EU network to ensure that a “One Health” approach is applied to ERA;	3 (additional RSS recommendation)	Support to EC provided "One Health" approach for ERA implemented	2021	2025	Increased use of "One Health" approach in ERA dossier / assessment

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Expand current ESVAC system to include other antimicrobials	4.1	Collection of data expanded to include all antimicrobials	2021	2023	ESVAC report to include all antimicrobials
Establish contributions to JIACRA under CVMP guidance and develop new processes that maintain Member State input and ensure EMA oversight	4.1	Establish and implement new process for JIACRA report to be led by EMA and CVMP in cooperation with EU MSs	2021	2023	4th JIACRA report developed via the new process
Adjust the methodology for analysis of antimicrobial data, by considering approaches developed internationally;	4.1	Analyse international approaches and integrate where possible in methodology	2021	2025	Methodology revised/updated
Define requirements for harmonised sales and use data collection for antimicrobial medicinal products used in animals;	4.1	Define new requirements Develop guidance on new requirements	2020	2023	New requirements applied and guidance finalised
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;	4.1	Actively participating to policy development	2020	2025	Policy includes vision from EMA
Participate in international initiatives to reduce the risk of AMR.	4.1	Actively participating in international fora	2020	2025	Track records of participation to International fora regarding AMR
Update existing guidelines, and initiate new guidance as needed	4.3	Develop relevant guidance	2020	2025	Guidance published
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	4.3	Reflection paper finalised and published	2020	2021	CHMP conclusions on H medicines based on V paper
Develop a regulatory approach/framework to promote alternatives to conventional antimicrobials and novel paradigms;	4.3	Framework developed Communication with stakeholders	2020	2025	Framework established and in use Increase of alternative products submission?
Enhance the promotion of the responsible use of antimicrobials via updated and/or new regulatory guidance and scientific opinion;	4.3	Guidance development Communication with stakeholders	2020	2025	Guidance published Awareness raised in the Network

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Provide scientific and regulatory support to encourage development of veterinary antimicrobials and alternatives, to fill therapeutic gaps, without adversely impacting public health;	4.3	Guidance development	2021	2025	Awareness raised in the Network Increase of alternative products submission
Work in partnership with EC, other EU Agencies and regulators and international bodies to promote the responsible use of antimicrobials and their alternatives;	4.3	Cooperation at EU and International level for events Common approach agreed	2021	2025	Awareness raised in the Network Increase of alternative products submission?
Acknowledge that different benefit-risk approaches are required for assessment of specific vaccine types (e.g. vaccines for zoonotic diseases, limited markets, exceptional circumstances);	4 (additional RSS recommendation)	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
Develop a regulatory framework for authorisation, under exceptional circumstances, of vaccines for emerging health threats and benefit-risk monitoring post-approval;	4 (additional RSS recommendation)	Guidance developed and implemented	2021	2022	Exceptional circumstances products submitted
Develop appropriate and proportionate guidance to maximise opportunities offered by Regulation (EU) 2019/6 for promoting availability of vaccines (vaccine antigen master files, vaccine platform technology master files and multi-strain dossiers);	4 (additional RSS recommendation)	Guidance developed and implemented	2020	2025	Increase of applications for vaccines
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;	4 (additional RSS recommendation)	Improve interaction with International organisations Best practices embedded in guidance	2020	2025	Track records of participation to International fora concerning antiparasitic resistance Take away points communicated

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Promote responsible use of antiparasitics in the EU.	4 (additional RSS recommendation)	Awareness events and enhanced dissemination of information	2020	2025	Better use of antiparasitics (decrease of AERs)
Veterinary Medicines Regulation: Preparation phase – 2021; Implementation phase from 2022.	6.1	Prioritised guidance, processes and IT systems in place in time for implementation	2020	2025	Submission and evaluation of procedures under 2019/6
Promote systematic application of structured benefit-risk methodology and quality assurance systems in the approach to assessment and consistency of decision-making;	6.2	Analysis of current methodologies, development of harmonised approach and guidance	2021	2025	Consistent decisions taken for B-R assessment of veterinary products
Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders, especially for novel technologies.	6.2	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		Deliverable 2021
		Start	End	
EVVet3 - Union Pharmacovigilance Database / EudraVigilance Veterinary v3.0	The EVVet3 project aims to provide a "Union veterinary pharmacovigilance system", by implementing any remaining requirements from Directive 2001/82/EC (as applicable, in relation to veterinary pharmacovigilance reporting), as well as the VICH guidelines relating to pharmacovigilance reporting	2017	2023	- Completion development of EVVet3 system compliant with legislation - End-to-end user acceptance testing - Go live Q4

Project title	Long term objective	Project timeframe		Deliverable 2021
		Start	End	
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	- Completion development of UPD system compliant with legislation - End-to-end user acceptance testing - Go live Q4
ESVAC - Collection of Antimicrobials Sales and Use Data [new]	The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project collects information on how antimicrobial medicines are used in animals across the European Union (EU). The objective obtains reliable data for input into risk profiling and risk assessment regarding antimicrobial resistance and for setting risk management priorities regarding AMR	Q1 2021	2023	- Amendment of ESVAC to additional requirements for collection of sales data
EudraGMDP - 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	2022	- Analysis/impact assessment of amendments and needed improvements to EudraGMDP

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 drives complex, digital change initiatives that impact on EMA's strategy, operational structure and operations in relation to the European 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.

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 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 data 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 2021 for the Task Force is currently foreseen at 12 staff (9 TAs, 3 CAs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

Pillar 2 – Public health activities

IRIS project. This the chosen online customer relationship management (CRM) platform for handling product-related regulatory procedures across the lifecycle for EMA staff, the network and industry stakeholders, and will translate and implement ongoing and future human and veterinary legislative initiatives into 'IRIS-ready' business processes.

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 business-process design, automation, information and knowledge-management.

Change Management. Establishing a Change Management Centre of Expertise to develop Agency-wide change management capabilities and capacity, taking a customer centric approach to delivery.

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, including investigating the possibility to expand EU NTC training to wider audiences outside of the EMRN.

Digital Academy - digital literacy, capability and capacity. These will be built through the development of a digital knowledge-sharing academy, capitalising on experience of the EU Network Training Centre (EU NTC).

Business and regulatory intelligence. This encompasses implementation of ongoing (veterinary legislation, medical devices and in vitro diagnostics regulations) 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 be in charge of designing policies and will set up governance frameworks to support a high standard of quality in EMA decision-making.

Workload indicators

	Results		Forecasts
	2019	2020	2021
New scientific, regulatory and telematics curricula developed	2	2	2
Number of training events advertised to the EU Network	40	46	40
Number of reimbursed training events to the EU Network	12	1	12
Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	10	7	10

Performance indicators

	Results		Targets
	2019	2020	2021
Number of users registered to the EU NTC Learning Management System	5,121	5,290	5400
Number of NCA experts registered to the EU NTC Learning Management System	4,143	4,297	4500

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

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Establish a digital innovation lab to explore, pilot and develop solutions and processes, across the drug regulation spectrum, that leverage novel digital technology and artificial intelligence to support increase in efficiency and regulatory decision-making;	2.2	Review and implement digital business transformation, using analytics, artificial intelligence and automation methodologies, across selected business functions supporting medicines' development, evaluation, supervision and administrative processes; Set up an innovation lab;	2021	2025	Targets delivered
Establish an EU collaboration on AI with other Agencies in the EU Network	2.2	Develop and promote AI community; Share knowledge and increase maturity; Collaborate for the implementation of common AI initiatives and projects	2021	2025	Regular community meetings established. Platform for exchange and capturing the information created.
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;	2.3	Develop a future state learning delivery model and landscape that serves new and existing audiences,in co creation with the EU-NTC; Deliver training on AI	2021	2025	Target/ Training module delivered Defined service model and related tools to expand the current learning ecosystem
Develop the integrated evaluation pathways for the assessment of combination products / companion diagnostics	3.4	Facilitate the regulatory pathway between notified bodies and medicines' regulators	2021	2023	Target delivered
Identify and enable access to the best expertise across Europe and internationally	3.4	Map all current working groups (i.e. at EMA, HMA/CAMD, NCA, EC) working on medical devices and in vitro diagnostic where there is	2021	2023	Approach established

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
		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			

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe		Deliverable 2021
		Start	End	
ECTD4: Implementation and adoption of eCTD v4.0 standard	The project aim at implementing the next generation standard defining the message for exchanging regulatory submission information electronically between applicants and Regulatory Authorities.	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)
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	- Scientific Advice hyper care after the Oct 2019 go-live - eAF Proof of concepts - Inspections - Variations process - Marketing Status - Supply Chain

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.

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

- Need to deliver EU Network Strategy to 2025 objectives to transform to data-driven medicines regulation
- Opportunity to leverage real world evidence as a complement to randomised controlled trials
- Move by stakeholders to novel clinical trial designs

The workforce available in 2021 for the Task Force is currently foreseen at 34 staff (22 TAs, 4 CAs, 8 SNEs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

Pillar 2 – Public health activities

EMA, in close collaboration with ECDC, EC and Member States is ensuring a robust monitoring of the COVID-19 vaccines. This includes obligations placed on MAHs through their RMPs, enhanced signal detection from reports of suspected Adverse Drug Reactions in EudraVigilance and commissioning of observational vaccine safety studies. Building on the foundational work initiated in 2020, through the EMA funded ACCESS consortium and the EMA funded bridging vaccine safety study initiated in late 2020, EMA will commission a large European vaccine safety study to run through 2021-2022 to both prospectively evaluate the safety of COVID-19 vaccines and to assess any emerging vaccine safety signals during this period. In addition to this, in the context of the vaccination campaigns and to support the monitoring of vaccine safety, the Agency will be supporting NCAs in performing some processing of COVID Vaccine-related ICSRs during 2021 and 2022.

Provide expert advice on study design and on the availability and suitability of existing data sources.

Provide, with EMA and Network collaborators, targeted data analyses to committees and WPs.

Provide an analytics advice service to the Agency and support to the EU Network.

Collaborate with the Digital Business Transformation Task Force (TDT) to ensure provision of an artificial-intelligence (AI) advice service to the Agency.

Pilot the analyses of patient-level data from clinical trials.

Lead and coordinate EU regulatory efforts in data standardisation, including data included in industry submissions and real-world data. Support the use of such data in IRIS.

Coordinate guideline development in data standards, terminologies, data-management, methodology, etc., and participate in guideline development at an international level.

Lead capacity-building in methodology, data-science and analytics for EMA and the EU network (including through EU-NTC).

Manage contracts with academic service providers for studies, including real world data (RWD) studies (thereby leveraging data that cannot be directly accessed).

Manage the EudraVigilance Data Management and Medical Literature Monitoring service contracts and relevant activities.

Maintain 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.

Influence and leverage EU and international initiatives (in collaboration with International Affairs).

Workload indicators

	Results		Forecasts
	2019	2020	2021
Number of MLM ICSRs created	9,676	9,950	15,000
Number of healthcare data sets to which EMA access and therefore its committees can integrate analyses into assessments	3	3	6

Performance indicators

	Results		Targets
	2019	2020	2021
Number of individual reaction-monitoring reports supplied to the Member States according to the agreed timelines and data quality indicators	99%	97%	90%

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

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Progress the development, construction and delivery of the Data Analytics and Real World Interrogation Network	2.1	To initiate a project to deliver DARWIN EU, including the sourcing of an external technical coordinator. A pilot with the European Health Data Space initiated.	2020	2023	Project plan presented to EMA Management Board. A contract with the DARWIN EU technical coordinator in place by Q4 2021. Protocol finalised for European Health Data Space pilot.
Deliver a sustainable platform to access and analyse healthcare data from across the EU (Data Analysis Real World Interrogation Network -DARWIN). Build the business case with stakeholders and secure funding to establish and maintain a secure EU data platform that supports better decision-making on medicines by informing those decisions with robust evidence from healthcare;	2.1	To initiate a project to deliver DARWIN EU, including the sourcing of an external technical coordinator. A pilot with the European Health Data Space initiated.	2020	2023	Project plan presented to EMA Management Board. A contract with the DARWIN EU technical coordinator in place by Q4 2021. Protocol finalised for European Health Data Space pilot.
Launch and carry out CHMP pilot for individual patient level data from clinical trials	2.1	Pre-pilot of at least one marketing authorisation application in 2021	2021	2023	Interim lessons learnt from the pre-pilot in Q3 2021. Presentation to CHMP of a draft protocol for a full pilot of IPD from CT in Q 4 2021.
Work with international partners to develop roadmap and guidance	2.1	Agreement of roadmap for international regulatory collaboration on real world evidence.	2020	2025	International regulatory summit on real world evidence held. Publication of the roadmap for international regulatory collaboration on real world evidence.

