EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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

The European medicines regulatory network (the Network) is based on a network of around 50 human and veterinary medicines regulatory authorities ('national competent authorities', or NCAs) from the 31 European Economic Area Member States, together with the European Medicines Agency (EMA). The network has access to thousands of experts from Member States across Europe, allowing it to source the best possible expertise for the regulation of medicines in the European Union (EU).

To deliver on its responsibilities, EMA works closely with the NCAs. This means the environment, trends, workload forecasts and implementation of a number of objectives and activities described in this programming document will impact the national authorities and their work as well.

Notwithstanding the role and contribution of the national competent authorities, the purpose of this document is to reflect the activities, work programme and contribution of the EMA.

EMA priority areas: Brexit and relocation of the Agency

The UK's decision to leave the European Union following the referendum has significant implications for EMA. Not only will the Agency leave London and, following the 20 November 2017 seat decision, move its seat to Amsterdam, it also has to find ways to comply with its legal role and continue to perform its activities on time and to the same high quality, and this in light of the loss of the UK expertise and anticipated staff loss.

Challenges and risks

The physical relocation presents a number of challenges – including making sure the new premises are available on time and fit-for-purpose; transferring and maintaining operational IT systems; ensuring the necessary procurements are run and services are provided; as well as the logistics of the actual move of the organisation and staff, with minimum disruption to its day-to-day activities. It is important in this respect that the new host Member State fully complies with its commitments, as stated in the offer to host EMA.

More significantly, the Agency and the wider Network will have to address the challenge of maintaining the Agency's scientific operations when faced with the departure of UK experts and some inevitable loss of EMA staff.

EMA's working scenario is that the UK will leave the EU as of 30 March 2019 and become a 'third country' as of that date. Any future relationship between the UK and EMA in the regulation of medicines is part of the negotiations between the EU and the UK. UK experts constitute 15% of the Agency's expert base and conduct around 20% of the scientific work. Loss of this expertise will have significant consequences not just for the Agency, but for the Network as a whole, and will require capacity building and re-distribution of workload among the Member States. In addition, the Network may lose access to some specific expertise, which requires further steps to ensure the quality of scientific output is not affected.

Depending on the actual level of staff loss, the relocation may have significant consequences not only for the Agency but also for the Network, and negatively impact EMA's role in the protection of public and animal health in Europe.

Taking into account the latest EMA staff survey, performed in September 2017 to inform the Agency's recruitment strategy to compensate for staff loss, it is anticipated that the relocation of EMA to Amsterdam could result in EMA retaining around 80% of its current staff. This would allow the Agency to stay operational throughout the transition period, although there will be disruption to the daily work. However, the actual staff loss will need to be closely monitored to ensure continuity of operations, as it is possible that some specific functions will experience significant staff attrition while the overall staff loss at the Agency level may remain rather low.

Preparations for the consequences of Brexit

In order to address the challenges presented by Brexit, in June 2016 EMA internally established the Operations and Relocation Preparedness (ORP) task force, to plan and prepare for the upcoming change, 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 4 work streams:

- **Relocation preparedness**, which includes activities enabling the scientific experts from the Network to continue attending scientific meetings at EMA; retaining staff, including a smooth relocation of staff and their families; as well as working with the Netherlands on the timely availability of the new premises and the required facilities, including telecommunication.
- **Operational and financial preparedness**, which focuses on the preparedness of the scientific committees and working parties, in particular with respect to how the scientific assessment and monitoring of medicines will be shared between the Member States, in view of the UK's withdrawal from the EU. It also includes the necessary activities to be undertaken to enable an undisrupted supply of medicines.

  This work stream also elaborates on the Agency's Brexit preparedness business continuity plan (BCP), which covers prioritisation and delivery of EMA activities in order to free-up the resources needed to prepare for Brexit, particularly the relocation, and to address potential staff loss.
- **Human resource-related matters**. This work stream encompasses the work to address HR-related aspects of the EMA preparedness and its implementation.
- **Communication activities**, covering both internal and external communication to EMA's staff, EMA's key stakeholders, and the wider public.

The task force is supported by ORP subgroups, devoted to specific activities and deliverables within these 4 work streams.

Preparations to date

During 2016-2017, the Agency has undertaken considerable work to prepare for the relocation, including but not limited to:

- Completing an impact assessment, identifying the key risks that the Agency would be facing in this environment;
- Preparing 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;
- Member State visits to EMA, and EMA site visits to candidate host countries upon request from a Member State;

- Conducting several staff surveys, to gauge the potential staff losses in view of their impact on the Agency's operations and to assess potential remedial actions;
- Developing a dedicated Brexit recruitment and selection strategy, to address the potential staff loss, including job and competency mapping to support succession planning;
- Reviewing current contracts for goods and services and preparing a procurement plan, to ensure the necessary contracts are in place at the time of the Agency's move to the new host Member State, including those for staff support during the transition;
- Developing support measures to maximise staff retention;
- Working with the Member States to address the workload issues arising from the loss of UK expertise;
- Issuing communications and preparing guidance for 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;
- Developing a dedicated EMA Brexit preparedness BCP, to address situations where a "business as usual" scenario is no longer possible;
- Beginning preparation for relocation of the Agency's data centres;
- Beginning liaison 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.

Future work

The work on preparing for the relocation and mitigating negative implications of this change is now intensifying, following the decision on the new seat of the Agency, and considering the very short timelines to complete the move to Amsterdam. Preparing for the move, managing the necessary changes and addressing challenges, such as potential loss of skilled and experienced staff, require considerable resources.

The following activities are foreseen for 2018-2019, in order to finalise preparations for and execution of the actual move of the Agency:

Work stream	Activity	2018	2019
Work stream 1: Relocation preparedness	Conclude Seat agreement	x	
	Conclude and implement a Memorandum of Understanding/ Cooperation Agreement with the Netherlands	x	
	Finalise the building approval process (Article 88 of the Financial Regulation)	x	
	Initiate the necessary procurement procedures enabling EMA operation in Amsterdam	x	x
	Prepare for contractual activities related to the existing providers of services	x	x
	Implement the staff retention and relocation support measures	x	x
	Prepare for and carry out the relocation of the Agency's data centres and the transfer of knowledge on IT systems and programmes	x	x

Work stream	Activity	2018	2019
	Prepare a plan for the new definitive building and work with the Dutch authorities on the new premises' development project	x	x
	Prepare a plan for relocating EMA to the temporary premises, in close collaboration with the Dutch authorities, and execute such plan	x	x
	Prepare for and execute the relocation of the Agency, including move of the archives	x	x
	Prepare for and implement changes stemming from the physical relocation, e.g. changes of contact details on all Agency templates		x
Work stream 2: Operational and financial preparedness	Finalise redistribution of work on evaluation and monitoring of medicines with NCAs	x	
	Conduct a follow-up survey as to the capacity and training needs within the Network	x	
	Prepare Q&As and guidance documents for pharmaceutical industry on Brexit-related changes to marketing authorisations	x	x
	Handle the additional, Brexit-related post-authorisation applications	x	x
	Monitor the status of the centrally authorised products, with regard to need for the MAHs to be established in the EU (or EEA) and with regard to the activities which must be performed in the EU (or EEA), e.g. batch release	x	x
	Implement the next phases of the EMA Brexit preparedness BCP, as need arises	x	x
	Develop and implement a dedicated EMA relocation BCP for the physical relocation of the Agency	x	x
	Monitor the implementation of the BCP and the staff loss, and undertake remedial actions as necessary	x	x
	Prepare for and implement changes to EMA IT systems	x	x
Work stream 3:HR related matters	Finalise the Brexit-specific recruitment procedures and any recruitments necessitated by staff loss	x	x
	Prepare for operational activities related to relocation of staff, including interaction with the Dutch authorities	x	x
Work stream 4: Communication	Provide timely and targeted communication to stakeholders and the pharmaceutical industry	x	x
	Provide timely communication to staff, contractors and interims	x	x
	Implement communications strategy on Brexit-related matters, with emphasis on communicating to relevant decision-makers and citizens in the Netherlands/Amsterdam	x	x
Project coordination	Includes budget-related activities	x	x
FTE workload forecast		**86 FTEs**	**62 FTEs**

Impact on the Agency's activities

The Agency's priority in these circumstances is to ensure that the activities relating to the authorisation, supervision and maintenance of medicines continue to be undertaken on time and to the same high quality the Agency's stakeholders have come to expect, and that patients in Europe continue to have access to high-quality, safe and effective medicines. The Agency will, for as long as possible, operate under a 'business as usual' scenario, while preparing for both the physical move to the new EMA premises in Amsterdam, and the impact on the Agency's operations.

However, the evolving situation may require a shift in priorities and focus. This work programme reflects the current BCP in operation since mid-2017, adjusted to reflect the need to free up additional resources for Brexit preparedness, assuming minimum disruption to the Agency's activities. As the scale of impact on EMA will become clearer over the next months, the Agency may need to review its priorities, postpone less urgent activities to guarantee the continued delivery of its core operations, and revise the work programme and budget, to ensure realistic representation of the work that can be done under Brexit conditions.

The Agency's Brexit preparedness BCP categorises and prioritises tasks and activities according to their impact on public health and the Agency's ability to function. The plan sets out three layers (or categories) of priority:

- **Category 1** includes the highest-priority activities that are either directly related to the Agency's core scientific activities for medicines, or vital to maintaining the infrastructure of the European regulatory system for medicines. These include, for example, the coordination of actions to protect the safety of patients in all EU Member States, inspections across the EU or maintenance of the functionality and security of critical IT applications used by all Member States. It is absolutely crucial to uphold these activities, as any disruption would almost immediately have a detrimental effect on the health and well-being of citizens in Europe, and would also jeopardise production and distribution of medicines in the EU.
- **Category 2** are medium-priority activities - either strategic activities, or other core activities not captured in category 1. They include activities such as the proactive publication of clinical data, and various initiatives aimed at promoting availability of medicines, as well as some political priorities of the EU, such as EMA's contribution to the fight against antimicrobial resistance, or the Agency's interactions with Health Technology Assessment (HTA) bodies for example. These activities will be maintained for as long as possible, workload and staffing situation permitting, in order to maintain the development of new medicines.
- **Category 3** activities are of the lowest priority and cover governance and support activities, such as corporate governance, audits, participation in and organisation of meetings and conferences.
- Some activities, such as missions, are topic-specific and cannot be classified into a single category, but are considered as part of the activity to which they contribute.

The options for managing the different priorities of activity in a business continuity scenario are that they will either:

- continue as 'business as usual', with the understanding that they will be performed to the same high standards as before;

- be temporarily reduced, with the understanding that such reduced output will also continue to adhere to the same high standards, although the reduced output may result in a reduction of volume, or a delay in the time to achieve the agreed deliverables;
- be temporarily suspended.

Activities that are temporarily scaled back (reduced) or suspended will remain that way until the Agency has the necessary capacity to restore them. Once the BCP scenario can be lifted, EMA activities will be restored in a stepwise manner, starting with the activities classified as highest priority, as outlined above, leading to a gradual resumption of all the Agency's activities.

In order to release resources to support EMA preparedness work, several category 3 activities were already temporarily suspended or scaled back, as of mid-2017. Now, that the EU decision on the new seat has been made, further resources will be required to support the preparations for the relocation, as well as to replace possible staff loss that can no longer be compensated through recruitment of replacement resource. Consequently, further reductions of activities are foreseen as of January 2018.

The list of activities temporarily suspended or reduced may be revised further, depending on the activities to be undertaken for Brexit and relocation preparedness, as well as the extent of staff loss.

