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European Medicines Agency

# Final programming document 2020-2022

**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

## 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 role

The European Medicines Agency is the European Union (EU) body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

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.

## 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.

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# Part I: General context

## Addressing Brexit consequences and relocation of the Agency

The UK's decision to leave the European Union (EU) following the 2016 referendum has had significant implications for EMA. Not only did the Agency leave London and moved its seat to Amsterdam in 2019, but it did so while continuing to comply with its legal role and to perform its activities on time and to the same high level of quality despite the loss of both UK expertise and staff.

### Challenges and risks

EMA will move once more in 2020 from the temporary premises in Amsterdam Sloterdijk to its permanent location in Amsterdam Zuidas. This will present additional challenges in the beginning of 2020 including transferring and maintaining operational IT systems, ensuring the necessary services are in place, as well as the logistics of the actual move of the organisation and staff with minimum disruption to the Agency's day-to-day activities.

In addition, EMA will have to continue its Brexit preparedness activities until the Brexit date. EMA's working scenario is that the UK will leave the EU as of 31 January 2020 and become a 'third country' as of that date. As regards any future relationship between the UK and EMA in the regulation of medicines after the Brexit date, this is part of the negotiations between the EU and the UK. UK experts constituted some 15% of the Agency's expert base and conducted around 20% of the scientific work. Loss of this expertise has had significant consequences not just for the Agency, but for the EU regulatory network as a whole. To manage this, the Agency and the Network have worked to ensure capacity building and re-distribution of the workload among the Member States.

EMA is still anticipating losing between 20% and 25% of the 901 staff it had at the end of 2018. The Agency is losing staff across all functions and profiles. More than 70% of loss so far has been from staff working on the core scientific activities considered the most critical 'category 1' priorities under the Agency's business continuity plan (such as initial evaluation, post-authorisation activities or committee, WP, SAG support/secretariat). In addition to this, staff loss is impacting key support/administrative areas, such as information management, HR, infrastructure and others. The Agency continues to monitor closely the situation with regard to loss of staff. The previous pattern of higher than usual numbers of staff leaving – and specifically resigning – continued throughout 2019. By 31 October 55 staff members (TA and CA) had either left the Agency or made known their intention to leave before the end of the year, with 82% or 45 of these staff members leaving the Agency by resignation. These have been the highest turnover figures the EMA has experienced since its establishment. As a comparison indicator EMA had an average of 45% (in the previous 5 years) of staff leaving due to resignations. 8 seconded national experts (SNE) have also left the organisation during 2019. Although recruitment is ongoing to replace staff who decide not to relocate, the Agency will not reach its previous headcount, which included a large number of staff on short-term contracts. Staff on short-term contracts included, EMA has lost a total of 159 resources within 2019 which puts the Agency's continuity of operations under significant pressure, including the EMA capacity to deliver core activities. As regards the forecast for staff retention in 2020, the staff numbers will increase, however, there is still uncertainty as to the impact of the end of the staff retention measures that are in place until 30 June 2020. The staffing levels will depend on the Agency's ability to maintain a high recruitment rate and the required expertise being available.

Finally, the Agency will be confronted with another unprecedented challenge, i.e. the need to manage the subletting agreement of its previous London premises.

## Organisational and operational aspects

In order to address the challenges presented by Brexit, in June 2016 EMA established an internal Operations and Relocation Preparedness (ORP) task force to plan and prepare for the upcoming changes, and to ensure that the Agency takes all the necessary steps to maintain continuity of its business operations both during and after this period of change.

The work of the ORP task force is organised into 2 areas of activities:

- EMA Brexit preparedness and implementation.
- EMA-Dutch Authorities collaboration for relocation to Amsterdam.

Each area of activity is divided into various work streams.

## Preparations to date

During 2016-2019 the Agency has undertaken considerable work to address the Brexit impact on the Agency's operations, including but not limited to:

- Completing an initial impact assessment, identifying also the key risks that the Agency would be facing in this environment.
- Preparing the Agency's requirements for the new location, including infrastructure requirements, technical specifications for the new premises, and other factors critical to operations of the Agency, and sharing this information with the interested Member States as well as the EU Institutions.
- Hosting Member State visits to EMA and EMA site visits to candidate host countries upon request from a candidate host Member State.
- Undertaking further analyses of the impact of the decision for the Agency to relocate to the Netherlands.
- Liaising with representatives from the new host city of Amsterdam and the government of the Netherlands following the Council decision of the new EMA seat on 20 November 2017.
- Relocating the Agency's data centres to Hamburg.
- Ensuring the necessary contracts were in place at the time of the Agency's move to the Netherlands.
- Conducting several staff surveys, to gauge the potential staff losses in view of their impact on the Agency's operations and assess potential remedial actions.
- Developing a dedicated Brexit recruitment and selection strategy to address the potential staff loss, including a job and competency mapping to support succession planning.
- Developing and implementing a dedicated EMA Brexit preparedness BCP, to address situations where a "business as usual" scenario is no longer possible.
- Putting in place supporting measures to maximise staff retention and to facilitate the relocation of staff to Amsterdam in addition to the support provided by the Dutch authorities.
- Working with the Member States to address the workload issues arising from the loss of UK expertise and agreeing on the re-distribution. Conducting surveys with the Member States to establish the capacity and training needs.

- Issuing communications and preparing guidance for the pharmaceutical industry, to ensure companies have the correct information and take the necessary steps to be able to operate in the EU 27, ensuring continued availability of their medicines to EU citizens.

## Future work

The Agency will strive for 2020 to be the final year of transition and for starting the relaunch of activities that were reduced or suspended during this period of change, albeit with a reduced number of staff compared to the staffing situation prior to the start of the Brexit preparatory work in 2016. In the first quarter of 2020 the Agency will move to its permanent location in Amsterdam. In parallel, work will, depending on the actual timing of Brexit, continue in terms of the regulatory changes to centrally authorised products due to Brexit.

The following Brexit related activities are foreseen for 2020, in order to execute the actual move of the Agency to its permanent building and other remaining activities due to Brexit:

| Work stream | Activity |
|---|---|
| Relocation preparedness | Continue in collaboration with the Dutch Authorities the implementation of the Memorandum of Understanding/ Host State Agreement and monitor such implementation |
| | Monitor the contractual activities related to the existing providers of services |
| | Monitor the implementation of the Dutch Authorities' plan for relocating EMA to the permanent premises |
| | Move the Agency's staff from the temporary to the permanent building in Amsterdam |
| | Prepare for and implement changes stemming from the physical move to the permanent premises |
| Operational and financial preparedness | Conduct with the NCAs the training identified through the capacity and training surveys through the EU NTC |
| | Prepare Q&As and guidance documents for pharmaceutical industry on the Brexit-related changes to marketing authorisations |
| | Handle the additional, Brexit-related post-authorisation applications |
| | Identify remedies to address supply shortages resulting from the impact of Brexit on the availability of centrally authorised products |
| | Implement additional business continuity measures during the move period in 2020 |
| | Prepare and implement a plan for reinstating activities following BCP |
| | Implement necessary changes to EMA IT systems |
| HR related matters | Undertake any recruitments necessitated by staff loss |
| Communication | Provide timely and targeted communication to the EU regulatory network, stakeholders and pharmaceutical industry |
| | Provide timely communication to staff and contractors |
| | Ensure adequate communication on the operation of EMA to relevant decision-makers and citizens in the Netherlands/Amsterdam |
| Project coordination | Undertake efficient coordination of the overall project relating to the EMA move to its permanent location and the Brexit impact on EMA operations, including robust budgeting |
| **WORKLOAD FORECAST** | **10 FTEs** |

# Future-proofing the Agency

The Agency operates in an environment of constant, continuous and rapid change. The pharmaceutical research and development landscape is evolving rapidly; new scientific developments and approaches, such as gene and cell therapies, genome editing, personalised medicines, are expected to become increasingly dominant in the medicines development landscape. Technologies are continuously evolving at an ever-increasing pace, providing new opportunities both for the development and assessment of medicines and for operational improvements and efficiencies (e.g. digitalisation of scientific data or automation of processes). The regulatory environment provides its own challenges, with new legislation in various stages of drafting, adoption and implementation bringing new roles, tasks and demands on regulators.

The Agency needs to be agile and adapt to these developments in order to keep pace with these rapid advances in science and technology, prepare for the future challenges and continue to effectively fulfil its role to safeguard public and animal health.

The recent move to Amsterdam and the upcoming senior management turnover presents opportunities for the Agency to review and recalibrate its ways of working. In order to achieve long-term sustainability, efficiency and effectiveness of the Agency operations, EMA is now embarking on a 'future proofing' exercise and taking the opportunity to strategically review and recast activities and roles, according to the expertise and knowledge that will be needed in the future.

To do this, a comprehensive review of the organisation structure is taking place and task forces will be set up, focusing on areas that are also key priorities for the Network, i.e. digital business transformation, data analytics and methods, regulatory science and innovation, and clinical trials and manufacturing strategy. Operations in the area of human medicines will be integrated to strengthen the therapeutic focus all along a medicine's lifecycle, with the ultimate aim of assuring the quality of scientific opinions and further improving support to the EMA scientific committees. In addition, as the Agency is gradually restoring the activities that were temporarily reduced or suspended during the BCP period, these will also be assessed for their fit with the future strategy.

This will allow EMA to focus its resources on the high impact areas, secure the quality of scientific output and further strengthen support to the scientific committees, and maximise staff development potential.

The Agency will focus efforts on four mission-critical functions:

## Digital business transformation

The aim of this function is to ensure that the Agency's overall strategic mission, business operating model and value proposition respond well to fundamental changes brought by legislative initiatives, digital technologies, global trends and increasing stakeholder needs and expectations and that the Agency is capable of managing complex and potentially disruptive changes. To be effective in the future, the Agency's processes must be designed and digital technologies used to support efficient and sustainable EMA core business.

This function aims to deliver a modern workplace, to increase efficiency, make best use of resources, skills and competences, and provide a system that supports an integrated knowledge management across EMA operations and is responsible for driving complex, potentially disruptive change initiatives that have a profound impact on the strategy of EMA, its operational structure and operation in relation to the EU medicines regulatory network, its partners and stakeholders.

The expected deliverables for this function are as follows:

*Digital Strategy*

- Translate and implement ongoing and future legislative initiatives into 'IRIS-ready' business processes, as the chosen online CRM (customer relationship management) platform to handle product-related regulatory procedures across the lifecycle, for EMA staff, the EU medicines regulatory network (EMRN) and industry stakeholders;
- Obtain insights on digital and global trends, legislative, regulatory and policy initiatives and create capacity to conduct relevant analysis and best-evidence generation in support of an EMA Digital business transformation strategy and planning;
- Seek and build Digital business transformation expertise, conduct business process and digital toolbox experimentation (Artificial Intelligence, robotics, Machine Learning) and provide ACE (analytics centre of excellence) leadership.

*Digital Governance*

- Perform a digital maturity assessment of EMA operations;
- Set up a governance capable to oversee the EMA Digital business transformation programme;
- Provide leadership on change management and digital capability building;
- Consolidate, as part of the Digital Business Transformation' Task Force, the Change management methodology and Digital capability building;

*Digital Awareness*

- Expand the EU Network Training Centre's scope to include a digital knowledge sharing academy and constitute it as part of a wider EU education ecosystem;
- Explore opportunities for increased 'shared services' across activities of the Digital business transformation task force.

## Data analytics and methods

The aim of this function is to ensure EMA is prepared for and can seize the opportunities provided by increasing availability of healthcare data; has access to healthcare data including real world data and is able to utilise new data sources in different business processes and to analyse and interpret different types of healthcare data, and is geared up to use real world data to generate evidence and support decisions on products.

This function aims to transform the Agency into a modern, data-driven organisation that supports the EU Regulatory Network, to provide efficient services in the delivery of evidence, to support benefit risk decision-making, to strengthen the promotion and protection of public health by supporting decisions on medicines with evidence derived from robust data, and increase accessibility of medicines by increased knowledge of product performance. It is responsible for 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.

The expected deliverables for this function are as follows:

- Creation of a task force on data analytics and study methods to catalyse EMA and EU regulatory network expertise and to bridge across disciplines including data science, biostatistics, pharmacoepidemiology and artificial intelligence;

- Delivery of a training curriculum on Big Data including specific training for assessors on real world data in committee assessment;
- Conduct of a pilot of rapid analytics of Electronic Health Records to support committee decision-making including increasing the EU healthcare data accessible for analysis;
- Development with stakeholders of a business case for an EU platform for healthcare data access and analytics;
- Review of the experience gained from patient level data (PLD) analysis by the EMA committees and formulation of a plan for a targeted pilot;
- Agreement of a work plan for agile guideline development on data, methods and evidence.

## Regulatory science and innovation

The aim of this function is to ensure the Agency is able to continuously monitor the developments and direction of the regulatory science, identifies the areas to invest strategically its resources for optimal impact and is able to support and enable innovation addressing patient needs to 2025 and beyond.

This function is responsible for addressing key scientific and technological trends and their translation through the development of regulatory science strategy, planning and governance, through operation of a regulatory science observatory. The goals of this task force will be to act as an 'observatory' for future challenges from innovative scientific developments that may require an integrated regulatory science response across the product development lifecycle; support innovation through the development of first contact functionalities embodied within the ITF/EU-IN/SME Office and Academic liaison framework; develop EMA's Regulatory Science Strategy to 2025, integrate it within EMRN 2025 Strategy and translate it into the work plans of the various committees and their working parties; enable and leverage research and innovation in regulatory science, and coordinate conduct and/or commission impact assessment studies into the effectiveness of committee operations.

The expected deliverables for this function are as follows:

- Gather a better insight of trends in science and technology, upcoming products, their impact of EMA's work, and their interplay with the data needs of stakeholders. Addressing storage of this knowledge and reusability across the Agency;
- Enabling and leveraging research and innovation in regulatory science;
- Coordination of the conduct and/or commissioning of impact assessment studies into the effectiveness of committee operations to demonstrate their value in facilitating access to new medicines.

## Global strategy for clinical studies and manufacturing

The aim of this function is to assess whether the current model of international and EU guidance best serves the rapidly evolving science of medicines; to ensure that EMA is prepared for the changing landscape of clinical development and we are collectively making best use of resources for ensuring GXP compliance at global level; as well as providing best support to the future Clinical Trial Information System, its users and content.

This function will be responsible for providing principles that can enable a more agile system of guidance to stakeholders; for providing a framework to enable the regulatory use of healthcare and clinical study data and ensuring that patients' right to privacy of their data is respected; for supporting a greater strategic input to preparation of the ICH work plan and guidance development; for driving

development of strategic standards for clinical study design, conduct and reporting; for promoting the establishment of an EU multi-stakeholder structure to support the evolution of clinical study standards and approaches; for supporting international alignment in the application of GXP standards and for developing the basis of a future Clinical Trial Information System service.

The expected deliverables for this function are as follows:

- Develop and guide agency strategy at EU and global level to support the facilitation of clinical studies and manufacturing.
- Develop a principle led approach that supports a learning regulatory system so it has sustained, contemporary, relevance as enabler and gatekeeper.
- Develop Agency strategy on implementation of GDPR and DPR in the context of use of clinical study and health related personal data.
- Continue development of the Clinical Trial Information System, and form this as a service ready for integration into the future operating structure of Agency.

To support the delivery of the above strategic functions, changes will also take place across the organisation, its business activities and supporting services:

## Human medicines

The focus of the human medicines division will be on how to best reassure the public that they can trust the medicines placed on the market to meet the required standards and be continuously monitored; how to ensure that scientific and technical innovation is harnessed for the benefit of public health and that medicines address the needs of patients and consumers. It will look into maintaining high standards of quality of the Agency's scientific outputs and maximising the relevance of EMA's work for the purpose of downstream decision-makers and the European healthcare systems. It will also seek to achieve a more integrated knowledge of a medicinal product during its lifecycle, increase the Agency's capacity to continuously adapt and optimise its ways of working as well as make best use of the internal expertise and skills, and build opportunities for staff development.

A single entity dealing with all operational aspects related to human medicines will be established, with the responsibility for the oversight of human medicines throughout their lifecycle, from evidence generation planning to interface with health care systems. An integrated way of working will be implemented, with emphasis on assuring the quality of the continuous assessment of the benefit risk, catalysing innovation for the generation of fit-for-purpose scientific evidence, effective management of knowledge generated throughout the products' lifecycle and continuously growing and improving the use of skills and expertise.

## Veterinary medicines

The aim of the Veterinary medicines division is to ensure a high level of scientific and administrative excellence is maintained to facilitate access to safe and effective veterinary medicines, to ensure the new veterinary regulation is properly implemented and to raise awareness internally and externally of veterinary medicines' contribution to public and animal health. It will also tackle internal aspects such as providing more opportunities for staff development, making best use of business process optimisation, including centralisation of activities, and adding value through more integration and interactions with different areas across the Agency.

## Administration and resource management

The Administration and resource management division will focus on optimising the use of resources (human, financial, in-house expertise and competencies) to cope with constraints, finding ways to best identify the skills and competencies needed for EMA to be fit in an ever-changing environment and making sure the Agency attracts and recruits the right talent, as well as provides opportunities for staff to develop their skills and careers. It will also explore possibilities to capitalise on synergies within financial and project governance areas.

The Administration transformation started in 2019 with process and technology improvements in integrated business and human resource planning, talent management and digitalisation of HR processes, meetings reimbursement and certain finance processes. It aims to enable the business to meet its future objectives by putting in place integrated, strategic and efficient ways of planning and managing the Agency's human and financial resources.

As part of the HR Digitalisation, the main focus will be the delivery of the on-boarding tool while optimising the current processes related to on-boarding, which will enable the talent acquisition and staff matters services to provide with a smoother and better quality service to our new comers to the Agency. Another key area the HR Digitalisation will be the implementation of a more modern and agile system to enable our managers and EMA staff to get continuous feedback to improve and maintain a high performance.

In line with the Administration transformation, the Staff Relations and support department has planned to enhance the ethics and employee life cycle by reinforcing the HR specialist role to ensure the best HR service to our staff.

Meetings Support service is also working on delivering the improved delegate reimbursement, travel and accommodation boarding processes and tool to provide the optimal support to our delegates.

As part of the Finance Digitalisation, in 2020 the effort will be focussed on delivering the relevant reports needed as well as the procurement and contract digitalisation.

## IT development and delivery

IT is a critical enabler of business operations modernisation, automation and scientific support, for implementing the pharmaceutical regulation and for realising objectives of the Regulatory Science Strategy that rely on IT in collaboration with other divisions and task forces (e.g. data analytics).

The IT Division will continue supporting the EU Medicines Regulatory Network with the necessary IT services while improving EMA's corporate IT tools in a context of human and financial constraints; to find ways to cope with our legacy systems while making best use of new technology and to enable the Agency's Information Management strategy to deliver more digital ways of working and build EMA's data analytics capability. It will also look into continued development of the necessary skills and capacity to direct and make best use of services provided externally

The I Division will be responsible for providing and maintaining required information technology solutions to support EMA's corporate activities and the work of the Network (i.e. Telematics systems), including design and delivery of IT solutions through the Agency's portfolio of programmes and projects, IT infrastructure services and IT security (including running two data centres), maintenance of IT services, and internal and external user support.

### Stakeholder engagement and communication

The Stakeholder engagement and communication Division will streamline and simplify communication related processes, to allow a more efficient and effective delivery and execution of the EMA's communication and stakeholder engagement strategy 2020-2025. They will support operational divisions within the matrix structure to further improve the quality of product related and other information targeted to the Agency's external audiences.

Building on existing and new synergies within the organisation in the areas of access to information, communication, data publication, and stakeholder engagement will allow strengthening of EMA's brand as a trusted regulator and source of information.

The division will further develop EMA website, as a resource for unbiased, high-quality information on medicines, consolidating external communication and stakeholder engagement activities. It will also streamline and simplify processes for handling requests for information, access to documents, and clinical data publication.

Finally, the transformation of EMA's communication will continue, embracing digital and social tools, building high quality products (documents/information/communication) and improving (stakeholder) meeting management oversight, planning and co-ordination.

## EMA priority areas and approach towards work programme 2020

In 2019 EMA continued to operate under business continuity conditions in order to safeguard the Agency's core activities related to the evaluation and supervision of medicines, whilst executing the actual relocation from London to the new host Member State and addressing the Brexit impact on the Agency's operations.

However, having successfully completed the first stage of relocation and moved to the temporary premises in Amsterdam, the Agency also assessed the possibility to start relaunching some suspended/scaled back activities, considering also the staffing situation. EMA started to reinstate some activities as of June 2019, focusing on activities and projects that aim to increase the efficiency of EMA's operations to ensure that the Agency is fit-for-purpose in the longer term, e.g. IT systems supporting medicines evaluation and the digitalisation of administrative processes. In addition, some of the EU Network working groups directly contributing to EMA's core activities were restarted.

In defining its work programme for 2020, EMA will focus on the core activities identified in the last phase of business continuity, i.e. phase 4, as a baseline and then prioritise additional activities dependent upon the available resources. However, it needs to be emphasised that this will be undertaken with a reduced number of staff compared to the staffing situation prior to the start of the Brexit preparatory work in 2016. Furthermore, it has to be stated that important new demands have been put on EMA, in particular the implementation of new legislation.

Therefore, the Agency's focus in 2020 will be on:

- Activities under BCP Phase 4 to ensure the core activities of the Agency can be dealt with. This includes activities related to the implementation of the new veterinary legislation (non-IT related aspects) and the medical device legislation.
- Additional activities that are considered core activities and had to be started in 2019, e.g. the handling of nitrosamine impurities in medicinal products.
- Activities aimed at ensuring the organisation of the Agency is fit-for-purpose longer term.

- Activities to prepare for the implementation of the EU-DPR legislation.
- Activities stemming from EC or HMA action plans.
- Activities relating to transparency/communication, international affairs and vaccines portal and strategy.

However, it should be noted that there remain still uncertainties about the availability of staff in 2020 and beyond. Therefore, the WP2020 will be reviewed at the June 2020 MB also in view of ongoing reviews of activities related to the relaunch of the working parties and clinical data publication.

# Part II: Multiannual programming 2020–2022

## Multiannual objectives

The Agency and National Competent Authorities (NCAs) have developed a common strategy to guide the work of our Network over 2016-2020. As part of this strategy, major drivers and themes for the work and contribution of the Network were identified and common multiannual objectives were agreed.

The Agency's multiannual work programme builds on the Network strategy and outlines main initiatives and activities that the Agency will undertake in the coming years, to support achievement of common goals. The annual work programme, in turn, details both the assessment activities and other legal commitments, and the additional efforts and activities to facilitate implementation of the Network strategy.

The EMA multiannual work programme reflects the structure of the Network strategy, and is structured into four themes, according to the societal, scientific and legislative nature of drivers. In line with the approach taken within the Network strategy (and explained in Chapter 2 of the Strategy), elements specific to veterinary medicines are elaborated in Theme 2 'Contributing to animal health and human health in relation to veterinary medicines'. In the other parts of this document (particularly those covering Themes 3 and 4 of the Strategy), where reference is made to 'the Network' or 'medicines', this can be assumed to cover both human and veterinary domains unless it is clear from the context that it relates to human or veterinary medicines alone.

The current integrated Network strategy covers the time period to 2020 and guides the EMA multi-annual work-programming. The Agency and the Network have started work on the next joint 5 year strategy that will cover the period of 2021-2025. While the new strategy is still being developed, the multiannual objectives and multiannual programming part continues to build on the themes and topics identified in the Network strategy 2016-2020. Once the new strategy is in place, a new multiannual work programme will be designed, to reflect the up-to-date strategic priorities and tasks, and will consequently be translated into annual work programmes as well as cascaded to individual scientific committee and working party work-plans.

### *Theme 1: Contributing to human health*

| Theme 1: contributing to human health | |
|---|---|
| **Objective 1:** Focus on key public health priorities including availability of medicines and antimicrobial resistance | **Main areas of work:** antimicrobial resistance, needs of specific populations, supply issues and availability |
| **Objective 2:** Ensure timely access to new beneficial and safe medicines for patients | **Main areas of work:** early access to medicines |
| **Objective 3:** Support for patient focused innovation and contribute to a vibrant life science sector in Europe | **Main areas of work:** clinical trial regulation, supporting innovation |
| **Objective 4:** Strengthen regulatory capability and transparency | **Main areas of work:** regulatory capability, transparency |

## *Theme 2: Contributing to animal health and human health in relation to veterinary medicines*

| **Theme 2: Contributing to animal health and human health in relation to veterinary medicines** | |
|---|---|
| **Objective 1:** Increase availability of veterinary medicines and promote development of innovative medicines and new technologies | **Main areas of work:** availability of veterinary medicines and supply issues, maximum residue limits, supporting innovation |
| **Objective 2:** Promote 'Better Regulation' | **Main areas of work:** veterinary legislation review, veterinary pharmacovigilance, quality of scientific output |
| **Objective 3:** Improve the functioning of the single market for veterinary medicines within the EU | **Main areas of work**: While no new activities initiated by EMA are identified at this time, the Agency continues contributing to a number of activities initiated and led by the Network. In addition, several EMA activities listed under all four themes aim to improve the functioning of the single market (e.g. Incident Management Plan, training, availability initiatives, development of advice that can support the work in Council and Parliament in relation to revision of the veterinary legislation) |
| **Objective 4:** Focus on key public and animal health priorities including antimicrobial resistance | **Main areas of work:** antimicrobial resistance, risk to environment, ensuring the supply of essential veterinary medicines |

## *Theme 3: Optimising the operation of the network*

| **Theme 3: Optimising the operation of the network** | |
|---|---|
| **Objective 1:** Reinforce the scientific and regulatory capacity and capability of the network | **Main areas of work:** regulatory capability and capacity, independence of scientific expertise |
| **Objective 2:** Strive for operational excellence | **Main areas of work:** sustainability of the regulatory system, quality of scientific output |
| **Objective 3:** Ensure effective communication of and within the network | **Main areas of work:** communication about strategy implementation, cross-EU communication about medicines, health emergency communication |
| **Objective 4:** Strengthen the links with other authorities and with stakeholders | **Main areas of work:** collaboration with partners and stakeholders |

## *Theme 4: Contributing to the global regulatory environment*

| **Theme 4: Contributing to the global regulatory environment** | |
|---|---|
| **Objective 1:** Assure product supply chain and data integrity | **Main areas of work:** supply chain and data integrity, information sharing |
| **Objective 2:** Convergence of global standards and contribution to international fora | **Main areas of work:** harmonisation of standards and approaches, contribution to international cooperation mechanisms, use of animals in medicines development |

| Theme 4: Contributing to the global regulatory environment | |
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| **Objective 3:** Ensure best use of resources through promoting mutual reliance and work-sharing | **Main areas of work:** work-sharing, information sharing and increasing reliance on European assessments |
| **Objective 4:** Support training and capacity building and promote the EU regulatory model | **Main areas of work:** non-EU regulators' training and capacity building |

# Multiannual work programme

The multiannual work programme outlines the Agency's medium-term objectives and the main initiatives and activities to achieve these. The objectives come from the Network strategy and describe what the Network, as a whole, will strive to achieve. The Agency's particular contribution is highlighted through the implementing activities and initiatives that follow each of the objectives.