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Collaborate with international initiatives on Big Data. Support the development of guidelines at international multilateral fora, a data standardisation strategy delivered through standards bodies, and bilateral collaboration and sharing of best practice with international partners;	2.1	Develop a set of documents to describe and establish a data standards development Strategy followed by a roadmap. Develop international guidelines to improve innovative drug development.	2021	2022	Targeted stakeholder consultation and workshop by Q4 2021. Participate to ICH E20 (adaptive design) and ICH MIDD (model-informed drug development) working group meetings in 2021.
Work to develop and implement EU framework	2.1	Consult stakeholders on data elements to be used as real world data meta-data for regulatory purposes.	2020	2024	Stakeholders consulted by Q4 2021
Establish an EU framework for data quality and representativeness. Develop guidelines, a strengthened process for data qualification through Scientific Advice, and promote across Member States the uptake of electronic health records, registries, genomics data, and secure data availability;	2.1	The final guidance on studies from registries published.	2020	2021	The final guidance published.
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);	2.1	Initiate a project to enhance the EU database of real world data resources (ENCePP database).	2021	2023	Business case made public.
Develop EU Network skills in Big Data. Develop a Big Data training curriculum and strategy based on a skills analysis across the Network, collaborate with external experts including academia, and target recruitment of data scientists, omics specialists,	2.2	Training curricula finalised on pharmacoepidemiology, biostatistics and data science. Integrate curriculum on modelling and simulation.	2021	2021	Curricula made public and at least one module delivered per curricula. Present draft curriculum plan on modelling and simulation to EU-

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
biostatisticians, epidemiologists, and experts in advanced analytics and AI;					NTC Steering Group by Q4 2021.
Create and maintain a Health Data Science and AI forum to engage with a diverse set of stakeholders in novel digital technologies and artificial intelligence. This will include the technical, ethical, legal, regulatory and scientific perspectives of the use of digital technologies, and AI-powered applications;	2.2	Stakeholder workshop on AI held.	2021	2021	Stakeholder workshop on AI held.
Develop Big Data learning initiative with a view to developing guidelines and processes that learn from applications	2.2	Review of real-world data in marketing authorisation applications from 2018 and 2019 completed and learnings presented to CHMP and Big Data Steering Group. Hold a workshop with stakeholders to learn from Big data in regulatory submissions.	2021	2025	Publication of the review. Hold a stakeholder's workshop.
Strengthen EU Network processes for Big Data submissions. Launch a 'Big Data learnings initiative' where submissions that include Big Data are tracked and outcomes reviewed, with learnings fed into reflection papers and guidelines. Enhance the existing EU PAS register to increase transparency on study methods;	2.2	Initiate project to upgrade the EU Post-Authorisation Studies Register with agreed meta-data and functionalities to enable posting of protocols and results and complex searches.	2021	2023	Publication of the business case.
Create an EU Big Data 'stakeholder implementation forum'. Dialogue actively with key EU stakeholders, including patients, healthcare professionals, industry, HTA bodies, payers, device regulators and technology companies. Establish key communication points in each agency and build a resource of key messages and communication materials on regulation and Big Data.	2.4	Multi-stakeholder forum on Big Data held.	2021	2021	At least one meeting in 2021.

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
The actions in this Regulatory Science Strategy relating to RWD are included within the 10 actions listed under Big Data. In addition, specific pilots of RWD analytics will be conducted and work on pharmacovigilance methods will continue: - Conduct a pilot of using rapid analytics of real-world data (including electronic health records) to support decision-making at the PRAC and CHMP; - Review of the utility of using electronic health records for detecting drug safety issues (including drug interactions);	2.4	The final report of PRAC rapid analytics pilot and initiate pilot with one other committee.	2020	2022	Publish the results of the PRAC pilot.
Develop the regulatory framework for emerging clinical data generation	3.2	Over a three-year period, compile a review of current experience of novel trial design concepts or statistical methods related to: estimands, master protocols, Bayesian, single arm trials, indirect comparison. To include considerations for special populations. Plan guidance drafting or revision where necessary. Implement recommendations, including via training.	2021	2023	2021: publish a review of current experience on relevant subjects. Publish draft ICH E11A guideline. 2022: Plan guidance drafting or revision. Publish draft ICH E20 guideline. 2023: roll out implementation and training.

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe		Deliverable 2021
		Start	End	
- Lifecycle Regulatory Submission Metadata	- Identify relevant data sources and by defining and standardising the structure of	2021	2022	- Perform a research and landscaping analysis of EU Regulatory standardisation needs

Project title	Long term objective	Project timeframe		Deliverable 2021
		Start	End	
	the information (i.e. defining the 'metadata' and supported through relevant standards), the scientific information will become more accessible			- Perform stakeholder analysis of current formal business processes and informal assessor practices used to gather scientific information needed for assessment to identify and prioritise relevant business cases
- 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	- Review of experience with Individual Patient Data and Pilot - Technology Proof of concept
- 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	- Metadata study, Data sources identification and Quality framework - Initiate work on catalogues 2nd half 2021.
- Observational Studies Rapid Analytics	- Increase the amount of real-world evidence and real-time evidence analysis in committee decision making	2020	2022	- Change management ad go-live - Review and report by Q4 2020
- 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 representativeness of EU health data	2021	2025	- Pilot with European Health Data Space - Coordinating centre preparation (service provider engagement, funding, rules and processes, governance) - Prepare EMA to be ready as a node - establish DARWIN Network Coordination Group - Training and change management
- Signal and Safety Analytics	- Increase saleability and efficiency in processing of signals & safety data	2021	2023	- Optimise Signal & Safety Analytics through improving the eRMR, aligning to agreed data standards and making more efficient the generation of evidence in support of benefit & risk decisions.

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 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 exchange of knowledge and expertise.

The workforce available in 2021 for the Task Force is currently foreseen at 21 staff (13 TAs, 4 CAs, 4 SNEs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

Pillar 2 – Public health activities

The SME Office Workstream

The European Medicines Agency (EMA) addresses the unique needs of micro, small and medium-sized enterprises (SMEs) through the SME office. This dedicated interface has the sole remit of providing regulatory, financial and administrative assistance to small pharmaceutical companies.

It was set up by Commission Regulation (EC) No 2049/2005 and promotes innovation and the development of new medicines for human and veterinary use by SMEs.

The Research and Innovation Workstream

Innovation and emerging therapies

The Agency 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.

The ITF serves as 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 ITF works closely with our partners within the network, academic specialists and the EU network of Innovation and Technology Forum Offices. The ITF also collaborates with the European institutions and international partners on ITF procedures, and links with ICMRA innovation project and its horizon scanning activities.

The EU Innovation Network aims to facilitate 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. In addition, it broadens dialogue with innovators at an EU level and provides a platform for regulators to share and improve the flow of knowledge from early stage innovators to NCAs and EMA scientific committees. It identifies and encourages sponsors of promising drug development projects to move to the next appropriate regulatory level for national and EU advice and evaluation.

Business analysis and forecasting

The Business Analysis and Forecast (BAF) team provides the Agency with forecasts and business intelligence on marketing-authorisation applications, to enable accurate budgeting, identification of the most appropriate resources and scientific expertise needed, and to facilitate internal operations.

Data acquisition relies on information available internally at EMA and the direct interaction with pharmaceutical industry. Interaction with industry entails regular acquisition of the product pipeline of pharmaceutical companies.

To engage in a deeper exchange on the development portfolio, we organise regular business pipeline meetings with pharmaceutical companies.

Horizon scanning

The rapid emergence of innovation is a major challenge facing regulators. To respond, the identification of future innovations and trends will be undertaken in a comprehensive, systematic and sustainable manner so that EMA, and our partners, can respond appropriately and enable innovations to reach the market with minimal developmental, legal, regulatory, process or procurement bottlenecks.

Academia Liaison and external regulatory research projects

As part of the implementation of the framework of collaboration with academia, an Agency-wide plan for interaction with academia is being developed, which aims (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.

Optimise core deliveries

Advance support to innovation through enhanced first-contact functionalities within the Innovation Task Force, SME Office and academic liaison.

Develop the horizon-scanning and outreach capabilities of EU-IN and SME Office, also in collaboration with ICMRA.

Expand business analysis and forecasting to deliver enhanced quality outputs to the Agency and the EU network.

Continue support to IMI2's closing projects, and plan and coordinate engagement with Horizon Europe and IHI.

Establish new processes to advance regulatory science

Define EMA's regulatory science research agenda.

Develop a systematic horizon-scanning capability to identify scientific and technological trends that will impact the regulatory system.

Coordinate the conduct and/or commissioning of impact-assessment studies.

Ensure continuous futureproofing

Translate EMA's 'Regulatory science strategy to 2025' into EMA's annual and multi-annual work programmes and its committees and working parties.

Develop the regulatory science observatory by activating a matrix of subject-matter experts across the product-development lifecycle

Workload indicators

	Results		Forecasts
	2019	2020	2021
Innovation Task Force briefing meetings	29	30	35
Innovation Task Force Art 57 CHMP opinion requests	4	0	3
Business Pipeline briefing meetings[1]	2[2]	20	22
Regulatory assistance, including SME briefing meetings[3]	195	232	223
Requests for SME qualification	536	518	532
Requests for SME status renewal	1,235	1,205	1,362

Performance indicators

	Results		Targets
	2019	2020	2021
Satisfaction level of SMEs	n/a	89%	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] Activity reduced in 2019 due to BCP
[3] New indicator introduced in work programme 2021

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Identification of new technologies via HS and scientific advice activities and their integration into the EU-NTC	3.1	New technologies identified and integrated within EU-NTC	2021	2025	Target delivered
Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	3.3	Emerging regulatory science research questions addressed in support of committee decision-making	2021	2025	Target delivered
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	3.3	Regulatory training modules developed	2021	2025	Target delivered
Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders.	3.4	Establishment of platform for systematic dissemination and exchange of knowledge and expertise on emerging innovation	2021	2024	Target delivered
Integrate EMA's Regulatory Science Strategy into the EMRN strategy, conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, identify gaps in expertise and provide continuous training through the EU Network Training Centre;	6.1	RSS integrated within EMAN Strategy Implementation tracked systematically to ensure delivery	2020	2025	Target delivered

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 2021 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 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 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 the in management of biological health threats and vaccine strategy, including where resource permits on antimicrobial resistance
- 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 2021 for the Task Force is currently foreseen at 22 staff (18 TAs, 4 CAs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

Pillar 2 – Public health activities

Clinical Trials Workstream

Preparation for the application of the Clinical Trials Regulation (see also Pillar 3) through development of the Clinical Trial Information System 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.

Development of Personal Data Protection approaches for the CTIS including pioneering Data Privacy Impact Assessement in joint work with the Legal Department (see also below).

Innovation in the conduct of clinical trials through contributing to the renovation of Good Clinical Practices (GCP) and through development of multi-stakeholder discussions on clinical trial innovation, including on new clinical trial approaches and designs.

Biological Health Threats and Vaccine Strategy Workstream

COVID-19 response: The Biological Health Threats and Vaccine Strategy team lead the agencies strategic response in supporting the development and evaluation of vaccines and therapeutics for the treatment and prevention of COIVD-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.

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 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.

Application of data privacy legislation in healthcare research: Developing approaches to ensuring DP legislation can become an enabler of Healthcare research, in conjunction with the Legal Department and Data Analytics Taskforce in the application of data protection legislation to the use of Healthcare Data in medicines research, in particular secondary use of healthcare data, through the development of policy and question and answer documents.

Providing leadership in conjunction with the Legal Department in the approach to conducting Data Privacy Impact Assessments at the Agency and in particular in the the development of Data Protection Impact Assessments for the Clinical Trial Information System, and also EudraVigilance.

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

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Develop data sharing principles with stakeholders and provide regulatory guidance	2.4	Questions and Answers (Q&As) on the GDPR and the Secondary Use of Data for Medicines and Public Health Purposes. Prepare a high level paper guiding the Agency and the stakeholders with respect to the use of clinical trial	2021	2021	Finalisation of Q&A at Agency level and publication.

Action	MAWP Strategic Goal	Expected result	Timeframe Start	Timeframe End	Performance indicator
		and other health data for the purpose of the development, authorisation and safety monitoring of medicines.			
Modernise the GCP regulatory oversight to enable decentralised models of clinical trials coupled with direct digital data accrual;	3.2	Finalisation of ICH E6 (R3) GCP (principles and Annexes 1 and 2).	2019	2024	KPI for 2021 Agreement of Step 2 at ICH for ICH E6 GCP (objectives and Annex 1).
Drive development and adoption of novel practices that facilitate clinical trial authorisation, GCP and HTA acceptance at EU and international level;	3.2	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).
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;	3.2	Establish a framework, mandate and objectives for a multi-stakeholder platform for discussion of new approaches for Clinical Studies.	2021	2025	2021 - Outline Framework, Mandate and Objectives established and published. 2021 - Two workshops to initiate platform focused on GCP Renovation, complex trials and launch of CT Regulation.
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;	3.2	Using the multi-stakeholder framework from 3.2.1.11 develop action plan and workstreams on complex clinical trials.	2021	2025	2021- Action and workstreams for complex clinical trials established.
Promote the inclusion of neglected populations such as pregnant and lactating women, the elderly and those of diverse ethnicity in clinical trials.	3.2	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 2021 - Agreement of Step 2 at ICH for ICH E6 GCP (objectives and Annex 1) and Step 4 for ICH E8. 2. For 2021 - Finalise guidance on clinical trials in

Action	MAWP Strategic Goal	Expected result	Timeframe Start	Timeframe End	Performance indicator
					pregnancy. 3. For 2022 - Develop guidance on clinical trials in the elderly/ very elderly.
Define approaches for review of data with international regulator	4.6	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.
Communicate proactively with key stakeholders on benefit-risk using evidence-based tools to tackle vaccine hesitancy;	4 (additional RSS recommendation)	Interaction with the ECDC and public health authorities and ICMRA	2021	2025	Update of the vaccination information portal.
Engage with public health authorities and NITAGs to better inform vaccine decisions;	4 (additional RSS recommendation)	Attend meetings of the NITAG and contribute.	2021	2025	At least two meetings per year.
Establish a platform for EU benefit-risk monitoring of vaccines post-approval;	4 (additional RSS recommendation)	Set up the platform and conduct first studies.	2021	2025	Studies of safety and effectiveness of vaccines.