Priority level	Temporarily suspended activities	Temporarily reduced activities
Category 3 (lowest-priority activities)	• EMA's contribution to the planning and preparation for the implementation of version 4.0 of the Electronic Common Technical Document (eCTD); • The development of a transparency roadmap that lays out future transparency measures of the Agency; • Participation in the benchmarking of medicines regulatory authorities in the EU; • IQM activities, except those related to core business processes; • Implementation of an environmental management system and registration to EMAS; • All missions relating to suspended activities.	• Audits (only maintain IAS and ECA audits, legally required audits, and a few audits based on the assessment of the risk and assurance map), reporting, corporate governance meetings and support activities (except governance related to core activities and Brexit); • Participation in meetings and conferences; • Organising meetings at EMA; • Training activities for staff (reduction by 75%); • Requests for information response capacity reduced by 50%, leading to increased response time, depending on the risk level allocated to the RFI; • Development of new/revision of existing internal and external policies, except work related to matrix@EMA, MNAT pre- and post-authorisation oversight implementation, and TAG-related work in the context of the clinical data publication policy; • e-submissions programme; • All missions relating to reduced activities. *All legal requirements are maintained.*
Category 2 (medium-priority	• Development of the European medicines web portal; • Development of extranet and intranet	• Interaction with patients, healthcare professionals and academia: – cancel 1 joint PCWP/HCP workshop

Priority level	Temporarily suspended activities	Temporarily reduced activities
activities)	functionality; • Interaction with pre-accession countries to support the IPA programme; • Update of guidance on managing medication errors; • Significant benefit: no follow-up workshop; • Influenza pandemic project (unless new pandemic emerges); • No new consortium memberships for IMI projects; • Contribution to training of non-EU countries, except India and China; • Development of fellowship programmes with new partners; • Unplanned visits to EMA from non-EU delegations; • Exchange of non-safety information with international partners; • All missions relating to suspended activities.	(out of 2 planned) – cancel 1 stakeholder workshop (out of 2 planned) – topic group meetings put on hold – streamline and simplify reporting on stakeholder activities – reduce other meetings with patients, healthcare professionals and academia, like the Accelerate workshop (1 out of 2), Enpr-EMA working group meetings (1 out of 3) • Interaction with industry stakeholders: – cancel 1 SME info day (out of 2 planned), – bilaterals with trade associations put on hold (except for Brexit-related topics) – survey of industry stakeholders postponed to 2019 – EMA Veterinary Medicines Info Day reduced and refocused on innovation – cancel 1 platform meeting on the centralised procedure (out of 2 planned) and focus on Brexit preparedness • Transparency, information, and non-product related communication – reduce production of brochures / info-sheets / leaflets – reduce number of workshop reports, giving priority to category 1 and 2A activities – reduction in exhibition services – reduction in translations by 50%, prioritising those legally required • Maintain the proactive clinical data publications, albeit at a slower pace; • Training of stakeholders and NCAs that is not essential to support capacity building for Brexit, to maintain category 1 or 2A activities (including training on guidelines) or to enable newly rolled out systems (e.g. ADRs); • Product-specific focus of engagement on geriatrics, rather than general guidance; • Training in areas such as GxP, general pharmacovigilance and quality topics; • Guidelines development, including

Priority level	Temporarily suspended activities	Temporarily reduced activities
		consultative meetings with stakeholders, including GVPs where priority will be given to category 1 activities with an urgent public/animal health need, followed by those that can be finalised or released for public consultation in first half of 2018; • Reduction of a number of meetings of the working parties and of QRD working group, NRG and GXP IWGs; • International cooperation: – Decreased activities with countries with which no MRA nor CA exists, and with neighbouring and accession countries – Limited number of fellowships to the FDA, or from the FDA and PMDA – Activities related to international reliance – Activities at DIA, TOPRA, RAPS to be topic-driven and to focus on category 1, 2A and Brexit-related topics – Development of new international clusters • Ongoing IMI projects (IMI-Advance, IMI-Adapt Smart and IMI-FluCop) will continue in 2018 but follow-up on the outcome of the projects will be reviewed; • Engagement in advisory boards of new IMI projects and follow-up on existing IMI projects will be reviewed on a case-by-case basis and generally scaled back; • Engagement with learned societies relevant for therapeutic area activities; • Selective collaboration and engagement with public health authorities in the EU (e.g. ECDC, HSC, joint actions) and globally (e.g. WHO); • All missions relating to reduced activities.
Category 1 (highest-priority activities)	• None	• Activities relating to IT maintenance will be reduced through a reduction in the number of change requests, to be decided on a risk-based approach.

Part II: Multiannual programming 2018–2020

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 the main initiatives and activities that the Agency will undertake in the coming years, to support the 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 fact that about 75 percent[1] 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.

Theme 1: Contributing to human health

Theme 1: contributing to human health	
Objective 1: Focus on key public health priorities, including the 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 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

[1] Louise H Taylor, Sophia M Latham and Mark E J Woolhouse, Phil. Trans. R. Soc. Lond. B (2001) 356, 983 -989. 'Risk Factors for human disease emergence'

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 the 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

Theme 4: Contributing to the global regulatory environment	
	medicines development
Objective 3: Ensure best use of resources through promotion of 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

Multiannual work programme outlines the Agency's medium-term objectives and the main initiatives and activities to achieve these. The multiannual 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.

Considering Brexit environment that EMA will be operating in over the next years, a column for indicating Brexit implications has been added in the multiannual work programme. For those entries that are either temporarily reduced or suspended during this time, the respective note has been added.

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	BREXIT implications	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	2020		• task force established and running • proposals given/implemented for EMA activities to address antimicrobial resistance
	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	2019		• number and proportion of TATFAR actions implemented (where EMA has a role) • -level of completion of the actions
		1.1-3	Contribute to the 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	2016	2018		• actual contribution to WHO • completion level and/or rate of implementation of actions in the action plan(s)

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			OIE strategy				

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

Public health needs and priorities	Ensure the 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)	2015	2019	Reduced activity in 2018 and 2019	• implementation of the actions in the GAAD
		1.1-5	Implement the geriatrics strategy	2011	2020	Reduced activity in 2018 and 2019 *Delivery of GVP module temporarily suspended.*	• level of strategy implementation: proportion of actions implemented • deliverables completed (guidelines, pilot outcomes, ~~GVP module)~~
		1.1-6	Support innovation, early dialogue, and research for paediatric medicines	2007	2021		• support of early engagement with developers of paediatric medicines (continue common commentaries with the FDA, other pre-submission interactions) • number of scientific workshops / expert meetings to support innovation in paediatric medicines
		1.1-7	Scientific and regulatory contribution enhancing drug safety in pregnancy	2015	2019		• delivery of the Product- or Population-Specific Considerations III on pregnant and breastfeeding women
		1.1-8	Strengthen scientific evaluation	2015	2019		• publication/availability of

			of orphan designation criteria by COMP at the time of MAA				additional guidance on the evaluation of significant benefit • publication of orphan maintenance assessment reports

Public-health emergencies	Enhance the ability to respond quickly to public-health emergencies	1.1-10	Facilitate early introduction of appropriate treatments or preventive measures	2015	2019		• time between starting point (e.g. application/request for advice) and EMA response (e.g. approval of medicine/SA letter)
		1.1-11	Improve Health Threats plan and update post-health-threat activity completion (e.g. Ebola, Zika etc.)	2015	2016		• action plan developed and process for rapid answers set up • number of 'lessons' implemented from the 'lessons learned' **[completed]** • other activities suspended

Supply issues and availability of new and well-established medicines	Minimise the risk and impact of shortages due to manufacturing problems and quality defects	1.1-12	Implement revised action plan regarding medicinal product supply shortages caused by manufacturing/good manufacturing practice compliance problems, including: • harmonised definition (criteria) of shortages • develop metrics for shortages • best practices on communication of shortages • 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
		1.1-13	Develop formal collaboration with WHO in the area of supply disruptions	2017	2021	Reduced activity in 2018 and 2019	• formal agreement with WHO • number of cases worked in collaboration
		1.1-14	Support to the European Observatory on the supply of medical radioisotopes	2017	2020	Reduced activity in 2018 and 2019	• 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
		1.1-15	Consolidate information on compliance issues and quality defects	2017	2019		• system of warning letters in case of GMP non-compliance issues implemented • improvements implemented

							in the coordination/handling of quality defects across the network
	Address the threat posed by illegal medicines supply chains	1.1-16	Continue to support the implementation of the Falsified Medicines Directive	2011	2019		• number of cases supported/coordinated by EMA in relation to falsified medicines in the supply chain
		1.1-17	Streamline process for reporting of suspected falsified medicines in the supply chain by MAHs	2011	2019		• implementation of the revised form for reporting quality defects and suspected falsified medicines
		1.1-18	Strengthen communication within the network, including with WGEO	2014	continuous		• timely sharing of relevant information related to illegal supply chain as it is notified to EMA
	Facilitate/support availability of already approved medicines	1.1-20	Contribute to the work of the EMA/HMA Joint task force on the 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	BREXIT implications	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	2018	Reduced activity in 2018 and 2019	• number of scientific advice procedures with proactive and prospective planning of evidence generation to meet the needs of downstream decision-makers (HTAs/payers)
		1.2-2	Provide reinforced regulatory and scientific advice for priority medicines (PRIME)	2014	2019		• number/increase in PRIME products that received scientific advice • time from request to final response, compared with other products and with previous period
		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 • number of HTA bodies involved • analysis on scientific views expressed by regulators and HTA bodies, respectively, on development programmes • deliverables of Joint Action 3 / work package 5a with regard to parallel regulatory-HTA scientific advice

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
	Support effective and efficient conduct of pharmacovigilance	1.2-4	Implement planned access and analysis of real-world data	2016	continuous	Reduced activity in 2018 and 2019	• 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	2016	2019		• patient registries actually used for novel medicines
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	2019		• processes to capture such values and preferences developed and implemented • increased number of cases where patient and healthcare professionals' input is incorporated in the scientific review • 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	BREXIT implications	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	2019*		• availability of functional IT tools/systems
		1.3-2	Update guidelines and inspection-related procedures in accordance with the new	2014	2018*		• level of completion or availability of updated guidelines/processes

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			legal requirements				

*Audit of the system is planned to take place in 2018, enabling the regulation to come into application in the second half of 2019.

Innovation	Facilitate translating innovation into medicinal products	1.3-3	Streamline interaction with academia	2016	2019		• implemented framework for collaboration with academia • 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 • number of cases where EUnetHTA relative efficacy assessment was facilitated following regulatory assessment, as part of Joint Action 3 / work package 4 • 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	Reduced activity in 2018 and 2019	• number of research areas/opportunities identified
		1.3-6	Explore opportunities to reduce regulatory and administrative	2017	2020		• number of opportunities identified and implemented,

			burden				including those raised through stakeholder platform meetings
		1.3-8	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	1.3-7	Review existing support measures and explore additional supportive measures to incentivise innovation by SMEs	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	BREXIT implications	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 the EU network is ready for the new EudraVigilance functionalities, including	2016	2018		• number of NCAs/MAHs trained on new functionalities

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			centralised reporting and the new data format				
		1.4-4	Explore the potential use of real-world databases, electronic healthcare records and 'big data'	2016	2020		• number of new data sources used in regulatory activities/decision-making

Transparency	Increase access to data for delivery of regulatory activities	1.4-3	Take forward discussion on making available individual patient data (IPD) from clinical trials to assessors	2016	2020	**SUSPENDED**	• 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	Reduced activity regarding clinical data policy in 2018 and 2019	• 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 assessments, 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	BREXIT implications	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	2021		• increased number/proportion of MUMS marketing-authorisation applications and MUMS products on the market • publication of MUMS annual report • publication of the revised MUMS/limited markets guidelines **[completed]**
	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	2020		• increased number of pre-submission requests and submissions of MAAs for vaccines in general and those against transboundary diseases in particular • completion of actions assigned to EMA/CVMP in the joint EMA/HMA action plan on availability of veterinary vaccines
		2.1-10	Participate in the HMA/EMA Task Force on 'Availability of authorised medicines for human and veterinary use'	2016	2020		• completion of actions assigned to EMA concerning veterinary medicines in the joint EMA/HMA task force on