## Theme 1: Contributing to human health

***Objective 1: Focus on key public health priorities including availability of medicines and antimicrobial resistance***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Antimicrobial resistance | Promote responsible use of antibiotics in human and veterinary medicine adopting a 'One Health' perspective* | 1.1-1 | Establish and run cross-Agency task force on antimicrobial resistance | 2015 | 2025 | - task force established and running **[completed]**<br>- proposals given/implemented for EMA activities to address antimicrobial resistance with the 'One Health' approach |
| | Contribute to European and international initiatives and collaborations in the area of AMR | 1.1-2 | Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative | 2016 | 2022 | - number and proportion of TATFAR actions implemented (where EMA has a role)<br>- level of completion of the actions **[some TATFAR actions have been completed]** |
| | | 1.1-3 | Contribute to implementation of the next phase of the EC Action Plan on antimicrobial resistance, and other action plans such as the WHO Global action plan and OIE strategy | 2016 | 2025 | - actual contribution to EU institutions activities including EP<br>- contribution to WHO led initiatives<br>-contribution to initiatives related to clinical trials networks and other funded projects, e.g. IMI<br>- completion level and/or rate of implementation of actions in the action plan(s) |

* Specific initiatives in the veterinary domain are covered under Theme 2: Objective 4.

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|---|---|---|---|---|---|---|
| Public health needs and priorities | Ensure needs of specific populations are met, including elderly, children, patients with rare diseases and others | 1.1-4 | Contribute to Global Action Against Dementia (GAAD) **[completed]** | 2015 | 2019 | - implementation of the actions in the GAAD **[completed]** |
| | | 1.1-5 | Implement the geriatrics strategy **[completed]** | 2011 | 2020 | Level of strategy implementation: proportion of actions implemented<br>- Frailty reflection paper **[completed]**<br>- Pilot review of outcomes **[completed]** |
| | | 1.1-6 | Support innovation, early dialogue and research for paediatric medicines | 2007 | 2021 | - support to early engagement with developers of paediatric medicines (continue common commentaries with the FDA, other pre-submission interactions)<br>- number of scientific workshops / expert meetings to support innovation in paediatric medicines<br>- Accelerate multi stakeholder forum<br>- EC/EMA multi stakeholder workshop<br>- Enpr-EMA working group meeting<br>- Enpr-EMA annual workshop |
| | | 1.1-7 | Scientific and regulatory contribution enhancing drug safety in pregnancy | 2015 | 2020 | delivery of the Product- or Population - Specific Considerations III on pregnant and breastfeeding women |
| | | 1.1-8 | Strengthen scientific evaluation of orphan designation criteria by COMP at the time of MAA | 2015 | 2020 | - publication/availability of additional guidance on the evaluation of significant benefit<br>- publication of orphan maintenance assessment reports |
| Public-health emergenci | Enhance ability to respond quickly to public-health emergencies | 1.1-9 | Facilitate early introduction of appropriate treatments or preventive measures | 2015 | 2025 | - interactions with developers in early phase (pre-Scientific advice) to Scientific advice and Marketing authorisation applications |

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| | | | | | | -international collaboration including clinical study design and emergency use |
| | | 1.1-10 | Improve Health Threats plan and update post-health-threat activity completion (e.g. Ebola, Zika etc.) **[completed]** | 2015 | 2018 | - action plan developed and process for rapid answers set up: **[completed]**<br>- number of 'lessons' implemented from the 'lessons learned' **[completed]** |

| | | | | | | |
|---|---|---|---|---|---|---|
| Supply issues and availability of new and well-established medicines | Minimise risk and impact of shortages due to manufacturing problems and quality defects | 1.1-11 | Implement revised action plan regarding medicinal product supply shortages caused by manufacturing/good manufacturing practice compliance problems, including<br>- harmonised definition (criteria) of shortages<br>- develop metrics for shortages<br>- best practices on communication of shortages<br>- review impact of implementation of tools developed by industry | 2017 | 2021 | - implementation of the action plan: level of completion of initiatives and proportion of initiatives implemented<br><br>Harmonised definition (criteria) of<br>- shortages **[completed]**<br>- metrics<br>- reporting guidance **[completed]**<br><br>- review impact of implementation of tools developed by industry |
| | | 1.1-12 | Develop formal collaboration with WHO in the area of supply disruptions | 2017 | 2021 | - formal agreement with WHO<br>- number of cases worked in collaboration |
| | | 1.1-13 | Support to the European Observatory on the supply of medical radioisotopes **[completed]** | 2017 | ongoing | - timely input provided to facilitate implementation by the regulatory network of the transition from the use of highly enriched uranium to low enriched uranium in the production of radiopharmaceuticals **[completed]** |
| | | 1.1-14 | Consolidate information on compliance issues and quality defects | 2017 | 2021 | - system of warning letters in case of GMP non-compliance issues implemented **[completed]** |

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| | | | | | | - improvements implemented in the coordination/handling of quality defects across the network |
| | Address the threat posed by illegal medicines supply chains | 1.1-15 | Continue to support the implementation of the Falsified Medicines Directive **[completed]** | 2011 | 2019 | - number of cases supported/coordinated by EMA in relation to falsified medicines in the supply chain **[completed]** |
| | | 1.1-16 | Streamline process for reporting of suspected falsified medicines in the supply chain by MAHs **[completed]** | 2011 | 2019 | - implementation of the revised form for reporting quality defects and suspected falsified medicines **[completed]** |
| | | 1.1-17 | Strengthen communication within the network, including with WGEO **[completed]** | 2014 | Continuous | - timely sharing of relevant information related to illegal supply chain as it is notified to EMA – sharing of information within the network and WGEO has been implemented and is an ongoing activity **[completed]** |
| | Facilitate/support availability of already approved medicines | 1.1-18 | Contribute to the work of the EMA/HMA Joint task force on availability of authorised medicines for human and veterinary use (TF AAM) | 2016 | 2021 | - progress in the implementation of actions by the various work-streams as per the task force action plan |

***Objective 2: Ensure timely access to new beneficial and safe medicines for patients***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Early access to medicines | Reduce time–to-patient of novel medicines through optimised use of existing and new assessment approaches within existing regulatory frameworks | 1.2-1 | Integrate 'adaptive pathways' concept into formal EMA scientific advice procedures | 2014 | 2020 | - number of scientific advice procedures with proactive and prospective planning of evidence generation to meet the needs of downstream decision-makers (HTAs/payers) |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | 1.2-2 | Provide reinforced regulatory and scientific advice for priority medicines (PRIME) **[completed]** | 2014 | 2019 | - number/increase in PRIME products that received scientific advice<br>- time from request to final response, compared with other products and with previous period **[completed]** |
| | | 1.2-3 | Develop/enhance collaboration with EUnetHTA, HTAN as well as HTA/pricing and reimbursement bodies in the area of parallel regulatory-HTA scientific advice, including contribution to specific deliverables in EUnetHTA Joint Action 3 | 2010 | 2020 | - number of procedures for parallel scientific advice<br>- number of HTA bodies involved<br>- analysis on scientific views expressed by regulators and HTA bodies, respectively, on development programmes<br>- deliverables of Joint Action 3 / work package 5a with regard to parallel regulatory-HTA scientific advice |
| | Support effective and efficient conduct of pharmacovigilance | 1.2-4 | Implement planned access and analysis of real-world data | 2016 | Continuous | - availability and use of tools and processes for analysing real-world data |
| | | 1.2-5 | Conduct planned surveillance using patient registries, also in collaboration with EUnetHTA Joint Action 3 **[completed]** | 2016 | Continuous | - patient registries actually used for novel medicines implemented and activity is now a routine activity (core business) **[completed]** |
| Benefit-risk assessment | Increase involvement of stakeholders in relevant regulatory activities | 1.2-6 | Capture and incorporate patients' values and preferences into the scientific review process, in particular in benefit-risk evaluation | 2016 | 2020 | - processes to capture such values and preferences developed and implemented<br>- increased number of cases where patient and healthcare professional input is incorporated in the scientific review<br>- number of patients involved in benefit-risk evaluation |

***Objective 3: Support for patient focused innovation and contribute to a vibrant life science sector in Europe***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Clinical trials | Implement the Clinical Trials Regulation | 1.3-1 | Deliver the required IT tools to allow implementation of the Clinical Trials Regulation | 2014 | 2021-2022 | - availability of functional IT tools/systems |
| | | 1.3-2 | Update guidelines and inspection-related procedures in accordance with the new legal requirements | 2014 | 2020 | - level of completion or availability of updated guidelines/processes |
| Innovation | Facilitate translating innovation into medicinal products | 1.3-3 | Streamline interaction with academia | 2016 | 2020 | - implemented framework for collaboration with academia<br>- increased number of interactions with academia |
| | | 1.3-4 | Strengthen collaboration with HTAN, EUnetHTA, HTA/pricing and reimbursement bodies to optimise the interface at market entry and to facilitate exchange between regulators and downstream decision makers | 2015 | 2020 | - report on cases of divergence between MAA and a sample of HTA bodies during the reporting period<br>- number of cases where EUnetHTA relative efficacy assessment was facilitated following regulatory assessment, as part of Joint Action 3 / work package 4<br>- number of webinars post-CHMP opinion |
| | | 1.3-5 | Identify areas in need of further science and innovation support for medicines development, in collaboration with the network, and communicate these to funding bodies | Continuous | Continuous | - number of research areas/opportunities identified |
| | | 1.3-6 | Explore opportunities to reduce regulatory and administrative burden | 2017 | 2020 | - number of opportunities identified and implemented, including those raised through stakeholder platform meetings |

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| | | 1.3-7 | Strengthen collaboration and integration across the Network and with academia to facilitate translation of innovation into medicinal products, through involvement of academia in early dialogue procedures (ITF, Innovation network, SA, paediatric procedures, PRIME, orphan designation) | 2016 | Continuous | - increase in the number of early dialogue procedures involving academia |
| | Provide adequate regulatory support to innovation stemming from SMEs and academia | 1.3-8 | Review existing support measures and explore additional supportive measures to incentivise innovation by SMEs and academia | 2016 | 2020 | - increasing use of the available support measures/incentives |

***Objective 4: Strengthen regulatory capability and transparency***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Regulatory capability | Strengthen pharmacovigilance capability across the network | 1.4-1 | Implement necessary processes to ensure capacity and capability to manage signals submitted by the pharmaceutical industry | 2016 | 2020 | - implementation of required processes |
| | | 1.4-2 | Ensure EU network is ready for the new EudraVigilance functionalities, including centralised reporting and the new data format | 2016 | continuous | - number of NCAs/MAHs trained on new functionalities **[completed]**<br><br>Training of MS will continue |
| | | 1.4-3 | Explore the potential use of real-world databases, electronic healthcare records and 'big data' | 2016 | 2022 | - number of new data sources used in regulatory activities/decision-making<br>– the inventory of the electronic healthcare data **[completed]** |

| | | | | | | |
|---|---|---|---|---|---|---|
| Transparency | Increase access to data for delivery of regulatory activities | 1.4-4 | Take forward discussion on making available individual patient data (IPD) from clinical trials to assessors | 2016 | 2022 | - draft reflection paper prepared and endorsed by the Management Board |
| | Increase transparency of the work of the network | 1.4-5 | Implement clinical data policy and provisions of the Clinical Trials Regulation regarding the transparency and availability of clinical trial data | 2014 | 2020 | - availability of clinical trial data/information |
| | | 1.4-6 | Improve provision of information to patients and prescribers **[completed]** | 2011 | 2017 | - better information to patients **[completed]** |
| | | 1.4-7 | Increase transparency on the work done during authorisation procedures to assess and manage risks to the environment arising from the use of medicines | 2015 | Continuous | - number of environmental risk assessment supported by EMA in initial marketing authorisation Assessment Report |

## Theme 2: Contributing to animal health and human health in relation to veterinary medicines

***Objective 1: Increase availability of veterinary medicines and promote development of innovative medicines and new technologies***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Availability of veterinary medicines | Provide support and incentives for development of new medicines for MUMS/limited markets | 2.1-1 | Provide a clear framework to industry on the classification and incentives for authorisation of products indicated for MUMS/limited markets | 2015 | 2022 | - increased number/proportion of MUMS marketing-authorisation applications and MUMS products on the market<br>- publication of MUMS annual report<br>- publication of the revised MUMS/limited markets guidelines **[completed]**<br>**-** training available in EU NTC |
| | Support development and availability of veterinary medicines | 2.1-2 | Identify and implement EMA contribution to the EU Network Strategy to 2020 in the area of promoting availability of vaccines within the EU | 2016 | 2022 | - increased number of pre-submission requests and submissions of MAAs for vaccines in general and those against transboundary diseases in particular |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | | | | | - completion of actions assigned to EMA/CVMP in the joint EMA/HMA action plan on availability of veterinary vaccines<br>- reflection paper on promoting availability of veterinary vaccines in emergency situation published |
| | | 2.1-10 | Participate in the HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use | 2016 | 2022 | - completion of actions assigned to EMA concerning veterinary medicines in the joint EMA/HMA task force on availability of authorised medicines for human and veterinary use |
| | Explore ways to limit attrition of existing products | 2.1-3 | Develop with the network a strategy and action plan to support retention on the market of long-used veterinary antimicrobials | 2016 | 2020 | - pilot project on extrapolation of data on existing antimicrobials to promote their retention on the market |
| | Explore new ways for specific sectors to improve availability | 2.1-4 | Cooperate with FishMed Plus coalition to increase availability of medicines for use in aquaculture | 2016 | 2022 | - regulatory activities initiated to address identified gaps in the availability of fish medicines **[completed]**<br>- CVMP advice and support provided to activities of FishMed Plus coalition in addressing relevant gaps identified in availability of medicines for use in aquaculture |
| | | 2.1-11 | Explore with relevant stakeholders approaches to best use of existing and new antiparasitic veterinary medicine so as to minimise development of antiparasitic resistance | 2016 | 2022 | - reflection paper on antiparasitic resistance developed and published<br>- contribution to VICH revision of anthelmintics guidelines<br>- revised guidelines on SmPC for anthelmintics, vector borne diseases and anticoccidials |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | | | | | - implemented recommendations of the reflection paper on anthelmintic resistance |
| Innovation | Promote innovation and use of new approaches in the development of veterinary medicines | 2.1-5 | Evaluate the impact of measures recently put in place to support innovation (ADVENT, ITF) and implement improvements in measures to support innovation | 2016 | 2022 | - increasing number of applications in novel therapies<br>- report on impact of measures to promote innovation published |
| | | 2.1-6 | Develop and implement regulatory guidance in priority areas for technologies that are new to veterinary medicine | 2015 | 2022 | - increased number of applications for innovative medicines<br>- guidance in areas of cell-based therapies and monoclonal antibodies published<br>- gap analysis on regulatory approaches to facilitate authorisation of alternatives to antimicrobials **[completed]** |
| Maximum residue limits | Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health | 2.1-7 | Review the approach on genotoxic impurities in veterinary medicinal products<br>**[completed]** | 2014 | 2018 | - guideline on DNA reactive impurities in veterinary medicines published **[completed]** |
| | | 2.1-8 | Finalise, in collaboration with ECHA and EC, the procedure for the establishment of MRLs for biocidal substances used in animal husbandry included in the 10-year review programme (long-used substances) | 2015 | 2022 | - role of EMA confirmed with the European Commission for establishment of MRLs for biocidal substances |
| | | 2.1-9 | Provide technical support to the European Commission in drafting implementing acts specified in Regulation 470/2009 | 2016 | 2018 | - recommendations and implementing acts sent to the EC **[completed]**<br>- "other provisions" in Regulation (EC) 37/2010 reviewed **[completed]** |

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| | | | **[completed]** | | | |

***Objective 2: Promote 'Better Regulation'***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Legislative framework | Plan for and implement the revised veterinary legislation | 2.2-1 | Provide necessary advice to the European Commission during the ordinary legislative procedure for the new veterinary legislation **[completed]** | 2014 | 2019 | - advice provided to the European Commission on request in a timely and accurate manner **[completed]** |
| | | 2.2-2 | Put in place the revised processes and related changes to IT systems | 2015 | 2022 | - gap analysis and impact assessment of new veterinary regulation on existing procedures and technical requirements<br>- level of implementation of IT systems and processes |
| | | 2.2-9 | Provide technical support to the European Commission in drafting implementing and delegated acts specified in the new veterinary legislation | 2019 | 2027 | - recommendations and implementing acts sent to the EC |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Veterinary pharmacovigilance | Support efficient and effective conduct of pharmacovigilance | 2.2-3 | Publish information to the general public on the surveillance of centrally authorised veterinary products on the market | 2016 | 2021 | - annual pharmacovigilance bulletin published |
| | | 2.2-4 | Ensure appropriate guidance, IT tools and data to allow effective signal detection for veterinary medicinal products | 2016 | 2021 | - data on nationally authorised products supplied for use in EudraVigilance<br>- data quality controlled and linked to adverse event information in the data warehouse<br>- recommendations for basic surveillance finalised **[completed]** |
| | | 2.2-5 | Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species | 2016 | 2020 | - increase in reporting of adverse reactions in food-producing species, following the publication of the revised reflection paper |
| | | 2.2-6 | Ensure effective procedures are in place to manage incidents and crises relating to veterinary medicinal products | 2016 | 2022 | - existing Incident Management Plan tested and updated in light of testing and experience **[completed]**<br>- continuous monitoring and update in light of experience |
| Quality of scientific output | Provide high-quality and consistent scientific outputs of the EMA | 2.2-7 | Develop and promote the uptake of the revised guideline, procedures and templates for CVMP assessment reports, including training in cooperation with EU NTC | 2016 | 2020 | - templates for assessors finalised **[completed]**<br>- high-quality assessment reports received<br>- training on updated templates developed and made available in EU NTC |
| | Ensure efficient operation of procedures within the Veterinary Medicines Division | 2.2-8 | Review operational procedures within the Veterinary Medicines Division **[completed]** | 2016 | 2019 | - improved performance metrics introduced, demonstrating an improvement in performance |

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| | | | | | | - procedural guidance on post authorisations updated **[completed]** |

***Objective 3: Improve the functioning of the single market for veterinary medicines within the EU***

Reflecting that the majority of veterinary products on the EU market are authorised at national level, the majority of specific activities under this strategic objective of the Network Strategy are led by the EU medicines regulatory network, mainly through CMDh/CMDv. Several activities identified throughout this work programme will contribute to the effective functioning of the single market (e.g. Incident Management Plan, training, availability initiatives, and implementation of new veterinary regulation)

***Objective 4: Focus on key public and animal health priorities including antimicrobial resistance***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Antimicrobial resistance | Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine | 2.4-1 | Engage with the EC and Member States to identify and, where possible, prioritise the referral of antimicrobials and other classes of products for which the conditions of use need to be both harmonised and aligned with the principles of prudent and responsible use, including in relation to environmental issues | 2010 | 2020 | - agreed list of priority and antimicrobial substances for referral to CVMP |
| | | 2.4-2 | Refine and continue data collection on the consumption of antimicrobials in veterinary medicine | 2010 | Continuous | - publish the outcome in the ESVAC annual report |
| | | 2.4-3 | Develop and validate methodology to measure the use of antimicrobials per species in the major food producing species **[completed]** | 2016 | 2018 | - methodology approved by the steering group **[completed]**<br>- guidance on methodology published **[completed]** |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | 2.4-4 | Provide advice to stakeholders on prudent and responsible use of veterinary antimicrobials | 2015 | 2019 | - reflection paper on aminoglycosides published **[completed]**<br>- reflection paper on extended-spectrum penicillins published |
| | | 2.4-5 | Provide scientific advice to the EC on optimising the use of antimicrobials in veterinary medicine | 2015 | 2022 | - EMA-EFSA opinion on how to reduce the need for antimicrobials in food-producing species published on EFSA and EMA website **[completed]**<br>- plan for follow up actions to the recommendations in the above EMA-EFSA opinion drafted **[completed]**<br>- second report with EFSA and ECDC on consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals prepared **[completed]**<br>- opinion on indicators regarding surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals prepared **[completed]**<br>- advice to EC updating previous advice on classification of antimicrobials used in veterinary medicinal products provided<br>- third report with EFSA and ECDC on consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals prepared |

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| Risk to the environment | Effectively manage risks to the environment arising from the use of veterinary medicines | 2.4-6 | Develop a strategic approach to persistent bioaccumulative and toxic substances within the authorisation procedure for veterinary medicinal products | 2014 | 2022 | - first draft of document published for consultation/adoption **[completed]**<br>- guidance on persistent bioaccumulative and toxic substances created/updated as necessary |
| | | 2.4-7 | Develop a guidance on risk assessment of veterinary medicinal products in relation to the environment | 2013 | 2022 | - finalised guideline on risk assessment of veterinary medicinal products in groundwater **[completed]**<br>- guideline on higher tier testing of the effects of veterinary medicines on dung fauna<br>- reflection paper on potential risk of use of veterinary medicines in aquaculture |
| | | 2.4-8 | Provide advice to the Commission with respect to veterinary medicines in relation to the preparation of their strategic approach to management of the presence of pharmaceutical substances in environment | 2015 | 2022 | - advice provided to the Commission |

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| Availability of veterinary medicines | Support increased availability of veterinary medicines | 2.4-9 | Work with the European Surveillance Strategy Group to review the existing approaches/systems for managing shortages of essential human medicines for relevance and adaptation to the veterinary domain | 2016 | 2020 | - initial review of human approaches/systems conducted |

## Theme 3: Optimising the operation of the network

***Objective 1: Reinforce the scientific and regulatory capacity and capability of the network***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Regulatory capability and capacity | Ensure 'fit-for-purpose' scientific capability of the network | 3.1-1 | Conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, and identify gaps in expertise | 2016 | Continuous | - inventory of needs available<br>- mapping of expertise versus needs available |
| | | 3.1-2 | Deliver curricula for competence development on the basis of the identified needs | 2016 | Continuous | - action plan available<br>- number of curricula drafted |
| | | 3.1-3 | Develop a catalogue of training material through the EU Network Training Centre | 2016 | Continuous | - training material catalogue developed<br>- number of training courses available<br>- number of NCAs that have opened their training for inclusion in EU NTC |
| | | 3.1-4 | Provide continuous training through the EU Network Training Centre in accordance with an agreed action plan | 2014 | Continuous | - training programme available and implemented<br>- number of training sessions provided<br>- number of experts trained, including in specific (gap) areas |
| | Ensure optimal organisation of the available expertise within the network for services provided to EMA | 3.1-5 | Monitor and improve implementation of the multinational assessment team (MNAT) approach pre-authorisation | 2016 | Continuous | - increase in the number of MNAT procedures<br>- implementation level of the identified improvements |
| | | 3.1-6 | Implement the multinational assessment team approach post-authorisation in a phased approach | 2016 | 2020 | - increase in the number of MNAT procedures<br>- implementation level of the identified improvements |
| | | 3.1-7 | Enhance outreach for academic expertise for services provided to EMA, | 2017 | 2019 | - implementation of the framework of interaction with academia |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | | in particular as regards innovation of medicines | | | |
| Scientific and regulatory expertise | Strike an optimal balance between ensuring impartiality/independence of experts and securing the best possible scientific expertise | 3.1-8 | Undertake annual review of the EMA independence policies to identify room for improvement to strike such balance | 2016 | Continuous | - annual review of all policies prepared and discussed by the Management Board<br>- agreed improvements implemented |

***Objective 2: Strive for operational excellence***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Sustainability of the regulatory system | Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations | 3.2-1 | Undertake a continuous review and improvement of the centralised procedural management | 2016 | 2020 | - processes maintained/updated using an agreed methodology<br>- key interfaces with network and industry enhanced (as demonstrated using surveys, workshops, etc.) **[completed]**<br>- increased efficiency of the processes **[completed]** |
| | | 3.2-2 | Undertake a continuous review and improvement of the EMA support to scientific committees/working parties/expert groups | 2016 | 2021 | - increased productivity of the committees<br>- optimised product support and guideline generation activities, following revision of the working party utilisation |
| | | 3.2-3 | Undertake a revision of the operation of the EU pharmacovigilance system for human medicines | 2017 | 2020 | - process improvements/efficiency gains implemented in the areas of ADR |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | | **[completed]** | | | reporting, signal management and incident management **[completed]** |
| | | 3.2-4 | Improve the efficiency of EMA corporate support activities | 2016 | 2020 | - integrated planning and reporting system introduced |
| | | 3.2-5 | Ensure EMA has the right capabilities to deliver its mission | 2016 | 2020 | - mapping of future needs versus current internal expertise **[completed]**<br>- targeted recruitment undertaken |
| | | 3.2-6 | Analyse experience with the current legal provisions to identify gaps and provide subsequent input to the EC for any review of current legislation | 2017 | 2020 | - number of analyses conducted<br>- number of contributions to the EC made |
| | | 3.2-7 | Participate in the BEMA exercise as per the agreed BEMA cycle | 2016 | 2020 | - participation undertaken as per the agreed BEMA cycle<br>- review of quality-management framework undertaken and resulting actions implemented |
| | | 3.2-8 | Provide regular training to BEMA assessors | 2016 | 2020 | - number of assessors trained within a BEMA cycle<br>- number of training sessions provided |
| | Achieve a sustainable financing model for the network | 3.2-9 | Complete the data-gathering initiative **[completed]** | 2015 | 2017 | - data-gathering initiative conducted as per the action plan **[completed]** |
| | | 3.2-10 | Contribute to external evaluation of the current fee regulation **[completed]** | 2016 | 2018 | - contribution available as per the agreed action plan **[completed]** |
| | Strive for adequate and inter-operable IT services | 3.2-11 | Deliver IT solutions in accordance with the Information Management Strategy aligned with the EU Telematics Strategy **[completed]** | 2016 | 2019 | - IT systems/solutions delivered and in operation **[completed]** |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | 3.2-12 | Establish and improve EMA information services **[completed]** | 2016 | 2019 | - information services operated with processes that are monitored and continuously improved **[completed]** |
| | | 3.2-13 | Share information on medicines within the network and with stakeholders | 2016 | 2019 | - access provided to clinical data – **[completed]**<br>- European Medicines Web Portal operational **[suspended]**<br>- improved provision of data and analytical capability |
| Quality of scientific outputs | Strengthen the quality of the scientific review processes | 3.2-14 | Achieve common standards of scientific quality across the network | 2016 | 2019 | - availability of improved templates and a guideline for completing the templates<br>- availability of accepted standards against which the quality of outputs can be measured |
| | | 3.2-15 | Develop and maintain state-of-the-art scientific guidelines | 2016 | Continuous | - revised procedure and harmonised standards for guideline development and revision<br>- number of new/revised guidelines **[suspended]** |
| | | 3.2-16 | Improve the benefit-risk methodology and expand it to post-authorisation updates | 2016 | 2019 | - utilisation of the effects table in pilot post-authorisation procedures – pilot **[completed]**<br>- explore benefit/risk modelling (CHMP activity) |