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe Start	Project timeframe End	Deliverable 2021
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	- CTIS integration with other EMA databases or systems - Translation of public user interface in all official EU languages - An evolved version of the CTIS release targeting a planned go live at the end of 2021 - Targeted communications to facilitate awareness and preparedness in the user community - Knowledge transfer to the user community through online training materials and delivery of training Guidelines - CTIS Helpdesk setup

4. Deputy Executive Director Division

Deputy Executive Director oversees a range of activities including:

Infrastructure services. These cover activities related to the Agency's premises and office accommodation, security, business continuity, health and safety, environment management, reception and switchboard, mail management, reprographics and offsite archives, as well as catering.

Corporate governance. These activities cover management of the Agency, including support to the Management Board and senior management of the Agency.

Deliver, upgrade and maintain effective and secure information services. To ensure sustainability of the information services it provides as well as its operations, it is essential that the information services that the Agency provides meet the required technical and information security standards. This also benefits public and animal health by enabling data and information managed by EMA to be leveraged by the network for better decision-making.

EU institutional services. These cover activities related to interactions with the EU institutions, including providing EMA input during the legislative procedure for new pharmaceutical legislation.

Policy issues. These cover activities related to the development and revision of EMA policies, as well as monitoring their implementation.

Emergency and crisis management. These activities relate to crisis management of emergency events (both product and non-product related) with policy, political, reputational consequences for the Agency, or important public-health related events. These activities include monitoring of shortages of medicinal products, provision of secretariat to the HMA/EMA Task Force on availability of authorised medicines for human and veterinary use (TF AAM) and to the EU Executive Steering Group on shortages of medicines caused by major events. With the possible formalisation of the new legal mandate for the Agency these activities may be scaled up.

The workforce available in 2021 for the Division is currently foreseen at 33 staff (27 TAs, 6 CAs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

Performance indicators[1]

	Results		Targets
	2019	2020	2021
Energy consumption (change in % per workstation)	n/a[2]	n/a[2]	n/a[2]
Water consumption (change in % per workstation)	n/a[2]	n/a[2]	n/a[2]

[1] The performance indicators concerning environmental management will be filled as of 2022, see also note below.
[2] Due to EMA's two-stage relocation to Amsterdam the environmental performance indicators cannot be estimated. During 2019-2021 EMA will occupy 3 buildings; 30 Churchill Place in London (Jan-Feb 2019), Spark building in Amsterdam (Mar-Dec 2019) and EMA building in Amsterdam (Jan 2020 to 2021 and beyond). To provide meaningful environmental targets, at least one base year of gathering data with regular building occupancy is required and therefore it is envisaged that the new environmental indicators will be set up only for 2022.

	Results		Targets
	2019	2020	2021
Paper consumption (change in % per workstation)	n/a[2]	n/a[2]	n/a[2]
Non-recyclable waste produced in restaurant and kitchenette (change in % per workstation)	n/a[2]	n/a[2]	n/a[2]
Recyclable waste produced (change in % per workstation)	n/a[2]	n/a[2]	n/a[2]
Recycling rate (change in % per workstation)	n/a[2]	n/a[2]	n/a[2]
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)	n/a[2]	n/a[2]	n/a[2]
Overall net CO_2 emissions (per workstation)	n/a[2]	n/a[2]	n/a[2]

In addition to the above, the Deputy Executive Director Division plans to undertake and progress the following additional activities:

Action	MAWP Strategic Goal	Expected result	Timeframe Start	Timeframe End	Performance indicator
Develop a common framework/methodology for forecasting demand data for medicines in the EU/EEA	1.1	Common Framework methodology for forecasting demand data for medicines in the EU/EEA developed and adopted by the network	2020	2021	Methodology developed and adopted by the end of 2021

5. Advisory functions (International affairs, Internal audit, Legal department)

The **international affairs** Division 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 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 developing countries and capacity building and training of non-EU regulators.
For the year to come, health crises (COVID-19 and Nitrosamines), extension of US MRA, supply chain, article 58, support to priority countries, capacity building (including IPA training) and scientific training are driving the work programme.

The **Internal audit** 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, whistleblowing, 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 European Commission representatives, and provides advice and support, among other things, on the implementation of new 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 is responsible for the preparation and implementation of the Agency's anti-fraud strategy and the related action plan.

The workforce available in 2021 for the Advisory functions is currently foreseen at 27 staff (20 TAs, 6 CAs, 1 SNE). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

Pillar 2 – Public health activities and Business Services

Workload indicators

	Results		Forecasts
	2019	2020	2021
Interactions with FDA	454	644	700
Interactions with PMDA/MHLW	96	132	200
Interactions with Health Canada	125	224	200
Interactions with any other stakeholders	506	866	700

	Results		Forecasts
	2019	2020	2021
Number of information and/or document exchanges	461	988	900
Number of teleconferences organised	142	235	150
ICMRA executive committee and full membership teleconferences	n/a	52	10
International stakeholders' visits (fellowships, experts, observers)	n/a	1	25
Organisation of International awareness sessions	n/a	0	2

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

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
COVID-19 and ICMRA secretariat	1.1	Continue demonstrating leadership of ICMRA: regulatory convergence and in particular, vaccine safety monitoring collaboration Regulatory communication	2020	2023	Collaborative projects undertaken Statements released Technical workshops organised
Nitrosamines	1.1 5.5	Participation in Nitrosamines International Steering Group (NISG)	2018	2024	Regulatory actions Information exchanged
Extension of US MRA	1.1 5.5	Extension to vaccines and vet medicines	2020	2023	Full capability of the EU, NCAs and FDA
Article 58 – EU-M4all	1.2	Support to developers and promotion of parallel art 58 and centralised submissions	2021	2023	Number of parallel submissions Number of art 58 opinions and new approvals
Develop International collaboration and reliance including through Confidentiality Arrangements	6.5	Update existing and putting in place new confidentiality arrangements	2019	Ongoing	Number of new (permanent and ad-hoc) or revised confidentiality arrangements

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
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	6.1	- Increased visibility of EMA - Training on acquis Communautaire of candidate and accessing countries	2020	2022	- Awareness sessions per year - successful IPA training (complete and positive evaluations)
Supply chain	5.2	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
Support to priority countries	5.2	India and Russia joining PIC/S and ICH, GMP and GCP improved compliance	2021	2024	Membership gained
OPEN project	6.5	Active collaboration of selected regulatory authorities in CHMP and European Task Force for COVID-19 MEDICINES	2021	2022	Number of authorities and number of medicines with participation in evaluation
Active participation in WHO activities, international fora and communication to stakeholders, including but not limited to ICDRA, DIA, ICH, IPRP.	1.1	Promote convergence of global standards and contribution to international fora	2016	Ongoing	Number of participations
Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries	5.3	Improve application of equivalent standards of good manufacturing and clinical practices throughout the world	Ongoing	Ongoing	Number of observed inspections
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	5.1	Assure product supply chain and data integrity	Continuous	Continuous	Progress in the quality management system project at ICMRA

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Increase the number of opportunities for non-EU regulators, in particular those of candidate and potential candidate countries, to participate in scientific and regulatory training activities[1]	6.1	Support training and capacity building of non-EU regulators	2016	Continuous	Maintenance of updated training calendar Increase participation of non-EU regulators in EU NTC
Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU	6.1	Support training and capacity building of non-EU regulators	2017	Continuous	Trainings delivered to non-EU regulators
Re-start of the International awareness sessions for regulators	6.1	Increase the awareness of the EU system through dedicated sessions	2020	continuous	Number of awareness sessions
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.	6.1	Capacity building through training	2020	Continuous	Trainings delivered
ICMRA secretariat management, including operational and financial contribution to bi-annual ICMRA meetings.	1.1	Communication	01 Oct 2019	30 Sept 2022	Number of plenary meetings
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.	1.1	Support to the International Affairs Division and its specific activities	ongoing	ongoing	Number of activities

[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.

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Support EU and EU/MRA team meetings	5.2	Reliance and supply chain integrity	Ongoing	ongoing	Number of meetings
Collaboration in the establishment of the African Medicines Agency (AMA)	6.1	Capacity building through providing adequate guidance	ongoing	ongoing	Comments on EMA relevant guidelines
Initial implementation of the EU-DPR	6.2	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 transfers; conclude appropriate contracts with data processors)	2019	ongoing	Positive feedback received from internal controllers
Full Implementation of the EU-DPR and monitoring of compliance	6.2	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.	2020	2025	Full implementation achieved

6. 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 2021 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.
- Finalisation of the next 5-year framework strategy for communication, together with a strategy for restart of clinical data publication once BCP measures are lifted.
- Continuing to ensure that the patient voice is systematically incorporated throughout medicine development and evaluation, and enhanced interaction with healthcare professionals, industry stakeholders and academia (in cooperation with TRS).

The workforce available in 2021 for the Division is currently foreseen at 72 staff (47 TAs, 23 CAs, 2 SNEs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

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.

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.

Micro, small and medium-sized enterprises. The Agency has an office specifically dedicated to supporting smaller companies, the SME Office. It provides eligible SMEs with access to various incentives and regulatory assistance, including fee reductions, administrative and procedural support, as well as assistance with translations of the product-information documents submitted in applications for marketing authorisation. 1922 SMEs were registered with the Agency at the end of 2018.

EU Network Training Centre. This is a joint EMA/HMA initiative to provide harmonised training for regulators in Europe, supported by the implementation of a common online platform for scientific and regulatory training, accompanied by a training strategy, curriculum and methodology.

Information 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.

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 Agency fosters productive relationships with the media, both general and specialist, through the provision of press materials, organising media interviews and press conferences, and responding to journalists' queries. The Agency's social-media activities include communication via a Twitter account and regular updates on LinkedIn and YouTube. The Agency has put in place a dedicated, centralised service to respond to queries received from patients, healthcare professionals and academia.

Workload indicators

	Results		Forecasts
	2019	2020	2021
Number of cases of patient/consumer engagement in EMA (medicines-related) activities	769	594	600
Number of cases of healthcare professionals' engagement in EMA (medicines-related) activities	212	127	200
Number of professional membership organisation events attended by participating Agency staff	n/a[1]	n/a[1]	40
Number of sessions with Agency representatives	n/a[2]	n/a[2]	150
Number of messages circulated via 'Early Notification System'	411	612	440

[1] New indicator introduced in 2021 Work Programme
[2] New indicator introduced in 2021 Work Programme

	Results		Forecasts
	2019	2020	2021
Number of EMA communications pro-actively sent to stakeholders	128	178	200
Number of EPAR summaries and EPAR summaries updates published	286	297	300
Number of summaries of orphan designation published	117	154	120
Access to documents, requests received	783	597	820
Access to documents, documents released	1,429	904	1,500
Requests for information received	7,200	7,062	7,500
Number of documents published on EMA website	9,012	5,963	7,500
Number of pages published and updated on EMA website	3,383	2,511	3,500
Number of press releases and news items published	143	217	170
Completed requests for interviews and comments by media representatives	1,476	1,770	1,200
Number of reports, brochures, leaflets laid out or printed, social media visuals	206	357	500

Performance indicators

	Results		Targets
	2019	2020	2021
Satisfaction level of patient and consumer organisations	n/a	n/a[1]	n/a[1]
Satisfaction level of Healthcare Professionals organisations	n/a	n/a[1]	n/a[1]
Triage of incoming requests received via AskEMA within set timelines	n/a[2]	n/a[2]	100%
Response to ATD within set timelines	89%	90%	90%
Response to RFI within set timelines	96%	82%	95%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	84%	83%	80%
Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"	n/a	78%	n/a[1]
Average rating given to pages on corporate website during the year	3.4	3.4	3.4

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

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

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Develop content strategy in key public health areas and hot topics e: - 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;	1 (additional RSS recommendation)	Delivery of communication campaigns on key topics, with focus on COVID-19	2020	2025	Communication plans finalised and executed, communication material developed, stakeholder consultation and user testing finalised

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe		Deliverable 2021
		Start	End	
e-PI set up	This e-PI set-up 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 information is currently only provided in PDF format.	2020	2021	- Standardisation of the Product Information - Proof of concept of a technological solution for Product Information - Roadmap for full delivery and implementation of e-PI

7. Information Management Division

The Information Management Division provides EMA and its partners and stakeholders with a core set of business applications, IT systems and services to support activities related to the regulation of human and veterinary medicines in the European Union. The activities of the Division focus on customer advocacy and delivery, developing strategic platforms and running core IT services, and aim at establishing and managing information as a key asset to support sound decisions and provide reliable information on medicines. This involves the delivery and operation of efficient and effective data and information-management services and increasing the Agency's information-processing capacity and requires management of in-house and outsourced information and technology services.

These activities are guided by the 'EMA information management strategy' endorsed annually by the EMA Management Board.

Drivers for the coming year:

- Deliver the initial operating capabilities required to support key legislative programmes for Clinical Trials and Veterinary Medicines
- Accelerate the modernisation of the Agency’s and the Network’s regulatory systems
- Assess the impact of new EMA mandates on the Information Systems landscape and establish implementation plan

The workforce available in 2021 for the Division is currently foreseen at 87 staff (72 TAs, 15 CAs). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

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 (DED-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.