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							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	2017		• 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	2021		• regulatory activities initiated to address identified gaps in the availability of fish medicines **[completed]** • 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 the best use of existing and new antiparasitic veterinary medicine so as to minimise development of antiparasitic resistance	2016	2020		• reflection paper on antiparasitic resistance developed and published • contribution to VICH revision of anthelmintics guidelines • revised guidelines on SmPC for anthelmintics, vector borne diseases and anticoccidials • implemented recommendations of the

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							reflection paper on anthelmintic resistance
Innovation	Promote innovation and the 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	2021		• increasing number of applications in novel therapies • 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	2021		• increased number of applications for innovative medicines • guidance in areas of cell-based therapies and monoclonal antibodies published • 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	2014	2018		• guideline on DNA reactive impurities in veterinary medicines published
		2.1-8	Finalise, in collaboration with ECHA and EC, the procedure for the establishment of MRLs for biocidal substances used in	2015	2018		• role of EMA confirmed with the European Commission for establishment of MRLs for biocidal substances

			animal husbandry, included in the 10-year review programme (long-used 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 • 'other provisions' in Regulation (EC) 37/2010 reviewed

Objective 2: Promote 'Better Regulation'

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	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	2014	2019		• advice provided to the European Commission on request in a timely and accurate manner
		2.2-2	Put in place the revised EMA business processes and IT systems, as envisaged in the revised legislation	2015	2020	Reduced activity in 2018-2019	• gap analysis and impact assessment of new veterinary regulation on existing procedures and technical requirements • level of implementation of IT systems and processes

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	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 • concept developed for proactive risk communication
		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 • data quality controlled and linked to adverse event information in the data warehouse • recommendations for basic surveillance finalised
		2.2-5	Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species	2016	2019	Reduced activity in 2018-2019	• 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	2018		• existing Incident Management Plan tested and updated in light of testing and experience • 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	2018		• templates for assessors finalised **[completed]** • high-quality assessment reports received • 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	2016	2018		• improved performance metrics introduced, demonstrating an improvement in performance • procedural guidance on post authorisations updated

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 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

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
Antimicrobial	Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary	2.4-1	Engage with the EC and Member States to identify and, where possible, prioritise the referral of antimicrobials and	2010	2019		• agreed list of priority and antimicrobial substances for referral to CVMP

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
	medicine		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				
		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	2016	2018		• methodology approved by the steering group **[completed]** • guidance on methodology published
		2.4-4	Provide advice to stakeholders on prudent and responsible use of veterinary antimicrobials	2015	2018		• reflection paper on aminoglycosides published • 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	2018		• EMA-EFSA opinion on how to reduce the need for antimicrobials in food-producing species published on EFSA and EMA website **[completed]** • plan for follow up actions to the recommendations in the above EMA-EFSA opinion

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							drafted **[completed]** • 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]** • opinion on indicators regarding surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals prepared **[completed]** • advice to EC, updating previous advice on classification of antimicrobials used in veterinary medicinal products, provided
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	2019	**SUSPENDED**	• first draft of document published for consultation/adoption **[completed]** • 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	2019	Reduced activity in 2018-2019	• finalised guideline on risk assessment of veterinary medicinal products in groundwater • guideline on higher-tier testing of the effects of veterinary medicines on dung fauna • 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 the environment	2015	2018		• advice provided to the Commission

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	BREXIT implications	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 • mapping of expertise versus needs available
		3.1-2	Deliver curricula for competence development on the basis of the identified needs	2016	2018		• action plan available • number of curricula drafted
		3.1-3	Develop a catalogue of training material through the EU Network Training Centre	2016	2019		• training material catalogue developed • number of training courses available • 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 • number of training sessions provided • 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-	2016	2020		• increase in the number of MNAT procedures • implementation level of the identified improvements

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			authorisation				
		3.1-6	Implement the multinational assessment team approach post-authorisation in a phased approach	2016	2019		• increase in the number of MNAT procedures • implementation level of the identified improvements
		3.1-7	Enhance outreach for academic expertise for services provided to EMA, in particular as regards innovation of medicines	2017	2019		• implementation of the framework of interaction with academia
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 • agreed improvements implemented

Objective 2: Strive for operational excellence

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
Sustainability of the regulatory	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 • key interfaces with network and industry enhanced (as demonstrated using surveys, workshops, etc.)

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							• increased efficiency of the processes
		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 • 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 reporting, signal management and incident management
		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 • 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	Reduced activity in 2018 and 2019	• number of analyses conducted • number of contributions to the EC made
		3.2-7	Participate in the BEMA exercise as per the agreed	2016	2020	**SUSPENDED**	• participation undertaken as per the agreed BEMA cycle

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			BEMA cycle				• review of quality-management framework undertaken and resulting actions implemented
		3.2-8	Provide regular training to BEMA assessors	2016	2020	**SUSPENDED**	• number of assessors trained within a BEMA cycle • 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	2016	2018		• contribution available as per the agreed action plan
	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	2016	2020	*Under Brexit conditions, this entry refers to **prioritised** IT systems and solutions.*	• IT systems/solutions delivered and in operation
		3.2-12	Establish and improve EMA information services[2]	2016	2020		• information services operated with processes that are monitored and continuously improved
		3.2-13	Share information on medicines within the network and with stakeholders	2016	2020	European Medicines Web Portal is **SUSPENDED.**	• access provided to clinical data • European Medicines Web Portal operational **[suspended]** • improved provision of data

[2] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/12/WC500199073.pdf

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							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	2018		• availability of improved templates and a guideline for completing the templates • 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	Reduced activity in 2018 and 2019 *Guidelines that are ongoing will be finalised but no work on new guidelines to take place, unless an imperative public health need is identified by CHMP (e.g. guideline on first-in-human clinical trials).*	• revised procedure and harmonised standards for guideline development and revision • number of new/revised guidelines – *indicator temporarily **suspended***
		3.2-16	Improve the benefit-risk methodology and expand it to post-authorisation updates	2016	2017		• utilisation of the effects table in pilot post-authorisation procedures **[completed]**

Objective 3: Ensure effective communication of and within the network

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	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	2018		• public hearings for safety-related referrals implemented and lessons learned incorporated
		3.3-3	Upgrade the EMA corporate website	2016	2019		• EMA corporate website upgraded
		3.3-4	Develop and implement a social media strategy	2016	2020	Reduced activity in 2018 and 2019	• implementation level of the approved strategy
		3.3-5	Expand the range of digital and multimedia communication tools	2016	2020	Reduced activity in 2018 and 2019	• 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	2020		• all information for patients systematically user-tested • simplification of EMA information to patients and healthcare professionals agreed and implemented • all EPAR summaries available in all EU languages at time of their publication
		3.3-7	Capture communication needs and expectations of partners	2016	2020		• biennial perception survey implemented and analysed

			and stakeholders				
		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	2016	2020	**SUSPENDED**	• European Medicines Web Portal launched

Health emergencies and emerging events	Improve communication on health emergencies	3.3-10	Improve coordination of communication on emergency health threats across the network	2016	2020	Reduced activity in 2018 and 2019 *Focus will be on review of 2017 crisis simulation exercise and learnings.*	• crisis communication strategy endorsed and implemented • report on coordination of safety announcements finalised and improvements implemented **[completed]**

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

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	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	2019		• final output from ADVANCE project available • 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	2016	2020		• mapping of areas of common interest completed

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			common interest, taking into account memoranda of understanding where they exist				• 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	2017	2018		• extended scope achieved and implemented • number of medicinal products/APIs included in the sampling and testing programme
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 • frameworks for interaction with patients and HCPs and/or action plans revised, taking into account experience gained • framework for collaboration with academia implemented
		3.4-5	Increase engagement with GPs, thus fostering interaction with primary care	2016	2019		• virtual expert group with GPs created • 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	Reduced activity in 2018 and 2019 *Stakeholder survey postponed and number of meetings reduced.*	• 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	BREXIT implications	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	Continuous	Continuous		• timely sharing of relevant product information related to GMP inspections, quality defects and shortages
	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	**SUSPENDED**	• draft guidance published
		4.1-3	Develop joint communication and training in collaboration with the FDA	2016	Beyond 2020		• joint communication material developed • one joint training session per year delivered
	Ensure quality of medicines, wherever they are manufactured	4.1-4	Develop a procedure to facilitate populating of 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	2017	Beyond 2020		• increased coverage of GMP inspections in third countries, using fewer network resources
		4.1-6	Implement a risk-based approach to PMF inspections	2012	Beyond 2020	Reduced activity in 2018 and 2019	• implementation level of the risk-based approach to PMF inspections

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

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	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 • 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 • increase in number of non-EU observers participating in inspections
	Facilitate effective information-sharing by using international electronic standards	4.2-4	Implement first iteration of international electronic standards within the EU, and extend to non-EU countries	2012	2019		• implementation plan agreed • 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	2019		• 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	2019	Reduced activity in 2018-2019	• 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	**SUSPENDED**	• registration to EMAS, eco-friendly management system
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, IPRF, IGDRP	2017	Beyond 2020		• mechanism to ensure participation and feedback through pharmaceutical committee and HMA agreed
Use of animals in medicines development	Minimise the 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	2014	2020		• completed guidelines on applying 3Rs
		4.2-10	Improve the guidance available on regulatory acceptance of 3R principles in testing approaches	2014	2018		• availability of up-to-date guidance

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

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	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	2019		• 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	Reduced activity in 2018 and 2019 *Focus on product-related information exchange.*	• GCP initiative with PMDA established • pharmacovigilance inspection initiative with FDA established
		4.3-6 (previously 4.2-3)	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	Reduced activity in 2018 and 2019	• document on good-reliance practices • increased cooperation with the 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	Reduced activity in 2018 and 2019	• agreement on template for sharing confidential information

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
		4.3-5	Explore opportunities to leverage resources in other areas and increase reliance of other regulators on European assessments and outputs	2017	Continuous	Reduced activity in 2018 and 2019	• 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	BREXIT implications	Performance indicator(s)
Training and capacity-building for non-EU regulators	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	Reduced activity in 2018 and 2019	• number of training sessions organised with non-EU regulator participation • number of non-EU regulators' representatives trained
		4.4-2	Extend the Network Training Centre to involve non-EU regulators	2016	Continuous	Reduced activity in 2018 and 2019	• increased number of participants from developing countries / non-EU regulators

Resource outlook

Overview

The dominant influence on both human and financial resource requirements through 2018 and 2019 will be workload and cost attached to the activities needed to facilitate the successful relocation of the Agency, while at the same time coping with additional business-as-usual workload, and ensuring that scientific recommendations and supervision of medicines can continue to be delivered on time and to the same high quality, in light of loss of the UK expertise and anticipated staff loss. It is estimated that the relocation tasks and workload, described in detail in Part I of this document, will require 86 FTEs in 2018 and 62 FTEs in 2019. 11 temporary agents will be required to cope with additional fee-financed workload in 2019.

This will need to be achieved within an environment where 20% or more of experienced staff (i.e. circa 160 FTEs) may be either unable or unwilling to relocate with the Agency, with a consequent challenge to ensure that critical knowledge and skills are transferred and retained.

Concerning budgetary resources, the Agency will endeavour to cope with these additional budgetary challenges within the budgetary envelope originally approved by the budgetary authority and fee revenue, and will monitor the situation regularly to assess if additional funds need to be requested via an amending budget, to meet exceptional costs due to the relocation of the Agency from the UK to the Netherlands.

Concerning human resources, the Agency is requesting that a pool of an additional 40 'Brexit' contract agent posts (5% of existing 'business as usual' staffing levels) is approved exceptionally from 2018, for a limited period of three years. This will provide limited risk mitigation to ensure that relocation tasks are carried out successfully, and that knowledge transfer from experienced to new staff is secured.

Financial resources

In line with workload increase, revenues from fees and charges are expected to grow by €19.4 million (+6.8%) in 2018 compared with 2017, totalling €304.5 million, and are expected to continue to grow in 2019, by €7.7 million (2.5%). These forecasts assume no significant modifications to the fee structures of the General Fee Regulation (297/95) or the Pharmacovigilance Fee Regulation (658/2014) before 2020 - where a 3% increase is assumed - and also assume a continuation of the current and expected trends in workload and main fee application types. The Agency carries out regular reviews of fee forecasts and maintains close contact with the pharmaceutical industry to monitor early indications of possible fluctuations in the applications submitted.