***Objective 3: Ensure effective communication of and within the network***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Building/maintaining trust of civil society | Run necessary communication initiatives to support achieving strategic goals | 3.3-1 | Develop and implement a five-year EMA communication strategy | 2016 | 2020 | - framework strategy for external communication approved and implemented, supported by annual communication plans |
| | | 3.3-2 | Implement an Agency-wide structure for public hearings | 2016 | 2020 | - public hearings for safety-related referrals implemented and lessons learned incorporated<br>- report on lessons learned finalised and published |
| | | 3.3-3 | Upgrade the EMA corporate website **[completed]** | 2016 | 2020 | - EMA corporate website upgraded **[completed]** |
| | | 3.3-4 | Develop and implement a social media strategy | 2016 | 2020 | - implementation level of the approved strategy |
| | | 3.3-5 | Expand the range of digital and multimedia communication tools | 2016 | 2020 | - increased production of material with new communication tools |

| | | | | | | |
|---|---|---|---|---|---|---|
| Cross-EU communication about medicines | Ensure effective and consistent communication about medicines | 3.3-6 | Review and improve as needed the information on medicines for stakeholders, in particular information for patients and healthcare professionals | 2016 | Continuous | - critical information for patients and healthcare professionals (i.e. medicines overview, DHPCs and safety communications) systematically user-tested<br>- simplification of EMA information to patients and healthcare professionals agreed and implemented<br>- all EPAR summaries available in all EU languages at time of their publication |
| | | 3.3-7 | Capture communication needs and expectations of partners and stakeholders | 2016 | 2021 | - biennial perception survey implemented and analysed |
| | | 3.3-8 | Explore additional ways to assess the impact of EMA communications **[completed]** | 2016 | 2017 | - dedicated workshop with HCIN planned and organised **[completed]** |
| | | 3.3-9 | Advance the development of the European Medicines Web Portal **[suspended]** | 2016 | 2021 | - European Medicines Web Portal launched **[suspended]** |
| Health emergencies and emerging events communication | Improve communication on health emergencies | 3.3-10 | Improve coordination of communication on emergency health threats across the network | 2016 | 2020 | - crisis communication strategy endorsed and implemented<br>- report on coordination of safety announcements finalised and improvements implemented<br>**[completed]** |

***Objective 4: Strengthen the links with other authorities and with stakeholders***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Collaboration with partners | Increase collaboration with other EU decentralised agencies | 3.4-1 | Establish a framework for monitoring the safety and effectiveness of vaccines, in collaboration with ECDC and the Member States | 2017 | 2025 | - final output from ADVANCE project available – final report published end 2018 **[completed]**- contribution to the Joint Action on Vaccination led by France and DG Santé, in accordance with the work programme of the Joint Action |
| | | 3.4-2 | Strengthen cooperation with other EU agencies in areas of common interest, taking into account memoranda of understanding where they exist | 2016 | 2020 | - mapping of areas of common interest completed<br>- existing memoranda of understanding reviewed and updated, taking into account such mapping exercise |
| | Strengthen collaboration with EDQM | 3.4-3 | Extend the scope of collaboration in the area of sampling and testing as part of the renewal of the contract **[completed]** | 2017 | 2018 | - extended scope achieved and implemented<br>- number of medicinal products/APIs included in the sampling and testing programme<br>Contract was renewed taking into account above indicators **[completed]** |
| Collaboration with stakeholders | Increase collaboration with civil-society representatives | 3.4-4 | Involve patients, healthcare professionals and academia more, to further integrate clinical practice and real-life experience of disease and its management along a medicine's lifecycle | 2016 | 2020 | - increase in number of patients, HCPs and academia involved in EMA activities<br>- frameworks for interaction with patients and HCPs and/or action plans revised, taking into account experience gained<br>- framework for collaboration with academia implemented |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | 3.4-5 | Increase engagement with GPs, thus fostering interaction with primary care | 2016 | 2020 | - virtual expert group with GPs created<br>- number and implementation level of joint recommendations between EMA/UEMO/EFPC/WONCA for GPs' involvement in EMA activities |
| | Streamline interactions with corporate stakeholders | 3.4-6 | Formalise and structure interactions with pharmaceutical industry associations | 2016 | 2020 | - framework for interaction with corporate stakeholders implemented |

## Theme 4: Contributing to the global regulatory environment

***Objective 1: Assure product supply chain and data integrity***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Supply chain and data integrity | Ensure adequate control and monitoring through all stages of the manufacturing and supply chain | 4.1-1 | Increase information-sharing between regulators responsible for oversight of different stages of manufacturing **[completed]** | Continuous | Continuous | - timely sharing of relevant product information related to GMP inspections, quality defects and shortages – activity has been implemented and has become a routine activity **[completed]** |
| | Improve knowledge and understanding of data integrity, and implications for regulatory decision-making | 4.1-2 | Develop guidance on data integrity in collaboration with PIC/s | 2017 | 2020 | - draft guidance published |
| | | 4.1-3 | Develop joint communication and training in collaboration with the FDA | 2016 | beyond 2020 | - joint communication material developed<br>- one joint training session per year delivered |
| | Ensure quality of medicines wherever they are manufactured | 4.1-4 | Develop a procedure to facilitate populating the EudraGMDP Planning module **[completed]** | 2016 | 2017 | - information on planned GMP inspections systematically introduced in the existing EudraGMDP planning module by inspectorates **[completed]** |
| | | 4.1-5 | Develop and implement Union procedure for the coordination of inspections in third countries, to make best use of network resources **[completed]** | 2017 | beyond 2020 | - increased coverage of GMP inspections in third countries, using fewer network resources **[completed]** |
| | | 4.1-6 | Implement a risk-based approach to PMF inspections **[completed]** | 2012 | beyond 2020 | - implementation level of the risk-based approach to PMF inspections **[completed]** |

***Objective 2: Convergence of global standards and contribution to international fora***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Harmonisation of international standards and approaches | Improve application of equivalent standards of good manufacturing and clinical practices throughout the world | 4.2-1 | Develop (through relevant inspector working groups) and apply an integrated and consistent approach to cooperation with key authorities (such as China and India) | Continuous | Continuous | - Network approach to inspections and training collaboration agreed, with particular focus on China and India<br>- agreed procedures for cooperation |
| | | 4.2-2 | Invite non-EU regulators to relevant training activities and to observe GCP and GMP inspections | Continuous | Continuous | - increase in number of non-EU inspectors participating in relevant training activities<br>- increase in number of non-EU observers participating in inspections |
| | Facilitate effective information-sharing by using international electronic standards | 4.2-3 | Implement first iteration of international electronic standards within the EU, and extend to non-EU countries | 2012 | 2020 | - implementation plan agreed<br>- increase in the number of international partners using the standards |
| | Promote uptake of harmonised standards for veterinary medicines at international level | 4.2-5 | Consider international scientific approaches for the establishment of MRLs for harmonisation purposes | 2016 | 2020 | - a report on the outcome of discussions with Codex Alimentarius presented to the CVMP |
| | | 4.2-6 | Participate in training events that raise awareness and enhance uptake of VICH standards by non-VICH countries | 2016 | 2020 | - EU systems and approach presented at international training events |
| Compliance with global standards | Contributing to European and international initiatives and collaborations regarding environmental friendliness | 4.2-7 | Implement a structured approach to environmental management, with objective-setting and monitoring, with a target to reduce the carbon footprint of the Agency's activities | 2016 | Continuous | - registration to EMAS, eco-friendly management system **[suspended]** |

| | | | | | | |
|---|---|---|---|---|---|---|
| International cooperation mechanisms | Ensure appropriate representation in relevant fora, to ensure convergence of standards | 4.2-8 | Implement mechanisms to ensure representative and consistent representation of the network in international fora, and to provide feedback to the network, including ICH, VICH, WHO, OIE, IRCH and PIC/S, ICMRA, IPRP | 2017 | beyond 2020 | - mechanism to ensure participation and feedback through pharmaceutical committee and HMA agreed |

| | | | | | | |
|---|---|---|---|---|---|---|
| Use of animals in medicines development | Minimise use of animals in medicines research and development activities | 4.2-9 | Contribute to the development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch-testing of veterinary vaccines and other relevant areas **[completed]** | 2014 | 2017 | - completed guidelines on applying 3Rs **[completed]** |
| | | 4.2-10 | Improve the guidance available on regulatory acceptance of 3R principles in testing approaches | 2014 | 2018 | - availability of up-to-date guidance **[completed]** |

***Objective 3: Ensure best use of resources through promoting mutual reliance and work-sharing***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Efficient use of global resources | Expand work-sharing and mutual-reliance initiatives | 4.3-1 | Support the Commission with the implementation of the Mutual Recognition Agreement with the US | 2016 | 2020 | - mutual recognition agreed and implemented for certain group of medicines |
| | | 4.3-2 | Increase information-sharing between regulators responsible for the conduct of clinical trials and pharmacovigilance activities | Continuous | Continuous | - GCP initiative with PMDA established |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | 4.3-6 | Leverage the technical, procedural and scientific advancements resulting from the EU pharmaceutical legislation to improve convergence with other regions | 2017 | Beyond 2020 | - systematic reporting to WHO of EU ADR reports and use of EU pharmacovigilance products by non-EU regulators, such as medical literature monitoring and on single assessment periodic safety update reports |
| | Increase reliance of other regulators on European assessments and outputs | 4.3-3 | Extend cooperation on the evaluation of generic medicines, to promote leveraging regulatory authorities' collective resources | 2017 | Beyond 2020 | - document on good-reliance practices<br>- increased cooperation with FDA on generics |
| | | 4.3-4 | Improve existing mechanisms for sharing and exchanging information with other regulators on products throughout their lifecycle | 2017 | Beyond 2020 | - agreement on template for sharing confidential information |
| | | 4.3-5 | Explore opportunities to leverage resources in other areas and increase reliance of other regulators on European assessments and outputs | 2017 | continuous | - number of areas identified where reliance on European assessments can be increased |

***Objective 4: Support training and capacity building and promote the EU regulatory model***

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| Training and capacity | Support capacity-building of non-EU regulators | 4.4-1 | Organise regular training courses for GXP inspectors, with participation of non-EU regulators | Continuous | Continuous | - number of training sessions organised with non-EU regulator participation<br>- number of non-EU regulators' representatives trained |

| Area | Medium-term objective | No | Initiative(s) | Start | End | Performance indicator(s) |
|---|---|---|---|---|---|---|
| | | 4.4-2 | Extend the Network Training Centre to involve non-EU regulators | 2016 | Continuous | - increased number of participants from developing countries/non-EU regulators |

# Resource outlook

***Overview***

The 2020 budget reflects the 2020 work programme assumption that the Agency will gradually exit from business continuity (BCP) mode during the first half of 2020, reintroducing activities that have been suspended or reduced during the relocation period, and subject to budget availability.

This assumption may need to be revised depending on the actual level of staff availability in 2020, and activities will only be reintroduced following a thorough review of opportunities for efficiency and effectiveness gains. The permanent loss of short-term staff left behind in London means that the Agency faces significant resource challenges going forward, as highlighted in the 2018 Annual Activity Report.

As described in Part I of this document, EMA will move once more in 2020 to its permanent location in Amsterdam. This will present some challenges including transferring and maintaining operational IT systems, ensuring the necessary services are in place, as well as the logistics of the actual move of the organisation and staff with minimum disruption to the Agency's day-to-day activities. The workload associated with 2020 Brexit-related activities is estimated at 10 FTEs.

The 2020 budget includes €40.8 million of Brexit-related costs, representing 11.4% of overall expenditure, and mainly consisting of financial inducements to be paid to the sub-tenant of the Agency's former headquarters in Canary Wharf, London.

Equally, the 2021 preliminary draft budget includes €4.4 million of Brexit-related costs. It is expected that 2021 will be the last year with Brexit-related costs in the Agency's budget.

During 2020 the Agency will also continue to take steps to prepare for the future (2021-2025 strategy), with emphasis on fostering the sustainability of the Network in the face of the challenges and opportunities around new science, new technology and new legislation. Implementing the "future-proofing" initiatives described in Part I will be an important priority in 2020 and 2021, focused on implementing a framework for continuous improvement that creates the right environment for change and improvement now and in the future.

Equally, the Agency will continue to work on workforce planning from a strategic perspective, to ensure the right competencies are in place to meet the needs of the Agency and its stakeholders both now and in the future, and to maximise the use of scarce resources.

**Financial resources**

Revenues from fees and charges are expected to grow by €9.6 million (+3.2%) in 2020 compared with 2019 budget, totalling €306.8 million, before growing again in 2021 by €12.9 million (+4.2%). The Agency will carry out regular reviews of fee forecasts and maintain contact with the pharmaceutical industry to monitor early indications of possible fluctuations in the applications submitted.

The preliminary forecasts for fees and charges from 2022 onward assume that the outcome of the revision of the Fee Regulation will ensure that fees will continue to be set at a level that enables the Agency to continue to deliver on all the multi-annual work programme activities.

The 2020 budget includes EU/EEA contributions amounting to €51 million. This is made up of a general contribution of €33 million, a contribution earmarked for OMP fee reductions of €16 million and one for the implementation of the new veterinary regulation (NVR) of €2 million. The general contribution is fully utilised in partially covering the exceptional Brexit-related costs described above, with the remainder of the cost being borne from fee income. The exceptional costs in 2020 outlined above mean that the Agency has been obliged to suspend or slow down certain activities in order to balance the budget, including the level of investment in preparation for the New Veterinary Regulation and also the possibility to invest in digitalisation initiatives to improve the effectiveness and efficiency of the Agency's operations.

In addition to the amount charged to the Agency's 2020 budget, there will be fitting-out expenditure on the permanent EMA building in Amsterdam, amounting to €14 million. A further €1 million was already spent on IT investments in 2019. These investments will be funded by incentives from the Dutch government. In addition, a further €3 million of incentives will be converted into rent reductions over the duration of the lease (2020 to 2039).

The ongoing cost related to the lease on the Agency's former headquarters in Canary Wharf will be matched by payments from the sub-tenant, WeWork, and will amount to €19.1 million in 2020. This contractual arrangement is foreseen to continue for the duration of the lease, i.e. until 2034.

2021 will be the first year of the new EU Multi-annual Financial Framework (MFF) which under current proposals will see the EU contribution to the Agency's budget decline, initially to €24.2 million in 2021, and to €16.7 million by 2027. This significant reduction compared to the current MFF ceiling of over €40 million, plus the uncertainty concerning the outcome of the revision of the Fee Regulation (scheduled for 2022) means there is currently a high level of uncertainty on the structure and sustainability of the EMA funding model from 2022 onwards. The Agency will continue to closely monitor funding availability versus funding needs and, if necessary, will propose amendments to the 2021-2023 programming document and budgets if it becomes evident that certain activities can no longer be funded.

Please refer to Appendix 1 of this document for a more detailed Activity Based Budget analysis of how human and financial resources are allocated to the activities of the Agency in 2020 and 2021.

**Human resources**

The Agency was required to reduce 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) has increased by approximately 31% in the five year period ending in 2018, and increased to around 35% by the end of 2019. The fee-related workload continues to grow every year as the portfolio of products increases, but the -10% establishment plan cuts remain in place.

EMA temporary agent posts for 2020 will be 596 including the 5 additional posts granted (out of 8 requested) for the NVR by the budgetary authority. For 2021, EMA is requesting 11 additional fee-financed posts to compensate for additional fee-financed workload, and remaining 3 posts to support the preparation for the implementation of the New Veterinary Regulation, bringing the establishment plan total to 610

For 2020, the Agency has requested 193 FTE (full time equivalent) contract agents (CAs) and 33 seconded national experts (SNEs), in addition to the temporary agent posts described above, to maintain the 'Business as Usual' workload of the Agency. Assuming that the temporary agent posts are granted then no additional CA posts are requested for 2021.

Considering the exceptional transitional 'Brexit' challenges still facing the Agency, EMA is also requesting approval to continue to employ up to a maximum of an additional 35 contract agents in 2020, falling to 25 in 2021, to ensure a smooth relocation and knowledge transfer transition. This is within the ceiling of a maximum of 40 short-term contract agents authorised in 2019 specifically for this purpose, to be recruited on contracts of a maximum of three years duration.

***New tasks***

The Agency has not been entrusted with new tasks, apart from the tasks related to the relocation of the Agency as described in Part I of this document. Workload of existing tasks however is projected to increase as described below.

***Growth of existing tasks***

The fee-related workload continues to grow every year as the portfolio of authorised products increases. Other activities are also increasing as a result of changes of legislation, for example the implementation of the new veterinary legislation and the general data protection legislation.

***Efficiency gains / Negative priorities / decrease of existing tasks / Redeployment of resources in view of budgetary constraints***

THE NEW VETERINARY LEGISLATION

Although 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, these do not meet the Agency's initial request and needs. The implementation of the new legislation will require significant investment to set up new pan-European business processes and IT systems. Consequently, the EMA and the national agencies will struggle to fulfil all the elements of their mandates because of the resulting regulatory gaps.

This shortage of resources will also negatively impact the work on implementation of policies to tackle antimicrobial resistance (AMR) in Europe, innovation and availability of veterinary medicines, as detailed in the objectives of the new veterinary regulation. EMA will therefore experience severe difficulties to prepare effectively for the implementation of the legislation or will be obliged to reduce or suspend other ongoing public health activities in 2020 and beyond.

The risk of effectively managing these new tasks without appropriate resources is further exacerbated by the enforced relocation of the Agency caused by "Brexit", with the associated loss of staff and knowledge.

OTHER NEGATIVE PRIORITIES AND BUSINESS CONTINUITY (BCP) DUE TO RELOCATION TO A NEW MEMBER STATE AND IMPACT ON RESOURCES

- Relevant IT upgrades were postponed due to resources diverted to relocation. This increased risk to the performance of IT systems;
- The development of several scientific guidelines has been put on hold and guideline publications are delayed:
  - In 2019, a total 92 guidelines have been impacted from various human medicines areas;
  - 24 guidelines and other guidance documents were put on hold for veterinary medicines areas;
- For the first time there has been a delay in the processing of mainly certificates and parallel distribution annual updates leading to a backlog;
- In addition, there have been delays in the validation of some variation procedures;
- Postponement of crucial workshops and trainings for stakeholders;
- Development of EMA's project portfolio and project management capabilities had to be put on hold;
- Decreased participation by Agency at external stakeholder fora and consequent reduced level of engagement with key stakeholder groups.

***Conclusion on the evolution of resources compared to the Commission Communication 2014-2020***

Full compliance with these requirements, taking into account the 3 additional posts authorised by the Budgetary Authority for 2016

**Establishment plan**

| Year | Management Board request | EC proposal | Adopted by Budgetary Authority |
|---|---|---|---|
| 2013 | 611 | 611 | 611 |
| 2014 | 611 | 599 | 599 |
| 2016 | 636 | 599 | 602 |
| 2017 | 596 | 596 | 596 |
| 2018 | 591 | 591 | 591 |

| Year | Management Board request | EC proposal | Adopted by Budgetary Authority |
|---|---|---|---|
| 2019 | 602 | 591 | 591 |
| 2020 | 602 | 591 | 596 |
| 2021 | 610 | tbc | tbc |

**Implementation of agreed 5% staff cuts**

| | 2013 establishment plan | 5% staff reduction | 1% annual levy for the pool | New tasks posts | Gross target |
|---|---|---|---|---|---|
| **EMA** | 611 | -30.5 | -30.5 | 38 | 588 |

# Part III: Work programme 2020

As a result of the UK decision to leave the EU, EMA has been operating under BCP conditions over the last few years. This meant that some activities had to be temporarily reduced or suspended, in order to maintain the same level of quality and timeliness of assessment and supervision of medicines and ensure that patients in Europe continue to have access to high quality, safe and effective medicines while the Agency prepares for and manages the impact of this change, including (but not limited to) rearranging the business operations to account for the loss of the UK expertise and moving to a new host country.

Having moved from London to Amsterdam in 2019, the Agency is now gradually resuming normal operations and is starting to reinstate step by step the activities that had been suspended or reduced during the BCP period. Depending on the availability of staff and budget resources, 2020 work programme should result in lifting the limitations imposed by the Brexit environment and relaunching Agency's activities.

## Structure of the work programme

The work programme is a reflection of the European Medicines Agency's (EMA) priorities and main focus areas for 2020. It describes the objectives and activities planned for 2020. The document consists of four parts:

1. **Human medicines evaluation activities**. This chapter covers all Agency activities specifically related to the human medicines area. These are split into pre-authorisation, initial evaluation, post-authorisation, pharmacovigilance and referrals sections. Any other activities within the human medicines area are covered in the last section of this chapter.
2. **Veterinary medicines evaluation activities**. This chapter covers all activities done in regard to veterinary medicines evaluation and monitoring, and has a similar structure to the human medicines chapter.
3. **Horizontal activities**. These are business activities that span both human and veterinary areas and enable and support the evaluation activities. These cover committee coordination, inspections, partner and stakeholder relationship management, and information management.
4. **Corporate governance and support activities**. These are non-business specific corporate support functions and activities — finance, human resources, quality management, and others — which exist in all organisations and are performed to ensure continuous operation of the Agency.

Each section is structured as follows:

**Activity areas.** This is a short description of the types of activities undertaken — what they entail and what the Agency does in each of those areas.

**Drivers.** This is a reflection of the key trends, initiatives and events that are expected to influence the Agency's focus and activities in 2020-2021.

**Workload indicators.** For the core business-related activities, forecasts and statistics of main workload drivers are included, where applicable.

**Performance indicators.** These are significant measures indicating what is considered good performance in the progress and achievement of the above objectives.

**Additional objectives and activities.** These are the objectives set for 2020-2021, and the main activities carried out to achieve these objectives, to achieve the EMA's longer-term strategic goals and to mitigate risks that may affect the fulfilment of the Agency's mission.

**Resources.** This is an overview of human and financial resources involved in the activity areas. Human-resource data reflect the utilisation of resources in full-time equivalents, and not the allocation and number of posts.

Information on the main **projects** planned for 2020 is set out in Annex 10. The delivery of new information and technology solutions for the Agency and the European medicines regulatory network is described as part of the projects falling under human medicines, veterinary medicines and horizontal activities.

# 1. Evaluation activities for human medicines

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].

## *1.1. Pre-authorisation activities*

### Activity areas

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 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.

**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.

**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.

[1] Reference: *1.4. Referrals*

**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).

**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, providing advice on product eligibility for EMA scientific services and procedures, 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. The Agency has also set up the Modelling and Simulation Working Group (MSWG), which provides specialist input in the assessment of modelling and simulation methodologies in the context of scientific advice, PIPs and MAA procedures.

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.

**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.

## Drivers

Medicines development continues to become more individualised and oriented towards prevention, targeted drugs and adaptation of treatment to the individual's characteristics and needs. PRIME is fully established and has allowed priority medicines to be identified and benefit from scientific advice on their evidence generation plans. The activity has been especially intense for ATMPs where marketing authorisations have been granted already for 3 medicines. Several ATMPs are now in late stage development and pre-authorisation activity continues to grow; marketing authorisation applications addressing areas of unmet medical needs are submitted. The continuous evolution of state-of-the-art knowledge and technologies in drug development, new ways of integrating development and use of medicines and medical devices, and development of new approaches for safety testing will all contribute to increasing the complexity of scientific advice and other Agency activities. Following closely these developments and ensuring the preparedness of the regulatory system will therefore be important.

The face of the pharmaceutical industry is changing, with an increasing number of small or medium-sized enterprises as well as academia undertaking the early stages of new medicines development. Recent initiatives have introduced opportunities for stronger support to priority developments that are addressing unmet medical needs. There is a constant need for continuous improvement of our processes and approaches to ensure that prospective medicines reach their patients in such an environment.

The expected growing need for industry and academia to approach regulators early in their endeavours will increase the role of the Agency in facilitating such contact and early knowledge-sharing. Opportunities for optimisation of interfaces for interactions with regulators during the development

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Scientific advice/protocol assistance pre-submission meetings | 118 | 97 | 90 | 102 |
| Scientific-advice and protocol-assistance requests, of which: | 630 | 634 | 674 | 674 |
| Parallel scientific advice with international regulators requests | 3 | 2 | 2 | 5 |
| Joint scientific advice with HTA bodies requests | 29 | 27 | 20 | 23 |
| Scientific advice for PRIME products | 28 | 36 | 26 | 29 |
| Protocol assistance | 159 | 168 | 137 | 155 |
| Novel technologies qualification advice/opinions | 19 | 9 | 16 | 18 |
| PRIME eligibility requests received | 81 | 57 | 60 | 55 |

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Scientific advice finalised | 490 | 444 | 530 | 535 |
| Protocol assistance finalised | 156 | 170 | 137 | 150 |
| Orphan medicines applications | 277 | 236 | 233 | 280 |
| Submitted applications on the amendment of an existing orphan designation | 2 | 1 | 1 | 5 |
| Oral explanations for orphan designation | 80 | 86 | 68 | 85 |
| Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks) | 630 | 669 | 671 | 500 |
| Finalised procedures for compliance check on PIPs | 67 | 96 | 94 | 70 |
| Annual reports on paediatric deferred measures processed | 197 | 270 | 242 | 170 |
| EMA paediatric decisions processed | 402 | 407 | 433 | 350 |
| Requests for classification of ATMPs | 46 | 55 | 70 | 50 |
| Innovation Task Force briefing meetings | 33 | 22 | 29 | 25 |
| Innovation Task Force Art 57 CHMP opinion requests | 0 | 5 | 4 | 1 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Scientific advice/protocol assistance procedures completed within regulatory timeframes | 100% | 100% | 100% | 100% |
| PRIME eligibility requests assessed within regulatory timeframe | 100% | 100% | 100% | 100% |
| Orphan designation opinions delivered within the legal timeframe | 100% | 100% | 100% | 100% |
| PDCO opinions sent to applicants within legal timelines | 99.75% | 99.9% | 99.5% | 100% |
| Increase in scientific-advice requests | 8% | 0.6% | 6.5% | 7% |
| SME requests for SA (% of total SA requests) | 31% | 31% | 28% | 30% |

## Additional objectives and activities

In addition to delivering its regular pre-authorisation activities for human medicinal products, the Agency plans to undertake and progress the following additional activities:

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Facilitate research and development of new medicines | 1.3-5 | Identify areas in need of further research and communicate findings to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects | Before 2015 | After 2020 |
| | | Identify recurring topics from ITF discussions with the highest potential benefit in terms of driving science and innovation | 2015 | After 2020 |
| | | Based on the horizon-scanning activities and gaps identified, organise workshops with key opinion leaders and innovators, involving also NCAs, to address specific areas for innovation | Q2 2016 | 2020 |
| | 1.3-8 | Reinforce collaboration via EU innovation Network with academia and research hospitals that could benefit most of the innovation offices regulatory support | 2018 | 2020 |
| | 3.1-1 | Use business forecasting and analysis tools to better inform the EU Network about past and prospective development, and improve regulatory preparedness | 2015 | After 2020 |
| | 3.2-2 | Establish a platform for project-specific engagement with developers in priority from SMEs and academia, to optimise activities during the development phase | 2017 | 2020 |
| Ensure needs of specific populations are met, including elderly, children, patients with rare diseases, and others | 1.1-6 | Identify specific actions for EMA and PDCO that allow implementation of the European Commission/EMA action plan following the 10-year report on the Paediatric Regulation | 2016 | 2020 |
| | | Contribute scientifically to methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders | Before 2015 | 2020 |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product lifecycle | 1.2-3 | Coordinate delivery of actions under the EMA/EUnetHTA work plan, in conjunction with Joint Action 3 | Before 2015 | 2020 |
| Increase involvement of stakeholders in relevant regulatory activities | 1.2-6 | Capture and incorporate patients' values and preferences into the scientific review process, in particular in benefit-risk evaluation | 2016 | 2020 |
| Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations | 3.2-6 | Analyse experience with selected legislative provisions, identify gaps in regulatory framework and provide technical support to the EC and the Network in relation to optimising existing regulatory framework, including development and/or implementation of new or amended laws and regulations | Before 2015 | 2022 |
| | | Prepare for implementation of Medical Devices and In vitro Diagnostics Legislation, in relation to the implementation of the new consultation procedures involving the Agency, i.e., consultation on borderline products, on products that may be systemically absorbed by the human body, and on companion diagnostics | 2017 | 2022 |
| Ensure and run highly effective and efficient processes | 3.2-2 | Review and implement digital business transformation across selected business functions supporting medicines' development, evaluation and supervision, including knowledge management | 2017 | 2022 |
| Prepare EU to prevent or manage an Opioid misuse in Europe | 1.1-21 | Establish a Task force and a Steering group to prevent Opioid misuse in Europe: Opioid abuse, misuse and dependence crisis in US and Canada ongoing. | Q3 2019 | Continuous |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 36,102 | 39,909 | 42,839 |
| Human resources (FTEs) | 81 | 88 | 91 |
| Of which Human resources – Brexit preparedness (FTEs) | 1 | 0 | - |

## *1.2. Initial evaluation activities*

## Activity areas

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 (so-called Article 58 applications).