Workload indicators	Results		Forecasts
	2019	2020	2021
Number of Telematics information services provided by EMA	25	25	26
Number of ongoing Telematics IT projects where EMA is the delivery organisation	3	5	7
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	8	8	6

Performance indicators

	Results		Targets
	2019	2020	2021
Satisfaction of EMA internal and external users	87.9%	92.8%	80%
Availability of Telematics/corporate IT systems and corporate website	88.8%	98.2%	98%

Pillar 3 – Programmes and projects

Project title	Long term objective	Project timeframe		Deliverable 2021
		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	- Impact analysis and requirement gathering for a new Agency wide Document Management system

8. 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:

- Efficiently and effectively filling the positions granted by the budgetary authority to manage COVID-19 workload
- Efficiently and effectively managing additional budget, staffing and procurements stemming from the extension of the mandate
- Fostering integrated planning and talent management processes and practices.
- Supporting the staff management and development and launch first parts of the performance and development programme; completing the development and transition into the implementation of the competency framework
- Enhancement of the administrative processes, including the domains of procurement, finance and budget, accounts; human resource management; planning and monitoring; programme management; risk management.

Those drivers will support the vision of the Administration division which is reinforcing its business enabler role by fostering his advisory capability.

Business Services

More specifically, the area covers the general functions and activities that are necessary to ensure continuous operations of the Agency but are not business-specific. These 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 trainee programme, managing staff declarations of interests, providing 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 within the Agency. 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 falls within this area, as does maintaining a register of exceptions.

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 strategy and meet customer expectations.

The workforce available in 2021 for the Division is currently foreseen at 137 staff (103 TAs, 33 CAs, 1 SNE). This figure is subject to constant revision to take into account staff movements and workload fluctuation. The additional posts related to the EC mandate extension are not included yet.

Performance indicators/Forecast activity

	Results		Targets / Forecast
	2019	2020	2021
Posts on the Agency establishment plan filled	98.65%	100%	99%
Total TA staff recruited against vacant posts	36	51	90
Staff turnover rate (staff leaving against total no. of staff TA & CA)	7.25%	4.81%	6%
Time to run selection procedures from vacancy notice to establishment of reserve list	79% < 3 months	88% < 3 months	100%< 3 months
Revenue appropriations implemented	95.06%	104.30%	97%
Expenditure appropriations implemented	98.56%	98.83%	97%
Payments against appropriations carried over from year N-1	94.99%	95.49%	97%
The maximum rate of carryover to year N+1, of total commitments within the title			
Title 1	2.24%	4.62%	1%
Title 2	10.84%	20.71%	15%
Title 3	29.53%	31%	25%
Payments made within 30 days' time	97.59%	96%	98%
Receivable overdue for more than 30 days (including provision for bad debts)	7%	6%	<10%

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

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Develop and implement a framework for integrated planning and monitoring activities	6.2	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
Consolidate the human resource and talent management strategy	6.2	The strategy will consolidated 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.	2021	2021	The new strategy adopted
Implement a competency management framework	6.2	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.	2020	2022	100% job role profiles and descriptions completed
Digitalise HR-related processes (recruitment, onboarding, appraisal, continuous performance management, internal mobility, career development, succession planning)	6.4	Key HR processes are digitalised and automated to better support the HR teams and enable them to provide a better service with more active and added value tasks to performance and development of our staff members.	2020	2023	Related projects and initiatives launched and completed in line with plans
Digitalise procurement, contract management, risk management and some reporting processes.	6.4	Almost real time information is available for managers for decision making across contract management, budget, human resource domains. Introducing updated procurement, contract management; and risk management processes that reduce processing times and enables automating processes easier access to information	2020	2021	Project to implement procurement and contract management tool started Procurement/ HR/ Budget dashboards delivered

Action	MAWP Strategic Goal	Expected result	Timeframe		Performance indicator
			Start	End	
Review project governance in line with Agile development approach	6.2	Put in place a more agile governance by implementing a project planning tool and the SAFE methodology across programmes and projects in the organisation in collaboration with the IT Division.	2019	2021	100% projects are run based on Agile approach
New Fee Regulation: optimisation and review of revenue and expenditure process	6.3	Implementation of the New fee regulation with an optimised and more efficient revenue and expenditure process	2021	2022	Implementation of the Fee Regulation following the mandatory deadlines

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 during the relocation and pandemic emergencies.

This transformation encompasses programmes and large 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. The following Admin Digitalisation change initiatives are taking place during 2021:
1) Finalisation of the Performance and Development programme; 2) Intranet project; 3) Business Intelligence reporting; 4) Digital Personnel files; 5) enhancement of recruitment; 6) Procurement and contact management and; 7) aspects of integrated planning.

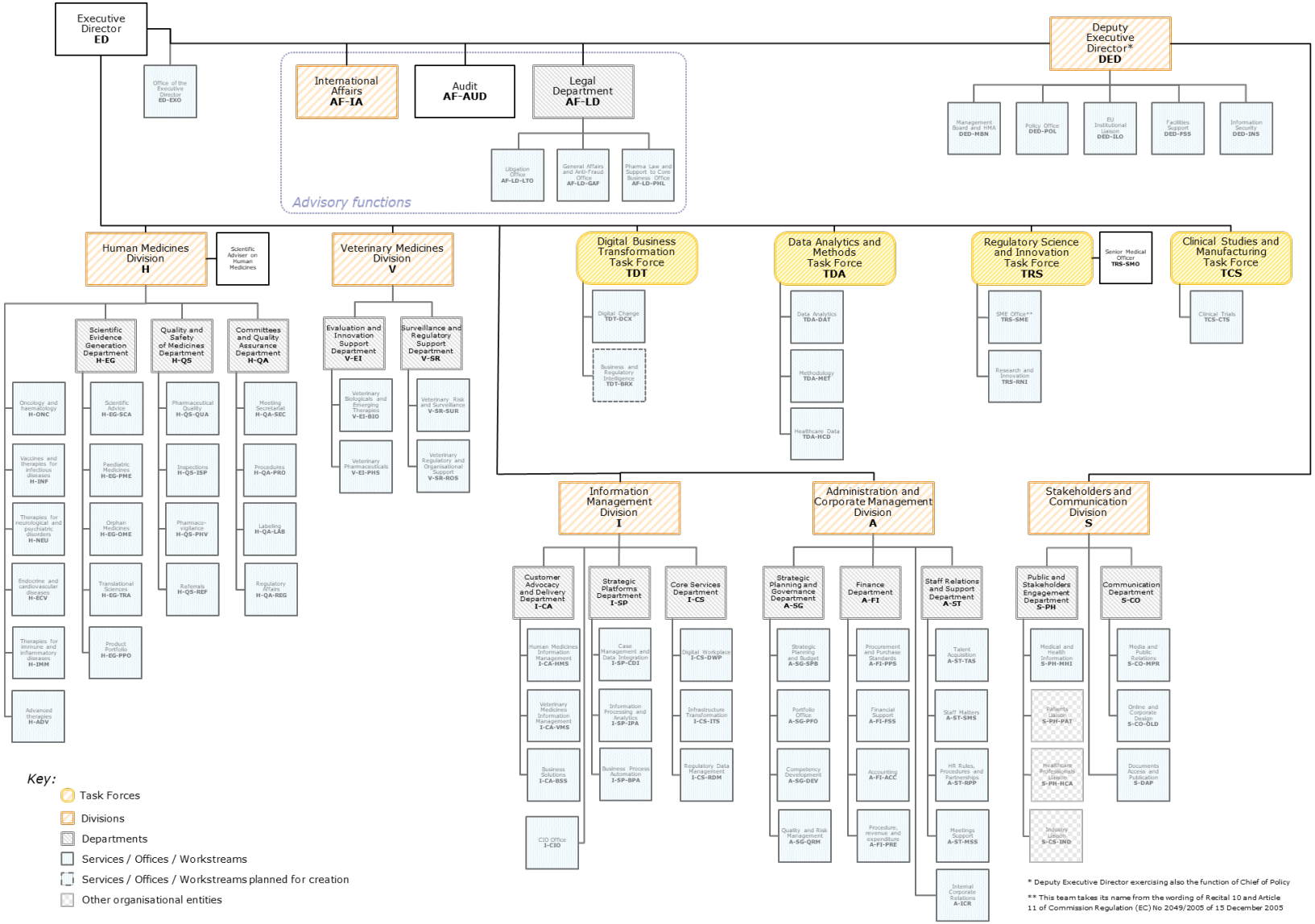
Project title	Long term objective	Project timeframe		Deliverable 2021
		Start	End	
Administration Digitalisation: Optimisation of the Administration supporting tools	Providing modern digital tools to support administration processes, increasing efficiency of processes, staff (as	2019	2022	- Provide better tools to overcome manual processing and repetitive tasks - New Goals and Performance system - New Succession Planning

Project title	Long term objective	Project timeframe		Deliverable 2021
		Start	End	
	customers) satisfaction with improved services and reducing manual work.			- Plan to gradually migrate the current HR system to modern tools and processes - Digitalisation of the personal files (as of today processes are mostly paper based) - Digitalises headcount allocation processes - Replacement of Intranet - Automation of the Procurement, Human Resource, Budget and Projects dashboards for a better decision-making process

Annexes

Annex I: Organisation chart

(data as of 31/12/2020)



Annex II: Resource allocation per activity 2021

Activity Based Budget 2021

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	**279**	**99**	**55,710**	**25,847**	**5,644**	**127,851**	**6,396**	**221,448**
Pre-authorisation activities	62	27	13,308	3,283	3,198	22,387	47	42,224
Initial evaluation activities	68	15	12,847	2,481	563	15,435	1,085	32,410
Post-authorisation activities	67	22	12,787	10,367	107	76,650	2,063	101,975
Referrals	12	3	1,992	421	67	-	265	2,745
Pharmacovigilance activities	42	23	8,853	3,047	976	13,379	2,927	29,183
Other specialized areas and activities	28	9	5,924	6,248	731	-	9	12,912
Evaluation activities for veterinary medicines	**30**	**15**	**6,377**	**11,310**	**1,112**	**4,211**	**559**	**23,570**
Pre-authorisation activities	2	0	256	69	148	268	1	743
Initial evaluation activities	10	3	1,737	389	288	1,119	230	3,763
Post-authorisation activities	9	3	1,509	734	70	2,823	201	5,337
Arbitrations and Referrals	1	2	266	70	86	-	114	537
Pharmacovigilance activities	1	2	423	301	192	-	13	930
Other specialized areas and activities	8	4	2,185	9,748	328	-	-	12,261
Public health activities and other areas	**161**	**87**	**34,601**	**25,159**	**5,362**	**1,980**	**5,599**	**72,701**
Committee coordination	34	15	6,834	1,461	2,008	-	-	10,302
Inspection and Compliance	23	21	5,354	1,547	479	1,980	299	9,659
Partners and Stakeholders	22	10	5,052	1,205	2,443	-	730	9,430
Transparency and access to documents	18	11	3,917	959	-	-	-	4,876
Information	25	17	5,498	2,368	29	-	319	8,215
International activities	9	6	2,490	417	94	-	-	3,000
Information Management (incl. EU Telematics)	30	8	5,457	17,203	309	-	4,250	27,219
Corporate Governance and Support activities	**150**	**47**	**28,241**	**8,172**	**318**	**-**	**31**	**36,762**
Governance, quality management and internal audit	31	15	7,528	1,304	318	-	-	9,150
Finance	29	10	5,041	1,917	-	-	31	6,989
Information technology	36	9	7,222	1,493	-	-	-	8,715
Human resources	46	13	7,224	2,895	-	-	-	10,120
Infrastructure services	9	1	1,226	563	-	-	-	1,789
Total	**621**	**248**	**124,930**	**70,489**	**12,436**	**134,042**	**12,584**	**354,481**

* FTEs are calculated as follows: (staff EXCLUDES additional resources linked to the new mandate)	FTEs
Temporary Agents	636
Vacancy rate	-15
Temporary Agents	621
Contract Agents (193 FTEs business as usual + 25 Brexit related)	218
Seconded National Experts	30
Total Staff	**869**

Brexit related expenditure and provision for new mandate	**30,688**
Budget 2021	**385,169**

Annex III: Financial Resources 2021 - 2023

Table 1 – Revenue

General Revenues

Revenues	2020	2021	2022	2023
	Revenue estimated by the agency	Budget forecast	Budget forecast	Budget forecast
EU contribution	€ 45,078,000	€ 55,448,000	€ 45,794,000	€ 46,215,000
Other revenue	€ 331,168,023	€ 330,471,000	€ 351,753,000	€ 358,788,000
PROVISIONAL REVENUE				
Total revenue	**€ 376,246,023**	**€ 385,919,000**	**€ 397,547,000**	**€ 405,003,000**

General Revenues							
REVENUES	Executed 2019[1]	Estimated by the agency 2020 [2]	2021		VAR 2021/2020 (%)	Forecast 2022	Forecast 2023
			agency request	budget forecast			
1 Revenue from services rendered	€ 293,953,058	€ 316,888,819	€ 330,409,000	€ 330,409,000	4.27%	€ 351,678,000	€ 358,711,000
2 EU and EEA contribution	€ 35,496,867	€ 45,078,000	€ 55,448,000	€ 55,448,000	23.00%	€ 45,794,000	€ 46,215,000
- of which special contribution for orphan medicinal products	€ 11,702,205	€ 11,374,395	€ 14,378,000	€ 14,378,000	26.41%	€ 14,378,000	€ 14,378,000
- of which assigned revenues deriving from previous years' surpluses	€ 14,468,303		p.m.	p.m.	p.m.	p.m.	p.m.
3 Third countries contribution	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'	incl. under '2 EU and EEA contribution'
- of which EEA/EFTA (excluding Switzerland)	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
- of which Candidate Countries	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
4 Other contributions	€ 0	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
- of which delegation agreement, ad hoc grants	€ 95,238	p.m.	p.m.	p.m.	p.m.	p.m.	p.m.
5 Administrative operations	€ 192,976	€ 0	€ 62,000	€ 62,000	#DIV/0!	€ 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	p.m.	€ 0	€ 0	€ 0	€ 0	€ 0
7 Correction of budgetary imbalances	€ 0	€ 13,802,754	p.m.	p.m.	p.m.	p.m.	p.m.
9 Miscellaneous revenue	€ 0	€ 476,450	p.m.	p.m.	n/a	p.m.	p.m.
TOTAL REVENUES	**€ 329,738,138**	**€ 376,246,023**	**€ 385,919,000**	**€ 385,919,000**	2.57%	**€ 397,547,000**	**€ 405,003,000**