Revenue from the EU contribution for 2018 is budgeted at €32 million, €8 million below the EU Multi-annual Financial Framework level of €40 million, but in line with the decision of the budgetary authority during the 2018 budgetary conciliation meetings to reduce it. As a consequence, the contribution from

the EEA member states is reduced to €521K, or 2.37% of new contributions from the EU budget. The combined EU/EEA contribution is reflected in Annex 2 of this document. Of the overall EU contribution, €10.1 million is funded by the positive balance of the EMA budget outturn in 2016, leaving €21.9 million to be funded out of new 2018 credits from the EU budget (compared to the EU Multi-annual Financial Framework level of €40.0 million). Out of this funding, €13.4 million is earmarked as special contribution to fund fee reductions for applications for orphan medicinal products, leaving €8.5 million to fund some of the non-fee financed general public health activities at EMA.

For 2019 and 2020, the EU contribution is budgeted in line with the EU Multi-annual Financial Framework, set at a flat level between €41.9million and €41.8 million over the period of this multi-annual work programme. As the timeframe of this programming document now extends beyond 2020, a 3% annual increase is assumed for 2021.

In 2018, the Agency will benefit from assigned revenue amounting to €148,000, earmarked for projects under the IMI programme. This will decrease to €19,000 in 2019. This is a significant decrease compared with 2017, where the Agency benefited from over €15.7 million in assigned revenue, primarily linked to the property-related financial incentives, granted by the landlord following the 2014 move to the current premises in London.

Due to the assigned revenue reduction described above, which partially offsets the increases in fee revenues and EU contribution, the overall increase in revenues from 2017 to 2018 is €20.4 million, or 6.4%. In 2019, revenues are expected to increase by a further €17.0 million, with €7.6 million generated by additional fee income and €9.4 million by EU contribution, in line with the Multi-annual Financial Framework.

Budgetary expenditure is planned to increase by €29.9 million (+9.7%) in 2018, and by a further €17.0 million in 2019. These figures include €14,762K of Brexit-related relocation costs in 2018, and €43,467K of further Brexit-related costs in 2019.

The 2018 Brexit costs are broken down into: €6,397K in Title I, of which the main elements are staff removal allowances and expenses associated with departure from the Agency, duty travel and the cost of 20 additional contract agent FTEs (€0.7 million) to cope with additional relocation workload and knowledge transfer; €7,389K in Title II, primarily covering the IT infrastructure aspects of the relocation; and €976K in Title III, where additional IT project costs are partially offset be a reduction in meeting reimbursements to delegates, due to a reduced capacity to hold non-plenary scientific meetings in 2018, in line with the Brexit-related business continuity plan outlined in Part I of this document.

The 2019 Brexit costs are broken down into: €18,920K in Title I, of which the main element is staff relocation allowances and expenses, with the remainder including the cost of 40 additional contract agent FTEs (€1.7 million) to cope with additional relocation workload and knowledge transfer; €9,046K in Title II, primarily covering the physical infrastructure aspects of the relocation; and a relatively small saving of €776K in Title III, due to a reduction in meeting reimbursements to delegates, due to a reduced capacity to hold non-plenary scientific meetings in 2019, in line with the Brexit-related business continuity plan outlined in Part I of this document.

In addition, the 2019 budget includes provisional appropriations under Title IX of the budget, totalling €16,277K earmarked for unforeseen Brexit-related expenditure. This amount is set at a level to be equivalent to the cost of continuing to settle property-related costs at the current premises throughout

the full year 2019. As set out in the negotiation directives of the Council of 22 May 2017, for the negotiation of an agreement with the United Kingdom, setting out the arrangements for its withdrawal from the European Union, the United Kingdom should fully cover any specific costs related to the withdrawal process. However, without prejudice to EMA's position that the Agency's relocation to a new host Member State is a direct effect of the UK notification of its decision to leave the European Union, which is an event beyond EMA's control, on the basis of sound financial management it seems prudent for the Agency to budget its capacity to pre-finance these, or other, withdrawal costs in 2019, prior to a final settlement and in line with the negotiation directives of the Council cited above.

It should be noted that the Brexit-related costs outlined above do not include any budget appropriations for fitting out the temporary or permanent premises in Amsterdam, for which there are no clear indications yet. Equally, any one-off financial incentives described in the bid by the new host Member State are not included in either the 2018 or preliminary 2019 budget figures, pending formal agreement concerning the new premises, which is itself subject to finalisation of the building approval process, in compliance with Article 88 of the Financial Regulation. In the event that unexpected costs arise as the relocation process progresses, these will need to be addressed through an amending budget.

Furthermore, neither the 2018 or 2019 budgets include provision for early termination costs, in relation to the existing premises in London, under the assumption that a) EMA is not responsible for the early termination of the current lease agreement; and b) should any such costs arise they will be borne by the UK, in line with the negotiation directives of the Council cited earlier. In the event that any such liabilities arise and need to be pre-financed prior to final settlement, these will also need to be addressed through an amending budget.

Finally, it should also be noted that both 2018 and 2019 budgets assume that the relocation transition will proceed as planned, including the assumption that approximately 80% of current staff will be prepared to relocate with the Agency. If the transition does not proceed as planned, resulting in a significantly lower proportion of experienced staff relocating, then both work programme and budget assumptions may need to be revised.

Please refer to Annex I of this document for a more detailed Activity Based Budget analysis of how human and financial resources are allocated to the 'business as usual' and Brexit activities of the Agency in 2018 and 2019.

Human resources

The Agency has been 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. EMA temporary agent posts will decrease from 596 in 2017 to 591 in 2018, to fully comply with these requirements, taking into account the 3 additional posts, authorised by the Budgetary Authority for 2016. However, EMA is also requesting 11 additional fee-financed posts in 2019, to compensate for additional fee-financed workload (reflecting a 2.5% increase in income from fee-financed activities).

For 2018, the Agency is requesting 180 FTE (full-time equivalent) contract agents (CAs) and 39 seconded national experts (SNEs), in addition to the temporary agent posts described above, to maintain the 'business as usual' workload of the Agency. This reflects a relatively slight readjustment between the split of CAs and SNEs proposed in the draft programming document 2018-2020 (+6 CAs and -6 SNEs). Taking into account the exceptional Brexit challenges the Agency will be facing in 2018 and 2019, EMA is also requesting approval to employ an additional 40 contract agents for a three-year period to ensure a smooth relocation and knowledge transfer, equating to total of 20 additional CA FTEs in 2018 and increasing to a total of 40 additional CA FTEs in 2019 and 2020, before leaving the Agency in 2021. These additional resources would be funded within the existing fee allocations.

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.

Growth of existing tasks

The Agency envisages some increase in workload related to existing tasks. Fee-related activities will continue to grow steadily as reflected in the 2018 6.8% increase in fee-related revenues. Other activities are also increasing as a result of changes of legislation. For example, the implementation of the new general data protection legislation or the impact of the new veterinary regulation will need to be assessed for resource implications.

Efficiency gains / negative priorities / decrease of existing tasks / redeployment of resources in view of budgetary constraints

EMA priority under Brexit circumstances is to ensure that the assessment and supervision of medicines continues to be delivered on time and to the same high-quality level that the Agency's stakeholders have come to expect, and that patients in Europe continue to have access to high quality, safe and effective medicines. The Agency will, for as long as possible, operate under a 'scaled down, business as usual' scenario in many areas (in line with its business continuity plans), while preparing both for the physical move to the new EMA premises in Amsterdam, and for the impact on the Agency’s operations.

However, the evolving situation may require a further shift in priorities and focus. As the scale of impact on EMA becomes known, the Agency may need to review its priorities and work programme, and further postpone activities that do not have direct public health impact, to guarantee the continued delivery of its core operations. This is outlined in the dedicated chapter at the beginning of this document, as well as in detailed business continuity plans that the Agency has developed for this situation.

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

Establishment plan

Year	Management Board request	EC proposal	Adopted by Budgetary Authority
2013	611	611	611
2014	611	599	599
2015	599	599	599
2016	636	599	602
2017	596	596	596
2018	591	*591*	*591*

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

Note: In 2018, the Agency will, notwithstanding additional Brexit-related workload, reduce 5 TA posts to comply with the Commission Communication 2014-2020 target of 588 TA posts (plus the 3 additional posts authorised by the Budgetary Authority for 2016). Please note that if the Agency was only applying the 5% staff reduction, the establishment plan target would be set at 618 FTEs (plus the 3 additional posts authorised by the Budgetary Authority for 2016).

Part III: Work programme 2018

EMA priority in Brexit circumstances is to ensure that the assessment and supervision of medicines continues to be delivered on time and to the same high-quality level the Agency's stakeholders have come to expect, and that patients in Europe continue to have access to high quality, safe and effective medicines. The Agency will, for as long as possible, operate under a 'business as usual' scenario, while preparing both for the physical move to the new EMA premises in Amsterdam, and for the impact on the Agency's operations.

However, the evolving situation may require a shift in priorities and focus. Work programme 2018 is developed in line with, and reflects the current BCP, while assuming minimum disruption to Agency's activities. It also reflects current impact on the planned activities: a column 'Brexit implications' has been added to the tables outlining additional activities EMA has been planning for 2018, and for those entries that are either temporarily reduced or suspended during this time, the respective note has been added. The suspended activities have also been greyed-out.

As the scale of impact on EMA becomes known, the Agency may need to review its priorities, postpone other, less urgent activities to guarantee the continued delivery of its core operations, and revise the work programme and budget, to ensure realistic representation of the work that can be done under Brexit conditions.

Structure of the work programme

The work programme is a reflection of the European Medicines Agency's (EMA) priorities and main focus areas for 2018. It describes the objectives and activities planned for 2018. 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 2018.
- **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 2018, 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 2018 is added at the end of the relevant sections of the work programme. 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. 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 promoting 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.
- **Designation of orphan medicines** and related maintenance procedures. To foster the availability of medicines for rare diseases, the Agency gives its opinion on the designation of medicinal products as orphan products and on maintenance of this status at the time of marketing authorisation. The designation status granted by the European Commission allows sponsors and marketing-authorisation holders to benefit from a number of important incentives, designed to encourage the development of products which, for economic reasons, would otherwise not be pursued.
- **Development of medicines for children**. To improve the availability of medicinal products specifically authorised for children, the Agency issues decisions on paediatric investigation plans (PIPs), with or without deferrals, or — where justified — agrees to waivers. When the studies or measures

are completed, 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, of 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 for scanning the horizon and exchanging information and establishing networks to develop and maintain expertise in the field. The ITF works closely with our partners within the network, academia 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, by making the regulatory support available at national and EU level more visible and attractive to innovators since early stage. In addition, it reinforces dialogue with innovators with a wider EU exposure and provides a platform for regulators to share and improve the flow of knowledge from early stage innovators, to NCAs and to EMA scientific committees. It identifies and encourages sponsors of promising drug development projects to move into 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 older-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

n/a

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Scientific advice/protocol assistance pre-submission meetings	89	117	118	129
Scientific advice and protocol assistance requests, of which:	510	582	630	682
Parallel scientific advice with international regulators requests	3	6	3	5
Joint scientific advice with HTA bodies requests	30	23	29	32
Scientific advice for PRIME products	n/a	4	28	24
Protocol assistance	137	126	159	165
Novel technologies qualification advice/opinions	20	14	19	22
PRIME eligibility requests received	n/a	84	81	100
Scientific advice finalised	386	439	490	522
Protocol assistance finalised	139	122	156	155
Orphan medicines applications, of which:	258	329	260	250
Parallel orphan applications with international regulators	86	96	55	60
Submitted applications on the amendment of an existing orphan designation	1	4	2	5
Oral explanations for orphan designation		87	80	95
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	515	549	630	500
Finalised procedures for compliance check on PIPs	67	73	67	70
Annual reports on paediatric deferred measures processed	172	189	197	170
EMA paediatric decisions processed	319	369	402	350
Requests for classification of ATMPs	61	60	46	50
Innovation Task Force briefing meetings	35	41	33	25
Innovation Task Force Art 57 CHMP opinion requests	0	2		1