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).

## Drivers

Patient access to medicines, in which marketing authorisation is the first step on the medicine's path to patients, requires a collaborative and coordinated approach in order to achieve robust and sound outcomes. The need to consider the involvement and requirements of other stakeholders mandates increased cooperation with them and decision-making bodies, such as health technology assessment bodies (HTAs), in relation to the exchange of information around the time of licensing, and to introducing a more comprehensive approach for the planning of, and data-generation for post-authorisation measures. To that

extend a scheme such as PRIME is in place to facilitate early dialogue and provide continuous support and cross committee collaboration to help building knowledge ahead of a marketing-authorisation application, with a view of facilitating accelerated assessment at the time of an application for marketing authorisation.

Increasing stakeholder expectations that medicines should be available to treat various conditions, and the continuing need for flexible and fast reaction to new public-health threats, highlight the importance of maintaining the quality of scientific assessments while contributing to faster patient access to medicines on the market.

The complexity of the assessments needed to authorise a medicine increases with the advance of technological, methodological and scientific knowledge. 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.

In an effort to better meet patients' needs, the focus remains on incorporating patients' views and values in the assessment of medicines throughout their lifecycle, including exploring possibilities for involving patients in the benefit-risk assessment process and reflecting transparently the benefit risk balance and its uncertainties in the Agency public documents.

Transparency of the decision-making process throughout the whole lifecycle of medicines will remain a key driver. The initial evaluation and post authorisation activities are subjects to more intense scrutiny by stakeholders and the community as a whole, with impact on public trust in the Agency's work. This transparency driver also extends to outputs related to the authorisation of medicines, with clear and well-reasoned scientific-assessment documentation.

Product information on the safe and effective use of a medicine is a key source of information for various stakeholders. The quality and consistency of labelling are therefore under increased scrutiny, as it is important to ensure that the product information meets the needs of users.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Number of MAA pre-submission meetings | 63 | 71 | 72 | 70 |
| Initial evaluation applications, of which: | 111 | 84 | 103 | 114 |
| New non-orphan medicinal products | 32 | 31 | 33 | 36 |
| New orphan medicinal products | 19 | 17 | 27 | 27 |

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Similar biological products | 17 | 9 | 13 | 14 |
| Generic, hybrid and abridged products | 15 | 23 | 29 | 34 |
| Scientific opinions for non-EU markets (Art 58) | 1 | 1 | 0 | 2 |
| Paediatric-use marketing authorisations | 2 | 0 | 0 | 1 |
| Number of granted requests for accelerated assessment | 10 | 11 | 13 | 8 |
| Number of consultations of SAGs / Ad-hoc expert groups in the context of MAAs | 14 | 19 | 15 | 24 |
| Reviews on the maintenance of the orphan designation criteria at MAA stage | 24 | 45 | 40 | 60 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Applications evaluated within legal timeframes | 100% | 100% | 100% | 100% |
| Average assessment time for new active substances and biosimilars | 175.7 | 205.3 | 192.8 | 205 |
| Average clock-stop for new active substances and biosimilars | 136.9 | 195.2 | 178.1 | 180 |
| % of MAAs initiated under accelerated assessment that have been completed as accelerated assessment | 58% | 44% | 43% | 75% |
| % of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice | 69% | 68% | 68% | 80% |
| Labelling review of the English product information Annexes for new MAAs and line extensions by Day 10 and Day 140 of the evaluation process | 95% | 96% | 98% | 90% |
| % of therapeutic guidelines progressed to next step or finalised (vs planned)[1] | 60% | 70% | 80% | 70% |
| % of early background summaries drafted and sent to assessment teams (vs planned) | 100% | 100% | 100% | 100% |
| % of outcomes/results of workshops on therapeutic objectives published on EMA website | 90% | 100% | n/a | 100% |

[1] guideline development is reduced and the indicator only refers to the guidelines finalised and not those progressing through other stages of the process.

## Additional objectives and activities

In addition to delivering its regular initial-evaluation activities for human medicinal products, the Agency plans to undertake and progress the following additional activities:

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Provide high quality, robust, scientifically sound and consistent product information | 3.3-6 | Implement EMA action plan on EC's report to improve Product Information with regards to ePI | 2018 | Beyond 2020 |
| Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners | 1.3-4 | Support activities stemming from Joint Action 3/work package 4, by providing relevant information from regulatory assessment to HTA bodies for relative effectiveness assessments | 2015 | 2020 |
| Provide high quality, robust, scientifically sound and consistent scientific assessments | 3.2-15 | Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: Increase patients' involvement in assessment work and support the IMI PREFER project | 2018 | After 2020 |
| | 3.2-15 | Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: Explain the rationale for single-arm trials-based approvals to the public and explore the need for wider discussion of such approvals | 2018 | 2020 |
| Contributing to the global regulatory environment | 4.1-xx | Develop position paper on trial integrity in the presence of interim results in on-going clinical trials and handling of its confidentiality | 2020 | 2022 |
| | | Review the experience gained from patient level data (PLD) analysis by the EMA committees and formulation of a plan for a targeted pilot | 2020 | 2022 |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 26,764 | 32,064 | 34,367 |
| Human resources (FTEs) | 75 | 82 | 85 |

## *1.3. Post-authorisation activities*

## Activity area

Post-authorisation activities include all the activities performed by the Agency to maintain authorised medicines on the market and ensure that products on the EU market are kept up to date with scientific advances and in line with the needs of authorisation holders. Activities covered in this area include those described below.

**Variations to marketing authorisations.** These can be either minor (type IA or IB) or major (type II) changes to the product information and dossier with regards to the quality, safety and efficacy of the authorised product, including new or extended therapeutic indications and risk-management plans.

Applications for **line extensions of marketing authorisations.** These include fundamental changes to the medicinal product, such as changes to the active substance, changes to the strength, pharmaceutical form or route of administration of the medicinal product.

**Maintenance activities.** These include follow-up on certain obligations and measures that marketing-authorisation holders need to fulfil following the granting of marketing authorisations (MAs). These include reassessment and renewal of MAs, post-authorisation measures, transfers of MAs, and Article 61(3) notifications.

## Drivers

The workload of post-authorisation activities is expected to continue to increase, due to the increase in the number of centrally authorised products. To ensure its ability to handle these increasing volumes, the Agency will continue to simplify, rationalise and remove duplications when handling post-authorisation changes within the current regulatory framework.

Product profiles change and evolve as new data on medicines are gathered and introduced after obtaining marketing authorisation. This raises the importance of maintaining a high quality of product information throughout the lifecycle of the medicine and will be scrutinised to ensure product information is consistently up to date and meets the needs of the users.

With optimised use of early access tools for the authorisation of medicines, it is important that post-authorisation data generation is closely followed up and new data are regularly evaluated. This covers both efficacy and safety data. Regulatory tools are in place for supporting appropriate decision-making during post-authorisation.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Variations applications, of which: | 6,257 | 6,716 | 7,434 | 6,506 |
| Type-IA variations | 3,049 | 3,433 | 3,886 | 3,154 |
| Type-IB variations | 1,985 | 2,164 | 2,425 | 2,200 |
| Type-II variations | 1,223 | 1,119 | 1,123 | 1,152 |
| Line-extensions of marketing authorisations | 21 | 20 | 27 | 19 |
| PASS scientific advice through SAWP | 0 | 3 | 3 | 2 |
| Number of consultations of SAGs / Ad-hoc expert groups in the context of post-authorisation activities | 15 | 13 | 10 | 12 |
| Renewal applications | 94 | 90 | 107 | 81 |
| Annual reassessment applications | 19 | 22 | 25 | 27 |
| Transfer of marketing authorisation applications | 47 | 377 | 63 | 50 |
| Article 61(3) applications | 234 | 258 | 286 | 220 |
| Post Authorisation Measure data submissions | 795 | 812 | 776 | 900 |
| Plasma Master File Annual update and variation applications | 22 | 19 | 17 | 38 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Post-authorisation applications evaluated within the legal timeframes | 99% | 99% | 99% | 99% |
| Average assessment time for variations that include extension of indication | 162 | 157 | 165 | 180 |
| Average clock-stop for variations that include extension of indication | 67 | 66 | 76 | 90 |
| % of submitted risk management plans peer reviewed by the Agency as part of the extension of indication and line extensions | 100% | 100% | 100% | 100% |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 88,094 | 91,182 | 97,366 |
| Human resources (FTEs) | 79 | 92 | 95 |
| Of which Human resources – Brexit preparedness (FTEs) | 1 | 0 | - |

## *1.4. Referrals*

## Activity area

**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.

## Drivers

The expected number of referrals is difficult to estimate, given that the drivers are usually unpredictable events. Considering the forecasting challenges for referrals, it is expected that they will remain within the total range of the previous year.

High-quality assessment of these procedures is to be maintained, and this raises the challenge of ensuring that data provided by applicants/marketing-authorisation holders are married with additional scientific evidence from different sources to best inform robust decisions on matters of public health. The voice of other important stakeholders, such as healthcare professionals and patients, is also recognised as value added, and will continue to be sought where applicable to best inform these decisions.

In accordance with the pharmacovigilance legislation, the Agency may hold public hearings for safety-related referrals.

With the aim to optimise the use of referrals as a regulatory tool HMA approved in 2017 a proposal to initiate a strategic reflection on how to optimise the use of referrals amongst existing regulatory tools, to ensure the best possible outcome for public health at EU level, to better manage reputational aspects, and to ensure the best and proportionate use of EU network resources. This initiative is supported by CHMP, PRAC and CMDh. The aim is to develop, with CHMP/PRAC/CMDh, mechanisms to support an early dialogue and to reinforce awareness throughout the Network through case studies and lessons learned. Topics will include triggering of referrals, their evaluation, and the subsequent implementation of the referral outcomes.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Pharmacovigilance referrals started | 7 | 2 | 8 | 8 |
| Non-pharmacovigilance referrals started | 3 | 15 | 7 | 8 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Referral procedures managed within the legal timelines | 100% | 100% | 100% | 100% |

## Additional objectives and activities

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Development of a common understanding with the Network on the best use of Referrals | 3.2-1 | The need to develop a common understanding within the Network on the best use of referrals was adopted by HMA in November 2017 (referrals roadmap). Working groups have been formed with the relevant Committees (PRAC, CHMP and CMDh). An agreement on deliverables for 2018 has been reached in Q1-Q2 2018. Finalisation of this activity to be expected for 2020 | 2017 | 2020 |
| Reliance | | Review of Nitrosamines impurities in medicinal products | 2019 | Ongoing |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro)* | 1,220 | 2,473 | 2,718 |
| Human resources (FTEs)* | 6 | 13 | 14 |

* Excludes resources related to pharmacovigilance referrals

## *1.5. Pharmacovigilance and epidemiology activities*

## Activity area

**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;

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.

**Epidemiology** covers the use of real world data to study populations, diseases and the performance of medicines and it can be used to support regulatory decisions through the life of medicinal products.

## Drivers

Pharmacovigilance plays a critical role throughout the lifecycle of medicines, from early pre-authorisation planning of data collection prior to release of products onto the market, through to operation of pharmacovigilance systems for the monitoring of products and the rapid detection of and action taken on emerging safety issues, and evaluation of the impact of these actions. A robust pharmacovigilance system is key to ensuring timely patient access to innovative medicines. Therefore, the Agency will continuously improve the planning and operation of pharmacovigilance and risk management to ensure continuous support of patient health promotion and protection.

Regulatory sciences provide the evidence to support process improvements in pharmacovigilance. The PRAC Impact Strategy is a key driver of the evidence to improve pharmacovigilance and process improvements will be implemented. In addition, the availability of new IT tools further supports the conduct of pharmacovigilance and preparation for better tracking of safety signals and product incidents will be prioritised. Such evidence-based process improvements and optimal use of IT help deliver more effective and efficient pharmacovigilance.

The increasing role of information technology in health-related matters, including new data sources, methodologies and technologies, as well as the use of e-health records and databases, mobile communications and social media by consumers and healthcare professionals, offers unprecedented opportunities to access and analyse real-world data to support decision-making of the EMA scientific committees. Such real world data complements more traditional data sources notably clinical trials. The report of the HMA Joint Big Data Task Force was adopted by the EMA Management Board in December 2019 and the recommendations will be subject to a prioritised implementation together with complementary recommendations from the EMA Regulatory Science Strategy. Both have big data, including real-world data at their core and realising the promise of data is a key opportunity for 2020 and beyond.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Number of signals peer-reviewed by EMA | 2062 | 2,204 | 1,806 | 1,800 |
| Number of signals assessed by PRAC | 60 | 74 | 50 | 40 |
| PSURs (standalone CAPs only) started | 555 | 554 | 554 | 572 |
| PSUSAs started | 372 | 327 | 246 | 332 |
| Number of imposed PASS protocol procedures started | 6 | 17 | 12 | 15 |
| Number of imposed PASS result procedures started | 6 | 8 | 3 | 8 |
| Number of emerging safety issue notifications received | 21 | 8 | 5 | 10 |
| Number of notifications of withdrawn products received | 302 | 413 | 462 | 400 |
| Cumulative number of products on the list of products to be subject to additional monitoring | 336 | 351 | 342 | 350 |
| Number of products included in the list of additional monitoring[1] | n/a | 76 | 55 | 60 |
| Number of products removed from the list of additional monitoring[1] | n/a | 60 | 60 | 60 |
| Number of Incident Management Plans triggered | 4 | 11 | 3 | 7 |
| Number of non-urgent information (NUI) or Rapid Alert (RA) notifications submitted through EPITT | 61 | 44 | 43 | 55 |
| Number of external requests for EV analyses | 32 | 17 | 13 | 15 |
| Number of MLM ICSRs created | 14,193 | 13,275 | 9,676 | 14,000 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Periodic Safety Update Reports (PSURs standalone CAPs only) assessed within the legal timeframe | 100% | 100% | 100% | 100% |
| Periodic Safety Assessment Reports (PSUSAs result procedures) assessed within the legal timeframe | 100% | 100% | 100% | 95% |
| Protocols and reports for non-interventional imposed post-authorisation safety studies assessed within the legal timeframe | 100% | 100% | 100% | 100% |
| Number of individual reaction-monitoring reports supplied to the Member States according to the agreed timelines and data quality indicators | 97% | 95% | 99% | 94% |
| PRAC recommendations on signals and translation of labelling changes in EU languages published | 100% | 100% | 100% | 100% |

[1] New indicator from 2018

## Additional objectives and activities

In addition to delivering its regular pharmacovigilance activities for human medicinal products, the Agency plans to undertake and progress the following additional activities:

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes and services | 1.2-4 | Coordinate data collection and analysis to measure pharmacovigilance impact as feedback to improve processes | Ongoing | Ongoing |
| | 1.4-1 | Finalise GVP product- or population-specific considerations III on pregnant and breastfeeding women post public consultation in 2020 | 2018 | 2020 |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| | | Prepare for public consultation (2020) and finalise (2021) GVP Module XVI on Risk minimisation measures: selection of tools and effectiveness indicators | 2019 | 2021 |
| Maximise benefits to public health promotion and protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through the use of high-quality data, information and knowledge | 1.2-4 | Build and maintain capacity for EU Network analysis of real world data including development with stakeholders of a business case for an EU platform for healthcare data access and analysis. | 2016 | Continuous |
| | | Continue to develop and maintain inventory to facilitate access to data on real-world data in line with recommendations of the Big Data Taskforce | 2016 | 2021 |
| | | Conduct of a pilot of rapid analytics of Electronic Health Records to support committee decision-making including increasing the EU healthcare data accessible for analysis. Initiate at least eight in 2020 and twelve in 2021 EMA studies on real world evidence data | 2016 | Continuous |
| | 1.2-5 | Provide increased support to the use of registries for targeted products on the EU market from learnings including finalised guidance in 2020 | Before 2016 | Continuous |
| | 1.4-1<br>3.2-3 | Based on the analysis of the pilot of MAH signal detection in EudraVigilance implement the decision of the European Commission on extension beyond the pilot phase, including new business process for MAH signals. | Before 2016 | 2020 |
| | | Deliver a training curriculum on methodology and Big Data including specific training for assessors on real world data in committee assessment | 2020 | 2021 |
| | | Agree on a work plan for the development of guidelines on data, methods and evidence. | 2020 | 2020 |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro)* | 32,598 | 29,652 | 32,093 |
| Human resources (FTEs)* | 96 | 71 | 73 |

* Includes resources related to pharmacovigilance referrals and ICT resources involved in pharmacovigilance projects

## *1.6. Other specialised areas and activities*

## Activity area

This area covers EMA activities in the human medicines field, other than evaluation and monitoring of medicines. This includes work regarding the following:

**Clinical trials**. The growing trend for conducting clinical trials outside the EU/EEA raises the importance of ensuring the trials meet certain clinical, ethical and quality standards, and provide comprehensive, reliable data for assessment and decision-making requirements. Cooperating with international partners, the Agency contributes to improving the design, management, oversight and analysis of the clinical trials, as well as working to provide capacity-building and develop information exchanges and shared planning of GCP inspections.

**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.

**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.

## Drivers

Increasing globalisation of the conduct of clinical trials drives the need to ensure that the expected GCP standards are met. To do this, close collaboration with other organisations in the conduct of inspections or information exchanges continues to be increasingly important. This is also an opportunity for increasing efficiency gains, as collaboration provides opportunity for increased coverage without investing significant additional resources.

The Clinical Trials Regulation published in May 2014 requires the Agency to develop the systems necessary for its implementation, in collaboration with the EC and the Member States. The clinical trial information system (CTIS) provides an IT platform covering a large range of regulatory processes and a high and diverse number of stakeholders involved in making applications to conduct clinical trials and in their supervision. Following a review in 2018 the approach and the contract for delivery have been restructured. The performance of the IT supplier is being carefully monitored and assessed against agreed key performance indicators. Development is following a new agile and iterative delivery model that was implemented in June 2019 and provides for greater and closer interaction between the developers and nominated Products owners from Member States, clinical trial sponsors and the European Commission. Member States and sponsor stakeholders will perform an operational assessment of CTIS (Q4 2019) to identify critical business blockers still to be developed for the auditable version, to enable the Board to consider the timing of the audit required before a decision can be made by the EMA Management Board on a fully functional system enabling implementation of the Clinical Trials Regulation.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Herbal monographs, new | 4 | 4 | 0 | 5 |
| Herbal monographs, reviewed[1] | n/a | 7 | 13 | 12 |
| Herbal monographs, revised | 8 | 15 | 2 | 7 |
| List entries | 0 | 0 | 0 | 1 |

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

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | | 2018 | 2019 | 2020 |
| n/a | | | | |

## Additional objectives and activities

| Medium-term objective | MAWP initiative | Activity description | Timeframe Start | Timeframe End |
|---|---|---|---|---|
| Promote application of harmonised international standards | 4.2-5 | Provide technical and scientific contribution to the development of ICH safety guidelines (Carcinogenicity assessment document evaluation for ICH S1) | Before 2015 | 2020 |
| Effectively manage risks to the environment arising from the use of human medicines | 4.2-6 | Collaborate with the EC on the roadmap "Strategic approach to pharmaceuticals in the environment" and update EMA guideline on environmental risk assessment (ERA). Participate in EC cross-service group on medicines in the environment | 2018 | 2020 |
| Promote responsible use of antibiotics in human and veterinary medicine adopting a 'One Health' perspective* | 1.1-1 | Establish and run cross-Agency Task Force on anti-microbial resistance. Provide proposals and implement them for EMA activities to address antimicrobial resistance | 2015 | 2025 |
| Enhance ability to respond quickly to public-health emergencies | 1.1-9 | Collaborate with international stakeholders on the clinical study design and emergency use of medicines in case of a public health emergency and interact with medicines developers in the early stages of the development to facilitate early introduction of appropriate treatments or preventive measures | 2015 | 2025 |
| Contribute to European and international initiatives and collaborations in the area of AMR | 1.1-2 | To implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative | 2016 | 2022 |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Contribute to European and international initiatives and collaborations in the area of AMR | 1.1-3 | Contribute to implementation of the next phase of the EC Action Plan on antimicrobial resistance, and other action plans such as the WHO Global action plan and OIE strategy | 2016 | 2025 |
| Enhance ability to respond quickly to public-health emergencies | 1.1-9 | Contribute to Joint Action on Vaccines and EC vaccines task force on vaccines (action the plan from the Council Recommendations on vaccination). This includes activities related to support R&D of vaccines including dialogue with NITAGs; discussion with EC and ECDC on platform for benefit/risk monitoring of vaccines<br>*Expected to be resumed in 2020 (subject to resource availability)* | 2018 | 2025 |
| Update guidelines and inspection related procedures in accordance to the new legal requirements | 1.3-2 | Finalise the new and revised guidelines related to the implementation of the Clinical Trials Regulation, considering as applicable the comments received during public consultation | 2015 | 2020 |
| | | Collaboration with ECDC on European Vaccine Information portal and development of vaccine outreach strategy | 2019 | 2021 |
| Develop Agency approach to implementation of GDPR in relation clinical trial participants/patient data received from 3rd parties | | Prepare a paper guiding the Agency approach and where appropriate Q and A or guidance for the Agency and stakeholders | 2018 | 2020 |
| Strategy on GMP evolution in light of new technologies and medicines and on supply chain challenges | | Develop strategy paper on GMP evolution and supply chain challenges | 2020 | 2021 |
| Implementation of the EU-DPR | | Initial implementation of the EU-DPR | 2019 | 2020 |
| Further development of the implementation of the EU-DPR | | Full Implementation of the EU-DPR and monitoring of compliance<br>*Expected to continue in 2020 (subject to resource availability)* | 2020 | 2025 |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 9,339 | 13,656 | 14,323 |
| Human resources (FTEs) | 16 | 29 | 30 |

# 2. Evaluation activities for veterinary medicines

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[2] of new diseases that have affected humans over the past decade 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.

## *2.1. Pre-authorisation activities*

### Activity area

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. Products for food-producing species that are classified as MUMS are eligible for financial incentives, to encourage development of products that would otherwise not be developed in the current market conditions. Product eligibility for all types of products is reviewed on a five-yearly basis.

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.

## Drivers

In 2020, the focus in terms of pre-authorisation activities will remain on promoting access to market of veterinary products, particularly those based on novel technologies, those indicated for MUMS/limited markets and vaccines.

The ADVENT (established in 2015), will continue in 2020 its work on developing and delivering guidance in accordance to its work plan.

The EU Medicines Agencies Network Strategy to 2020 will provide strategic direction with respect to both human and veterinary medicines and has specific objectives both to stimulate innovation and promote authorisation of vaccines for use in animal-health emergencies. The Agency's contribution to these objectives through delivery of the agreed action plan will continue to be a major driver in this area.

To facilitate increased effectiveness in the support provided to industry during the product development phase, revised business procedures will be implemented by the Agency.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Innovation Task Force briefing requests | 7 | 5 | 6 | 5 |
| Scientific advice requests received | 17 | 25 | 21 | 17 |
| Requests for classification as MUMS/limited market, of which | 25 | 32 | 34 | 25 |
| Re-classification requests | 8 | 5 | 9 | 5 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Scientific advice procedures completed within set timeframes | 100% | 96% | 95% | 100% |

## Additional objectives and activities

In addition to delivering its regular pre-authorisation activities for veterinary products, the Agency plans to undertake and progress the following activities:

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Provide support and incentives to development of new medicines for MUMS/limited markets | 2.1-1 | Publish annual report on MUMS/limited market activities | Continuous | Continuous |
| | | Revise existing MUMS guidance in line with new veterinary legislation provisions | 2020 | 2022 |
| Promote innovation and use of new approaches in development of veterinary medicines | 2.1-5 | Promote access to the Agency's Innovation Task Force through presentations to industry, and as part of existing pre-authorisation procedures | Before 2015 | Continuous |
| | 2.1-6 | Develop regulatory guidance and strategy for technologies that are innovative to veterinary medicine | 2020 | 2022 |
| | | Finalise a reflection paper including an action plan on specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials to control infectious disease in animals | 2017 | 2020 |
| Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners | 2.1-5 | Explore ways to promote the uptake of parallel scientific advice with the FDA, as part of pre-submission advice | Before 2015 | 2021 |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Support development and availability of veterinary medicines | 2.1-2 | Review recommendations from the CVMP ad hoc group on veterinary vaccine availability (CADVVA) and agree on CVMP and working parties' actions | 2018 | 2021 |
| | | Develop a reflection paper on promoting availability of veterinary vaccines in emergency situations | 2016 | 2021 |
| | | Field efficacy trials guidance to be developed as follow up of recommendations from the Field efficacy trials focus group held in 2017 | 2020 | 2022 |
| | 2.1-4 | Provide advice and input to address gaps in availability identified in the FishMed Plus Coalition where relevant to CVMP activities | 2017 | 2021 |
| | 3.2-15 | Revise guideline on anticoccidials used for the therapy of coccidiosis | 2017 | 2020 |
| | | Revise guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases | 2015 | 2021 |
| | | Finalise revision of note for guidance on DNA vaccines non amplifiable in eukaryotic cells for veterinary use | 2015 | 2021 |
| | | Finalise concept paper and start revision of SmPC guideline for anthelmintic | 2016 | 2022 |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 710 | 682 | 785 |
| Human resources (FTEs) | 3 | 2 | 2 |

## *2.2. Initial evaluation*

### Activity area

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.

### Drivers

The Agency expects to see continued interest in submission of applications for marketing authorisation for innovative veterinary medicinal products, including therapies that are completely new to veterinary medicine. These will present particular challenges for the Committee for Medicinal Products for Veterinary Use (CVMP) in terms of benefit-risk assessment.

The number of applications for new MRLs is expected to remain at a similar level, indicating a continued interest of the industry in developing new veterinary medicines for food-producing animals.

### Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Initial evaluation applications | 17 | 15 | 23 | 18 |
| New MRL applications | 3 | 3 | 3 | 3 |
| MRL extension and modification applications | 3 | 2 | 4 | 1 |
| MRL extrapolations | 0 | 0 | 0 | 0 |

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Art 10, Biocides | 0 | 0 | 0 | 0 |
| Review of draft Codex MRLs | 0 | 5 | 0 | 5 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Procedures completed within legal timeframes | 100% | 100% | 100% | 100% |

## Additional objectives and activities

In addition to delivering its regular initial evaluation activities for veterinary products, the Agency plans to undertake and progress the following activities:

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Provide high-quality and consistent scientific outputs | 2.2-7 | Evaluate training material on revised guideline, procedures and templates for CVMP assessment reports and provide training on these with emphasis on benefit-risk | 2017 | 2021 |
| Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health | 2.1-8 | Finalise, in collaboration with ECHA and the EC, the procedure for the establishment of MRLs of biocidal substances used in animal husbandry, included in the 10-year review programme (long-used substances) | 2015 | 2021 |
| | | Cooperate with ECHA and EFSA to harmonise assessment methodologies for MRLs [including consideration of international approaches] | 2020 | 2022 |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 3,064 | 4,102 | 4,416 |
| Human resources (FTEs) | 12 | 14 | 15 |

## *2.3. Post-authorisation activities*

## Activity area

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 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.