1) Data as per final 2019 accounts
2) Data as per provisional 2020 accounts

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

REVENUES	2020	2021	2022	2023
	Revenues estimated by the Agency	Budget forecast	Budget forecast	Budget forecast
TOTAL REVENUES	€ 0	€ 43,000	€ 43,000	€ 43,000

REVENUES	Executed 2019[1]	Estimated by the Agency 2020	2021		VAR 2021/2020 (%)	Forecast 2022	Forecast 2023
			Agency request	Budget forecast			
ADDITIONAL EU FUNDING STEMMING FROM GRANTS (FFR Art.7)	€ 254,919	€ 0	€ 43,000	€ 43,000	n/a	€ 43,000	€ 43,000
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	€ 0	€ 43,000	€ 43,000	0%	€ 43,000	€ 43,000

1) Data as per final accounts 2019

Table 2 – Expenditure

Expenditure	2019 [1]		2020		2021		2022		2023	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1 - Staff expenditure	€ 115,386,743	€ 115,386,743	€ 114,634,112	€ 114,634,112	€ 128,126,000	€ 128,126,000	€ 134,349,000	€ 134,349,000	€ 137,939,000	€ 137,939,000
Title 2 - Infrastracture and operating expenditure	€ 83,734,373	€ 83,734,373	€ 82,926,883	€ 82,926,883	€ 56,175,000	€ 56,175,000	€ 54,735,000	€ 54,735,000	€ 54,688,000	€ 54,688,000
Title 3 - Operational expenditure	€ 142,647,872	€ 142,647,872	€ 167,872,236	€ 167,872,236	€ 176,226,000	€ 176,226,000	€ 189,182,000	€ 189,182,000	€ 192,966,000	€ 192,966,000
Title 9 - Provisional appropriations					€ 25,392,000	€ 25,392,000	€ 19,281,000	€ 19,281,000	€ 19,410,000	€ 19,410,000
Total expenditure	**€ 341,768,988**	**€ 341,768,988**	**€ 365,433,232**	**€ 365,433,232**	**€ 385,919,000**	**€ 385,919,000**	**€ 397,547,000**	**€ 397,547,000**	**€ 405,003,000**	**€ 405,003,000**

1) Data as per final 2019 accounts

Expenditure	2019			2020			2021			2022			2023		
	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	€ 63,889,581	€ 51,497,162	€ 115,386,743	€ 66,991,315	€ 47,642,797	€ 114,634,112	€ 69,993,320	€ 58,132,680	€ 128,126,000	€ 73,434,499	€ 60,914,501	€ 134,349,000	€ 75,396,776	€ 62,542,224	€ 137,939,000
Title 2 - Infrastracture and operating expenditure	€ 28,429,476	€ 55,304,897	€ 83,734,373	€ 43,760,469	€ 39,166,414	€ 82,926,883	€ 24,497,453	€ 31,677,547	€ 56,175,000	€ 25,449,787	€ 29,285,213	€ 54,735,000	€ 25,427,933	€ 29,260,067	€ 54,688,000
Title 3 - Operational expenditure	€ 133,758,179	€ 8,889,693	€ 142,647,872	€ 152,581,955	€ 15,290,281	€ 167,872,236	€ 153,146,289	€ 23,079,711	€ 176,226,000	€ 168,213,502	€ 20,968,498	€ 189,182,000	€ 171,578,092	€ 21,387,908	€ 192,966,000
Title 9 - Provisional appropriations				€ 0	€ 0	€ 0	€ 0	€ 25,392,000	€ 25,392,000	€ 0	€ 19,281,000	€ 19,281,000	€ 0	€ 19,410,000	€ 19,410,000
Total expenditure	**€ 226,077,236**	**€ 115,691,753**	**€ 341,768,988**	**€ 263,333,739**	**€ 102,099,493**	**€ 365,433,232**	**€ 247,637,062**	**€ 138,281,938**	**€ 385,919,000**	**€ 267,097,788**	**€ 130,449,212**	**€ 397,547,000**	**€ 272,402,801**	**€ 132,600,199**	**€ 405,003,000**
% of total expenditure	**66%**	**34%**	**100%**	**72%**	**28%**	**100%**	**64%**	**36%**	**100%**	**67%**	**33%**	**100%**	**67%**	**33%**	**100%**
* Full-time Equivalent	536	318	**854**	509	348	**857**	498	400	**898**	523	409	**932**	499	389	**888**
% of total FTEs	63%	37%	**100%**	59%	41%	**100%**	55%	45%	**100%**	56%	44%	**100%**	56%	44%	**100%**

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

EXPENDITURE	Commitment appropriations						
	Executed budget 2019[1]	Estimated by the Agency, 2020[2]	Draft budget 2021		VAR 2021/2020 (%)	Forecast 2022	Forecast 2023
			Agency request	Budget forecast			
Title 1 - Staff Expenditure							
11 Staff holding a post provided for in the list of posts	€ 106,653,925	104,979,006.27	€ 112,009,000	€ 112,009,000	6.70%	€ 117,679,000	€ 118,033,000
- of which establishment plan posts							
- of which external personnel							
12 Expenditure relating to staff recruitment	€ 309,776	199,235.04	€ 300,000	€ 300,000	50.58%	€ 300,000	€ 306,000
13 Duty travel expenses and incidental expenditure	€ 1,196,654	137,782.04	€ 750,000	€ 750,000	444.34%	€ 1,015,000	€ 1,035,000
14 Socio-medical infrastructure	€ 2,927,886	1,695,263.40	€ 2,734,000	€ 2,734,000	61.27%	€ 2,644,000	€ 2,697,000
15 Staff training	€ 246,816	555,731.22	€ 770,000	€ 770,000	38.56%	€ 830,000	€ 847,000
16 External services	€ 3,935,591	7,000,918.29	€ 11,438,000	€ 11,438,000	63.38%	€ 11,741,000	€ 14,878,000
17 Receptions and events	€ 116,096	66,175.87	€ 125,000	€ 125,000	88.89%	€ 140,000	€ 143,000
Total Title 1	**€ 115,386,743**	**€ 114,634,112**	**€ 128,126,000**	**€ 128,126,000**	11.77%	**€ 134,349,000**	**€ 137,939,000**
Title 2 - Infrastructure and operating expenditure							
20 Investment in immovable property, renting of buildings and associated costs	€ 50,931,784	41,541,361.61	€ 15,397,000	€ 15,397,000	-62.94%	€ 15,606,000	€ 15,918,000
21 Corporate information and communication technology	€ 22,522,428	32,334,229.36	€ 29,382,000	€ 29,382,000	-9.13%	€ 30,232,000	€ 29,697,000
22 Movable property and associated costs	€ 794,809	1,221,640.78	€ 648,000	€ 648,000	-46.96%	€ 660,000	€ 673,000
23 Current administrative expenditure	€ 5,460,622	886,939.65	€ 3,890,000	€ 3,890,000	338.59%	€ 1,157,000	€ 1,180,000
24 Postal and delivery services	€ 123,024	35,404.32	€ 60,000	€ 60,000	69.47%	€ 61,000	€ 62,000
25 Other meetings	€ 304,050	269,686	€ 320,000	€ 320,000	18.66%	€ 324,000	€ 330,000
26 Restaurant and catering	€ 1,924,635	1,703,201.05	€ 1,061,000	€ 1,061,000	-37.71%	€ 1,222,000	€ 1,246,000
27 Information and publishing	€ 999,827	1,240,950.49	€ 2,567,000	€ 2,567,000	106.86%	€ 2,663,000	€ 2,716,000
28 Business consultancy and audit services	€ 673,195	3,693,470.16	€ 2,850,000	€ 2,850,000	-22.84%	€ 2,810,000	€ 2,866,000
Total Title 2	**€ 83,734,373**	**€ 82,926,883**	**€ 56,175,000**	**€ 56,175,000**	**-32.26%**	**€ 54,735,000**	**€ 54,688,000**
Title 3 - Operational expenditure							
300 Meetings	€ 6,499,017	1,309,092	€ 7,000,000	€ 7,000,000	434.72%	€ 8,240,000	€ 8,405,000
301 Evaluation of medicinal products	€ 121,589,667	133,570,796.06	€ 134,042,000	€ 134,042,000	0.35%	€ 144,773,000	€ 147,668,000
302 Translations	€ 3,964,005	5,046,745.99	€ 5,184,000	€ 5,184,000	2.72%	€ 5,533,000	€ 5,644,000
303 Scientific studies and services	€ 2,978,496	7,490,375.67	€ 7,400,000	€ 7,400,000	-1.21%	€ 12,636,000	€ 12,889,000
31 Expenditure on business related IT projects	€ 7,616,686	20,455,226.98	€ 22,600,000	€ 22,600,000	10.49%	€ 18,000,000	€ 18,360,000
Total Title 3	**€ 142,647,872**	**€ 167,872,236**	**€ 176,226,000**	**€ 176,226,000**	**4.98%**	**€ 189,182,000**	**€ 192,966,000**
900 Provisional appropriations	€ 0	€ 0	€ 25,392,000	€ 25,392,000	indef.	€ 19,281,000	€ 19,410,000
Total Title 9	**€ 0**	**€ 0**	**€ 25,392,000**	**€ 25,392,000**	**€ 0**	**€ 19,281,000**	**€ 19,410,000**
TOTAL EXPENDITURE	**€ 341,768,988**	**€ 365,433,232**	**€ 385,919,000**	**€ 385,919,000**	**5.61%**	**€ 397,547,000**	**€ 405,003,000**

1) Data as per final accounts 2019

2) Data as per provisional 2020 accounts

EXPENDITURE	Payment appropriations						
	Executed budget 2019[1]	Estimated by the Agency, 2020[2]	Draft budget 2021		VAR 2021/2020 (%)	Forecast 2022	Forecast 2023
			Agency request	Budget forecast			
Title 1 - Staff Expenditure							
11 Staff holding a post provided for in the list of posts	€ 106,653,925	104,979,006.27	€ 112,009,000	€ 112,009,000	6.70%	€ 117,679,000	€ 118,033,000
- of which establishment plan posts							
- of which external personnel							
12 Expenditure relating to staff recruitment	€ 309,776	199,235.04	€ 300,000	€ 300,000	50.58%	€ 300,000	€ 306,000
13 Duty travel expenses and incidental expenditure	€ 1,196,654	137,782.04	€ 750,000	€ 750,000	444.34%	€ 1,015,000	€ 1,035,000
14 Socio-medical infrastructure	€ 2,927,886	1,695,263.40	€ 2,734,000	€ 2,734,000	61.27%	€ 2,644,000	€ 2,697,000
15 Staff training	€ 246,816	555,731.22	€ 770,000	€ 770,000	38.56%	€ 830,000	€ 847,000
16 External services	€ 3,935,591	7,000,918.29	€ 11,438,000	€ 11,438,000	63.38%	€ 11,741,000	€ 14,878,000
17 Receptions and events	€ 116,096	66,175.87	€ 125,000	€ 125,000	88.89%	€ 140,000	€ 143,000
Total Title 1	**€ 115,386,743**	**€ 114,634,112**	**€ 128,126,000**	**€ 128,126,000**	11.77%	**€ 134,349,000**	**€ 137,939,000**
Title 2 - Infrastructure and operating expenditure							
20 Investment in immovable property, renting of buildings and associated costs	€ 50,931,784	41,541,361.61	€ 15,397,000	€ 15,397,000	-62.94%	€ 15,606,000	€ 15,918,000
21 Corporate information and communication technology	€ 22,522,428	32,334,229.36	€ 29,382,000	€ 29,382,000	-9.13%	€ 30,232,000	€ 29,697,000
22 Movable property and associated costs	€ 794,809	1,221,640.78	€ 648,000	€ 648,000	-46.96%	€ 660,000	€ 673,000
23 Current administrative expenditure	€ 5,460,622	886,939.65	€ 3,890,000	€ 3,890,000	338.59%	€ 1,157,000	€ 1,180,000
24 Postal and delivery services	€ 123,024	35,404.32	€ 60,000	€ 60,000	69.47%	€ 61,000	€ 62,000
25 Other meetings	€ 304,050	269,686	€ 320,000	€ 320,000	18.66%	€ 324,000	€ 330,000
26 Restaurant and catering	€ 1,924,635	1,703,201.05	€ 1,061,000	€ 1,061,000	-37.71%	€ 1,222,000	€ 1,246,000
27 Information and publishing	€ 999,827	1,240,950.49	€ 2,567,000	€ 2,567,000	106.86%	€ 2,663,000	€ 2,716,000
28 Business consultancy and audit services	€ 673,195	3,693,470.16	€ 2,850,000	€ 2,850,000	-22.84%	€ 2,810,000	€ 2,866,000
Total Title 2	**€ 83,734,373**	**€ 82,926,883**	**€ 56,175,000**	**€ 56,175,000**	**-32.26%**	**€ 54,735,000**	**€ 54,688,000**
Title 3 - Operational expenditure							
300 Meetings	€ 6,499,017	1,309,092	€ 7,000,000	€ 7,000,000	434.72%	€ 8,240,000	€ 8,405,000
301 Evaluation of medicinal products	€ 121,589,667	133,570,796.06	€ 134,042,000	€ 134,042,000	0.35%	€ 144,773,000	€ 147,668,000
302 Translations	€ 3,964,005	5,046,745.99	€ 5,184,000	€ 5,184,000	2.72%	€ 5,533,000	€ 5,644,000
303 Scientific studies and services	€ 2,978,496	7,490,375.67	€ 7,400,000	€ 7,400,000	-1.21%	€ 12,636,000	€ 12,889,000
31 Expenditure on business related IT projects	€ 7,616,686	20,455,226.98	€ 22,600,000	€ 22,600,000	10.49%	€ 18,000,000	€ 18,360,000
Total Title 3	**€ 142,647,872**	**€ 167,872,236**	**€ 176,226,000**	**€ 176,226,000**	**4.98%**	**€ 189,182,000**	**€ 192,966,000**
900 Provisional appropriations	€ 0	€ 0	€ 25,392,000	€ 25,392,000	indef.	€ 19,281,000	€ 19,410,000
Total Title 9	**€ 0**	**€ 0**	**€ 25,392,000**	**€ 25,392,000**	**€ 0**	**€ 19,281,000**	**€ 19,410,000**
TOTAL EXPENDITURE	**€ 341,768,988**	**€ 365,433,232**	**€ 385,919,000**	**€ 385,919,000**	**5.61%**	**€ 397,547,000**	**€ 405,003,000**

1) Data as per final accounts 2019

2) Data as per provisional 2020 accounts

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

Budget outturn	2017	2018	2019[1)]	2020[2)]
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 2019 accounts

2) Data as per provisional 2020 accounts

The financial outturn, a deficit of approx. EUR 8.28 million, representing 2.39% of the final budget, was caused mainly by lower than expected fee-related income being collected at the end of the year.