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Scientific advice/protocol assistance procedures completed within regulatory timeframes	100%	99.5%	100%	100%
Products included in PRIME scheme (% of applications)		17.9%	23.5%	22%
Increase in scientific-advice requests	-8%	14%	8%	0%
SME requests for SA (% of total SA requests)	32%	30%	31%	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		BREXIT implications
			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	Reduced activity in 2018-2019, limited to high-level EMA presence in IMI scientific Committee, with no proactive identification of new research topics
		Identify recurring topics from ITF discussions with the highest potential benefit in terms of driving science and innovation	2015	After 2020	**SUSPENDED**
		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	**SUSPENDED**
	1.3-8	Reinforce collaboration via EU innovation Network with academia and research hospitals that could benefit most of the innovation offices regulatory	2018	2020	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		support			
	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 2019	
	3.2-2	Establish a platform for project-specific engagement with developers, to optimise activities during the development phase.	2017	2020	Reduced activity in 2018-2019
	1.3-5	Support a coordinated approach to ATMP-related activities in the Agency and maximise the outputs by involving all relevant actors and stakeholders	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 to the activities of the International Neonatal Consortium (INC)	2015	2020	Reduced activity in 2018-2019
		Contribute scientifically to methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders	Before 2015	2020	**SUSPENDED**
	1.3-5	Review the experience with the "Orphan Notice" and interaction with stakeholders	2017	2018	Reduced activity in 2018
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	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	1.2-2	Build Network capacity to support accelerated development pathways (including PRIME), with a focus on quality aspects on critical development path	2016	2018	
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	3.2-6	Analyse experience with 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	2020	Reduced activity in 2018 and 2019
		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	2020	
Contribute to removing obstacles to optimal utilisation of biosimilar medicines	1.3-5	Coordinate efforts and drive activities to enhance the benefits of biosimilar medicines for public health	2017	2019	
Ensure and run highly effective and efficient processes to deliver pre-	3.2-2	Review and implement optimised operations for all functions supporting medicines' development, including knowledge management	2017	2019	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
authorisation activities					

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	34,616	41,640
Human resources (FTEs)	90	87
of which human resources – Brexit preparedness (FTEs)	n/a[2]	1

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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 regard to the requirements for demonstrating quality, safety and efficacy of a medicine.

The scientific review of the committees' evaluation is documented in an assessment report, which is made publicly available as a European public assessment report (EPAR).

Drivers

The complex path to patient's access to medicines, where marketing authorisation is just one of the steps on the medicine's path to patients, requires a coordinated approach towards robust and sound outcomes. The need to consider the involvement and requirements of other stakeholders leads to increased cooperation with them and the 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.

Increasing stakeholder expectations to have medicines available to treat various conditions, in combination with the continuous need for flexible and fast reaction to new public-health threats, highlight the importance of contributing to faster patient access to medicines on the market, while maintaining the quality of scientific assessments. To improve the use of various mechanisms for bringing medicines to market, the available regulatory tools that allow patient access to medicines for conditions with unmet medical need, including accelerated assessment and conditional marketing authorisation, have been reviewed. The Agency is committed to working in collaboration with the European Commission and the STAMP expert group in the development and implementation of tools to improve timely access of medicines for patients.

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.

Transparency of the decision-making process throughout the lifecycle of medicines will remain a key driver. The initial evaluation is thus subject 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
	2015	2016	2017	2018
Number of MAA pre-submission meetings	102	85	63	60

	Results			Forecasts
	2015	2016	2017	2018
Initial evaluation applications, of which:	111	114	90	109
New non-orphan medicinal products	36	41	32	49
New orphan medicinal products	25	27	19	26
Similar biological products	12	12	17	15
Generic, hybrid and abridged products	37	31	15	15
Scientific opinions for non-EU markets (Art 58)	1	0	1	3
Paediatric-use marketing authorisations	1	1	2	1
Number of granted requests for accelerated assessment		12	10	10
Number of consultations of SAGs / Ad-hoc expert groups in the context of MAAs	7	8	14	22
Reviews on the maintenance of the orphan designation criteria at MAA stage		20	24	40

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Applications evaluated within legal timeframes	100%	99%	100%	100%
Average assessment time for new active substances and biosimilars	200.7	197.2	175.7	205
Average clock-stop for new active substances and biosimilars	138.4	136.1	136.9	180
% of requests granted for accelerated assessment		48%	63%	70%
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment		43%[1]	58%	75%
% of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	82%	63%	69%	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		97%	95%	90%
% of comments on product information submitted during assessment procedure and taken on-board by assessors			95%	95%

	Results			Targets
	2015	2016	2017	2018
% of therapeutic guidelines progressed to next step or finalised (vs planned)[2]			60%	70%[2]
% of early background summaries drafted and sent to assessment teams (vs planned)			100%	100%
% of outcomes/results of workshops on therapeutic objectives published on EMA website			90%	100%

[1] In 2016, 11 MAA procedures were started under the accelerated assessment (AA). By 31 December 2016, 3 of these were completed as AA, and 4 had reverted to standard timelines. Four procedures were still ongoing and are not counted towards the result of the indicator.
[2] under Brexit conditions 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		BREXIT implications
			Start	End	
Ensure and run highly effective and efficient processes to deliver initial evaluation activities	3.2-14	Streamline and strengthen the process of input by Quality Working Party and other quality of medicines working groups to the relevant parts of assessment report	2015	2018	
Provide high-quality, robust, scientifically sound and consistent scientific assessments	3.2-15	Continuously improve the tools (guidance, and databases) available to EMA staff, supporting scientific evaluation activities of the committees	Before 2015	2018	Reduced activity in 2018
	3.2-14	Strengthen the support in clinical pharmacology and non-clinical aspects to centrally-authorised products along their life-cycle	Before 2016	2019	
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	2018	Beyond 2020	… (Except workshop on digital Product Information which will be held in Q3 2018)

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Reduce time-to-patient of medicines through the 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	

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	33,537	32,682
Human resources (FTEs)	87	76
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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 regard 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 an 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
	2015	2016	2017	2018
Variations applications, of which:	5,999	6,204	6,267	6,526[1]
Type-IA variations	2,864	3,019	3,080	3,135[1]
Type-IB variations	1,980	2,000	2,054	2,084
Type-II variations	1,155	1,185	1,133	1,307[1]

	Results			Forecasts
	2015	2016	2017	2018
Line-extensions of marketing authorisations	14	25	21	20
PASS scientific advice through SAWP	1	2	1	2
Number of consultations of SAGs / Ad-hoc expert groups in the context of post-authorisation activities		6	15	10
Renewal applications		107	94	85
Annual reassessment applications		25	19	27
Transfer of marketing authorisation applications		35	47	291[1,2]
Article 61(3) applications		216	234	500[1]
Post-Authorisation Measure data submissions		1,016	795	900
Plasma Master File Annual update and variation applications		19	22	17

[1] include current estimates (and assumption for split between 2018 and 2019) for additional Brexit-related workload.
[2] forecast may change, depending on the applicant's readiness to transfer before April 2019

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Post-authorisation applications evaluated within the legal timeframes	99%	99%	99%	100%
Average assessment time for variations that include extension of indication	160	165	162	180
Average clock-stop for variations that include extension of indication	65.5	73	67	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%

Additional objectives and activities

In addition to delivering its regular post-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		BREXIT implications
			Start	End	
Ensure and run highly effective and efficient processes to deliver post-authorisation activities	3.2-1	Optimise processes that include interactions among multiple Committees	2017	~~2018~~ 2020	Reduced activity in 2018 and 2019 End date extended, to consider Brexit implications.
Further promote the use of scientific advice throughout the lifecycle of the product, including further development of authorised medicines (e.g. extensions of indications, post-authorisation safety and efficacy studies)	1.3-6	Analyse the impact of scientific advice on the likelihood of obtaining a positive opinion for extensions of indication	2017	2018	**SUSPENDED**

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	89,316	95,664
Human resources (FTEs)	92	94
of which human resources – Brexit preparedness (FTEs)	n/a[2]	1

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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, or by the marketing-authorisation holder that markets the medicine.

Drivers

The 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 is implementing public hearings for safety-related referrals.

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Pharmacovigilance referrals started	5	8	7	8
Non-pharmacovigilance referrals started	16	10	3	8

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Referral procedures managed within the legal timelines	100%	100%	100%	100%

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
n/a					

Resources

	2017[2]	2018
Financial resources (cost, thousand Euro)[1]	1,952	1,732
Human resources (FTEs)[1]	8	6
of which human resources – Brexit preparedness (FTEs)	n/a[3]	0

[1] Excludes resources related to pharmacovigilance referrals

[2] figures based on the 2017 provisional accounts

[3] EMA ORP BCP was developed in March/April 2017 and at the time of preparing the activity-based budget 2017, no staff was earmarked for Brexit activities

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.

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. Therefore, the Agency will further 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. New regulatory science results will become available (for example from the ADVANCE and WEBRADR projects) and existing results that have demonstrated efficiency gains will be fully implemented (notably for signal detection based on the EU PROTECT project). In addition, the availability of new IT tools will further support the conduct of pharmacovigilance. Such evidence-based process improvements and roll-out of IT (including the new EudraVigilance functionalities) help deliver better pharmacovigilance and respond to calls for simplification.

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 rather than replaces more traditional data sources, notably clinical trials. The work of the HMA/EMA joint big data task force will continue to develop the approach of European Regulators in this area.

Society wants to see the impact of pharmacovigilance and calls for an increased transparency and engagement with patients and healthcare professionals. This will drive a number of work items, including the conduct of public hearings and work to measure the impact of pharmacovigilance (based on the PRAC Impact strategy adopted in January 2016).

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Number of signals, peer-reviewed by EMA	2,372	2,076	2,062	1,800
Number of signals, assessed by PRAC, of which:	102	94	82	75
Signals validated by EMA	61	48	43	35
Signals validated by Member States	41	46	39	40
PSURs (standalone CAPs only) started	512	518	555	557
PSUSAs started	268	243	365	356
Number of imposed PASS protocol procedures started	31	12	6	20
Number of imposed PASS result procedures started	2	3	6	10
Number of emerging safety issue notifications received	34	21	21	15

	Results			Forecasts
	2015	2016	2017	2018
Number of notifications of withdrawn products received	160	118	302	220
Cumulative number of products on the list of products to be subject to additional monitoring	261	301	336	320
Number of Incident Management Plans triggered		7	4	9
Number of non-urgent information (NUI) or Rapid Alert (RA) notifications submitted through EPITT		49	61	55
Number of external requests for EV analyses		34	32	40
Number of MLM ICSRs created		8,495	14,193	11,000

Performance indicators

	Results			Targets
	2015	2016	2017	2018
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	98.5%	100%	100%	95%
Protocols and reports for non-interventional imposed post-authorisation safety studies, assessed within the legal timeframe	98.4%	100%	100%	100%
Reaction-monitoring reports supplied to the lead Member State monthly	100%	97%	97%	100%
PRAC recommendations on signals and translation of labelling changes in EU languages published		100%	100%	100%

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		BREXIT implications
			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, and to provide input into the EC report on EU network pharmacovigilance tasks in 2018	ongoing	ongoing	
	3.4-1	Support ECDC in the delivery of the vaccine risk/benefit blueprint, as a follow-up to implement the output of the IMI ADVANCE project, by providing governance and code of conduct for such studies and regulatory support, as required	2016	2019	Reduced activity in 2018 and 2019
	3.3-2	Conduct a lessons-learned exercise after one year's experience of public hearings	Q1 2017	Q1 2018	
	1.4-1	Launch public consultation (2018) and finalise (2019) GVP product- or population-specific considerations III on pregnant and breastfeeding women	2016	2019	Reduced activity in 2018 and 2019
		Finalise GVP product- or population-specific considerations IV on the paediatric population. Conduct public consultation and finalise GVP product- or population-specific considerations V on geriatric population	2016	2018	Reduced activity in 2018
		Consider review of GVP Module VII on Periodic safety update report and GVP Module XVI on Risk minimisation measures: selection of tools and effectiveness indicators	2016	2018	Reduced activity in 2018
Maximise benefits to public health promotion and	1.2-4	Build and maintain capacity for EU Network analysis of epidemiological data	2016	2020	Reduced activity in 2018 and 2019