## Drivers

No major changes are expected in the area of post-authorisation activities during the period covered by this plan. The workload of post-authorisation activities is expected to continue to increase, due to the organic increase in the number of centrally authorised products. The internal procedures for variations for veterinary products will continue to be reviewed alongside other business processes, taking into account the best practice developed in the management of procedures for human medicines applications in the Agency.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Variations applications, of which: | 454 | 560 | 568 | 401 |
| Type I A variations | 238 | 331 | 356 | 206 |
| Type I B variations | 130 | 137 | 139 | 135 |
| Type II variations | 86 | 92 | 73 | 60 |
| Line extensions of marketing authorisations | 5 | 1 | 2 | 3 |
| Transfers of marketing authorisations | 3 | 17 | 24 | 5 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Post-authorisation applications evaluated within the legal timeframes | 100% | 99.9% | 100% | 100% |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 4,433 | 5,009 | 5,547 |
| Human resources (FTEs) | 10 | 14 | 14 |
| Of which Human resources – Brexit preparedness (FTEs) | 1 | - | - |

## *2.4. Arbitrations and referrals*

## Activity area

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.

## Drivers

The Agency expects more referral procedures compared with the lowered workload that has been experienced for referrals in the last couple of years.

Referrals concerning individual antibiotics or classes of antibiotics that are particularly important for use in human medicine would continue to be a priority area. Some of these referrals might be triggered by the European Commission as part their Action plan against the rising threats from antimicrobial resistance (AMR), and as a result of the advice provided to the Commission in 2014 on the risks to human health that may arise from the use of antimicrobials in veterinary medicine.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Arbitrations and Community referral procedures initiated | 1 | 5 | 9 | 6 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Referral procedures managed within the legal timelines | 100% | 100% | 100% | 100% |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 372 | 586 | 598 |
| Human resources (FTEs) | 2 | 1 | 2 |

## *2.5. Pharmacovigilance activities*

### Activity area

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.

In the case of veterinary medicines, safety relates to the safety of the animal, the user and the environment. Activities covered include:

management and assessment of adverse event (AE) reports;

management and assessment of periodic safety update reports (PSURs).

### Drivers

Veterinary pharmacovigilance represents an area with considerable scope for simplification and reduction of duplication through improved cooperation within the EU regulatory network. In addition to providing technical support to the European Commission with respect to future changes that are envisaged in the new veterinary legislation, the Agency will work with the NCAs to develop improved IT tools to underpin the current and future pharmacovigilance systems of the network. There will be continued effort to align the signal detection activities with the PSUR related activities. Signal detection activities for nationally authorised products are also envisaged by the Network once the majority of product data have been transferred by the Member States to a central product database (Eudrapharm Veterinary and/or the Product Management System). The update of the EudraVigilance Veterinary reporting system to align with international standards and improve usability will be another milestone. There will be a continued focus on

further direct engagement with target species specialised practitioners in view of improved post-marketing monitoring of VMPs in some major species groups.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Periodic safety-update reports (PSURs) | 161 | 158 | 159 | 160 |
| Total AERs, of which: | 50,885 | 66,844 | 70,392 | 70,000 |
| Adverse-event reports (AERs) for CAPs | 26,671 | 35,835 | 33,656 | 35,000 |
| Adverse-event reports (AERs) for NAPs | 24,214 | 31,009 | 36,736 | 35,000 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| PSURs evaluated within the established timeline | 98% | 99% | 96% | 90% |
| AERs for CAPs monitored within the established timelines | 98% | 98% | 95% | 95% |

## Additional objectives and activities

In addition to delivering its regular activities in veterinary pharmacovigilance, the Agency plans to undertake and progress the following activities:

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes | 2.2-5 | Organise dedicated focus groups with specialised veterinarians/healthcare professionals to obtain further detailed insight on key aspects to improve pharmacovigilance reporting, and feedback for further development | 2018 | 2022 |
| Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners | 2.2-3 | Publish the veterinary pharmacovigilance annual bulletin | 2019 | Continuous |

### Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 1,080 | 3,079 | 1,206 |
| Human resources (FTEs) | 5 | 4 | 5 |

## *2.6. Other specialised areas and activities*

### Activity area

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

**Implementation of new veterinary regulation**. Following the adoption of the new veterinary regulation adopted in 2018, the Agency will provide support to the European Commission in drafting the specified implementing and delegated acts specified and will review its processes and guidance to fit the new provisions.

**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 focused in particular 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, harmonised authorisation requirements will benefit both the animal health industry and European competitiveness.

## Drivers

The new veterinary regulation was adopted on in 2018 and aims to promote availability of veterinary medicines and to reduce the administrative burden for both industry and applicants: it will have a significant impact on the work of the Agency. In the upcoming years the Agency will face a period of intense workload preparing for the implementation of the new provisions that will come into effect in 2022, both in terms of adapting the work of the Agency to the new requirements of the legislation and in providing advice to the Commission with respect to the various implementing provisions that will apply. In addition, the new regulation foresees an expanded role for IT systems to support and promote effective and efficient working. The Agency will need to work with the Commission and with the Network to develop the strategy by which these systems can be developed and deployed.

Antimicrobial resistance and efforts to combat risks arising from antimicrobial resistance will continue to be a main driver for the Agency, with increased collaboration with other EU and international bodies and the promotion of a One Health approach. Following the publication of a joint scientific opinion by EMA and EFSA on measures to reduce the need to use antimicrobial agents in animal husbandry in the EU, the Agency is working to implement the recommendations that fall under its scope.

The publication in 2014 of answers to a series of questions from the European Commission on how best to control the risks to man from the use of antimicrobials in animals has led to a mandate to further elaborate on those recommendations during 2019. The Agency will continue to provide input to measures initiated by the Commission, such as additional advice, referrals and the production of guidance documents, including joint recommendations and opinions with the European agencies (ECDC and EFSA).

In addition to the continued annual monitoring and reporting on the consumption of veterinary antimicrobials across the EU, over the next years the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) will focus on providing guidance on the collection and analysis of data by animal species, including further exploring the use of the recently published standardised units of consumption (e.g. Defined Daily Doses Animals). During 2018-2021 ESVAC will also explore the feasibility of stratifying sales data by animal species.

Involvement in the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) will continue, especially on the identification of knowledge gaps in the transmission of antimicrobial resistance from animals to man.

In 2015, an updated strategy for the next five years was developed and adopted for the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). In 2020 VICH will adopt priorities for the period 2021-2025. As for the previous

five years period there is expected to be a particular focus on VICH outreach activities which aim to extend uptake of VICH guidelines to countries throughout the world with less developed regulatory systems. The Agency will continue to contribute to the implementation of all VICH priorities.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| n/a | | | | |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| n/a | | | | |

## Additional objectives and activities

| Medium-term objective | MAWP initiative | Activity description | Timeframe Start | Timeframe End |
|---|---|---|---|---|
| Plan for and implement the revised veterinary legislation | 2.2-2 | Revise business processes to fit the new veterinary legislation provisions | 2018 | 2022 |
| | | Develop new guidance and revised existing one to support new procedures and processes for the new veterinary legislation | 2018 | 2022 |
| | | Develop and implement new IT systems required by the new veterinary legislation | 2018 | 2022 |
| | 2.2-9 | Provide technical support to the European Commission in drafting implementing and delegated acts specified in the new veterinary legislation | 2019 | 2027 |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Support increased availability of veterinary medicines | 2.1-3 | Consider regulatory tools to implement recommendations of pilot project on the harmonisation of old veterinary antimicrobials (PPHOVA) | 2018 | 2021 |
| | 2.1-11 | Finalise a reflection paper on resistance in ectoparasites | 2015 | 2020 |
| | | Contribute to EU position for the revision of VICH guidelines on anthelmintics (GL7, 12-16 and 19-21) | 2016 | 2021 |
| | | Follow up on recommendations of the reflection paper on anthelmintics resistance | 2020 | 2022 |
| | 2.1-10 | Contribute to the EMA/HMA task force on availability of authorised human and veterinary products | 2016 | 2022 |
| | 2.4-9 | Contribute to the considerations of the proposals for the joint HMA task force on availability at the European Surveillance Strategy group for the perspective of CAPs, as part of developing systems to facilitate management of shortages and ensure the adequate supply of essential veterinary medicines | 2017 | 2022 |
| Provide high-quality and consistent scientific outputs | 3.2-15 | Finalise revision of guideline on summary of product characteristics for antimicrobials | 2017 | 2021 |
| | 2.2-7 | Revise training needs of the veterinary network and develop training in cooperation with EU NTC in areas identified by CVMP to build network assessment capacity | 2018 | 2022 |
| Promote uptake of harmonised standards at international level | 4.2-6 | Contribute to training events that raise awareness and enhance uptake of VICH standards by non-VICH countries | Before 2015 | 2022 |
| | 4.2-5 | Continue dialogue with international risk assessment bodies with a view to increasing harmonisation of scientific approaches and methodologies for the establishment of MRLs | Before 2015 | 2022 |
| | 2.4-4 | Finalise the reflection paper on extended-spectrum penicillins | 2015 | 2020 |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine in 2018-2019 | 2.4-3 | Finalise report on stratification of sales data per species as part of the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals | 2018 | 2020 |
| | 1.1-2 | Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative | Continuous | Continuous |
| | 1.1-3 | Contribute to implementation of the next phase of the EC action plan on antimicrobial resistance, the WHO global action plan, OIE strategy and other action plans (such as the G8) | Continuous | Continuous |
| | 2.4-2 | Refine and continue data collection on the consumption of antimicrobials in veterinary medicine and publish the outcome in the ESVAC annual report | 2010 | Continuous |
| | 2.4-5 | Finalise in cooperation with EFSA and ECDC the third report on consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals | 2019 | 2021 |
| Effectively manage risks to the environment arising from the use of veterinary medicines | 2.4-7 | Finalise reflection paper on higher tier testing of the effects of veterinary medicinal products on dung fauna, taking into account the 2017 workshop outcome | 2018 | 2021 |
| | | Draft a concept paper as starting point for a guideline development on the potential risks associated with the use of veterinary medicinal products in aquaculture | 2020 | 2022 |
| | 2.4-6 | Reflect on a methodology that could be used to better characterise the exposure to the environment following the use of veterinary medicinal products containing PBTs | 2018 | 2021 |
| | 2.4-8 | Provide advice to the European Commission to assist the implementation of their strategy on managing pharmaceuticals in environment | 2013 | 2022 |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 490 | 4,409 | 6,967 |
| Human resources (FTEs) | 3 | 14 | 14 |

# 3. Horizontal activities and other areas

Horizontal activities of the Agency cover those business-related activities that are not specific to either human or veterinary medicines, but span both areas and define, enable and support the medicines evaluation activities. These activities are directly linked to, and are necessary for delivering, the core services of the Agency, and include coordinating the work of the scientific committees, maintaining necessary IT systems and coordinating inspections, as well as stakeholder and partner relationship management.

In this part of the annual work programme, where reference is made to 'the Network' or 'medicines', this can be assumed to cover both human and veterinary domains unless it is clear from the context that it relates to human or veterinary medicines alone.

## *3.1. Committees and working parties*

### Activity area

The scientific opinion-making of the Agency is done primarily through committees and working parties. The Agency has seven scientific committees, each focusing on a specific area of work. Six committees provide scientific opinions regarding human medicines (CHMP, COMP, PDCO, HMPC, CAT and PRAC), and one focuses on veterinary medicines (CVMP). The Agency's committees typically meet on a monthly basis, and the Agency provides all support for organising and conducting these meetings.

The activities within this domain include the following:

**Scientific Coordination Board**. The Scientific Coordination Board (SciCoBo) is composed of the chairs of the scientific committees, CMDh and the Scientific Advice Working Party, as well as members of the Agency's senior management. The SciCoBo has a strategic role and a coordination role which are closely linked. Strategically, it is responsible for identifying key priorities where new or enhanced engagement is essential to the continued success of the Agency's mission and consequently essential to shape and influence the vision for the next EU medicines agencies network strategy. It analyses trends in science, technology and regulatory science tools captured by horizon scanning with a view to generating and overseeing 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's divisions, 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.

**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.

## Drivers

The medicines-evaluation process increasingly needs to consider aspects such as incorporating patients' preferences in the benefit-risk assessment, considering the needs of stakeholders (e.g. HTAs) when planning post-authorisation measures, the impact of 'real life' evidence data and full provision of PASS and PAES given by the pharmacovigilance legislation. This will impact the way the scientific committees evaluate medicines, and consequently the workload of the Agency, both in its endeavour to support the scientific assessment work of the committees and in its role as key provider of training and technical and methodological guidance for the scientific work. An emphasis on the consistency of scientific and regulatory decision-making will require robust internal processes and expansion of the overall capabilities of the NCAs and EMA.

The mandate of the Scientific Coordination Board has been extended to address its strategic role, in particular its responsibility for identifying key priorities where new or enhanced engagement is essential.

Due to the specific nature of many of the topics and challenges in the veterinary domain, activities related to the CVMP can be found in the annual work programme under Section 2: Evaluation activities for veterinary medicines.

The focus on further strengthening the Agency's transparency policy for publication of agendas and minutes of the committees has led to an extension of publication to CHMP ORGAM agendas and minutes and the annexes to the CHMP agendas and minutes, in efforts to increase transparency of the committees' discussions and decision-making processes throughout the lifecycle of medicines.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Number of reimbursed meetings | 529 | 408 | 321 | 488 |
| Committee and Management Board meetings[1] | 76 | 76 | 76 | 76 |
| Trainings[2] | 30 | 29 | 29 | 14 |
| Workshops | 32 | 35 | 4 | 15 |
| Others (working groups, working parties, ad hoc expert meetings, SAG etc.) | 396 | 273 | 212 | 388 |
| Number of virtual meetings (audio-, video- and web-conferences) | 4,802 | 4,793 | 3,443 | 5000 |
| Number of reimbursed delegates | 8,743 | 7,214 | 6,015 | 9182 |
| Number of non-reimbursed delegates | 1,464 | 1,064 | 523 | 1,500 |

[1] Indicator updated to include Management Board meetings

[2] Includes EU Network training centre meetings.

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Delegate satisfaction with meeting support services | n/a[1] | n/a[1] | n/a[1] | 85% |
| Up-to-date electronic declarations of interests submitted by committee members prior to participating in a scientific committee meeting | 100% | 99% | 99% | 100% |
| First-stage evaluations of conflicts of interests for committee members completed prior to their participation in the first committee meeting after the submission of a new or updated declaration of interests | 100% | 100% | 100% | 100% |
| Ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts' database | 99% | 100% | 96% | 100% |

[1] As of 2017, delegate survey is being aligned with the annual delegate survey conducted by the Scientific Committees Service of the Agency

## Additional objectives and activities

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations | 3.2-1 | Support the activities of the HMA Regulatory Optimisation Group (ROG) to simplify and optimise Regulatory operations | 2017 | 2020 |
| Ensure 'fit-for-purpose' scientific capability of the network | 3.1-1 | Finalise the regulatory science strategy, addressing evolution in science, technology and regulatory tools for human and veterinary medicines and translate to implementation phase | 2016 | 2020 |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 9,597 | 9,260 | 10,110 |
| Human resources (FTEs) | 65 | 52 | 54 |

## *3.2. Inspections and compliance*

## Activity area

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. 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.

**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 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 caused by quality defects or GMP non-compliance. 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.

## Drivers

Increasing numbers of manufacturing sites located and clinical trials conducted outside the EU will continue to be a trend. As a result, increased focus on ensuring the medicines tested and manufactured outside the EU meet the EU requirements will drive efforts to develop and strengthen collaboration with international partners regarding collaborative inspections, information exchange, capacity-building and greater mutual reliance.

The newly implemented GMP related mutual recognition agreement with the US FDA will continue to impact on the organisation of inspections, exchange of information on their conduct and management of their outcome. Focus for the next years will be the extension of the scope of the MRA (veterinary medicines, vaccines and plasma derived medicinal products).

Increasing complexity and globalisation of the medicines supply chain will also contribute to information exchange and closer, more streamlined cooperation among authorities, to ensure product and data integrity, and continuity of the medicines supply chain. The Agency will strengthen its activities on capacity building within the EU Network but also look to increased international cooperation.

The forecasts for the number of inspections do not account for the additional GCP, PhV and GMP inspection coverage that the Agency aims to attain through information exchange on inspections performed by other non-EU authorities. The numbers in the workload indicators do not take into account the impact of the new veterinary regulation as the preparation for the implementation phase is ongoing.

New methodologies in clinical trials and novel manufacturing technologies will require adaptation of GCP/GMP regulatory oversight.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| GMP inspections | 314 | 332 | 386 | 220[1] |
| GLP inspections | 0 | 1 | 0 | 1 |
| GCP inspections | 136 | 140 | 137 | 135 |
| Pharmacovigilance inspections | 15 | 20 | 9 | 14 |
| PMF inspections | 83 | 84 | 111 | 65 |
| Notifications of suspected quality defects | 161 | 147 | 175 | 200 |
| Notifications of GMP non-compliances[2] | 23 | 25 | 19 | 20 |
| Medicinal products included in the sampling and testing programme | 58 | 53 | 67 | 70 |
| Standard certificate requests received | 4023 | 3,703 | 2,565 | 3,500 |
| Urgent certificate requests received | 531 | 1,069 | 2,399 | 1,500 |
| Parallel distribution initial notifications received | 2,639 | 2,304 | 2,468 | 2300 |
| Parallel distribution notifications of change received | 1975 | 2,184 | 2,103 | 2,100 |
| Parallel distribution notifications of bulk changes received | 6 | 11 | 12 | 15 |
| Parallel distribution annual updates received | 3798[3] | 5,245 | 4,270 | 5,500 |

[1] The reduction of GMP inspections is linked to the implementation of the EU-US MRA, the EMA is working on focussing resources on inspections in other third countries
[2] Previously: "Other GMP inspections related notifications"
[3] Excludes approximately 1,900 notifications received in 2017 but processed in 2018

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Inspections conducted within established regulatory timeframes | 100% | 100% | 100% | 100% |
| Standard certificates issued within established timelines (10 working days) | 64.2% | 0%[1] | 28% | 90% |
| Average days to issue standard certificate | 10.3 | 27.3 | 59.6 | 10 |
| Urgent certificates issued within established timelines (2 working days) | 100% | 99% | 97% | 100% |
| Parallel distribution initial notifications checked for compliance within the established timeline | 96% | 97% | 37% | 90% |
| Additional GCP inspections addressed through information exchange on inspections carried out by international partners | 39% | 38% | 42% | 35% |
| Outcome reports of the Sampling and Testing for centrally authorised products followed up with the MAH within one month of receipt | 100% | 100% | 100% | 100% |

[1] Backlog delay

## Additional objectives and activities

In addition to delivering its regular activities regarding inspections and compliance, the Agency plans to undertake and progress the following activities:

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Increase efficiency, consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities | 4.3-2 | Strengthen collaboration with trusted international partners, in particular those with confidentiality agreements in place on GCP and pharmacovigilance compliance, and inspections activities in areas of interest | Before 2016 | Continuous |
| | 4.1-5 | Enhance the co-operation with member states in co-ordinating third country inspections | 2017 | 2021 |
| Minimise risk and impact of shortages due to manufacturing problems and quality defects | 1.1-14 | Provide regulatory support to the work of the EU Observatory, to facilitate the transition from high enriched uranium to low enriched uranium | 2014 | Continuous |

| Medium-term objective | MAWP initiative | Activity description | Timeframe Start | Timeframe End |
|---|---|---|---|---|
| | 1.1-20<br>1.1-12<br>1.1-11 | Support and collaborate with the EMA/HMA task force on the availability of authorised human and veterinary medicines | 2017 | 2021 |
| | | Support the implementation of the agreed Work Plan of the EMA/HMA task force on the availability of authorised human and veterinary medicines and provide the secretariat for the task force | 2017 | 2021 |
| | | Support the operation of the Single Point of Contact system and provide the secretariat for the system | 2017 | 2021 |
| Improve application of equivalent standards of good manufacturing and clinical practice throughout the world | 4.2-1 | Support training activities in India and China, including establish a panel of European inspectors available to participate in capacity-building workshops in these countries | Continuous | Continuous |
| Support capacity building of non-EU regulators | 4.4-1 | Deliver training and capacity-building for inspectors and assessors from international regulators | Before 2016 | Continuous |
| Expand work-sharing and mutual-reliance initiatives | 4.3-1 | Coordination of Joint Audit Programme in support to the implementation and extension of the EU US MRA | 2016 | 2022 |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 9,230 | 11,372 | 11,755 |
| Human resources (FTEs) | 34 | 40 | 41 |

## *3.3. Partners, stakeholders, communication and transparency*

## Activity area

Activities covered in this area include the following:

**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.

## Drivers

The process of regulating medicines is becoming more and more complex, with a multitude of stakeholders involved from the early stages of development through to patients accessing and using these medicines. As EMA enhances its efforts to share knowledge and information with the NCAs, patients, healthcare professionals, the media and other stakeholders, the central coordination role of the Agency becomes increasingly important.

This environment requires EMA to increase its visibility and to ensure that its public-health messages continue to be heard and understood. The success of an increasing number of EMA initiatives depends on the Agency's ability to effectively engage with stakeholders and audiences, including those not yet familiar with the organisation. Clear communication using the right channels to provide meaningful content to these stakeholders is guiding the outreach activities of the Agency.

Academia, SMEs and public-private partnerships are an increasingly important source of innovation in medicines. The ongoing work within the European medicines regulatory network to strengthen early support for innovative medicines, teamed with the roll-out of further funding opportunities, such as the SME instruments within Horizon 2020 and Horizon Europe, will mean the number of SMEs registered with the EMA for assistance should continue to grow. The Agency will consider how to further reinforce its development support to these stakeholder groups, taking into account the long-term experience accumulated within the SME Office, the EMA SMEs action plan and the framework for collaboration between EMA and academia. There will also be a need to offer assistance to SMEs on the new Veterinary, Medical Devices and In vitro Diagnostics legislations.

Delivering clear, coordinated messages via appropriate communication channels will be key to facilitating access to timely, authoritative, consistent, reliable and understandable information on medicines by the public across the EU.

The multitude of traditional and social media contributing to an ever accelerating news cycle means that the reputation of an organisation can be under threat at any time. Safeguarding EMA's reputation requires continuous monitoring of press and social media, as well as the ability to respond quickly and effectively to public concerns.

The EU NTC will focus on the development and delivery of training in the priority areas for capacity increase in the Network which included the results of the 2018 HMA survey and consultation of the EMA committees and SciCoBo. These priorities particularly aim to deliver capacity needed because of the increase in workload for NCAs caused by the UK’s withdrawal from the EU.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Requests for SME qualification | 553 | 488 | 536 | 597 |
| Requests for SME status renewal | 1,335 | 1,333 | 1,235 | 1,613 |

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Number of cases of patient/consumer engagement[1] in EMA (medicines-related) activities | 950 | 493 | 769 | 550 |
| Number of cases of healthcare professionals' engagement in EMA (medicines-related) activities | 450 | 212 | 212 | 200 |
| Interaction with Membership organisations | 104 | 118 | 128 | n/a[2] |
| Number of Membership organisations' speaker requests answered | 125 | 103 | 129 | n/a[2] |
| New scientific, regulatory and telematics curricula developed | 0 | 2 | 2 | 2 |
| Number of training events advertised to the EU Network | 100 | 60 | 40 | 60 |
| Number of reimbursed training events to the EU Network | 20 | 8 | 12 | 15 |
| Number of messages circulated via 'Early Notification System' | 383 | 440 | 411 | 440 |
| Number of EMA communications pro-actively sent to stakeholders | 144 | 175 | 128 | 175 |
| Number of EPAR summaries and EPAR summaries updates published | 299 | 343 | 286 | 300 |
| Number of summaries of orphan designation published | 240 | 169 | 117 | 150 |
| Access to documents, requests received | 865 | 822 | 783 | 900 |
| Access to documents, documents released | 2,807 | 2,422 | 1,429 | 2,700 |
| Requests for information received | 6,735 | 7,554 | 7,200 | 7,500 |
| Number of documents published on EMA website | 6,736 | 8,367 | 9,012 | 7,000 |
| Number of pages published and updated on EMA website | 3,754 | 3,510 | 3,383 | 4,000 |
| Number of press releases and news items published | 181 | 183 | 143 | 150 |
| Requests for interviews and comments by media representatives | 1,862 | 1,517 | 1,476 | 1,000 |
| Number of reports, brochures, leaflets laid out or printed | 60 | 85 | 206 | 30 |

[1] These include any interaction that a patient, consumer, carer or healthcare professional may have with the agency, such as, acting as a committee/working party member, reviewing a package leaflet or being invited to a SAG meeting or any other activity which entail engagement from both sides. The figures represent number of interactions (not patients, as the same patient may be involved several times, within different activities at the Agency

[2] Forecast to be determined with completion of tracking of activities suspended due to BCP

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Satisfaction level of patient and consumer | n/a | n/a[1] | n/a | 95% |
| Satisfaction level of Healthcare Professionals | n/a | n/a[1] | n/a | 95% |
| Satisfaction level of SMEs | 93% | 95% | n/a | 80% |
| Response to ATD within set timelines | 96% | 96% | 89% | 92% |
| Response to RFI within set timelines | 98% | 97% | 96% | 97% |
| Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI | 81% | 85% | 84% | 80% |
| Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System | 8 | 7 | 10 | 10 |
| Number of users registered to the EU NTC Learning Management System | 3,583 | 4,424 | 5,121 | 5,100[2] |
| Number of NCA experts registered to the EU NTC Learning Management System | 2,668 | 3,480 | 3,143 | 4,100[2] |
| Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication" | 82% | n/a | n/a | 80% |
| Average rating given to pages on corporate website during the year | 3.3 | 3.1 | 3.4 | 3.3 |

[1] No survey due to BCP
[2] Higher than expected activity seen signing up to the EU NTC learning system due to 'registration drivers' in HPRA, BfArM, AEMPS, AIFA, PEI and ANSM.