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

• lower expenditure on salaries, mainly due to staff resignations and postponement of recruitment due to the relocation of the Agency. This affected mostly contract agent staff and seconded national experts. Moreover, expenditure on allowances and payments related to staff members' relocation to the Netherlands was lower than forecast. These savings were partially offset by higher than budgeted expenditure on employer's social security payments and duty station weightings;

• lower than budgeted contributions to European schools, due to initial numbers of children registered being lower than expected.

Title II

• higher than estimated costs related to the Agency's former headquarters in London, in particular rent and service charges, legal fees and building-related expenditure;

• partially offset by savings realised on IT maintenance cost and lower expenditure on corporate IT projects including business consultancy, due also to the impact of the relocation of the Agency to another member state.

Title III

• lower expenditure on business IT development, due to delays incurred in various projects.

The agency managed to comply 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: 2.19%, title II: 10.79%, title III: 29.16%.

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 2019			2020			2021	2022	2023	2024
ESTABLISHMENT PLAN POSTS	**Authorised Budget**	**Actually filled as of 31/12/2019**	**Occupancy rate %**	**Authorised Budget**	**Actually filled as of 31/12/2020[1]**	**Occupancy rate %[1]**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**	**Envisaged staff**
Administrators (AD)	365	364	99.7%	395	395	100%	472	494	473	486
Assistants (AST)	226	219	96.9%	201	201	100%	185	185	180	182
Assistants/Secretaries (AST/SC)	0	0	N/a	0	0	0%	0	0	0	0
TOTAL ESTABLISHMENT PLAN POSTS	**591**	**583**	**98.6%**	**596**	**596**	**100%**	**657**	**679**	**653**	**668**
EXTERNAL STAFF	**FTE corresponding to the authorised budget**	**Executed FTE as of 31/12/2019**	**Execution Rate %**	**FTE corresponding to the authorised budget**	**Executed FTE as of 31/12/2020**	**Execution Rate %**	**FTE corresponding to the authorised budget**	**Envisaged FTE**	**Envisaged FTE**	**Envisaged FTE**
Contract Agents (CA)	233	187	80.3%	228	199	87%	226	223	205	205
Seconded National Experts (SNE)	30	28	93.3%	30	28	93%	30	30	30	30
TOTAL EXTERNAL STAFF	263	215	81.7%	258	227	88%	256	253	235	235
TOTAL STAFF	**854**	**798**	**93.4%**	**854**	**823**	**96%**	**913**	**932**	**888**	**903**

1) EMA makes use of article 38(2) FR to offset workforce loss through part-time work taken by TA staff.
The average part-time loss in 2020 was -9.69 FTE which has been offset by the appointment of 9 additional staff not included above.

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

Human Resources	2020	2021	2022	2023
	Envisaged FTE	Envisaged FTE	Envisaged FTE	Envisaged FTE
Contract Agents (CA)	0.3	0.3	0.3	0.3
Seconded National Experts (SNE)	0.3	0.3	0.3	0.3
TOTAL	0.3	0.3	0.3	0.3

- **C. Other Human Resources**
  - Structural service providers

	Actually in place as of 31/12/2019
Security	9
IT service desk	16
IT maintenance and support 'time&means' contracts only	10
Reception[1]	5
Building maintenance[2]	4
Cleaning	13
Catering	26
Reprographics and mail services	7

1) Security 24/7 service

2) Building maintenance: included in the rental package

  - Interim workers

	Total FTEs in year 2019
Number	10

Table 2 – Multi-annual staff policy plan 2021 – 2024

Function group and grade	2019				2020				2021		2022		2023		2024	
	Authorised budget		Actually filled as of 31/12/2019		Authorised budget		Actually filled as of 31/12/2020[1]		Envisaged		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		3		3		3		3		3
AD 14		7		7		8		8		9		10		11		12
AD 13		11		10		12		12		13		13		13		13
AD 12		43		43		44		44		45		50		55		60
AD 11		43		43		47		47		51		52		53		54
AD 10		43		43		44		44		51		50		49		48
AD 9		43		43		46		45		55		62		69		76
AD 8		59		59		66		67		71		77		77		77
AD 7		65		65		76		69		94		97		100		103
AD 6		23		23		46		52		65		67		43		40
AD 5		25		25		3		4		15		13		0		0
AD TOTAL	**0**	**365**	**0**	**364**	**0**	**395**		**395**	**0**	**472**	**0**	**494**	**0**	**473**	**0**	**486**
AST 11		2		2		2		2		2		2		2		2
AST 10		7		7		7		7		7		7		7		7
AST 9		7		6		8		8		9		10		11		12
AST 8		16		16		19		19		10		13		16		19
AST 7		22		22		15		15		19		19		19		19
AST 6		27		25		15		15		20		26		32		38
AST 5		35		33		39		39		38		43		48		53
AST 4		57		55		52		52		46		42		35		31
AST 3		46		46		44		44		32		23		10		1
AST 2		7		7		0		0		2		0		0		0
AST 1		0		0		0		0		0		0		0		0
AST TOTAL	**0**	**226**	**0**	**219**	**0**	**201**		**201**	**0**	**185**	**0**	**185**	**0**	**180**	**0**	**182**
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**	**591**	**0**	**583**	**0**	**596**		**596**	**0**	**657**	**0**	**679**	**0**	**653**	**0**	**668**

1) EMA makes use of article 38(2) FR to offset workforce loss through part-time work taken by TA staff. The average part-time loss in 2020 was -9.69 FTE which has been offset by the appointment of 9 additional staff not included above.

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 2019	Executed FTE as of 31/12/2019	Headcount as of 31/12/2019	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	FTE corresponding to the authorised budget 2022	FTE corresponding to the authorised budget 2023	FTE corresponding to the authorised budget 2024
Function Group IV	52	76	79	52	78	76	110	122	134	144
Function Group III	131	56	60	131	62	62	81	81	71	61
Function Group II	10	41	32	10	28	26	10	0	0	0
Function Group I	0	0	0	0	0	0	0	0	0	0
Additional CA[1]	40	14	28	35	31	33	25	20	0	0
TOTAL	**233**	**187**	**199**	**228**	**199**	**197**	**226**	**223**	**205**	**205**

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

Seconded National Experts

Seconded National Experts	FTE corresponding to the authorised budget 2019	Executed FTE as of 31/12/2019	Headcount as of 31/12/2019	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	FTE corresponding to the authorised budget 2022	FTE corresponding to the authorised budget 2023	FTE corresponding to the authorised budget 2024
Total	30	28	31	30	28	32	30	30	30	30

Table 3 – Recruitment forecasts 2021 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 officer (new veterinary regulation)		3 posts required for the new veterinary regulation	AD06-AD08	AD06	
Scientific officers		11 posts for increased workload	AD06-AD08	AD06	
Head of Policy Office	TA, retirement		AD08-AD10	AD08	
Competency development officer	TA, retirement		AD06-AD08	AD06	
Head of Audit	TA, retirement		AD09/AD12	AD09	
Procedure assistant	TA, retirement		AST03-AST09	AST3	
Head of deputy executive direcor office	TA, retirement		TBC	TBC	
Head of International Affairs	TA, retirement		TBC	TBC	
Head of Clinical Studies and Manufacturing task force	TA, retirement		TBC	TBC	
Senior Medical office	TA, retirement		TBC	TBC	

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							
	2016	2017	2018	2019	2020	2021 [1]	Actual average over 5 years	Average over 5 years (According to decision C(2015)9563)
AD05	5.05	5.39	2.29	4.23	2.27		4.4	2.8
AD06	4.46	3.46	3.34	4.96	3.47		4	2.8
AD07	4.28	4.14	3.05	3.61	4.37		3.8	2.8
AD08	3.9	4.59	3.52	4	4.96		4.2	3
AD09	5.49	5.31	4.55	5.09	5		5	4
AD10	5.05	5.37	5.43	2.97	4.71		4.9	4
AD11	8.33	8	5.62	3	6.33		6.3	4
AD12		5.97	7.2	7.1	10		7.3	6.7
AD13		6.22	6.55		6		6.3	6.7
AST1	5.12	4.73	5.45	5.24			5.2	3
AST2	5.25	4.13	3.61	5.43	3		4.3	3
AST3	3.57	3.8	3.36	3.41	4.73		3.7	3
AST4	5.5	4.3	3.24	5.43	3.33		3.9	3
AST5	4.66		3.97	5.66	4		4.4	4
AST6		3.89	4.55	7	7.75		5.8	4
AST7		5.33	5.54	4.5	7.5		6.2	4
AST8	6	4		2	5		4.2	4
AST9								N/A
AST10 (Senior assistant)								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 2021

Table 2 -Reclassification of contract staff

Function Group	Grade	Staff in activity at 1.01.2018	How many staff members were reclassified in 2019	Average number of years in grade of reclassified staff members 2019	How many staff members were reclassified in 2020	Average number of years in grade of reclassified staff members 2020	Average number of years in grade of reclassified staff members according to Decision C(2015)9561
CA IV	17	1	1	3			Between 6 and 10 years
	16	3	1	2.71	1	2.16	Between 5 and 7 years
	15	17	1	3	1	3	Between 4 and 6 years
	14	24	6	3.48	4	3.37	Between 3 and 5 years
	13	12	4	4.06	3	2.29	Between 3 and 5 years
CA III	11						Between 6 and 10 years
	10	4	1	2			Between 5 and 7 years
	9	9	3	3.75	2	2	Between 4 and 6 years
	8	6			1	2	Between 3 and 5 years
CA II	6	18	1	3	3	3.33	Between 6 and 10 years
	5	43	3	5.31	10	3.24	Between 5 and 7 years
	4	8	1	4.21	1	6.21	Between 3 and 5 years
CA I	2						Between 6 and 10 years
	1						Between 3 and 5 years

C. Gender representation

Table 1 - Data on 31/12/2019 /statutory staff (only officials, AT and AC)

		2019							
		Official		Temporary		Contract Agents		Grand Total	
		Staff	%	Staff	%	Staff	%	Staff	%
Female	Administrator level	0	N/a	170	29%	73	37%	243	31%
	Assistant level (AST & AST/SC)	0	N/a	210	36%	86	43%	296	38%
	Total	**0**	**N/a**	**380**	**65%**	**159**	**80%**	**539**	**69%**
Male	Administrator level	0	N/a	171	29%	25	13%	196	25%
	Assistant level (AST & AST/SC)	0	N/a	32	5%	15	8%	47	6%
	Total	**0**	**N/a**	**203**	**35%**	**40**	**20%**	**243**	**31%**
Grand Total		**0**	**N/a**	**583**	**100%**	**199**	**100%**	**782**	**100%**

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

	2015		2019	
	Number	%	Number	%
Female Managers	**14**	**45%**	**11**	**37%**
Male Managers	**17**	**55%**	**19**	**63%**

D. Geographical balance

Table 1 - Data on 31/12/2019 - statutory staff only (officials, AT and AC)

Nationality	2019					
	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	9	2%	4	1%	13	2%
Belgium	16	4%	3	1%	19	2%
Bulgaria	8	2%	11	3%	19	2%
Croatia	6	1%	1	0%	7	1%
Cyprus	0	0%	1	0%	1	0%
Czech Republic	1	0%	16	5%	17	2%
Denmark	5	1%	6	2%	11	1%
Estonia	1	0%	8	2%	9	1%
Finland	5	1%	7	2%	12	2%
France	64	15%	30	9%	94	12%
Germany	33	8%	20	6%	53	7%
Greece	34	8%	20	6%	54	7%
Hungary	9	2%	16	5%	25	3%
Ireland	15	3%	2	1%	17	2%
Italy	62	14%	37	11%	99	13%
Latvia	3	1%	6	2%	9	1%
Lithuania	3	1%	13	4%	16	2%
Luxembourg	0	0%	0	0%	0	0%
Malta	0	0%	0	0%	0	0%
Netherlands	3	1%	4	1%	7	1%
Norway	1	0%	1	0%	2	0%
Poland	13	3%	35	10%	48	6%
Portugal	26	6%	13	4%	39	5%
Romania	16	4%	11	3%	27	3%
Slovakia	5	1%	19	6%	24	3%
Slovenia	1	0%	1	0%	2	0%
Spain	59	13%	37	11%	96	12%
Sweden	6	1%	7	2%	13	2%
United Kingdom	35	8%	14	4%	49	6%
Other	0	0%	0	0%	0	0%
TOTAL	439	100%	343	100%	782	100%

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	2015		2019	
	Number	%	Number	%
Italian	87	11.8%	99	12.7%

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

As a response to the audit performed by the European court of Auditors in 2013 that was followed by the special report in 2014 on '**How do the EU institutions and bodies calculate, reduce and offset their greenhouse gas emissions?'** the Agency approved a Strategy for Environmental activities in October 2013.