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through the use of high-quality data, information and knowledge		Further develop and maintain inventory to facilitate access to data on real-world data	2016	2020	Reduced activity in 2018 and 2019
		Initiate at least four EMA studies on real world evidence data	2016	continuous	Reduced activity in 2018 and 2019
		Review the scientific advice process for post-authorisation studies, to identify possible process improvement opportunities	2016	2020	Reduced activity in 2018 and 2019
	1.4-4 1.4-2	Continue leadership of work package for WebRADR on governance aspects of social media monitoring	Before 2016	2018	
	1.2-5	Based on evaluation of the options and feasibility, provide increased support to the use of registries for targeted products on the EU market from learnings from the pilot process.	Before 2016	continuous	
		Implement the recommendations from 2017 guidance on key principles for use of registries from a regulatory perspective	Before 2016	2019	
	1.4-1	Implement phase 1 of the pilot on the new process of signals submitted by MAHs, including analysis of operational capacity, functionality of EV tools, added value of MAH involvement, and areas of process and guidance improvements (2018-2019). Analyse the outcome of phase 1 of the pilot and initiate phase 2 of the pilot (2019-2020).	Before 2016	2020	

Resources

	2017[2]	2018
Financial resources (cost, thousand Euro)[1]	42,720	41,175
Human resources (FTEs)[1]	117	106
of which human resources – Brexit preparedness (FTEs)	n/a[3]	0

[1] Includes resources related to pharmacovigilance referrals and ICT resources involved in pharmacovigilance projects

[2] figures based on the 2017 provisional accounts

[3] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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 a 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 will 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. In 2018, an audit of the EU Portal and Database will take place and, on the basis of the audit report, the EMA Management Board will confirm if the EU Portal and Database have achieved full functionality. The Regulation can then become applicable in the second half of 2019.

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Herbal monographs, new	14	8	4	5
Herbal monographs, revised	3	9	8	12
List entries	0	2	0	1

Performance indicators

	Results			Targets
	2015	2016	2017	2018
n/a				

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Strengthen the quality of the scientific review processes	3.2-14	Establish a pragmatic approach setting European standards for herbal combination products	2016	~~2018~~ 2020	**SUSPENDED** End date extended, to consider Brexit implications
Promote application of harmonised international standards		Provide technical and scientific contribution to the development of ICH safety guidelines (Carcinogenicity assessment document evaluation for ICH S1)	Before 2015	2019	
Implement the Clinical Trials Regulation	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	2018	
Reduce prescription medicines misuse		Cooperate with Horizontal Drug Group of the Council on the topic of misuse and dependence on prescribed medicines	2017	2018	
Effectively manage risks to the environment arising from the use of human medicines		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	2018	2020	

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
		environment			

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	13,852	13,557
Human resources (FTEs)	23	26
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

1.7. 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 2018-2019. The deliverables for 2019 provide a high-level overview and will be detailed during the preparation of the final work programme 2019.

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 2018	Budget 2018
Pharmacovigilance programme					
EudraVigilance auditable requirements **[continues]**	• Directive 2001/83/EC, art.107 • Regulation (EC) 726/2004, art.24 • Commission implementing	Q4 2013	Q2 2018	• Implementation of post go-live enhancements • Lessons learned • Project closure	€351,587

Programme / Project	Legal basis	Start date	End date	Deliverables 2018	Budget 2018
	regulation (EU) 520/2012, art.18, 23, 25-28 and chapter V				
Clinical trials programme					
EU portal and clinical trials database **[continues]**	• Regulation (EC) 536/2014, art.80-82	Q3 2014	2019	• Deliver the EU portal and database release for audit • Conduct of audit of EU portal and database • Prepare training materials and commence delivery of training to stakeholders • Prepare user guidance documentation • Implement a communication plan	€5,260,276
Safety reporting **[continues]**	• Regulation (EC) 536/2014, art.40-43	Q4 2014	2019	• Deliver safety reporting requirements • Integrate safety reporting and EU portal and database systems • Prepare training materials and commence delivery of training to stakeholders • Prepare user guidance documentation • Implement a communication plan	€1,860,237
EudraCT & EU Portal (EudraCT legacy) **[continues]**	• Regulation (EC) 536/2014, art.80-82, 98	2018	2020	• Initial business case completed for approval • Design completed	€1,502,080
Standalone projects					
eCTD4 pre-project activities **[suspended]**	n/a	2018	2018	• Environmental analysis to examine available eCTD4 tools • Impact assessment to provide an estimation of cost for adapting the EMA systems to eCTD4	€54,228

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[3] 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

[3] Louise H Taylor, Sophia M Latham and Mark E J Woolhouse, Phil. Trans. R. Soc. Lond. B (2001) 356, 983 -989. 'Risk Factors for human disease emergence'

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-year 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 put in place the Ad hoc 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 on and are implementing an action plan to help increase the availability of veterinary vaccines in the EU.

Drivers

In 2018, the focus in terms of pre-authorisation activities will remain on promoting access to market of veterinary products, particularly those based on novel technologies, and those indicated for MUMS/limited markets and vaccines.

In 2018, the ADVENT (established in 2015) will continue 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 to promote authorisation of vaccines for use in animal-health emergencies. The Agency's contribution to these objectives, through the delivery of an agreed action plan, will continue to be a major driver during 2018 and beyond.

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

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Innovation Task Force briefing requests	2	4	7	4
Scientific advice requests received	27	18	17	25
Requests for classification as MUMS/limited market, of which	30	25	25	25

	Results			Forecasts
	2015	2016	2017	2018
Re-classification requests	1	6	8	5

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Scientific advice procedures completed within set timeframes	100%	100%	100%	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		BREXIT implications
			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	
		Develop training material on the latest revision of MUMS guidelines on data requirements and other guidance	2018	2018	
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	2021	
		Conduct (2018) and evaluate (2019) user surveys on improvements identified as a result of the measures recently put in place to support innovation and development of medicines	Q1 2017	2019	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		(ADVENT, ITF, scientific advice)			
		Organise exchange with stakeholders on innovation	2018	2019	
	2.1-6	Develop and publish Q&As developed by ADVENT in priority areas for technologies that are new to veterinary medicine	Before 2016	2019	
		Develop an action plan on specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials, to control infectious diseases in animals	2017	2018	
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	
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	2019	
		Develop a reflection paper on promoting availability of veterinary vaccines in emergency situations	2016	2019	
		Follow up from the focus group on field efficacy trials, on how to improve predictability to applicants with respect to the requirements for field efficacy trials	2018	2018	
	2.1-4	Provide advice and input to address gaps in	2017	2020	

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
		availability identified in the FishMed Plus Coalition, where relevant to CVMP activities			
	3.2-15	Revise guideline on anticoccidials used for the therapy of coccidiosis	2017	2019	
		Revise guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases	2015	2019	
		Revise Note for guidance on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use	2015	2019	**SUSPENDED**
		Develop a concept paper for revision of SmPC guideline for anthelmintics	2016	2018	
	2.1-11	Finalise an action plan for CVMP on how to follow up on the recommendations of the reflection paper on anthelmintic resistance	2018	2018	

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	1,286	929
Human resources (FTEs)	2	2
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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 regard 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.
- Implementation and fine tuning of streamlined business processes will continue in 2018, to provide increased harmonisation and efficiency in procedures.

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Initial evaluation applications	10	21	17	18
New MRL applications	4	6	3	3
MRL extension and modification applications	3	1	3	4
MRL extrapolations	1	0	0	1
Art 10, Biocides	0	0	0	0
Review of draft Codex MRLs	0	5	0	5

Performance indicators

	Results			Targets
	2015	2016	2017	2018
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		BREXIT implications
			Start	End	
Provide high-quality and consistent scientific outputs	2.2-7	Finalise training material on revised guideline, procedures and templates for CVMP assessment reports, and provide training on these, with emphasis on benefit-risk	2017	2018	
Ensure the establishment of	2.1-9	Provide technical support to the European	Before	2018	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
MRLs supports the safe use of veterinary medicines in regard to their impact on human health		Commission in drafting implementing acts, specified in Regulation 470/2009	2015		
		Develop principles for the approach for MRL for biologicals	2016	2018	
	2.1-9	Review MRL entries in the Annex of Regulation 37/2010 with regard to substances with restrictions of use, and recommend on a risk assessment basis the ones to be maintained and the ones to be deleted	2017	2018	
	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	
Promote uptake of harmonised standards at international level	4.2-5	Reflect on the need for increased international harmonisation in relation to the evaluation of consumer safety of veterinary medicines	2018	2020	Reduced activity in 2018-2019

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	4,616	4,903
Human resources (FTEs)	16	15
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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 regard 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.

An increased number of Brexit-related, post-authorisation activities are anticipated in 2018-2019, when marketing authorisation holders are obliged to move activities such as manufacturing (including batch release) or pharmacovigilance responsibilities away from UK-based companies and furthermore to transfer MAs away from UK-based MA holders.

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Variations applications, of which:	373	410	446	392[1]
Type I A variations	196	243	238	225[1]
Type I B variations	116	126	130	120
Type II variations	61	41	78	47[1]
Line extensions of marketing authorisations	3	3	5	4
Transfers of marketing authorisations				4[1]

[1] includes current estimates (and assumption for split between 2018 and 2019) for additional Brexit-related workload.

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Post-authorisation applications evaluated within the legal timeframes	100%	100%	100%	100%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Ensure efficient delivery of post-authorisation procedures	2.2-8	Revise and update post-authorisation procedural guidance	2018	2018	

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	5,748	5,187
Human resources (FTEs)	11	11
of which human resources – Brexit preparedness (FTEs)	n/a[2]	1

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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 so 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 significantly fewer referral procedures compared to the high workload that has been experienced for referrals in recent 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 in 2018-2019. Some of these referrals might be triggered by the European Commission as part of 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
	2015	2016	2017	2018
Arbitrations and Community referral procedures initiated	7	7	1	4

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Referral procedures managed within the legal timelines	100%	100%	100%	100%

Additional objectives and activities

In regard to referrals in the veterinary area, the Agency will continue its regular activities in the coming years.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	2.4-1	Provide the EC with CVMP recommendation on prioritisation developed in 2017, for the EC to consider the need for further referrals	2018	2019	

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	666	768
Human resources (FTEs)	2	3
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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 still 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 proposals for new 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
	2015	2016	2017	2018
Periodic safety-update reports (PSURs)	159	175	161	160
Total AERs, of which:	31,467	38,162	50,885	30,000
Adverse-event reports (AERs) for CAPs	14,387	18,419	26,671	13,500
Adverse-event reports (AERs) for NAPs	17,080	15,257	24,214	16,500

Performance indicators

	Results			Targets
	2015	2016	2017	2018
PSURs evaluated within the established timeline	99%	98%	98%	90%
AERs for CAPs monitored within the established timelines	98%	96%	98%	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		BREXIT implications
			Start	End	
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes	2.2-4	Support Member States in the upload and quality control of data into the European database of veterinary medicinal products, and link this data to adverse event reports for CAPs and non-CAPs, to allow signal detection	Before 2016	2018	Reduced activity in 2018
		Evaluate pilot on safety surveillance and finalise the recommendation for basic surveillance	2018	2018	Reduced activity in 2018
	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	2019	Reduced activity in 2018-2019
	2.2-6	Revise the process for incident management plans, in light of the lessons learned from a simulation exercise and recent experiences	2016	2018	
Provide consistent, high-quality information on pharmacovigilance topics to stakeholders and partners	2.2-3	Publish the veterinary pharmacovigilance annual bulletin	2018	2018	
		Develop and implement criteria for proactive risk communication concerning CAPs	2018	2020	Reduced activity in 2018-2019

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	1,765	815
Human resources (FTEs)	9	4
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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:

- **Revision of the legislation governing veterinary medicines**. The Agency will provide technical support to the European Commission in relation to the discussion of the EC's proposals by the European Parliament and the Council, following the publication of these proposals in September 2014.
- **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

Discussion to finalise a new regulation governing veterinary medicinal products is expected to reach a conclusion before the end of the current term of the European Parliament, in early 2019 at the latest. The new regulation aims to promote availability and reduce the administrative burden for both industry and applicants, and will have a significant impact on the work of the Agency with respect to veterinary medicines. The Agency faces a period of intense activity in the run-up to adoption of the new regulation, and during the implementation period that will follow, 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. 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 the 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 the '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.