## Additional objectives and activities

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Strengthen stakeholder relations, focusing on patients and consumers, healthcare professionals, industry associations, and academia | 1.3-3<br>3.1-7 | Implement a framework for collaboration with academia with respect to human medicines, and consider the need for any specific adaptations to the framework with respect to veterinary medicines | Q4 2017 | 2020 |
| | 3.4-6 | Publish annual report on EMA interactions with industry associations | Q4 2019 | Continuous |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| | 3.4-4 | Publish annual report on EMA interactions with patients, consumers, healthcare professionals, and their organisations | Q4 2019 | Continuous |
| | 3.4-5 | Participation in CIOMS Working Group XI-on patient involvement in clinical development and safe use of medicines | 2019 | 2020 |
| Further develop support to, and strengthen stakeholder relations with SMEs | 1.3-8 | Implement the action plan arising from the 10-year report on the implementation of the SME Regulation | 2017 | 2020 |
| Further strengthen Agency's transparency and open data commitments | 1.4-5 | Plan the relaunch of clinical data publication | Q1 2020 | Q4 2020 |
| | | Hold regular discussions in the technical group on anonymisation of clinical data | Q2 2017 | Continuous |
| | 1.4-5<br>1.4-6<br>1.4-7 | Agree draft principles of transparency | Q3 2017 | Q4 2020 |
| Ensure a more optimal organisation of the available expertise within the network for services provided to EMA | 3.1-5 | Monitor and improve implementation of the multinational assessment team (MNAT) approach pre-authorisation | 2016 | Continuous |
| | 3.1-6 | Implement the second phase (2020) and launch the third phase (2021) of the multinational assessment team approach post-authorisation | Q1 2018 | 2021 |
| Ensure 'fit-for-purpose' scientific capability of the Network | 3.1-1 | Identify emerging topics and gaps in expertise which require action to increase capability of the EU Network | 2017 | Continuous |
| | | Develop in collaboration with the Network, the EU Medicines Agencies Network Strategy to 2025 | 2019 | 2020 |
| | | Develop the Regulatory science observatory with a collaborative methodology to contribute to the EU Medicines Agencies Network Strategy to 2025. | 2017 | 2020 |
| | 3.1-3 | Work with the Network to prioritise training needs | 2018 | Continuous |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| | 3.1-2 | Review and update selected existing curricula to ensure provision of up-to-date training | 2015 | Continuous |
| | 1.3-8 | Strengthen collaboration among the EU Innovation offices on regulatory challenges identified to promote harmonisation and consistency | 2017 | 2020 |
| | | Foster the visibility and activities of the EU Innovation office network to ensure effective and harmonised support to early innovators at local and European level | 2017 | 2020 |
| Increase awareness on the evolution of the regulatory framework | 1.3-8 | Identify in cooperation with the EU Innovation office network and the scientific committees' priority areas (therapeutic areas, technologies, other) for which there is a need to develop communication tools, such as regulatory guidelines, white papers, publications in peer review journals etc. | 2017 | 2020 |
| Provide stakeholders and partners with consistent, high-quality, timely, targeted and accessible information on Agency work, outputs and medicinal products | 3.3-10 | Improve EMA's crisis communication by drafting and testing a crisis communication plan | 2016 | 2020 |
| | 3.3-7 | Carry out an EMA perception survey to better understand communication opportunities and challenges, and review the Agency's communication products and tools, as per the results of the survey | 2019 | 2020 |
| | 3.3-3 | Improve the corporate website by adding new tools and features, such as tools to improve search, search-engine optimisation, accessibility, analytics and others | 2017 | 2020 |
| | 3.3-1 | Develop and implement a five year EMA Communication Strategy | 2020 | 2025 |
| | | Develop and implement an annual communication plan, in line with the framework strategy for external communication | 2016 | 2020 |
| | 3.3-4 | Continue development and implementation of a social media strategy, including consolidation of social media channels and growth in followership | 2016 | 2020 |

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| | 3.3-5 | Develop new digital and multimedia communication tools | 2016 | 2021 |
| Improve provision of and access to strategic information resources | | Support open access publication of relevant scientific articles | 2017 | 2021 |

## Resources

| Area of activity | Financial resources (cost, thousand Euro) | | | Human resources (FTEs) | | | Of which Human resources – Brexit preparedness (FTEs) | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 |
| Partners and stakeholders | 7,904 | 7,509 | 8,315 | 40 | 32 | 33 | 4 | | - |
| Transparency and access to documents | 2,960 | 4,295 | 4,686 | 17 | 25 | 26 | 0 | 0 | - |
| Information | 7,231 | 7,540 | 8,616 | 40 | 41 | 42 | 1 | 0 | - |

## *3.4. International activities*

## Activity area

In its work, the Agency collaborates with non-EU competent authorities and regulators (mainly US FDA, Japanese PMDA/MHLW, Australian TGA, Health Canada, Swissmedic and others), as well as international organisations and forums (such as EDQM, WHO, ICH, ICMRA, VICH, OIE, ISO, HL7, IPRF and others). These interactions span most of the activities of the Agency, and activities covered in this area include the following:

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.

Specific **collaborative projects**, such as provision of parallel scientific advice (human and veterinary) with the FDA, qualification of novel methodologies, joint collaboration on orphan medicines, biosimilars, paediatric and advanced therapies, and in the area of nanomedicines. The potential

for further international work-sharing has led to additional cooperation activities, particularly in the areas of inspections, pharmacovigilance and signal-detection, as well as in transatlantic efforts to combat antimicrobial resistance and on generic medicine evaluation.

Supporting the **evaluation of medicines intended for use in developing countries**. The Agency has a specific legislative responsibility (Article 58 provision) to collaborate with the WHO on providing opinions for the evaluation of medicines intended for markets exclusively outside the European Union.

Supporting the **capacity building and training of non-EU regulators** through providing access to the scientific and regulatory training events organised by the EU Network via the EU Network Training Centre.

## Drivers

The global nature of medicines development and research continues to be a key driver of the Agency's international collaborative activities. In 2019, activities were affected by the restrictions imposed by the UK decision to withdraw from the EU; the restrictions implied that some activities were suspended. The priorities in terms of global development are to ensure and maintain supply chain and data integrity as both have a direct effect on patient safety. This will mean focusing on GMP and GCP inspections, in particular in the context of the implementation of the MRA with the US FDA. The capability assessment of all Member States has been completed in 2019 and the implementation included veterinary medicines. We will focus on training to raise standards of our main partners India and China, as major producers of medicines (in particular APIs, and generics).

EMA and the EU network will promote the provision of scientific opinions for non-EU countries, with a life-cycle approach, improving in particular post-opinion activities and provide support to collaborative registration, which avoids duplication and has been shown to speed up registration in resource-constrained countries.

At strategic level, the Agency will contribute to the agreed priorities of the International Coalition of Medicines Regulatory Authorities (ICMRA), in particular innovation in addition to the continuing participation as member of the Executive Committee.

The Agency and the Network will continue contributing to ICH (International Council for Harmonization) and VICH Outreach programme both to support the European Commission and to provide the necessary expertise for guidelines, according to resource availability.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Interactions with FDA | 654 | 584 | 454 | 700 |
| Interactions with PMDA/MHLW | 138 | 122 | 96 | 200 |

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Interactions with Health Canada | 91 | 175 | 125 | 700 |
| Interactions with any other stakeholders | 498 | 734 | 506 | 700 |
| Number of information and/or document exchanges | 929 | 920 | 461 | 900 |
| Number of teleconferences organised | 166 | 172 | 142 | 150 |
| ICMRA executive committee and full membership TC | n/a | n/a | n/a | 10 |
| International stakeholders' visits (fellowships, experts, observers) | n/a | n/a | n/a | 25 |
| Organisation of International awareness sessions | n/a | n/a | n/a | 2 |

[1] Forecast to be determined with completion of tracking of activities suspended due to BCP

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| n/a | | | | |

## Additional objectives and activities

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Reliance:<br>Ensure best use of resources through promoting mutual reliance and work-sharing | 4.2-3 | Optimise Article 58 scientific opinion activities, including enhance collaboration with WHO and concerned regulators | 2015 | Ongoing |
| Communication:<br>Promote convergence of global standards and contribution to international fora | 4.2-8 | Provide assistance to candidate countries, to align their standards and practices with those established in the European Union, and to further foster their integration process | 2016 | Ongoing |

| Medium-term objective | MAWP initiative | Activity description | Timeframe Start | Timeframe End |
|---|---|---|---|---|
| | | Active participation in international fora and communication to stakeholder, including but not limited to ICDRA, DIA, ICH, IPRP. | | |
| | | Support ICH GCP Renovation process by participation in ICH E8 and ICH E6 revisions as Regulatory chair | 2017 | Ongoing to 2025+ |
| | | Establish platform for EU expert governance in conjunction with EC | 2019 | Ongoing |
| Collaboration/supply chain: Improve application of equivalent standards of good manufacturing and clinical practices throughout the world | 4.2-2 | Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries | Ongoing | Ongoing |
| Collaboration/supply chain: Assure product supply chain and data integrity | 4.1-1 | Promote increased international cooperation in the area of supply chain security, in particular through efforts to coordinate and integrate initiatives at the level of ICMRA | Continuous | Continuous |
| Collaboration/capacity building: Support training and capacity building of non-EU regulators | 4.4-2 | 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[3] | 2016 | Continuous |
| | | A meeting/training related to IPA will be organised at EMA in November 2020. | 2020 | 2020 |
| | | Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU | 2017 | Continuous |
| | | In collaboration with WHO, increase non-EU regulators' awareness of scientific and regulatory training opportunities offered by the EU Network through the WHO training platform | 2016 | Ongoing |
| Collaboration/capacity building: | | Re-start of the International awareness sessions for regulators Organisation of the Veterinary awareness session | 2020 | Continuous |
| | | 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. | 2020 | Continuous |

[3] Including contributing to the IPA activities of the European Commission (Instrument for Pre-accession Assistance)

| Medium-term objective | MAWP initiative | Activity description | Timeframe | |
|---|---|---|---|---|
| | | | Start | End |
| Communication: | | ICMRA secretariat management, including operational and financial contribution to bi-annual ICMRA face to face meetings. | 01 Oct 2019 | 30 Sept 2022 |
| Core business: | | 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 | ongoing | ongoing |
| Reliance: | | support EU and EU/MRA team meetings | 2017 | ongoing |
| Collaboration/capacity building: | | Collaboration in the establishment of the African Medicines Agency (AMA) | ongoing | ongoing |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 2,546 | 2,705 | 2,957 |
| Human resources (FTEs) | 11 | 12 | 12 |

## *3.5. Information management*

## Activity area

Information-management activities aim to establish and manage information as a key asset to support sound decisions and provide reliable information on medicines for the promotion and protection of human and animal health in compliance with European pharmaceutical legislation. 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. The Agency is also leveraging synergies with the Network and EU Agencies. The main activity areas in this domain include the following:

**Information services** to support the work of the network and the Agency, and to provide data and information to the public. Information services involve accessing data necessary to support benefit risk decisions on medicines, the management of data and information in a disciplined and coordinated manner to optimise the value of investments in data/information assets, support effective and efficient operations, mitigate legal and regulatory risks, and improve the delivery of services to stakeholders. Activities cover the entire information lifecycle from data creation to data processing, information dissemination and archiving. Information services rely on the integrated management of information (content) and the delivery and maintenance of information technology.

**Data analytics** on information services involves the discovery and communication of meaningful patterns for the purpose of describing and predicting the efficacy and safety of medicines, as well as for regulatory activities and operational performance. This activity covers statistical data analysis, data warehousing and business intelligence.

**EU Telematics** aims to put in place and maintain common, effective information-technology services that add value and optimise support to the network in the evaluation and supervision of medicines. It is a joint endeavour of the European Commission, the EMA and medicines regulatory authorities in Member States. This activity covers the support and coordination of the Telematics governance and the delivery and maintenance of shared data, IT systems and infrastructure. The list of Telematics services can be found here.

## Drivers

Information management and information technology have become an integrated enabler which supports EMA's strategic business priorities, aligned with the Agency's organisational, regulatory and legislative processes and the requirements of EU legislation. The main drivers and resulting priorities are:

**Successfully relocate EMA's operations to the final building in Amsterdam** while assuring business continuity. After successful relocation of EMA's data centre facilities to Hamburg and EMA's operations to the temporary building in Amsterdam, the focus is going to be shifted towards move to the permanent building and establishment of operational stability.

**Maintain and improve operational excellence** as a recognised reference medicines regulatory authority with a focus on efficiency in light of EMA's staff capacity and particular emphasis on fulfilling legislative obligations in the context of evolving workload and increasingly complex environment.

**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 EMA has and dedicates the necessary resources to upgrading the information services it provides to meet required technical and information security standards. This will also benefit public and animal health by enabling data and information managed by EMA to be leveraged by the network for better decision-making.

**Develop the capability and capacity to access and analyse healthcare data**. To harness the potential for healthcare data to support the development and supervision of medicines, EMA should work collaboratively with the Network, EU Agencies and external stakeholders to increase the

access of regulators to healthcare data. These data should then be analysed to support recommendations by EMA Committees on the development, authorisation and on market benefit risk management of medicines.

## Workload indicators

Information Management workload indicators are directly related to those for the various business processes and data-management activities described under the specific business activities in this work programme.

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Number of Telematics information services provided by EMA | 23 | 25 | 25 | 25 |
| Number of ongoing Telematics IT projects where EMA is the delivery organisation | 11 | 3 | 3 | 7 |
| Number of ongoing non-Telematics IT projects where EMA is the delivery organisation | 6 | 4 | 8 | 7 |
| Number of healthcare data sets to which EMA access and therefore its committees can integrate analyses into assessments | | 3 | 3 | 4 |

## Performance indicators

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Satisfaction of EMA internal and external users | 94% | 91.92% | 87.9% | 80% |
| Availability of corporate/Telematics IT systems and corporate website | 99% | 98% | 88.8% | 98% |

## Resources

| | 2019 | 2020 | 2021 |
|---|---|---|---|
| Financial resources (cost, thousand Euro) | 11,160 | 18,070 | 19,970 |
| Human resources (FTEs) | 24 | 31 | 32 |

# 4. Support and governance activities

## Activity areas

This area covers all the general functions and activities performed at the Agency that are necessary to ensure continuous operations of the Agency but are not business-specific. These include the following:

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

**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 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.

**Information technology services**. IT provides and maintains required IT solutions to support the EMA's corporate activities and the work of the Network (i.e. Telematics systems). IT activities include design and delivery of IT solutions through the Agency's portfolio of programmes and projects, IT infrastructure services (including running two data centres), maintainability of IT services, internal and external user support, and IT security/risk-management.

**Legal services**. Legal activities refer to legal advice on matters such as pharmaceutical law, contracts and procurement, staff-related matters, whistleblowing, data protection and corporate governance, as well as on anti-fraud issues. These also include dealing with complaints submitted to the European Ombudsman and representing the Agency before the European Court of Justice. The EMA's legal department cooperates with European Commission representatives, and also provides advice and support, among other things, on the implementation of new legislation and legal scrutiny of scientific opinions for both human and veterinary medicinal products. It also interacts regularly with OLAF for and is responsible for the preparation and implementation of the Agency’s anti-fraud strategy and the related action plan.

**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.

**Internal audit**. 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.

**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.

**Project management**. The EMA's Portfolio Board ensures that the programmes and projects in the Agency's portfolio are delivered in line with strategy and meet customer expectations. The Portfolio Office ensures the programmes and projects are managed according to the Agency's standard methodology and arrangements, and monitors, controls and reports on the progress of the portfolio.

**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.

## Drivers

Brexit triggered staff attrition and relocation support will continue into 2020 and will require careful planning and management.

Lack of resources triggered by growing workload, including in fee related activities, will continue to challenge resource management as well as increase the need to automate processes and modernise tools.

A new Regulation on data protection (Regulation (EU) 679/2016, also known as the "General Data Protection Regulation", the GDPR) entered into force on 25 May 2018 for all private and public organisations. Regulation (EU) 2016/679 provided for the adaptation of Regulation (EC) No 45/2001, applicable to the EU institutions, agencies and bodies, in order to ensure a strong and coherent data protection framework in the Union and to allow its application in parallel with Regulation (EU) 2016/679. Therefore Regulation (EC) No 45/2001, has been repealed by a new GDPR-like Regulation (Regulation (EU) 2018/1725, also known as the EU-DPR), which applies to EMA as of 11 December 2018. The new EU data protection legislation entailed new obligations and responsibilities for EMA as Data Controller, new rights for the data subjects and new principles, such as the "accountability on the ground" and the data protection implementation "by design and by default". EMA has already complied with several obligations set forth in the EU DPR - procedures for the notification of data breaches to the EDPS and data subjects have been adopted, proper checks of risks inherent to any data processing operations are being conducted, maturing into data protection impact assessments where necessary, and training sessions have been offered to staff on the new rules. The implementation of the EUDPR at EMA is coordinated by the Data Protection Officer, in collaboration with Data Protection Coordinators, who assist the

internal data controllers in the daily activities. One critical issue is the need to properly staff the Agency to comply with the new rules, a subject which has been also brought to the attention of the Management Board in December 2019.

Expectations toward staff development and career progression due to changing scientific and technological environment, use of new IT tools which aim to alleviate manual work.

Implementation of delegate support processes will continue in order to provide delegates with modern tools to facilitate their travel to meetings and modernise reimbursement processes.

Relocation of the Agency to new premises following Brexit will put strain on infrastructure and IT services of the Agency. This will be further affected by the fact that former EMA's premises in London had to be sublet and the process will have to be managed.

With the move to Agile way of project delivery, project governance arrangements will have to evolve accordingly

New rules in the domain of HR will have to be implemented including recently adopted rules on contract agents.

The Agency is reviewing procurement and contract management processes with a view to centralise and automate certain activities.

## Workload indicators

| | Results | | | Forecasts |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| n/a | | | | |

## Performance indicators/Forecast activity

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Posts on the Agency establishment plan filled | 98% | 98.3% | 98.65% | 98% |
| Total TA staff recruited against vacant posts | 15 | 29 | 36 | 24 |
| Staff turnover rate (staff leaving against total no. of staff TA & CA) | 4.1% | 4.57% | 7.25% | 8% |
| Time to fill position from vacancy notice to establishment of reserve list: | | | | |
| Standard procedure[1] | >3 months | 85% < 3 months | 79% < 3 months | < 3 months |

| | Results | | | Targets |
|---|---|---|---|---|
| | 2017 | 2018 | 2019 | 2020 |
| Medium procedure[1] | >4 months | 100% < 4 months | n/a | < 4 months |
| Large procedure[1] | >6 months | 76% < 6 months | n/a | < 6 months |
| Revenue appropriations implemented | 96% | 93.88% | 95.06% | 97% |
| Expenditure appropriations implemented | 93% | 90.76% | 98.56% | 97% |
| Payments against appropriations carried over from year N-1 | 89.9% | 90.57% | 94.99% | 97% |
| The maximum rate of carryover to year N+1, of total commitments within the title | | | | |
| Title 1 | 1% | 1.23% | 2.24% | 1% |
| Title 2 | 11.8% | 16.31% | 10.84% | 15% |
| Title 3 | 28.1% | 30.21% | 29.53% | 25% |
| Payments made within 30 days' time | 97.3% | 97.04% | 97.59% | 98% |
| Receivable overdue for more than 30 days (including provision for bad debts)[2] | n/a | 8.10% | 7% | <10% |
| Availability of Telematics/corporate IT systems and corporate website (% of time) | 99% | 98% | 88.8% | 98% |
| Energy consumption (change in % per workstation) | -5% | -3%[3] | n/a[4] | n/a[4] |
| Water consumption (change in % per workstation) | 13% | -7%[3] | n/a[4] | n/a[4] |
| Paper consumption (change in % per workstation) | -13% | -8%[3] | n/a[4] | n/a[4] |
| Non-recyclable waste produced in restaurant and kitchenette (change in % per workstation) | 13% | -5%[3] | n/a[4] | n/a[4] |
| Recyclable waste produced (change in % per workstation) | 10% | -22%[3] | n/a[4] | n/a[4] |
| Recycling rate (change in % per workstation) | -4% | 3%[2] | n/a[4] | n/a[4] |
| Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates) | n/a | -6%[3] | n/a[4] | n/a[4] |
| Overall net $CO_2$ emissions (per workstation) | n/a | -14%[3] | n/a[4] | n/a[4] |

[1] *Standard procedure*: for a specific post
*Medium procedure*: for more than one post but limited to one job profile
*Large procedure*: generic competitions across multiple divisions
[2] New indicator from 2018
[3] Results only for premises at 30 Churchill Place in London, UK.
[4] Due to EMA relocation to Amsterdam (2019) and move from temporary to permanent premises (2019-2020), environmental performance indicators cannot be estimated. 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.

## Additional objectives and activities

| Medium-term objective | MAWP initiative | Activity description | Timeframe Start | Timeframe End |
|---|---|---|---|---|
| Ensure and further improve efficiency and effectiveness of the Agency's corporate activities | 3.2-4 | Develop and implement a framework for integrated planning and monitoring activities | 2017 | 2021 |
| | 3.2-5 | Implement a competency management framework | 2017 | 2021 |
| | | Digitalise HR-related processes (on-boarding tool, appraisal, career development) and gradually replace the overall HR management system | 2020 | 2021 |
| | | Digitalise procurement and some reporting processes | 2020 | 2021 |
| | | Review project governance in line with Agile development approach | 2019 | 2021 |
| | | Implement improved delegate reimbursement, travel and accommodation booking process and tools | 2020 | 2020 |
| Maintain high level of independence, integrity and transparency in all aspects of the Agency's work | 3.1-8 | Conduct the annual review of the Agency's handling of independence | Continuous | Continuous |
| | 3.1-8 | Implement the action plan of the anti-fraud strategy | 2019 | 2020 |
| | | Manage subletting arrangements of London premises | 2019 | Continuous |

## Resources

| Area of activity[1] | Financial resources (cost, thousand Euro) | | | Human resources (FTEs) | | | Of which Human resources – Brexit preparedness (FTEs) | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 |
| Governance, quality management and internal audit | 6,096 | 8,725 | 9,266 | 32 | 34 | 42 | 10 | 7 | - |
| Finance | 3,397 | 6,423 | 6,833 | 27 | 37 | 38 | 3 | - | - |
| Information technology | 12,331 | 7,311 | 8,005 | 58 | 38 | 40 | 17 | 1 | - |

| Area of activity[1] | Financial resources (cost, thousand Euro) | | | Human resources (FTEs) | | | Of which Human resources – Brexit preparedness (FTEs) | | |
|---|---|---|---|---|---|---|---|---|---|
| | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 | 2019 | 2020 | 2021 |
| Human resources | 8,324 | 8,654 | 9,564 | 60 | 51 | 53 | 19 | - | - |
| Infrastructure services | 2,039 | 1,245 | 1,359 | 15 | 7 | 9 | 5 | 2 | - |

[1] Legal services resources allocated to relevant activities throughout the work programme

# Annexes

# *Annex 1: Activity based budget 2020*

| Work programme chapters | Full Time Equivalence | | | Staff expenditure | Infrastructure, IT and project exp. | Meeting exp. (incl. overhead) | Evaluation Service (NCAs) | Other operational expenditure | Total expenditure | |
|---|---|---|---|---|---|---|---|---|---|---|
| | * Total FTEs | Business as usual | Brexit preparedness | €'000 | €'000 | €'000 | €'000 | €'000 | €'000 | % |
| | TA, CA & National Experts | | | Title 1 | Title 2 & Budget Item 3105 | Budget item 3000 | Article 301 | Articles 302, 303 & Item 3003 | | |
| **1 Evaluation activities for human medicines** | **375** | **375** | **0** | **53,023** | **23,162** | **9,732** | **117,208** | **5,812** | **208,937** | **65%** |
| 1.1 Pre-authorisation activities | 88 | 88 | 0 | 12,117 | 3,031 | 4,879 | 19,877 | 5 | 39,909 | 12% |
| 1.2 Initial evaluation activities | 82 | 82 | 0 | 12,480 | 2,454 | 1,743 | 14,435 | 951 | 32,064 | 10% |
| 1.3 Post-authorisation activities | 92 | 92 | 0 | 12,805 | 6,582 | 342 | 70,201 | 1,253 | 91,182 | 29% |
| 1.4 Referrals | 13 | 13 | 0 | 1,738 | 389 | 118 | - | 228 | 2,473 | 1% |
| 1.5 Pharmacovigilance activities | 71 | 71 | 0 | 9,140 | 2,881 | 1,566 | 12,695 | 3,370 | 29,652 | 9% |
| 1.6 Other specialized areas and activities | 29 | 29 | 0 | 4,743 | 7,825 | 1,083 | - | 5 | 13,656 | 4% |
| **2 Evaluation activities for veterinary medicines** | **50** | **50** | **0** | **6,658** | **5,479** | **1,172** | **4,155** | **403** | **17,867** | **6%** |
| 2.1 Pre-authorisation activities | 2 | 2 | 0 | 243 | 71 | 109 | 259 | - | 682 | 0% |
| 2.2 Initial evaluation activities | 14 | 14 | 0 | 1,928 | 431 | 418 | 1,168 | 158 | 4,102 | 1% |
| 2.3 Post-authorisation activities | 14 | 14 | 0 | 1,552 | 587 | 121 | 2,619 | 129 | 5,009 | 2% |
| 2.4 Arbitrations and Referrals | 1 | 1 | 0 | 171 | 42 | 148 | 109 | 116 | 586 | 0% |
| 2.5 Pharmacovigilance activities | 4 | 4 | 0 | 578 | 2,225 | 276 | - | - | 3,079 | 1% |
| 2.6 Other specialized areas and activities | 14 | 14 | 0 | 2,186 | 2,123 | 100 | - | - | 4,409 | 1% |
| **3 Horizontal activities and other areas** | **233** | **233** | **0** | **32,520** | **20,462** | **1,940** | **4,906** | **922** | **60,750** | **19%** |
| 3.1 Committee coordination | 52 | 52 | 0 | 6,829 | 1,583 | 848 | - | - | 9,260 | 3% |
| 3.2 Inspection and Compliance | 40 | 40 | 0 | 4,873 | 1,542 | 51 | 4,906 | - | 11,372 | 4% |
| 3.3 Partners and Stakeholders | 32 | 32 | 0 | 5,102 | 927 | 849 | - | 630 | 7,509 | 2% |
| 3.3a Transparency and access to documents | 25 | 25 | 0 | 3,397 | 863 | 34 | - | - | 4,295 | 1% |
| 3.3b Information | 41 | 41 | 0 | 5,428 | 1,808 | 11 | - | 292 | 7,540 | 2% |
| 3.4 International activities | 12 | 12 | 0 | 2,286 | 345 | 73 | - | - | 2,705 | 1% |
| 3.5 Information Management (incl. EU Telematics) | 31 | 31 | 0 | 4,604 | 13,394 | 72 | - | - | 18,070 | 6% |
| **4 Corporate Governance and Support activities** | **176** | **166** | **10** | **24,564** | **7,433** | **317** | **-** | **44** | **32,357** | **10%** |
| 4.1 Governance, quality management and internal audit | 41 | 34 | 7 | 6,835 | 1,574 | 317 | - | - | 8,725 | 3% |
| 4.2 Finance | 37 | 37 | 0 | 4,688 | 1,691 | - | - | 44 | 6,423 | 2% |
| 4.3 Information technology | 39 | 38 | 1 | 6,188 | 1,122 | - | - | - | 7,311 | 2% |
| 4.4 Human resources | 51 | 51 | 0 | 5,875 | 2,779 | - | - | - | 8,654 | 3% |
| 4.5 Infrastructure services | 9 | 7 | 2 | 978 | 267 | - | - | - | 1,245 | 0% |
| **Total** | **834** | **824** | **10** | **116,765** | **56,536** | **13,160** | **126,269** | **7,181** | **319,911** | **100%** |

| | |
|---|---|
| * FTEs are calculated as follows: | |
| Temporary Agents | 596 |
| Contract Agents (193 FTEs business as usual + 35 Brexit related) | 228 |
| Seconded National Experts | 33 |
| **Total Staff** | **857** |
| 3% vacancy rate | - 23 |
| Estimated FTEs for 2020 | **834** |

| | |
|---|---|
| **** Brexit related expenditure** | **38,160** |
| **Budget 2020** | **358,071** |

** BREXIT expenditure related to Staff of €2,647,000 is incorporated in the ABB table which added to the €38,160,000 makes a total of €40,807,000

## *Annex 2: Financial resources*

### Table 1 – Expenditure

| Expenditure | 2019 | | 2020 | |
|---|---|---|---|---|
| | Commitment appropriations | Payment appropriations | Commitment appropriations | Payment appropriations |
| **Title 1** | € 115,386,743 | € 115,386,743 | € 119,738,000 | € 119,738,000 |
| **Title 2** | € 83,734,373 | € 83,734,373 | € 83,646,000 | € 83,646,000 |
| **Title 3** | € 142,647,872 | € 142,647,872 | € 154,687,000 | € 154,687,000 |
| **Title 9** | € 0 | € 0 | € 0 | € 0 |
| **Total expenditure** | **€ 341,768,988** | **€ 341,768,988** | **€ 358,071,000** | **€ 358,071,000** |

### Table 2 – Revenues

| Revenues | 2019 | 2020 |
|---|---|---|
| | Revenue estimated by the agency | Budget estimate |
| **EU contribution** | € 35,496,867 | € 51,025,000 |
| **Other revenue** | € 304,392,632 | € 307,046,000 |
| **Total revenue** | **€ 339,889,499** | **€ 358,071,000** |

## *Annex 3: Human resource needs and establishment plan*

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

| Staff population | | Actually filled as of 31/12/2017 | Authorised under EU budget for 2018 | Actually filled as of 31/12/2018 | Authorised under EU budget for 2019 | Actually filled as of 31/12/2019 | Authorised under EU budget for 2020[1] | Actually filled as of 31/12/2020[1] | Envisaged for 2021 | Envisaged for 2022 |
|---|---|---|---|---|---|---|---|---|---|---|
| Officials | AD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | AST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | AST/SC | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TA | AD | 334 | 340 | 338 | 365 | 364 | 395 | 0 | 433 | 444 |
| | AST | 249 | 251 | 243 | 226 | 219 | 201 | 0 | 177 | 177 |
| | AST/SC | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total** | | **583** | **591** | **581** | **591** | **583** | **596** | **0** | **610** | **621** |
| | | | | | | | | | | |
| CA FG IV | | 57 | 85 | 60 | 52 | 76 | 52 | 0 | 102 | 107 |
| CA FG III | | 16 | 25 | 33 | 131 | 56 | 131 | 0 | 81 | 76 |
| CA FG II | | 72 | 70 | 66 | 10 | 41 | 10 | 0 | 10 | 10 |
| CA FG I | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Additional CA[2] | | 0 | 0 | 0 | 40 | 14 | 35 | 0 | 25 | 20 |
| **Total CA[3]** | | **145** | **180** | **159** | **233** | **187** | **228** | **0** | **218** | **213** |
| SNE[3] | | 36 | 39 | 32 | 30 | 28 | 33 | 0 | 33 | 33 |
| **Total TA+CA+SNE** | | **764** | **810** | **772** | **854** | **798** | **857** | **0** | **861** | **867** |
| *Structural service providers*[4, 5, 6] | | 125 | | 114 | | 90 | | | | |
| *External staff for occasional replacement*[7] | | 67 | | 66 | | 10 | | | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Fee related staff | | **546** | | **536** | | **509** | **0** | **517** | **515** |
| | | 67% | | 63% | | 59% | 0% | 60% | 59% |
| Non-fee[8] related staff | | **264** | | **318** | | **348** | **0** | **344** | **352** |
| | | 33% | | 37% | | 41% | 0% | 40% | 41% |
| **TOTAL** | | **810** | | **854** | | **857** | **0** | **861** | **867** |

1) To be completed in January 2021

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

3) FTE

4) Service providers are contracted by a private company and carry out specialised outsourced tasks of horizontal/support nature, for instance in the area of information technology. At the Commission the following general criteria should be fulfilled: 1) no individual contract with the Commission; 2) on the Commission premises, usually with a PC and desk; 3) administratively followed by the Commission (badge, etc) and 4) contributing to the value added of the Commission.