In 2014 the Agency commenced its work on developing an Environmental Management System in line with the EMAS regulation and aimed for registration to EMAS in 2016/2017. An internal audit was completed in December 2016 with implementation of improvement actions to follow to prepare for the registration to EMAS and verification by an accredited body. However, due to the Business Continuity situation that the Agency found itself in following the UK referendum and the imminent relocation from London to Amsterdam, the planned registration and verification to EMAS was put on hold. Taking into consideration that EMAS is site-based, the Agency decided to bring the prepared framework, adjust it to the new permanent premises in Amsterdam and pursue the registration to EMAS after the relocation was completed.

In March 2019 the Agency was relocated to temporary premises in Amsterdam with the permanent premises occupied as of 1 January 2020. Since April 2020 preparations for the Environmental Management activities to resume is ongoing and a "Roadmap for Environmental Management 2020 to 2024" with a target for registration to EMAS within that period has been put in place. As a first action the Environmental Policy has been reviewed and the staff involvement will be secured through re-initiation of the EMA Green Group by the end of 2020 in accordance with an updated mandate.

Starting in 2020 and throughout the first half of 2021 the Environmental Management System, EMS, is being updated with specifics of the Agency's new permanent premises. Once updated an internal audit is foreseen at the end of 2021 or early 2022. Following implementation of any improvement actions considered needed the Agency aim for registration to EMAS with validation by the external accredited competent body in the Netherlands by 2024.

To implement these Environmental Management activities the following resources have been allocated:

- an Environmental Lead to develop and coordinate the necessary activities;

- a facility officer for environmental activities to align operational facilities management;

- participation by staff as Environmental Ambassadors in the EMA Green Group for staff promotion and involvement in planned activities;

- nominating the Deputy Executive Director to report to the Agency Executive Director and the Executive Group for senior management leadership input.

The information regarding environmental management provided to staff on the EMA intranet will be updated in close collaboration with resources from the Internal Communication office and external stakeholder involvement will be coordinated in contact with the EMA External Communication Department. Information regarding environmental consideration and how to support an environmentally friendly approach at the EMA building is provided in the induction-training to all staff.

Since 2016 EMA have implemented Guidelines for Green Procurement with assessment of the Agency's procured contracts to assess the level of environmental requirements that are suitable for each. EMA is also participating in the inter-institutional tender procedure for Green criteria in procurements helpdesk services to be launched in late 2020.

The Agency's environmental footprint are tracked in the following areas:

- Energy and water consumption from occupancy of the building
- Waste management: active waste management with separation of glass, plastic, paper/cardboard, metal and food. Active prevention of waste production (paper) by follow-me print regime and laptops for all staff
- Duty travel by staff and Delegates
- Co2 emissions of the Agency operations

The European Union has within the Green Deal set a target of a 40% reduction by the year 2030 compared with 1990. This target is currently under review with a suggested amendment of the target to a reduction of 55-60%. EMA was founded in 1995 with continuous growth over time in line with its increased mission. Since 2013 the number of staff employed has been relatively stable which is therefore selected as the adjusted base year to use for reduction purposes. The 55-60% target is hence adjusted to 2013 by using a linear approach leaving the Agency with a long-term reduction target of 23.4 to 25.5% in comparison with year 2013.

Due to occupancy of the EMA building since January 2020 following temporary premises being occupied for a majority of 2019 (10 March until 31 December 2019) and compulsory tele-working due to the Covid-19 pandemic for a majority of 2020 (16 March to 30 September) and reduced office occupancy for the remainder of 2020, there are still fine-tuning to be expected in the EMA building also in 2021. The following targets and objectives for 2021 are therefore:

- 15% reduction of energy consumption per Sq.m of office space compared with the adjusted base year (2013)

- 15% reduction of water consumption per Sq.m of office space compared with the adjusted base year (2013)

Once the activities and occupancy of the office premises resumes to the full capacity and all building installations are fully tuned further targets will be introduced for active and continuous improvements.

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	10,507,286	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**	**10,507,286**					

Annex VIII: Privileges and immunities

Agency privileges	Privileges granted to staff	
	Protocol of privileges and immunities/diplomatic status	**Education/Day care**
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.	There are two European Schools in the Netherlands both located > 50km (but <60km) from the Agency's future seat in Amsterdam
Agency's premises, property and assets are inviolable, as well as Agency's archives	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.	Staff have access to Dutch national childcare benefit (kinderopvangtoeslag) on the same terms as Dutch nationals or other persons with the right to live and work in the Netherlands
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 of 1961.	Staff have no access to Dutch national child allowance/benefit (kinderbijslag)
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 of 1961.	
The Agency, its assets, income and other property are exempt from all direct taxes		
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 latest 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.

In 2017 the European Commission started preparing for the next evaluation and in 2018 it selected Ernst & Young (EY) to perform a study on the operation of centralised procedure (CP) and decentralised and mutual recognition procedures (MRP/DCP) for the authorisation and monitoring of medicinal products for human use during the period 2009-2017. The contractor delivered its analysis to the European Commission in March 2020, and the conclusions of the analysis will be considered in a general Commission report to the European Parliament and to the Council by approximately end 2020.

The aim of the second evaluation study is to assess: (1) the achievement of the objectives set by the regulatory framework for marketing authorisations in the EEA over the last 10 years, in particular as regards guaranteeing a high level of health protection for the people in the EU and achieving the internal market in pharmaceutical products and establishing a regulatory and legislative framework that favours the competitiveness of the European pharmaceuticals sector, and (2) the relationship between resources used and output generated in terms of adequacy and proportionality.

In terms of scope, the second evaluation study will have to analyse in particular the following five areas: (1) the European Medicines Regulatory Network, with a focus on its evolution across the last 10 years as regards effectiveness and efficiency of the system in delivering its mission; (2) the efficiency and effectiveness of the pre-submission procedures, including how these activities act as promoters of innovation and medicines development and facilitate the access of applicants to marketing authorisations procedures; (3) initial marketing authorisations procedures, with a focus on their sustainability, long term capacity to meet the increasing requirements of the system and aptitude to ensure predictability to applicants; (4) post-marketing authorisation procedures, including their suitability to deal with future scientific and technical developments, emergency needs and medicines shortages, as well as their efficient use of available resources and operational efficiency; (5) the effectiveness and efficiency of support activities, such as Telematics/digitalisation and communication.

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

As follow up to the Council's conclusions on 'strengthening the balance in the pharmaceutical systems in the EU and its Member States' of 17 June 2016, the European Commission has conductedan evidence-based analysis of the impact of incentives for developers of medicines in the

EU on innovation, availability and accessibility of medicines. In the context of this exercise, the following studies regarding the experience with the operation of other pieces of legislation applicable to the Agency have been published.

First, pursuant to the reporting requirement under Article 50(3) of Regulation (EC) No 1901/2006 on pediatric medicines, in October 2017 the European Commission presented to the European Parliament and the Council a comprehensive report on progress made in children's medicines 10 years after the Paediatric Regulation came into force. This study was built on a 10-year report prepared by the Agency and its Paediatric Committee in 2016 (EMA/231225/2015). Second, in line with the Commission's commitment in the context of its Better Regulation agenda to keep existing laws under review, in March 2018 the European Commission started preparing an evaluation of the functioning of the orphan regulation EC No 141/2000 over the period 2006-2017. A study was commissioned to Technopolis Group and ECORYS, which was delivered to the Commission in late 2019 and published in August 2020, in order to analyse the impact of the incentives provided in the EU orphan legislation on innovation, availability and accessibility of orphan medicinal products. Third, based on the evidence provided in the two studies above, on 11 August 2020 the European Commission published a Staff Working Document with the results of its joint evaluation of the orphan and paediatric regulations.

These studies, including the above mentioned EY report will be taken into account during the implementation of the European Commission's Pharmaceutical Strategy for Europe which was published on 24 November 2020. As a follow up to the Staff Working Document, an inception impact assessment for the revision of the orphan and pediatric regulation was published by the European Commission in late 2020.

Project and programme evaluations

The EMA Financial Regulation 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.

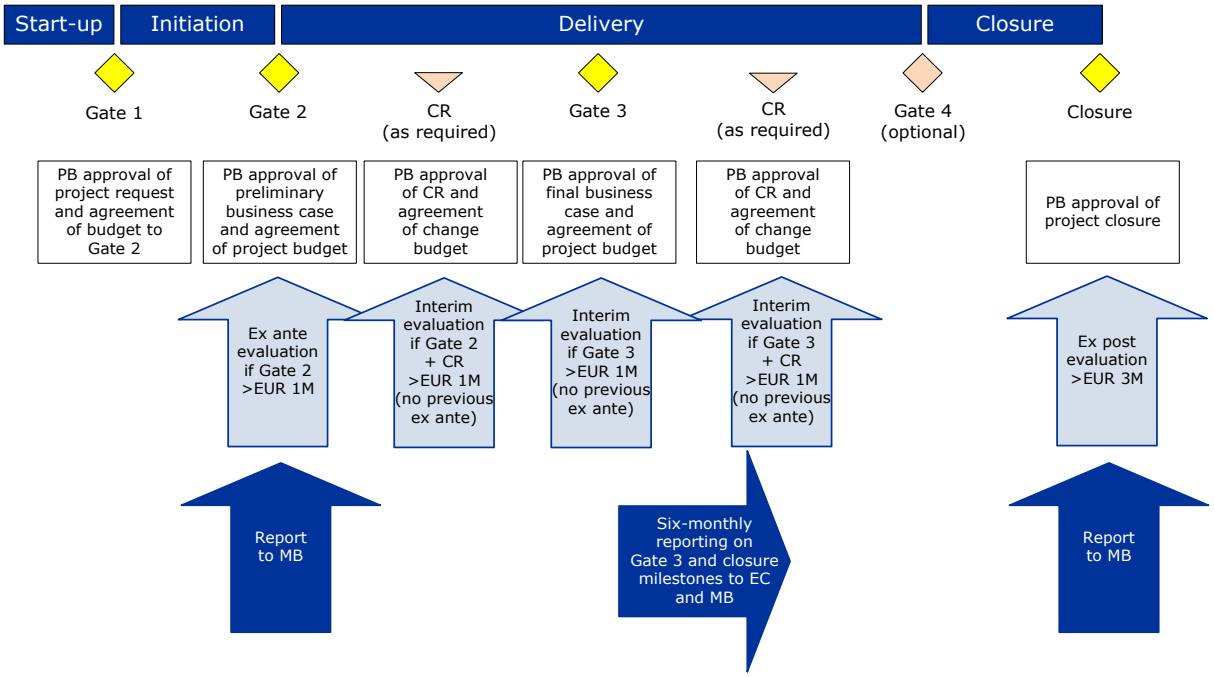
Ex ante evaluations are conducted at Gate 2 of the project procedure on the basis of the preliminary business cases (including cost estimates), before projects and budget expenditure are formally initiated. When the total project costs estimated at Gate 2 exceed EUR 1 million, the evaluation is conducted by the PB. 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.

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.

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[23]

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; and
- **Risk Management** Objectives – related to adequate management of the risks, including prevention, detection, correction and follow-up of fraud and irregularities.

EMA internal control framework is based on the COSO[24] model of internal control, and consists of five integrated internal control components, supported by seventeen principles.