Following the 2014 publication 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, a mandate has been received to further elaborate on those recommendations during 2018. The Agency will continue to provide input in measures initiated by the Commission, such as additional advice, referrals, and the production of guidance documents, including joint recommendations and opinions with other European agencies (ECDC and EFSA).

In addition to the continued annual monitoring and reporting on the consumption of veterinary antimicrobials across the EU, the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) will focus, over the next years, on providing guidance on the collection and analysis of data by animal species, including further exploration of 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). The Agency will continue to contribute to its implementation. A particular focus has been to foster the VICH Outreach programme, which aims to extend uptake of VICH guidelines to countries throughout the world with less developed regulatory systems.

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
n/a				

Performance indicators

	Results			Targets
	2015	2016	2017	2018
n/a				

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Support increased availability of veterinary medicines	2.1-3	Conclude the report on the pilot project on harmonisation of old veterinary antimicrobials (PPHOVA) and consider follow up	2018	2018	
	2.1-11	Develop a reflection paper on resistance in ectoparasites	2015	2019	
		Contribute to EU position for the revision of VICH guidelines on anthelmintics (GL7, 12-16 and 19-21)	2016	2020	
	2.2-1	Provide necessary input to the European Commission during the ordinary legislative procedure for new veterinary legislation	Before 2015	2019	
	2.2-2	Set up and develop a work plan for an ad hoc expert group, to explore practical measures that could form the basis for harmonisation of the SmPCs of veterinary medicinal products, in the context of the revision of the veterinary medicines legislation	2016	2021	
	2.1-10	Contribute to the EMA/HMA task force on availability of authorised human and veterinary	2016	2020	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		medicines			
	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	2019	
Provide high-quality and consistent scientific outputs	3.2-15	Revise guideline on summary of product characteristics for antimicrobials	2017	2019	
	2.2-7	Consider and develop training in cooperation with EU NTC in areas identified by CVMP, to build network assessment capacity	2018	2019	
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	2021	Reduced activity in 2018-2019
	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	2019	
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine in 2018-2019	2.4-4	Finalise the reflection paper on aminoglycosides and publish for consultation the reflection paper on extended-spectrum penicillins	2015	2018	
	2.4-3	Finalise guidance on provision of data on antimicrobial use by animal species from national data collection systems	2018	2018	
		Publish reports on existing systems within the EU for collection of data on use of antimicrobials in	2018	2018	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		chickens and cattle			
		Set up a system for the 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	2019	
	1.1-2	Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	2018	2019	
	1.1-3	Contribute to the 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)	2018	2019	
	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	2018	2019	
	2.4-5	Provide advice to the EC, in collaboration with ECDC and EFSA, on updating the previous advice on the impact on public health and animal health of the use of antibiotics in animals (categorisation of antimicrobials and early hazard characterisation)	2017	2018	
Effectively manage risks to the environment arising from the use of veterinary medicines	2.4-7	Develop a guideline on risk assessment of veterinary medicinal products in groundwater	2013	2018	
		Provide advice to the European Commission to assist the preparation of their strategy on	2013	2018	

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
		managing pharmaceuticals in the environment			
		Finalise the draft guideline on higher tier testing of the effects of veterinary medicinal products on dung fauna, taking into account the 2017 workshop outcome	2018	2018	**SUSPENDED**
		Develop a reflection paper on the potential risks associated with the use of veterinary medicinal products in aquaculture	2018	2019	
	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	2019	**SUSPENDED**
Minimise use of animals in medicines research and development activities	4.2-10	Finalise draft reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of 3Rs	2017	2018	
Plan for and implement the revised veterinary legislation	2.2-2	Update the gap analysis and impact assessment of new veterinary regulation on existing procedures and technical requirements	2018	2019	

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	1,845	1,510
Human resources (FTEs)	7	6
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

2.7. Projects

In order to support the Agency's work and the 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 2018-2019. The deliverables for 2019 provide a high-level overview and will be detailed during the preparation of the final work programme 2019.

The cross-Agency projects that relate to both human and veterinary medicines (e.g. SPOR, e-Submission including common repository) are described in the project section of the Horizontal activities' chapter (section 3.6).

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 2018	Budget 2018
Veterinary Change Programme					
EudraVigilance veterinary v3.0 **[continues, subject to budget availability]**	• Regulation (EC) 726/2004, art.57(d)	2017	2019	• Delivery of system design and implementation plan • Initiation of system implementation	€1,264,422
Governance/potential centralisation of functions **[suspended]**	• New veterinary legislation (under drafting)	Q1 2018	2018	• Delivery of revised internal governance within the V division of EMA	€281,083

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 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 to 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 the 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
	2015	2016	2017	2018
Number of reimbursed meetings	437	441	529	553
Committee meetings		71	71	72
Trainings[1]		21	30[2]	51
Workshops		66	32	27
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)		283	396	403
Number of virtual meetings (audio-, video- and web-conferences)	4,273	4,969	4,802	5,666
Number of reimbursed delegates	8,226	7,972	8,743	9,500
Number of non-reimbursed delegates	1,678	1,724	1,469	1,800

[1] includes EU Network training centre meetings.
[2] of these, 14 were EU NTC events.

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Delegate satisfaction with meeting support services	93%	n/a	n/a[1]	90%
Up-to-date electronic declarations of interests submitted by committee members prior to participating in a scientific committee meeting	99%	99%	100%	100%
First-stage evaluations of conflicts of interests for committee members completed prior to	100%	100%	100%	100%

	Results			Targets
	2015	2016	2017	2018
their participation in the first committee meeting, after the submission of a new or updated declaration of interests				
Ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts database	100%	100%	99%	100%

[1] as of 2017, delegate survey is being aligned with the annual delegate survey conducted by the Scientific Committees Service of the Agency. However, as this service will not be conducting a survey in 2017, no delegate satisfaction survey will take place in 2017.

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	1.3-4	Explore opportunities for collaboration and work with HTA organisations by providing support to the development and revision of methodological and disease-specific guidelines	Before 2015	~~2018~~ 2020	Reduced activity in 2018 and 2019
Improve collaboration and communication between committees, working groups and SAGs, to increase quality, efficiency and consistency of outputs	3.2-1	Analyse involvement of scientific advisory groups in evaluation activities, to identify gaps and improve guidance	2015	2018	Reduced activity in 2018
Ensure 'fit-for-purpose' scientific capability of the network	3.1-1	Develop a regulatory science strategy, addressing evolution in science, technology and regulatory tools for human and veterinary medicines	2016	2019	

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	4,146	5,078
Human resources (FTEs)	22	25
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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, instills 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 mutual recognition agreement with the US FDA will have a significant impact on the organisation of inspections, exchange of information on their conduct, and the management of their outcome.

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.

Parallel distribution is seeing a natural increase in the number of annual updates. There is a slight year-on-year increase in the number of certificates for medicinal products issued, which reflects the overall increase in marketing authorisations of centrally authorised products.

The forecasts for the number of inspections do not account for the additional GCP and GMP inspection coverage that the Agency aims to attain through information exchange on inspections performed by other non-EU authorities.

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
GMP inspections	567[1]	548	314	100
GLP inspections	1	0	0	1
GCP inspections	86	121	136	125
Pharmacovigilance inspections	14	8	15	14
PMF inspections	-[1]	124	83	45
Notifications of suspected quality defects	164	181	210	200
Notifications of GMP non-compliances[2]	18	17	21	60
Medicinal products included in the sampling and testing programme	48	48	58	55
Standard certificate requests received	3,221	3,787	4,023	3,750
Urgent certificate requests received	785	487	531	450
Parallel distribution initial notifications received	2,838	2,850	2,639	2,800
Parallel distribution notifications of change received	2,096	1,847	1,975[3]	2,000
Parallel distribution notifications of bulk changes received	13	8	6	11
Parallel distribution annual updates received	4,550[4]	3,815[5]	5,259[5, 6]	5,400

[1] PMF inspections included in GMP inspections results
[2] previously: 'Other GMP inspections-related notifications'
[3] includes 97 notifications received, but not processed, in 2016 / excludes approx. 110 notifications received, but not processed, in 2017
[4] includes 560 parallel distribution annual update notifications that were received in 2014, but processed in 2015
[5] 1,323 notifications received, but not processed in 2016 are included in the 2017 figures
[6] excludes approx. 1,900 notifications received, but not processed in 2017

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Inspections conducted within established regulatory timeframes	100%	100%	100%	100%
Standard certificates issued within established timelines (10 working days)	91%	91.6%	64.2%	90%
Average days to issue standard certificate	7	7	10.3	10
Urgent certificates issued within established timelines (2 working days)	100%	100%	100%	100%
Parallel distribution initial notifications checked for compliance within the established timeline	99%	99%	96%	90%
Additional GCP inspections addressed through information exchange on inspections, carried out by international partners	46%	34%	39%	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%

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		BREXIT implications
			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 (e.g. FDA and Japan) on GCP and pharmacovigilance compliance, and inspections activities in areas of interest	Before 2016	continuous	
	4.3-2 4.3-4	Explore the possibility to set up a pilot phase with the FDA on sharing information on pharmacovigilance inspections	2015	~~2018~~ 2020	Reduced activity in 2018 and 2019 End date extended, to consider Brexit implications.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
	4.1-5	Monitor and review the effect of implementing EudraGMDP rules for planning module on cooperation with Member States in coordinating third-country inspections	2017	2020	Reduced activity in 2018 and 2019
Minimise risk and impact of shortages due to manufacturing problems and quality defects	1.1-17 1.1-15	Implement the new form for reporting quality defects/suspected falsified medicinal products and start compiling information received, to analyse root causes for quality defects	2015	2018	
	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	2020	Reduced activity in 2018 and 2019
	1.1-20 1.1-12	Support and collaborate with the EMA/HMA task force on the availability of authorised human and veterinary medicines	2017	2019	
Ensure quality of medicines wherever they are manufactured	4.1-6	Develop (2018-2019) and finalise (2020) a Union procedure for risk-based approach to GMP inspection for plasma master file inspections	2017	~~2018~~ 2020	Reduced activity in 2018 and 2019 End date extended, to consider Brexit implications.
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 the establishment of a panel of European inspectors available to participate in capacity-building workshops in these countries	continuous	continuous	Reduced activity in 2018 and 2019
Improve knowledge and understanding of data integrity and implications for regulatory decision-making	4.1-2	Develop further GxP guidance for industry on data integrity	2018	2020	Reduced activity in 2018 and 2019
Address the threat posed by illegal supply chains of medicines	1.1-16	Review the practical use of the existing Rapid Alert mechanism for transmission of information related to stolen and falsified medicines	2017	2019	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Support capacity building of non-EU regulators	4.4-1	Deliver training and capacity-building for inspectors and assessors, including international regulators	Before 2016	continuous	Reduced activity in 2018 and 2019

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	15,377	10,703
Human resources (FTEs)	41	37
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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, provision of 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. 1,810 SMEs were registered with the Agency at the end of 2016.
- **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 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 instrument within Horizon 2020, 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 more than 10 years of 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 in the areas of pharmacovigilance and clinical-data transparency.