5) Structural service providers for EMA include (2019 FTEs): Reception (5), Security (9), Building maintenance (4), Cleaning (13), Catering (26), Reprographics and mail services (7), IT service desk (16), IT maintenance and support - 'time&means' contracts only (10). Excludes project-related consultancy work.

6) Please note that structural service providers are no longer reflected in Annex 10

7) For instance replacement due to maternity leave or long sick leave. Includes all interim staff, FTE.

8) Split between fee and non-fee in line with annex 2.

## Table 2 - Multiannual staff policy plan

| Category and grade | Establishment plan in voted EU budget 2018 | | Filled as of 31/12/2018 | | Modifications in 2018 in application of flexibility rule | | Establishment plan in voted EU budget 2019 | | Modifications in 2019 in application of flexibility rule | | Establishment plan in voted EU Budget 2020 | | Modifications in 2020 in application of flexibility rule | | Establishment plan in draft EU budget 2021 | | Establishment plan 2022 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Officials | TA | Officials | TA | Officials | TA | Officials | TA | Officials | TA | Officials | TA | Officials | TA | Officials | TA | Officials | TA |
| AD 16 | | 0 | | 0 | | | | 0 | | | | 0 | | | | 0 | | 0 |
| AD 15 | | 3 | | 3 | | | | 3 | | | | 3 | | | | 3 | | 3 |
| AD 14 | | 7 | | 6 | | | | 7 | | | | 8 | | | | 9 | | 10 |
| AD 13 | | 11 | | 11 | | | | 11 | | | | 12 | | | | 13 | | 14 |
| AD 12 | | 43 | | 42 | | | | 43 | | | | 44 | | | | 45 | | 46 |
| AD 11 | | 43 | | 43 | | | | 43 | | | | 47 | | | | 51 | | 55 |
| AD 10 | | 41 | | 41 | | | | 43 | | | | 44 | | | | 52 | | 53 |
| AD 9 | | 45 | | 45 | | | | 43 | | | | 46 | | | | 57 | | 60 |
| AD 8 | | 59 | | 59 | | | | 59 | | | | 66 | | | | 75 | | 84 |
| AD 7 | | 65 | | 65 | | | | 65 | | | | 76 | | | | 82 | | 88 |
| AD 6 | | 23 | | 23 | | | | 23 | | | | 46 | | | | 46 | | 31 |
| AD 5 | | 0 | | 0 | | | | 25 | | | | 3 | | | | 0 | | 0 |
| **Total AD** | **0** | **340** | **0** | **338** | **0** | **0** | **0** | **365** | **0** | **0** | **0** | **395** | **0** | **0** | **0** | **433** | **0** | **444** |
| AST 11 | | 2 | | 2 | | | | 2 | | | | 2 | | | | 2 | | 2 |
| AST 10 | | 7 | | 7 | | | | 7 | | | | 7 | | | | 7 | | 7 |
| AST 9 | | 6 | | 5 | | | | 7 | | | | 8 | | | | 9 | | 10 |
| AST 8 | | 16 | | 16 | | | | 16 | | | | 19 | | | | 10 | | 13 |
| AST 7 | | 22 | | 22 | | | | 22 | | | | 15 | | | | 19 | | 23 |
| AST 6 | | 42 | | 39 | | | | 27 | | | | 15 | | | | 20 | | 37 |
| AST 5 | | 46 | | 43 | | | | 35 | | | | 39 | | | | 38 | | 37 |
| AST 4 | | 57 | | 57 | | | | 57 | | | | 52 | | | | 44 | | 36 |
| AST 3 | | 46 | | 46 | | | | 46 | | | | 44 | | | | 28 | | 12 |
| AST 2 | | 7 | | 6 | | | | 7 | | | | 0 | | | | 0 | | 0 |
| AST 1 | | 0 | | 0 | | | | 0 | | | | 0 | | | | 0 | | 0 |
| **Total AST** | **0** | **251** | **0** | **243** | **0** | **0** | **0** | **226** | **0** | **0** | **0** | **201** | **0** | **0** | **0** | **177** | **0** | **177** |
| AST/SC1 | | | | | | | | | | | | | | | | | | |
| AST/SC2 | | | | | | | | | | | | | | | | | | |
| AST/SC3 | | | | | | | | | | | | | | | | | | |
| AST/SC4 | | | | | | | | | | | | | | | | | | |
| AST/SC5 | | | | | | | | | | | | | | | | | | |
| AST/SC6 | | | | | | | | | | | | | | | | | | |
| **Total AST/SC** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** |
| **Total** | **0** | **591** | **0** | **581** | **0** | **0** | **0** | **591** | **0** | **0** | **0** | **596** | **0** | **0** | **0** | **610** | **0** | **621** |

## *Annex 4: Human resources policies*

## A - Recruitment policy

**Officials**
The Agency does not have any posts for officials.

**Temporary agents**
The Agency employs temporary agents on long-term employment. Staff employed on these posts hold temporary agent contracts and carry out administrative or operational tasks.

The entry grades for recruitment are:

| | |
|---|---|
| Assistant | AST 1 to AST 4 |
| Administrator | AD5 to AD 8 |
| Head of Service/Office | AD6<br>AST 10/11 (internal mobility) |
| Head of Department | AD 9/14 – internal, inter-agency mobility<br>AD9/10- External selection procedure |
| Head of Division, Head of Task Force | AD12/14 – internal, inter-agency mobility<br>AD12 - External selection procedure |
| Adviser | AD13/14 (internal mobility) |

The length of the contract offered to temporary agents (TA2f) is 5 years, renewable for another 5 years, and the second renewal for an indefinite period. The contract period for the executive director (TA2a) is 5 years and only renewable once for another 5 years.

The Agency has used redeployment of its resources to manage additional workload where possible to be cost-effective and will continue to take this approach. The Agency will apply the provisions of Article 38 of the EMA Financial Regulations, whereby effects of part-time work may be offset by other appointments. This will keep the Agency staffing within FTEs agreed by the budgetary authority, while the headcount may go beyond the establishment plan in line with the corresponding provisions of the Financial Regulations.

**Contract agents**
The Agency also employs contract agent staff. The category of contract staff are normally employed for a period up to five years with a possible renewal of up to a further five years. Any further renewal will be for an indefinite period. Short-term contracts (in principle, not subject to renewal) have also been concluded in the context of the Agency's relocation to Amsterdam in order to ensure business continuity.

Contract staffs at the Agency are employed in function groups II, III and IV.

**Seconded national experts**
Seconded national experts (SNEs) are seconded to the Agency as they have their own employers for scientific/technical work/medium-term projects and to support initial work when legislation changes have meant new responsibilities for the Agency.

**Trainees**
The Agency will have a traineeship program in place and estimates to welcome around 70 trainees annually. The Agency is currently reviewing the traineeship program for 2020 in light of the EMA's relocation to Amsterdam.

**Structural service providers**
According to the guidance at the Commission, structural service providers are contracted by a private company and carry out specialised outsourced tasks of horizontal/support nature, for instance in the

area of information technology. At the Commission the following general criteria should be fulfilled: 1) no individual contract with the Commission; 2) on the Commission premises, usually with a PC and desk; 3) administratively followed by the Commission (badge, etc.) and 4) contributing to the value added of the Commission.

Structural service providers at the Agency are in the following areas:

| Key tasks assigned | Tender procedure | Contract duration |
|---|---|---|
| Reception/switchboard | Open tender<br>Contract no EMA/2019/12/DED<br>Contract start: October 2019 | 4 years |
| IT service desk | Open Tender;<br>Contract no EMEA/2018/33/SV<br>Contract start: 17.09.2018 | 4 years |

In addition to the above, structural service providers for EMA include also security, building maintenance, cleaning, catering, reprographics and mail services, IT maintenance and support ('time & means' contracts only). Project-related consultancy work is excluded from the notion of structural service providers.

## B - Appraisal of performance and reclassification/promotions

In line with the requirements of the Staff Regulations, the Agency adopted revised appraisal rules as of 2 October 2015, and revised reclassification rules as of 17 March 2016.

The Agency carries out an annual appraisal exercise for temporary and contract agents from January to March. The appraisal process is intended to formalise regular and structured feedback to the jobholder, improve performance and contribute to career development, as well as to set and evaluate objectives and performance measures for the next reporting period. All reports contain an overall evaluation to conclude whether the jobholder's performance has been satisfactory or unsatisfactory.

Job descriptions are in place for all staff from when the staff member first starts and their review forms part of performance appraisal.

The appraisal exercise aims to embed a culture of merit in the Agency and appraisal reports are among the elements taken into account during the reclassification exercise, which starts once the appraisal exercise is formally closed.

The number of reclassification possibilities is calculated taking into account the establishment plan and post availability, the number of eligible temporary agents per grade and the multiplication rates according to Annex IB of the Staff Regulations. Reclassifications are awarded by comparative merits of eligible staff taking into account appraisal reports, use of languages and level of responsibilities.

| Year | 2016 actual | 2017 actual | 2018 actual | 2019 actual | 2020 estimate | 2021 estimate |
|---|---|---|---|---|---|---|
| Number of reclassifications (TAs) | 78=<br>17% on average of eligible staff | 94 =<br>25% on average of eligible staff | 119 =<br>32% on average of eligible staff | 108 =<br>32% on average of eligible staff | Max percentage of eligible staff according to Annex I Staff Regulations | |

### *Table 1 - Reclassification of temporary staff / promotion of officials*

| Category and grade | Staff in activity at 01/01/2017 | | How many staff members were promoted / reclassified in 2018 | | Average number of years in grade of reclassified / promoted staff members | Staff in activity at 01/01/2018 | | How many staff members were promoted / reclassified in 2019 | | Average number of years in grade of reclassified / promoted staff members |
|---|---|---|---|---|---|---|---|---|---|---|
| | Officials | TA | Officials | TA | | Officials | TA | Officials | TA | |
| AD 16 | | | | | | | | | | |
| AD 15 | | 1 | | | | | 2 | | | |
| AD 14 | | 2 | | | | | 1 | | | |
| AD 13 | | 9 | | 1 | 10.0 | | 10 | | | |
| AD 12 | | 24 | | 2 | 5.7 | | 27 | | 4 | 7.1 |
| AD 11 | | 29 | | 3 | 2.7 | | 25 | | 2 | 3.0 |
| AD 10 | | 25 | | 7 | 5.7 | | 31 | | 3 | 3.0 |
| AD 9 | | 38 | | 8 | 4.7 | | 34 | | 11 | 5.1 |
| AD 8 | | 60 | | 11 | 4.8 | | 52 | | 4 | 4.0 |
| AD 7 | | 54 | | 14 | 4.9 | | 57 | | 13 | 3.6 |
| AD 6 | | 71 | | 18 | 4.9 | | 67 | | 15 | 5.0 |
| AD 5 | | 18 | | 2 | 2.3 | | 15 | | 6 | 4.2 |
| **Total AD** | **0** | **331** | **0** | **66** | | **0** | **321** | **0** | **58** | |
| AST 11 | | | | | | | | | | |
| AST 10 | | 3 | | | | | 3 | | | |
| AST 9 | | 4 | | | | | 3 | | | |
| AST 8 | | 4 | | | | | 4 | | 1 | 2.0 |
| AST 7 | | 13 | | 1 | 4.0 | | 13 | | 2 | 4.5 |
| AST 6 | | 19 | | 4 | 3.3 | | 22 | | 1 | 7.0 |
| AST 5 | | 36 | | 8 | 4.9 | | 32 | | 6 | 5.7 |
| AST 4 | | 45 | | 10 | 4.4 | | 35 | | 7 | 5.4 |
| AST 3 | | 64 | | 14 | 3.8 | | 69 | | 17 | 3.4 |
| AST 2 | | 33 | | 9 | 3.3 | | 35 | | 7 | 5.4 |
| AST 1 | | 31 | | 7 | 4.5 | | 45 | | 9 | 5.2 |
| **Total AST** | **0** | **252** | **0** | **53** | | **0** | **261** | **0** | **50** | |
| AST/SC1 | | | | | | | | | | |
| AST/SC2 | | | | | | | | | | |
| AST/SC3 | | | | | | | | | | |
| AST/SC4 | | | | | | | | | | |
| AST/SC5 | | | | | | | | | | |
| AST/SC6 | | | | | | | | | | |
| **Total AST/SC** | **0** | **0** | **0** | **0** | | **0** | **0** | **0** | **0** | |
| **Total** | **0** | **583** | **0** | **119** | | **0** | **582** | **0** | **108** | |

### *Table 2 - Reclassification of contract staff*

| Function group | Grade | Staff in activity at 01/01/2017 | How many staff members were reclassified in 2018 | Average number of years in grade of reclassified members | Staff in activity at 01/01/2018 | How many staff members were reclassified in 2019 | Average number of years in grade of reclassified members |
|---|---|---|---|---|---|---|---|
| **CA IV** | **18** | | | | | | |
| | **17** | 1 | | | 1 | 1 | 3.0 |
| | **16** | 2 | | | 3 | 1 | 2.71 |
| | **15** | 5 | | | 17 | 1 | 3.00 |
| | **14** | 36 | 10 | 3.87 | 24 | 6 | 3.48 |
| | **13** | 10 | 1 | 3.75 | 12 | 4 | 4.06 |
| **CA III** | **12** | | | | | | |
| | **11** | | | | | | |
| | **10** | 2 | | | 4 | 1 | 2.00 |
| | **9** | 8 | 1 | 3.87 | 9 | 3 | 3.75 |
| | **8** | 5 | 2 | 3.31 | 6 | | |
| **CA II** | **7** | | | | 1 | | |
| | **6** | 13 | 1 | 5.00 | 18 | 1 | 3.00 |
| | **5** | 40 | 8 | 2.64 | 43 | 3 | 5.30 |
| | **4** | 21 | 7 | 3.32 | 8 | 1 | 4.21 |
| **CA I** | **3** | | | | | | |
| | **2** | | | | | | |
| | **1** | | | | | | |
| **Total** | | **143** | **30** | | **146** | **22** | |

## C - Mobility policy

**Internal mobility**

TA2f Posts are published internally in line with the applicable implementing rules. Temporary agents as well as contract agents may also apply for any position advertised externally at any time, provided they meet the requirements of the selection procedure announcement. A periodic management information report is prepared on the status of mobility of staff. Given the overall size of the Agency, for management positions, or where specialised scientific knowledge is needed, the pool of internal candidates within the Agency has grown over the years

| Year | 2016 | 2017 | 2018 | 2019 | 2020 estimates | 2021 estimates |
|---|---|---|---|---|---|---|
| Internal vacancy announcements/calls for expression of interest and internal selection procedures | 12 | 10 | 25 | 26 | 30 | 20 |

**Mobility between the agencies**

Under the general implementing provisions on the procedure governing the engagement and use of temporary staff under article 2(f) the agency is open for interagency mobility.

Mobility under these rules are reserved for temporary staff 2(f) who, on the closing date for applications and on the day of filling the vacant post, are employed within their agency on a grade and function group corresponding to the published grade bracket and function group. They further should have at least two years' service within their agency before moving and successfully having completed the probationary period in the relevant function group. A contract concluded from an interagency mobility shall be without interruption of the contract concluded with the Agency of origin and shall fulfil the requirements regarding the same grade and seniority in the grade as the preceding contract and the same step and seniority in the step as the preceding contract.

As a matter of fact, due to its specific activities, i.e. Medicinal products, the Agency employs a high proportion of highly qualified staff, such as physicians, pharmacists, veterinarians, biologists and others, which limits the scope for recruitment from other EU agencies.

## D - Gender and geographical balance

The Agency believes in equality between men and women and is committed to the provision of equality of opportunity for its staff through its employment practices, policies and procedures. It undertakes to provide a working environment that is sensitive to differences in sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation.

We aspire to reach a more gender-balanced organisation whilst adhering to principles of fair treatment and meritocracy.

**Gender balance**

| Contract Type[1] | Men | Women | Total |
|---|---|---|---|
| Temporary Agents | 203 | 380 | **583** |
| Contract Agents | 40 | 159 | **199** |
| National Experts | 15 | 16 | **31** |
| **Total** | **258** | **555** | **813** |
| Trainees | 0 | 0 | **0** |
| **Grand total** | **258** | **555** | **813** |

1) Data as of 31/12/2019

| Status 31/12/2019 | Category AD | | | | Category AST | | | | TA/CA - all grades | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Men | | Women | | Men | | Women | | Men | | Women | |
| Ratio TA | 171 | 50% | 170 | 50% | 32 | 13% | 210 | 87% | 203 | 35% | 380 | 65% |
| Ratio CA | 25 | 26% | 73 | 74% | 15 | 15% | 86 | 85% | 40 | 20% | 159 | 80% |
| **Total** | **196** | **45%** | **243** | **55%** | **47** | **14%** | **296** | **86%** | **243** | **31%** | **539** | **69%** |

**Gender balance of the Agency management**

| Status 31/12/2019 | Men | | Women | | Total management | |
|---|---|---|---|---|---|---|
| ED, DED, HDiv, AF | 8 | 62% | 5 | 38% | 13 | 14% |
| Hdept | 11 | 65% | 6 | 35% | 17 | 18% |
| Hservice/office | 38 | 61% | 24 | 39% | 62 | 67% |
| **Total ED, HDiv, HDep, AF** | **19** | **63%** | **11** | **37%** | **30** | **33%** |
| **All management** | **57** | **62%** | **35** | **38%** | **92** | **100%** |

**Geographical balance**

The Agency believes in equality and is committed to the provision of equality of opportunity for its staff through its employment practices, policies and procedures. It undertakes to provide a working environment that is sensitive to differences in sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation.

We aspire to reach a more geographically-balanced organisation whilst adhering to principles of fair treatment and meritocracy.

| Status 31/12/2019 | Temporary Agents | | | Contract Agents | National experts | Trainees | Total |
|---|---|---|---|---|---|---|---|
| | AD | AST | Total | | | | |
| Austria | 7 | 2 | 9 | 4 | 1 | 0 | **14** |
| Belgium | 14 | 1 | 15 | 4 | 1 | 0 | **20** |
| Bulgaria | 5 | 4 | 9 | 10 | 0 | 0 | **19** |
| Croatia | 4 | 0 | 4 | 3 | 1 | 0 | **8** |
| Cyprus | 0 | 0 | 0 | 1 | 0 | 0 | **1** |
| Czech Republic | 1 | 13 | 14 | 3 | 0 | 0 | **17** |
| Denmark | 5 | 6 | 11 | 0 | 1 | 0 | **12** |
| Estonia | 0 | 7 | 7 | 2 | 1 | 0 | **10** |
| Finland | 5 | 7 | 12 | 0 | 0 | 0 | **12** |
| France | 55 | 25 | 80 | 14 | 0 | 0 | **94** |
| Germany | 30 | 17 | 47 | 6 | 5 | 0 | **58** |
| Greece | 22 | 12 | 34 | 20 | 0 | 0 | **54** |
| Hungary | 5 | 10 | 15 | 10 | 0 | 0 | **25** |
| Ireland | 13 | 2 | 15 | 2 | 2 | 0 | **19** |
| Italy | 44 | 22 | 66 | 33 | 4 | 0 | **103** |
| Latvia | 2 | 5 | 7 | 2 | 0 | 0 | **9** |
| Lithuania | 2 | 8 | 10 | 6 | 0 | 0 | **16** |
| Luxembourg | 0 | 0 | 0 | 0 | 0 | 0 | **0** |
| Malta | 0 | 0 | 0 | 0 | 0 | 0 | **0** |
| Netherlands | 3 | 3 | 6 | 1 | 2 | 0 | **9** |
| Norway | 0 | 1 | 1 | 1 | 0 | 0 | **2** |
| Poland | 10 | 25 | 35 | 13 | 2 | 0 | **50** |
| Portugal | 20 | 8 | 28 | 11 | 3 | 0 | **42** |
| Romania | 9 | 6 | 15 | 12 | 0 | 0 | **27** |
| Slovakia | 3 | 15 | 18 | 6 | 0 | 0 | **24** |
| Slovenia | 0 | 1 | 1 | 1 | 0 | 0 | **2** |
| Spain | 44 | 28 | 72 | 24 | 1 | 0 | **97** |
| Sweden | 6 | 3 | 9 | 4 | 2 | 0 | **15** |
| United Kingdom | 32 | 11 | 43 | 6 | 4 | 0 | **53** |
| Other | 0 | 0 | 0 | 0 | 1 | 0 | **1** |
| **Total** | **341** | **242** | **583** | **199** | **31** | **0** | **813** |

## E – Schooling

The Agency's staff merits the same extent of social support for childcare and the same system of advantages as offered to staff employed under the Staff Regulations in other locations. Article 1d(6) of the Staff Regulations prohibits discrimination and promotes equal opportunity, linking both principles to legitimate objectives in the general interest in the framework of staff policy.

Furthermore, Article 1e refers to access to measures of a social nature, and the European crèche system would fall within this concept.

Based on the above Articles the Agency introduced social measures with regards to childcare and education. These social measures however are distinct from and do not affect the provisions of Article 3 of Annex VII of the Staff Regulations which have been implemented strictly in accordance with the statutory ceilings and have not been modified by the Agency. Regarding the education contribution under social measures the Agency followed the advice of the Commission and has since concluded direct contract agreements with each school for each pupil (see schooling section below for further information).

**Pre-school**

Taking into account the size and geographical extension of London (transitional period, i.e. July 2020) and now the Netherlands (due lack of housing, childcare and EU schooling in Amsterdam, EMA staff is living in a greater metropolitan area (including cities such as The Hague, Utrecht, etc.) to cover those needs), the undesirability of having small children travelling long distances (e.g. 1-1.5 hours or more) and the actual cost of establishing a crèche facility in London and Amsterdam, it is considered more cost effective as well as equitable to provide an additional reimbursement for Agency staff for moderately priced crèche services.

The policy for additional reimbursement came into force in 2007 and covers full-time or part-time crèche costs. Since 2014, the policy has been amended to cover pre-educational costs for children below the age of 5, in line with the principle and rationale of the support required. Only nurseries/pre-educational establishments in the UK/NL are considered, as the maximum reimbursement is based on actual costs. Total household income is considered, so the financial contribution of the other parent, whether the couple is married or not, is taken fully into account. The amount deducted as the parental financial contributions well as any allowance received elsewhere, follows the Commission approach and that of other agencies. The cost increase is due to a larger population of children.

| **Budget year** | **Total cost to Agency, EUR** | **Average payment per child, EUR** |
|---|---|---|
| 2016 (117 children, actual) | 415,740 | 3,553 |
| 2017 (133 children, actual) | 483,233 | 3,633 |
| 2018 (140 children, actual) | 478,368 | 3,987 |
| 2019 (220 children, *actual:* 200 NL – 20 in UK) | 753,000 | 3,422 |
| 2020 (220 children, *estimate:* 200 NL – 20 in UK) | 2,000,000 | 10,000 |
| 2021 (220 children estimated in NL) | 2,000,000 | 10,000 |

**Schooling**

Following relocation to the NL and the presence of two European Schools, i.e. Bergen and The Hague, both at distances greater than 50 km from the Agency's address, the Agency follows the provisions of Annex VII to the Staff Regulations.

Only exceptionally, as a special social measure during the transitional period of the relocation (i.e. until end of academic year 2019/20), some additional contribution has been put in place to support the families with children in the final two years of qualifications that lead to access to a higher education (i.e. A levels).

Overview of number of children falling under additional education contribution only:

| **Budget year** | **Total cost to Agency, EUR** | **Average payment per child, EUR** |
|---|---|---|
| 2016 (252 children, actual) | 1,474,858* | 5,853* |
| 2017 (281 children, actual) | 1,530,786* | 5,448* |
| 2018 (282 children, actual) | 2,243,422* | 7,955* |
| 2019 (163 children, actual) | 1,041,522* | 6,389* |
| 2020 (38 children, estimate) (NL & UK) | 366,887 | 9,654 |
| 2021 estimate *(no budget expenditure as the social measure stops August 2020, see text above)* | 0 | 0 |

*As the payments are in GBP, exchange rate variations apply.