Organisational management

Internal control governance, roles and responsibilities

[23] Information included in this annex represents the executive summary of the EMA strategy for the organisational management and internal control system
[24] Committee of Sponsoring Organizations of the Treadway Commission (COSO) Internal Control - Integrated Framework, May 2013

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 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 and non-compliance** 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 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[25]					Financial and HR impact					
	Actual or expected date of the signature	Total amount of contribution	Duration	Counterpart	Short description		2020	2021	2022	2023	2024
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	2,000	-	-	-
						Number of Cas/FTE	tbc	tbc	tbc	tbc	tbc
						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	0.24	0.24	0.24	0.24	0.24
						Number of SNEs/FTE	0	0	0	0	0
3. PREMIER	29/06/2020	EUR 47,000	72 months as of 01/09/2020	Innovative Medicines Initiative 2 Joint Undertaking	Prioritisation and Risk Evaluation of Medicines in	Amount	8,000	8,000	8,000	8,000	8,000
						Number of CAs/FTE	0.06	0.06	0.06	0.06	0.06
						Number of SNEs/FTE	0	0	0	0	0

[25] 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".

					the EnviRonment						
4. SISAQOL	not known	not known	not known	Innovative Medicines Initiative 2 Joint Undertaking	Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life endpoints	Amount	p.m.	p.m.	p.m.	p.m.	p.m.
						Number of Cas/FTE	p.m.	p.m.	p.m.	p.m.	p.m.
						Number of SNEs/FTE	p.m.	p.m.	p.m.	p.m.	p.m.
Total grant agreements						Amount	27,000	27,000	25,000	25,000	8,000
						Number of Cas/FTE	0.3	0.3	0.3	0.3	0.3
						Number of SNEs/FTE	0	0	0	0	0
Contribution agreements											
IPA 2020-2022	19/12/2019	EUR 254,919	36 months as of 01/01/2019	European Union	Participation of candidate countries and potential candidates in EMA trainings and activities	Amount	85,000	85,000	-	-	-
						Number of CAs/FTE	tbc	tbc	tbc	tbc	tbc
						Number of SNEs/FTE	0	0	0	0	0
Total contribution agreements						Amount	85,000	85,000	-	-	-
						Number of Cas/FTE	0	0	0	0	0
						Number of SNEs/FTE	0	0	0	0	0
Service-level agreements											
EMA does not provide services for other EU entities, hence has no corresponding service level agreements						Amount	-	-	-	-	-
						Number of Cas/FTE	-	-	-	-	-
						Number of SNEs/FTE	-	-	-	-	-
Total service-level agreements						Amount	0	0	0	0	0
						Number of Cas/FTE	0	0	0	0	0

	Number of SNEs/FTE	0	0	0	0	0
Total	Amount	112,000	112,000	25,000	25,000	8,000
	Number of Cas/FTE	0.3	0.3	0.3	0.3	0.3
	Number of SNEs/FTE	0.3	0.3	0.3	0.3	0.3

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, ICH and VICH 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.

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 (Brazil, Singapore, Korea, Taiwan); these are limited in scope and time. The UK would be expected to engage in such arrangement once the Brexit negotiations are completed. UNICEF is also a potential candidate for such arrangement to facilitate better quality medicines tenders.

Confidentiality arrangements are essential tools of collaboration, allowing exchange of meaningful and utile information; they allow better use of resources and should be developed with more authorities with a positive mindset. This should include the countries (Brazil, 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

Complementary to the confidentiality arrangements in place, 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.

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 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. 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.

Recently, Health Canada assessors participated in the remdesivir evaluation as experts for the CHMP, contributing to the peer-review step. Further participation in COVID-19 related assessments is planned. This is also potentially a model to develop.

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).[26]

Early Notification System

The Agency shares advance notice of upcoming safety issues relating to medicinal products within the scope of its activities with several 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 (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.

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

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. EMA Executive Director is chairing ICMRA (2019-2021).

The COVID-19 pandemic was addressed through ICMRA 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.

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 (2020-2022)

Considering the successive reduction in activities due to Brexit, the Agency moves, and now COVID-19, international activities are prioritised:

- Continue involvement in international management of COVID-19 pandemic, 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 countries in a more efficient way.
- 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 accession of candidate countries to the EU, as part of the IPA. The Agency has a contract with the EU to provide training on the acquis Communautaire over 3 years (2020-2022).
- Continue collaborative activities with WHO (e.g. Vaccines, pandemic, prequalification, guidance etc.). Support activities on certificates of medicinal products and transition from paper to electronic. Promoting article 58 eligible medicines (incl. vaccines) which are intended to prevent or treat diseases of major public health interest. This activity has had a demonstrated impact[27] despite the low number of opinions so far. Promote allowing parallel submissions of a centralised MA and the art 58 opinion.
- Russia: provide support, but currently low priority for political reasons, except in the context of COVID-19
- Promote the European approach to scientific excellence through workshops, training activities, and awareness sessions, participation in international conferences such as ICDRA, DIA, etc., and national initiatives in priority countries (resources and priorities permitting).

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

Annex XIII: Procurement plan

Procurement plan 2021

Activity statement:	**Social worker contractor for new starters and existing staff**
Value:	€ 600,000
Financial year:	2021-2023
Type of contract:	Framework service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q4 2020
Indicative timeframe for contract:	Expected to be signed in Q3 2021
Budget line:	1420

Activity statement:	**Studies framework (re-tender EMA/2017/09/PE)**
Value:	€ 12,000,000
Financial year:	2021-2025
Type of contract:	Framework service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q1 2021
Indicative timeframe for contract:	Expected to be signed in Q3 2021
Budget line:	3030

Activity statement:	**COVID-19 Vaccine safety studies**
Value:	€ 35,000,000
Financial year:	2021-2027
Type of contract:	Framework service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q1 2021
Indicative timeframe for contract:	Expected to be signed in Q2 2021
Budget line:	3030

Activity statement:	**DARWIN EU Network Programme**
Value:	€ 52,000,000
Financial year:	2022-2025
Type of contract:	Direct service contract
Type of procedure	Competitive procedure with negotiation
Indicative timeframe for procurement:	Expected to be launched in Q2 2021
Indicative timeframe for contract:	Expected to be signed in Q1 2022
Budget line:	3030

Activity statement:	**Real world data subscription (re-tender EMA/2020/12/TDA)**
Value:	€ 6,000,000
Financial year:	2021-2026
Type of contract:	Service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q4 2020
Indicative timeframe for contract:	Expected to be signed in Q3 2021
Budget line:	3030

Activity statement:	**Validation of data sources**
Value:	€ 1,000,000
Financial year:	2021-2025
Type of contract:	Service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q1 2021
Indicative timeframe for contract:	Expected to be signed in Q3 2021
Budget line:	3030

Activity statement:	**Medical Literature Monitoring (MLM) (retendering of existing FWC)**
Value:	€ 6,500,000
Financial year:	2021-2027
Type of contract:	Framework service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q4 2020
Indicative timeframe for contract:	Expected to be signed in Q2 2021
Budget line:	3030

Activity statement:	**Property advisory services (UK market) including managing agent services**
Value:	€ 1,117,718
Financial year:	2021-2025
Type of contract:	Framework service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q3 2020
Indicative timeframe for contract:	Expected to be signed in Q3 2021
Budget line:	2050

Activity statement:	**THIN database (re-tender)**
Value:	€ 1,200,000
Financial year:	2021-2027
Type of contract:	Service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q4 2020
Indicative timeframe for contract:	Expected to be signed in Q3 2021
Budget line:	2700

Activity statement:	**DIMSIS II - Tender 5 (Specific services)**
Value:	€ 20,000,000
Financial year:	2021-2025
Type of contract:	Framework service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q1 2021
Indicative timeframe for contract:	Expected to be signed in Q4 2021
Budget line:	3105, 2114

Activity statement:	**Efficacy and safety studies on medicines (place holder ROC's 2021)**
Value:	€ 2,000,000
Financial year:	2021-2022
Type of contract:	Service contract
Type of procedure	Re-opening of competition
Indicative timeframe for procurement:	Expected to be launched in Q3 2021
Indicative timeframe for contract:	Expected to be signed in Q4 2021
Budget line:	3030

Activity statement:	**Books on demand (print & digital)**
Value:	€ 220,000
Financial year:	2021-2025
Type of contract:	Framework service contract
Type of procedure	Open tender
Indicative timeframe for procurement:	Expected to be launched in Q3 2021
Indicative timeframe for contract:	Expected to be signed in Q2 2022
Budget line:	2700

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 2021-2022. The deliverables for 2022 provide a high-level overview and will be detailed during the preparation of the final work programme 2022.

Brexit conditions may still have some implications on the projects as some protocols may need to be reflected in some IT systems. And the COVID-19 situation pandemic is adding a high risk to all the portfolio.

Programme / Project	Legal basis	Start date	End date	Deliverables 2021	Budget 2021
Clinical Trials Programme – CT					
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	- CTIS integration with other EMA databases or systems - Translation of public user interface in all official EU languages - An evolved version of the CTIS release for go live Q4 2021 - Targeted communications to facilitate awareness and preparedness in the user community - Knowledge transfer to the user community through online training materials and delivery of training Guidelines - CTIS Helpdesk setup	€ 7,714,000
e-Submission Programme					
ECTD4: Implementation and adoption of eCTD v4.0 standard [restart]	n/a	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)	€ -
Single Submission Portal: (eAF replacement): NCA led initiative to develop a single submission gateway and portal for the European Medicines Regulatory Network	n/a	-	-	- Part of this scope will be delivered by the Regulatory Business Process Optimisation Programme (**RBPOP**), i.e. eAF replacement. - Agree approach to other CESP activities outside the eAF scope	-

Programme / Project	Legal basis	Start date	End date	Deliverables 2021	Budget 2021
[cancelled]					
New Veterinary Medicine Regulation Programme - VMP-Reg					
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	- Completion development of EVVet3 system compliant with legislation - End-to-end user acceptance testing - Go live Q4	€ 4,340,000
UPD - Union Product Database [continues]	- Regulation (EU) 2019/6; associated implementing act	Q1 2020	Q3 2022	- Completion development of UPD system compliant with legislation - End-to-end user acceptance testing - Go live Q4	€ 5,000,000
ESVAC - Collection of Antimicrobials Sales and Use Data [new]	- Regulation (EU) 2019/6; associated implementing act and delegated act	Q1 2021	2023	- Amendment of ESVAC to additional requirements for collection of sales data	€ 1,300,000
EudraGMDP - Union Manufacturers and Wholesale Distributors Database [new]	- Regulation (EU) 2019/6; associated implementing act and delegated act	2021	2022	- Analysis/impact assessment of amendments and needed improvements to EudraGMDP	€ 1,300,000
Online Programme					
European Medicines web portal [restart in 2022]	- Regulation (EC) 726/2004 - Regulation (EC) 1235/2010, art.26	2022	2023	- Suspended until 2022 but: 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.	n/a
Data integration programme					n/a
SPM&S - Substances and products management services [merged]	- Regulation 726/2004, art.57(2) - Regulation (EC) 520/2012, art.25 and 26 - Clinical trials regulation 536/2014, art.8193) - Pharmacovigilance fees regulation 658/2014, art.7	2017	-	- Merge for delivery optimisation into the Regulatory Business Process Optimisation Programme (**RBPOP**) in Q2 2020	

Programme / Project	Legal basis	Start date	End date	Deliverables 2021	Budget 2021
	Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU				
Regulatory Business Process Optimisation Programme - RBPOP (new)					
IRIS: Platform to support regulatory business processes of the Agency [continues]	n/a	2019	2025	- Scientific Advice hyper care after the Oct 2019 go-live - eAF Proof of concepts - Inspections - Variations process - Marketing Status - Supply Chain	€ 3,800,000
SPM&S - Substances and products management services [continues]	- Regulation 726/2004, art.57(2) - Regulation (EC) 520/2012, art.25 and 26 - Clinical trials regulation 536/2014, art.8193) - Pharmacovigilance fees regulation 658/2014, art.7 - Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	2017	2024	- Deliver requirements set out in the pharmacovigilance legislation to provide an ISO IDMP compatible substance and product repository, linked to EU-SRS, and messaging format.	€ 2,600,000
Data Analytics Programme (new)					
- Lifecycle Regulatory Submissions Raw Data	n/a	2021	2024	- Review of experience with Individual Patient Data and Pilot - Technology Proof of concept	€ 500,000
- Lifecycle Regulatory Submissions Meta Data	n/a	2020	2022	- Perform a research and landscaping analysis of EU Regulatory standardisation needs	€ 600,000

Programme / Project	Legal basis	Start date	End date	Deliverables 2021	Budget 2021
				- Perform stakeholder analysis of current formal business processes and informal assessor practices used to gather scientific information needed for assessment to identify and prioritise relevant business cases	
- Real-world Metadata, Quality Framework and Catalogues	n/a	2021	2025	- Metadata study, Data sources identification and Quality framework - Initiate work on catalogues 2nd half 2021.	€ 1.200,000
- Observational Studies Rapid Analytics	n/a	2020	2022	- Change management ad go-live - Review and report by Q4 2020	€ 6500,000
- Observational Studies DARWIN EU	n/a	2021	2025	- Pilot with European Health Data Space - Coordinating centre preparation (service provider engagement, funding, rules and processes, governance) - Prepare EMA to be ready as a node - establish DARWIN Network Coordination Group - Training and - Change management	- to be estimated the (expected to funded by the EC)
- Signal and Safety Analytics	n/a	2021	2023	- Optimise Signal & Safety Analytics through improving the eRMR, aligning to agreed data standards and making more efficient the generation of evidence in support of benefit & risk decisions.	€ 1.400,000
IRIS: S-REPS Phase 3 SIAMED with Knowledge Management [merged]	n/a	2019	2020	- Merged into the Regulatory Business Process Optimisation Programme (**RBPOP**)	-
e-PI set up [new]	n/a	2020	2021	- Standardisation of the Product Information - Proof of concept of a technological solution for Product Information - Roadmap for full delivery and implementation of e-PI	-
DREAM Replacement Agency Document: Management system end of lifecycle and need to be replaced [new]	n/a	2021	2023	- Impact analysis and requirement gathering for a new Agency wide Document Management system	€1,500,000

Programme / Project	Legal basis	Start date	End date	Deliverables 2021	Budget 2021
Administration Digitalisation: Optimisation of the Administration supporting tools [continues]	n/a	2019	2022	- Provide better tools to overcome manual processing and repetitive tasks - New Goals and Performance system - New Succession Planning and start of the migration of SAP HR to Employee Central in the cloud - Digitalisation of the personal files (as of today mostly on paper) - Automation of the Procurement, Budget and Projects dashboards for a better decision-making process	€2,000,000