**Exceptional education allowance**

For information, the Agency allocates €30,000 for expenditure relating to the exceptional education allowance.

## *Annex 5: Building policy*

## Current building(s)

| | Name, location and type of building | Name, location and type of building |
|---|---|---|
| | **30 Churchill Place, London, E14 5EU** | **Domenico Scarlattilaan, 6 Amsterdam, 1083 HS** |
| Lettable floor area/ Surface area (in $m^2$) | 30,340 | 31,496 |
| • of which office space | 17,946 | 21,282 |
| • of which non-office space | 12,394 | 10,214 |
| Annual building charges, of which | n/a (sublet) | EUR 13,628,000 |
| • rent | n/a (sublet) | EUR 8,669,000 |
| • maintenance costs | n/a (sublet) | EUR 1,818,000 |
| • permanent operating costs | n/a (sublet) | EUR 3,141,000 |
| Type and duration of rental contract | Rental agreement with Canary Wharf Ltd of 25 years from 1 July 2014 Premises sub-let from 1 July 2019 with full assignment of the lease | Rental agreement with CGREA (NL government Agency) of 20 years from 1 January 2020 |
| Host country grant or support | Reduction in business rates | 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. |
| Present value of the building | Not applicable | Not applicable |

**Building project under planning phase:**

In accordance with European Parliament and Council Regulation (EU) 2018/1718 the Agency's seat moved to Amsterdam from 30 March 2019. As a consequence EMA had submitted the following building project to the Budgetary Authority:

1) Lease of a building in Amsterdam/NL offered by the Dutch Government; positive opinion by the Budgetary Authority in March 2018:

   - The Dutch government offered the Agency a fully fitted and furnished premises (EMA Building) to be constructed (charged at rent of EUR 280/$m^2$ plus 40 $m^2$ for building related maintenance) as well as an incentive of EUR 18 million for fit-out enhancements of the future permanent building and/or an overall reduction of the annual lease. In addition the Dutch government provided the Agency with a temporary building (SPARK Building) at no rental cost to the Agency for the interim period from 1 January 2019, whilst the final premises are being constructed and fitted out

   - The Agency agreed with the Dutch government to use EUR 15 million of the incentive to contribute to fit-out costs and EUR 3.0 million to obtain yearly rent reductions of EUR 150,000 over the 20-year duration of the lease (January 2020 – December 2039). Furthermore, the Agency agreed with the Dutch Government on additional maintenance charges for business related elements.

2) Sub-letting of premises in in 30 Churchill Place, Canary Wharf, London/UK; positive opinion by Budgetary Authority received in June 2019.

In January 2020 the Agency will move into its permanent premises at Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands, and does not have any other planned building projects.

## *Annex 6: 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 7: 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 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 is expected to deliver its analysis to the European Commission by end 2019, while a formal Commission report is to be delivered to the European Parliament and to the Council by mid-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 is conducting an 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 or will be published soon.

First, pursuant to the reporting requirement under Article 50(3) of Regulation (EC) No 1901/2006, 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 by June 2019, 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, the European Commission is currently preparing and planning to publish in late 2019 a Staff Working Document on the orphan and paediatric regulations to assess the functioning of the EU legislation on medicines for special purposes. These and other studies will serve as a basis for the next European Commission to consider the need for possible changes to the EU legislative framework on pharmaceuticals after 2020.

**Project and programme evaluations**

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

Project oversight is the responsibility of two Agency boards: the Executive Board (EXB) and the Portfolio Board (PB). The PB is responsible for approving projects throughout the stages in their lifecycle. In exceptional circumstances, as defined in the PB's terms of reference, the PB may refer approvals or other project issues to the EXB for resolution.

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

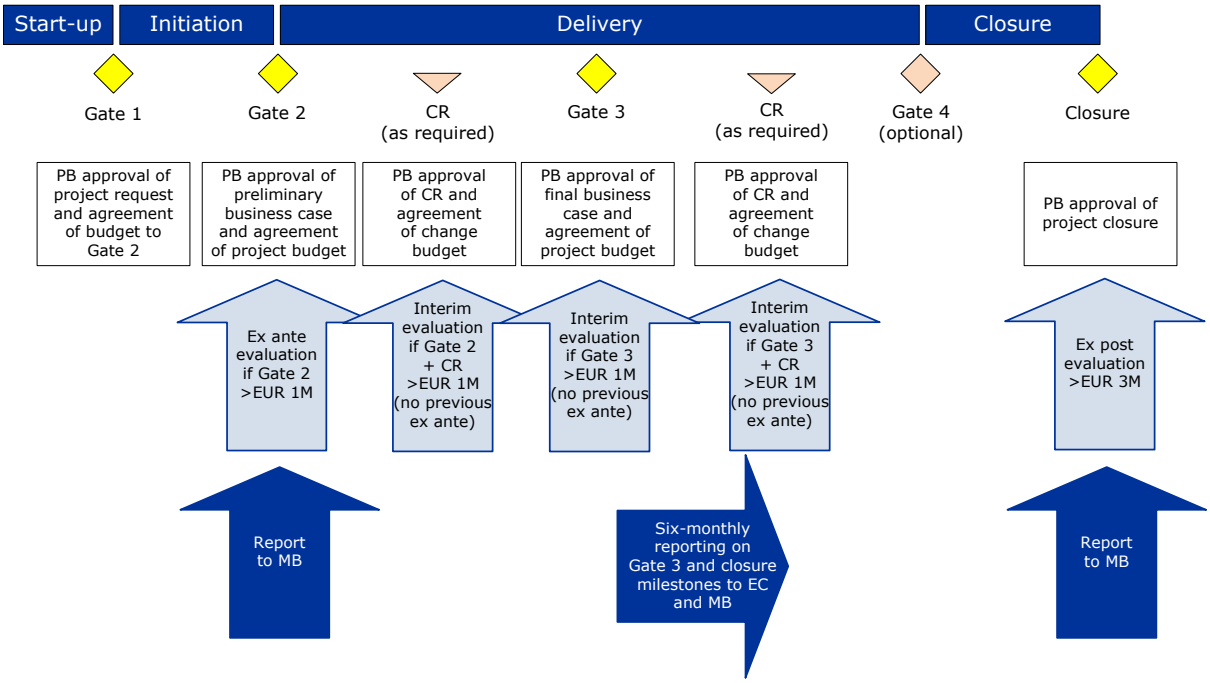
Ex ante evaluations are conducted at Gate 2 of the project procedure on the basis of the preliminary business cases (including cost estimates), before projects and budget expenditure are formally initiated. When the total project costs estimated at Gate 2 exceed EUR 1 million, the evaluation is conducted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

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

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

The results of ex ante and ex post 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.

**Figure 1.** Project oversight and evaluations



## *Annex 8: Risks*

In 2020 the most significant risks that could potentially impact the Agency's activities and achievement of its objectives are still related to Brexit. The Agency has been continuously assessing these risks since the result of the UK referendum and designed a risk mitigation strategy.

The significant risks and respective mitigating actions are outlined in the table below. These risks, should they materialise and the consequences not be appropriately managed, would result in operational, reputational, legal or financial implications for the Agency.

### Brexit consequences

| Risk | Mitigating actions and controls |
|---|---|
| Loss of existing staff resulting in loss of professional competencies and knowledge | The Agency has implemented staff support measures aiming to make the transition to our new location as smooth as possible for colleagues who relocate with the Agency. These include entitlements and allowances available in the Staff Regulations or already in place at the Agency, as well as additional provisions put in place for a transitional period.<br><br>Several new recruitment procedures have been launched to compensate for the possible loss of staff. |
| Loss of UK expertise in the scientific work | UK experts constituted 15% of the Agency's expert base and conducted around 20% of the scientific work. Losing these resources implies:<br>• significant increase in workload for EU experts;<br>• potential loss of specific expertise.<br>A dedicated ORP subgroup has been set up to assess the impact of Brexit on the Agency's core activities and propose remedial actions. The group has been focussing on the following remedial actions:<br>• Redistribution of UK product portfolio.<br>• Distribution of workload for initial marketing-authorisation applications, including reassignment of procedures not yet started but currently assigned to the UK.<br>• Distribution of workload for scientific-advice procedures.<br>• Distribution of workload for PRAC procedures, for which the contribution of the CMDh is required concerning nationally authorised medicinal products.<br>• Distribution of workload for initial marketing-authorisation applications and maximum residue limits (MRLs), including reassignment of procedures not yet started but currently assigned to the UK (veterinary medicines).<br>• Distribution of workload for pharmacovigilance procedures for centrally authorised products (veterinary medicines).<br>• Operational adjustments. |
| Delays in relocating the Agency headquarters to the final EMA building. | A joint governance structure between EMA and government authorities in the Netherlands has been set up to enable close collaboration between our Agency and the Dutch authorities at national and local levels, and to monitor progress of the relocation. |

### Fraud

| Risk | Mitigating actions and controls |
|---|---|
| Intentional leak of confidential information to external parties by internal employees, interims, trainees or contractors who have access to | • Data access management in place<br>• Firewall system in place to protect the information systems<br>• Antivirus system in place<br>• Datacentre access limited to relevant resource |

| Risk | Mitigating actions and controls |
|---|---|
| EMA's information systems with the purpose of personal gain | • Checklist in place to manage Contractors access to IT systems that has not been added to the SAP HR system.<br>• Tools to encrypt Data are in place to allow the transfer between the parties outside of the EMA network, for example via an encrypted USB stick<br>• Contractor rates data access is restricted using access control lists<br>• Passwords are required to be updated regularly<br>• USB restriction on EMA laptops.<br>• EMA Security Policy adopted (Policy 0076)<br>• (11) Internal guidance on access control to Agency premises approved on 27/09/2017 (doc ref EMA/276354/2017) |
| Sensitive and/or confidential data is intentionally accessed or removed from EMA network for personal gain through a cyber-attack | • Monitoring of traffic across EMA firewalls is undertaken by IT<br>• Penetration test and vulnerability assessment performed regularly<br>• Intrusion Prevention and Detection system systems in place<br>• Security policy in place detailing how employees can protect data |
| The NCA experts participating in EMA assessment work at national level (not included in the EMA Experts database) are not independent | • Legal requirements for independence (Article 63(2) of Regulation (EC) No 726/2004.).<br>• Contractual arrangements and memorandum of understanding with NCAs |
| Incorrect scientific opinion because of infringement of compliance involving data fraud by applicant or third party supplying data =>> public, animal health, legal and reputational risk | • Cross-Agency infringement action group established<br>• Increased transparency to third parties through access to documents encouraging reporting of infringements<br>• EMA Policy 0072 on handling of information from external sources disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision and maintenance of human and veterinary medicinal products was adopted on 17/03/2017<br>• EMA Policy 0070 on publication of clinical data for medicinal products for human use was adopted on 02/10/2014 |

## *Annex 9: Procurement plan 2020*

The list below reflects the intended procurement procedures that have budgetary impact on Title 3 items.

| | |
|---|---|
| **Activity statement:** | **Business Data Management (EudraVigilance and SPOR Data Management)** |
| **Objective:** | See Work programme 2020, heading 3.6 ,1.5 |
| **Value:** | € 12,500,000 |
| **Financial year:** | 2020-2024 |
| **Type of contract:** | Framework service contract |
| **Type of procedure** | Open tender |
| **Indicative timeframe for procurement:** | Expected to be launched in Q4 2019 |
| **Indicative timeframe for contract:** | Expected to be signed in Q3 2020 |
| **Budget line:** | 303 |

| | |
|---|---|
| **Activity statement:** | **DIMSIS II - Tender 1 (Development & Maintenance)** |
| **Objective:** | See Work programme 2020, heading 3.5, 3.7, 1.7, 2.7 |
| **Value:** | € 100,000,000 |
| **Financial year:** | 2020-2024 |
| **Type of contract:** | Framework service contract |
| **Type of procedure** | Open tender |
| **Indicative timeframe for procurement:** | Expected to be launched in Q4 2019 |
| **Indicative timeframe for contract:** | Expected to be signed in Q2 2020 |
| **Budget line:** | 3105 |

| | |
|---|---|
| **Activity statement:** | **DIMSIS II - Tender 2 (Infastructure)** |
| **Objective:** | See Work programme 2020, heading 3.5, 3.7 |
| **Value:** | € 10,000,000 |
| **Financial year:** | 2020-2024 |
| **Type of contract:** | Framework service contract |
| **Type of procedure** | Open tender |
| **Indicative timeframe for procurement:** | Expected to be launched in Q4 2019 |
| **Indicative timeframe for contract:** | Expected to be signed in Q2 2020 |
| **Budget line:** | 3105 |

| | |
|---|---|
| **Activity statement:** | **DIMSIS II - Tender 3 (Technology specific services)** |
| **Objective:** | See Work programme 2020, heading 3.5, 3.7 |
| **Value:** | € 20,000,000 |
| **Financial year:** | 2020-2024 |
| **Type of contract:** | Framework service contract |
| **Type of procedure** | Open tender |
| **Indicative timeframe for procurement:** | Expected to be launched in Q1 2020 |
| **Indicative timeframe for contract:** | Expected to be signed in Q4 2020 |
| **Budget line:** | 3105 |

| | |
|---|---|
| **Activity statement:** | **Hotel and travel service provider** |
| **Objective:** | See Work programme 2020, heading 3.1, 4 |
| **Value:** | € 28,000,000 |
| **Financial year:** | 2020 |
| **Type of contract:** | Service contract |
| **Type of procedure** | Open tender |
| **Indicative timeframe for procurement:** | Expected to be launched in Q1 2020 |
| **Indicative timeframe for contract:** | Expected to be signed in Q4 2020 |
| **Budget line:** | 3000; 3003; 2500; 1300 |

| | |
|---|---|
| **Activity statement:** | **Efficacy and safety studies on medicines (Relaunch of competition 2020)** |
| **Objective:** | See Work programme 2020, heading 1.5 |
| **Value:** | € 2,000,000 |
| **Financial year:** | 2020-2024 |
| **Type of contract:** | Service contract |
| **Type of procedure** | Re-opening of competition |
| **Indicative timeframe for procurement:** | Expected to be launched in 2020 |
| **Indicative timeframe for contract:** | Expected to be signed in 2020 |
| **Budget line:** | 3030 |

| | |
|---|---|
| **Activity statement:** | **Validation of data sources** |

| | |
|---|---|
| **Objective:** | See Work programme 2020, heading 1.5 |
| **Value:** | € 1,000,000 |
| **Financial year:** | 2020-2024 |
| **Type of contract:** | Service contract |
| **Type of procedure** | Open tender |
| **Indicative timeframe for procurement:** | Expected to be launched in Q2 2020 |
| **Indicative timeframe for contract:** | Expected to be signed in Q4 2020 |
| **Budget line:** | 3030 |

| | |
|---|---|
| **Activity statement:** | **Medical Literature Monitoring** |
| **Objective:** | See Work programme 2020, heading 1.5 |
| **Value:** | € 6,500,000 |
| **Financial year:** | 2020-2024 |
| **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 Q1 2021 |
| **Budget line:** | 3030 |

| | |
|---|---|
| **Activity statement:** | **ABC V - Consultancy, advisory and benchmark services** |
| **Objective:** | Non EMA-led procurement initiative |
| **Value:** | € 4,000,000 |
| **Financial year:** | 2020-2024 |
| **Type of contract:** | Framework service contract |
| **Type of procedure** | Open tender |
| **Indicative timeframe for procurement:** | Non EMA-led procurement initiative |
| **Indicative timeframe for contract:** | Non EMA-led procurement initiative |
| **Budget line:** | 3030 |

## *Annex 10: Projects*

In order to support the Agency's work and achievement of set objectives, a number of programmes and projects will be undertaken. The table below details the main projects, their timelines and deliverables that the Agency will pursue in 2020.

Brexit implications on the projects are added next to the project title, indicating whether a project continues, is suspended, or will continue, pending certain conditions.

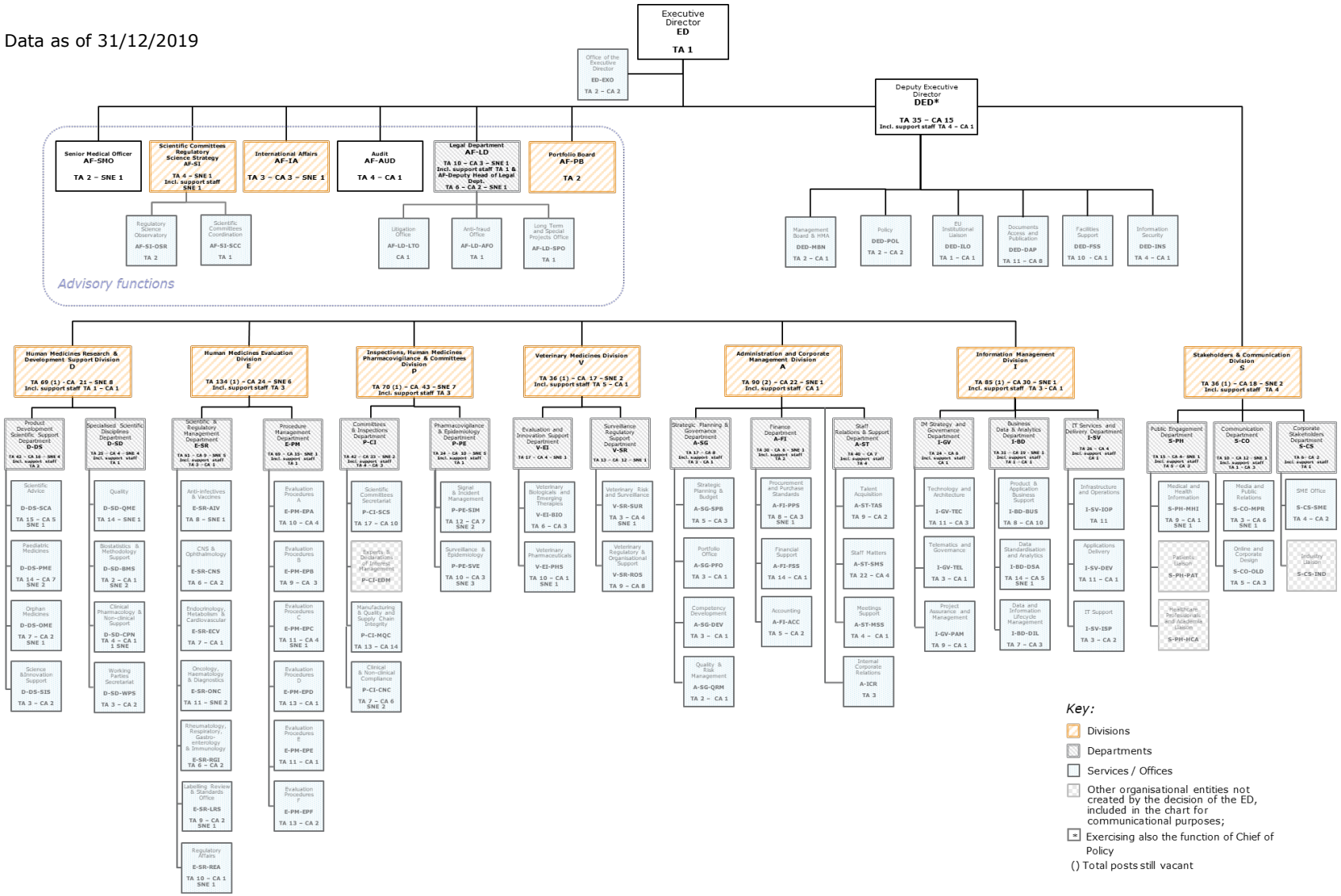
| Programme / Project | Legal basis | Start date | End date | Deliverables 2020 | Budget 2020 |
|---|---|---|---|---|---|
| ***Clinical Trials Programme*** | | | | | € 1,013,700 |
| • CTIS – Clinical Trials Information System (formerly EU portal and clinical trials database, renamed including a merger with SUSAR) **[continues]** | • Regulation (EC) 536/2014, art.80-82 | Q3 2014 | 2021-2022 | • Continue development of CTIS version for audit<br>• User testing of intermediate CTIS versions<br>• Commence delivery of training to stakeholders<br>• Fully implement communication plan | € 8,749,000 |
| EudraCT linked to CTIS (EudraCT legacy) **[continues]** | • Regulation (EC) 536/2014, art.80-82, 98 | 2018 | 2021-2023 | Preliminary business case towards the integration of legacy clinical trials data with the EU Portal and Database system, depending on progress of CTIS | € - |
| ***e-Submission Programme*** | | | | | |
| eCTD4 pre-project activities **[suspended]** | n/a | 2021 | 2022 | Suspended until 2021 | |
| Single Submission Portal **[suspended]** | n/a | 2021 | 2022 | Suspended until 2021 | |
| ***Veterinary Change Programme*** | | | | | € 280,000 |
| EudraVigilance veterinary v3.0 **[continues, subject to budget availability]** | • Regulation (EC) 726/2004, art.57(d) | 2017 | 2022 | • Initiation of system implementation as a first step towards a Union veterinary pharmacovigilance system<br>• Initiation of testing of 1st release | € 2,625,000 |
| New Veterinary Legislation **[continues, subject to budget availability]** | • New veterinary legislation under drafting | Q1 2019 | 2022 | • Project initiation and analysis of requirements (for one IT component to be identified)<br>• Preliminary business case<br>• Delivery of revised internal governance within the V division of EMA | € 2,250,000 |

| Programme / Project | Legal basis | Start date | End date | Deliverables 2020 | Budget 2020 |
|---|---|---|---|---|---|
| | | | | | |
| ***Online Programme*** | | | | | |
| European Medicines web portal **[suspended]** | • Regulation (EC) 726/2004<br>• Regulation (EC) 1235/2010, art.26 | 2021 | 2022 | Suspended until 2021 | |
| EMA Intranet | n/a | 2021 | 2022 | Suspended until 2021 | |
| EMA Extranet | n/a | 2021 | 2022 | Suspended until 2021 | |
| ***Data integration programme*** | | | | | €- |
| Substances and products management services (including veterinary Union database) **[temporarily suspended]** | • Regulation 726/2004, art.57(2)<br>• Regulation (EC) 520/2012, art.25 and 26<br>• Draft veterinary regulation, art.51<br>• Clinical trials regulation 536/2014, art.8193)<br>• Pharmacovigilance fees regulation 658/2014, art.7<br>• Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU | 2017 | 2024 | • Activities have been redirected under the New Veterinary Legislation programme in order to support the delivery of the Union Product Database. | €- |
| Administration Digitalisation | n/a | 2019 | 2021 | • Provide better tools to overcome manual processing and repetitive tasks<br>• New Time & Attendance Management system<br>• New Goals and Performance system<br>• New Succession Planning and start of the migration of SAP HR to Employee Central in the cloud | €2,000,000 |
| IRIS Scientific advice SIAMED with Knowledge Management | n/a | 2019 | 2021 | • Provide a more integrated business process and Information based on the new IRIS Portal<br>• Better capture and manage the scientific knowledge<br>• Process and system analysis and design<br>• Start of implementation | €1,470,000 |
| Data centre refresh **[new]** | n/a | 2020 | 2020 | • Upgrade and replacement of old hardware in the Data centres | €2,050,000 |
| AM & D Sourcing Project | n/a | 2019 | 2020 | • Replacement of IT Framework Contract, which arrives at their end and needs to be replaced | €827,000 |

| Programme / Project | Legal basis | Start date | End date | Deliverables 2020 | Budget 2020 |
|---|---|---|---|---|---|
| Knowledge Transfer to the new DIMSIS contractor | n/a | 2020 | 2020 | • Train and coach the new contractor staff on our Applications | €2,050,000 |

# *Annex 11: Organisational chart*

Data as of 31/12/2019



## *Annex 12: Terms and abbreviations*

| Term/abbreviation | Definition |
|---|---|
| 3Rs | '3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement |
| 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 |
| 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 |
| ASaT/SC | secretarial and clerical category post |
| ATD | access to documents |
| ATMP | advanced-therapy medicinal product |
| BCP | business continuity 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 |
| CHMP | Committee for Medicinal Products for Human Use |
| CHMP ORGAM | a meeting to discuss CHMP organisational matters |
| CMDh | Coordination Group for Mutual Recognition and Decentralised Procedures - Human |
| CMDv | Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary |
| $CO_2$ | carbon dioxide |
| Commission | European Commission |
| committee(s) | scientific committee(s) of the Agency |
| COMP | Committee for Orphan Medicinal Products |
| 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 |
| DHPC | direct healthcare professional communication |
| DIA | Drug Information Association |
| DIMSIS II | development, implementation and maintenance support of information systems |
| DoI | declaration of interests |

| Term/abbreviation | Definition |
|---|---|
| DPR | Data Protection Regulation for EU Institutions |
| 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 |
| EFPC | European forum for primary care |
| 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 |
| 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 |
| GAAD | Global action against dementia |
| 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) |
| HCIN | Heads of Communication and Information Network of EU agencies |
| HCP | healthcare professional |
| HCWPW | healthcare professionals' working party |
| HL7 | Health Level 7 |
| HMA | Heads of Medicines Agencies |
| HMPC | Committee on Herbal Medicinal Products |
| Horizon 2020 | EU Research and Innovation programme |
| HPRA | Health Products Regulatory Authority (Ireland) |
| HR | human resources |
| HSC | EU Health Security Committee |
| HTA | health technology assessment |

| Term/abbreviation | Definition |
|---|---|
| HTAN | the HTA network |
| IAS | Commission's Internal audit service |
| ICDRA | International Conference of Drug Regulatory Authorities |
| ICH | International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| ICMRA | International coalition of medicines regulatory authorities |
| ICSR | individual case-safety report |
| ICT | information and communication technologies |
| 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 |
| IPRF | International Pharmaceutical Regulators Forum |
| IPRP | International Pharmaceutical Regulators Programme |
| IRCH | International Regulatory Cooperation for Herbal Medicines |
| IRIS | Regulatory & Scientific Information Management Platform |
| ISO | International Organisation for Standardisation |
| IT | information technology |
| ITF | Innovation Task Force |
| IWG | inspectors working group |
| 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 |
| MNAT | multinational assessment team |
| 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 |
| 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 |
| ORP | EMA Operation and Relocation Preparedness task force, focusing on the Agency's preparedness for any scenario following the UK's eventual exit from the EU |
| PAES | post-authorisation efficacy study |
| Parliament | European Parliament |
| PASS | post-authorisation safety study |
| PB | EMA Portfolio Board |
| PBT | persistent bioaccumulative and toxic substance |

| Term/abbreviation | Definition |
|---|---|
| PDCO | Paediatric Committee |
| PCWP | patient and consumer working party |
| PEI | Paul-Ehrlich-Institut, agency of the German Federal Ministry of Health |
| PhV | Pharmacovigilance |
| PIC/s | Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme |
| PIP | paediatric investigation plan |
| PLD | Patient level data |
| PMDA | Pharmaceuticals and Medical Devices Agency |
| 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) |
| QRD | quality review of documents |
| Q&A | questions and answers |
| RA | rapid alert |
| R&D | Research and development |
| RAPS | The Regulatory Affairs Professionals Society |
| RFI | request for information |
| ROG | Regulatory Optimisation Group |
| 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 |
| SPOR | Substances, Products, Organisations, Referentials |
| SUSAR | serious unexpected suspected adverse reaction |
| TA | temporary agent |
| TATFAR | Transatlantic Taskforce on Antimicrobial Resistance |
| 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 |