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 identification of priority areas for capacity increase in the Network in 2018, and the development and delivery of training in these priority areas, taking into account the anticipated increase in workload for NCAs, due to the UK’s withdrawal from the EU.

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Requests for SME qualification	793	582	553	715
SME status renewal requests	994	1,185	1,335	1,540
Number of cases of patient/consumer engagement[1] in EMA activities	743	750	916	700
New scientific, regulatory and telematics curricula developed	1	8	0	1
Number of training events advertised to the EU Network	105	140	100[2]	100
Number of reimbursed training events to the EU Network	7	25	20[3]	31

	Results			Forecasts
	2015	2016	2017	2018
Number of messages circulated via 'Early Notification System'	310	380	383	400
Number of EMA communications pro-actively sent to stakeholders	138	172	144	150
Number of EPAR summaries and EPAR summaries updates published	340	283	299	300
Number of summaries of orphan designation published	230	240	168	250
Access to documents, requests received	701	823	865	850
Access to documents, documents released	2,972	2,876	2,807	2,700
Requests for information received	4,573	4,843	6,735	5,500
Number of documents published on EMA website	7,154	7,369	6,736	8,056
Number of pages published and updated on EMA website	2,911	4,790	3,754	5,071
Number of press releases and news items published	190	197	181	150
Requests for interviews and comments by media representatives	2,268	2,149	1,862	1,800
Number of reports, brochures, leaflets laid out or printed	7	25[4]	60	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 entails engagement from both sides. The figures represent the number of interactions (not patients, as the same patient may be involved several times, within different activities at the Agency)
[2] lower forecasts than in previous years due to the change in the system used to promote training events
[3] including 14 events by EU Network training centre
[4] sharp increase in 2016 due to high demand for graphic representation of reports, and for posters and infographics

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Satisfaction level of patient and consumer organisations	n/a	97%	n/a	95%
Satisfaction level of SMEs	92%	94%		80%
Response to ATD within set timelines	94%	97%	96%	90%
Response to RFI within set timelines	97%	98%	98%	97%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	81.7%	77%	81%	70%

	Results			Targets
	2015	2016	2017	2018
Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	6	14	8	10
Number of users registered to the EU NTC Learning Management System	n/a	2,117	3,583	5,000
Number of NCA experts registered to the EU NTC Learning Management System	n/a	1,225	2,668	4,000
Satisfaction level of partners/stakeholders with EMA communications as per 'EMA perception survey for communication'	80%	n/a	82%	n/a
Average rating given to pages on corporate website during the year		3.6	3.3	3.5

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Strengthen stakeholder relations, focusing on patients and consumers, healthcare professionals, industry associations, and academia	1.3-3 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	2019	
	3.4-6	Publish annual report on EMA interactions with industry associations	Q4 2018	continuous	Streamline reporting on stakeholder activities
	3.4-4	Publish annual report on EMA interactions with patients, consumers, healthcare professionals, and their organisations	Q4 2017	continuous	Streamline reporting on stakeholder activities
	3.4-5	Implement recommendations to promote GPs' interactions with EMA and support regular engagement with GPs, including through written consultations, teleconferences, participation in dedicated meetings and other	2016	2020	
Further develop support to,	1.3-7	Implement the action plan arising from the 10-	2016	2020	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
and strengthen stakeholder relations with, SMEs		year report on the implementation of the SME Regulation			
Further strengthen the Agency's transparency and open data commitments	1.4-3	Complete the reflection paper on providing access to individual patient data	Q3 2017	2020	**SUSPENDED**
	1.4-5	Assess implementation of the policy on publication of clinical data and publish annual report	2019	continuous	**SUSPENDED**
		Hold regular discussions in the technical group on anonymisation of clinical data	Q2 2017	2019	Reduced activity in 2018-2019
	1.4-5 1.4-6 1.4-7	Publish the transparency road map for public consultation (2018). Agree draft principles of transparency (2019)	Q3 2017	Q4 2020	**SUSPENDED**
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	2018	
	3.1-6	Implement the second phase (2018) and launch the third phase (2019) of the multinational assessment team approach post-authorisation	Q1 2018	Q4 2019	
Ensure 'fit-for-purpose' scientific capability of the Network	3.1-1	Identify emerging topics and gaps in expertise which require action, to increase the capability of the EU Network	2017	continuous	
	3.1-3	Work with the Network to include training courses in NTC learning management system and to promote the use of NTC courses, to maximise the use of the EU NTC learning management system	2015	2019	
		Work with the Network to prioritise training needs	2018	continuous	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
	3.1-2	Review and update 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 as promoting harmonisation and consistency	2017	2020	
	1.3-8	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 the Agency's work, outputs and medicinal products	3.3-6	Review and improve the format and content of EMA information on medicines for patients and healthcare professionals (i.e. EMA summaries in lay language)	2016	2019	
	3.3-6 3.3-7	Implement user-testing for EMA communication products which target the general public	Before 2016	2020	Implementation will depend on the Agency's relocation and staff retention in the context of BCP
	3.3-10	Run a pilot to test and improve the crisis communication plan	2017	2020	Focus will be on the review of 2017 crisis simulation exercise and learnings
	3.3-3	Improve the corporate website by adding new tools and features, such as tools to improve	2017	2019	

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		search, search-engine optimisation, accessibility, analytics, and others			
	3.3-1	Develop and implement an annual communication plan, in line with the framework strategy for external communication	Q1 2018	Q1 2019	
	3.3-4	Continue development and implementation of a social media strategy, including the consolidation of social media channels and growing followership	2016	2020	Reduced activity in 2018 and 2019
	3.3-5	Develop new digital and multimedia communication tools	2016	2020	

Resources

Area of activity	Financial resources (cost, thousand Euro)		Human resources (FTEs)		Of which Human resources – Brexit preparedness (FTEs)	
	2017[1]	2018	2017	2018	2017	2018
Partners and stakeholders	10,646	12,178	38	41	n/a[2]	4
Transparency and access to documents	4,014	3,535	21	19	n/a[2]	0
Information	3,558	3,082	14	16	n/a[2]	0
Communication (corporate)	4,959	4,544	28	23	n/a[2]	1

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

3.4. International activities

Activity area

In its work, the Agency collaborates with non-EU competent authorities and regulators (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 2018-2019, these activities will be affected by the restrictions imposed by the decision of the UK to withdraw from the EU; the restrictions will mean that priorities only *might* be implemented. The priority, in terms of global development, is 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. It is expected that the capability assessment of all Member States will be completed in 2019, and that the implementation will include veterinary medicines. We will focus on the training to raise standards of our main partners India and China as main producers of medicines, in particular APIs and generics.

EMA and the EU network will look at promoting the provision of scientific opinions for non-EU countries, improving the life-cycle approach, in particular post-opinion and support to the collaborative registration, which has been shown to avoid duplication and overall 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 leading on innovation, in addition to the participation as a member of the Executive Committee.

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

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
Interactions with the FDA				700
Interactions with PMDA/MHLW				200
Interactions with Health Canada				90
Interactions with Membership organisations				100
Interactions with any other stakeholders				500
Answers to membership organisations' speaker requests				100
Number of information and/or document exchanges				750
Number of teleconferences organised				150

Performance indicators

	Results			Targets
	2015	2016	2017	2018
n/a				

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Ensure the best use of resources through promoting mutual reliance and work-sharing	4.2-3	Optimise Article 58 scientific opinion activities, including the enhance collaboration with WHO and concerned regulators and develop additional communication tools	2015	ongoing	
Promote convergence of global standards and contribution to international fora	1.1-4	Contribute to global dementia activities/programme, in collaboration with other partner agencies, the EC, and international organisations	2016	2018	
		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	2018	**SUSPENDED**
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	Reduced activity in 2018 and 2019
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	
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	2016	continuous	Reduced activity in 2018 and 2019
		Explore and foster opportunities for the EU	2017	ongoing	**SUSPENDED**

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		Network to contribute to scientific and regulatory training events organised outside the EU			
		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	**SUSPENDED**

Resources

	2017[1]	2018
Financial resources (cost, thousand Euro)	3,613	2,814
Human resources (FTEs)	14	11
of which human resources – Brexit preparedness (FTEs)	n/a[2]	0

[1] figures based on the 2017 provisional accounts

[2] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

3.5. Information management

Activity area

Information-management activities aim to establish and manage information as a key asset to supporting sound decisions and providing 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 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 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, 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

After more than 20 years of operating an information management and technology function, the European Medicines Agency recognises the achievements of the past, but also acknowledges that its operating model must change and improve in order to deliver agile, cost-effective technology which responds to staff, partner and stakeholder needs. Therefore, information management and technology has become an integrated enabler which supports EMA's strategic business priorities and tracks to 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 as a result of Brexit:* During the relocation period, the priority will be to support the relocation of EMA data centre facilities, support the work to equip the new premises, invest in technology to ease recruitment of new staff, improve internal communication and collaboration, and reconfigure existing business applications and services to cater for the new composition of the European Union.
- *Maintain and improve operational excellence:* EMA is moving away from the historical model of building, hosting and maintaining all information management and technology assets on premise, through largely time-and-means contracts with bespoke, highly-customised code. Instead, emphasis is placed on use of fixed price contracts and commodity cloud services (where feasible) to lower development and maintenance costs through shifting low-value activities offsite, and to reduce bespoke development and the cyclical maintenance burden. It also provides for a gradual replacement of standalone, legacy applications (orphans database, paediatrics database, SIAMED etc.) and incorporation of their processes and functionality into larger, enterprise platforms (customer relationship management, document management, identity management etc.) to bring data together and

support process alignment. Information services will be extended and augmented to support the operationalisation of clinical trials, the pharmacovigilance and veterinary legislation.

- *Deliver and maintain effective information services:* The operating model of the EMA Information Management Division will be continually refined to deliver the information management strategy: competencies and skills will be identified and grown, and teams appropriately grouped. Industry-standard IT management frameworks (COBIT5, ITL) will be used to support effective management of people and processes. Management of the relationship with the Network and implementation of the Telematics strategy is carefully curated by the Telematics office, to ensure that services meet user needs. Security controls and management tools will be deployed and linked to the Agency's information classification policy, allowing users to access information on mobile devices and give them increased control over sharing of information. Investments will continue in master data management (SPOR Programme) and other enterprise initiatives, to ensure reuse of core data across systems and applications.

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
	2015	2016	2017	2018
Number of Telematics information services provided by EMA	20	22	23	24
Number of ongoing Telematics IT projects where EMA is the delivery organisation	18	13	11	8
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	11	6	6	8

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Satisfaction of EMA internal and external customers of information services (% satisfied and very satisfied)	n/a	94%	94%	80%

Additional objectives and activities

In order to deliver the IT solutions required by EU law, the Agency will continue implementing a number of projects, including on master data management services, enhanced EudraVigilance system for human medicines, European clinical trial system, and others. More detailed information on these can be found under the project sections of the work programme.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
n/a					

Resources

Information management covers a wide range of Agency activities, hence resources are allocated to the relevant activities and chapters throughout this work programme.

3.6. 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 2018-2019. The deliverables for 2019 provide a high-level overview and will be detailed during the preparation of the final work programme 2019.

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 2018	Budget 2018
Data integration programme					
Substances and products management services (including veterinary Union database)	• Regulation 726/2004, art.57(2) • Regulation (EC) 520/2012, art.25 and 26 • Draft veterinary regulation, art.51	2017	2020	• A new ISO IDMP compliant MDM hub for substances and medicinal products (also covering Vet and other needs) • Product data migration • Substance data migration	€3,524,201

Programme / Project	Legal basis	Start date	End date	Deliverables 2018	Budget 2018
[temporarily reduced]	• Clinical trials regulation 536/2014, art.8193) • Pharmacovigilance fees regulation 658/2014, art.7 • Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU			• * IDD access for products • * Feedback loop of medicinal product information (including S, R and O) to xEVMPD • * IDD access for substances • * data quality assurance/data entry of human medicinal product information by EMA and possibly by some NCAs *Please note functionality marked with '*' depends on the Agency relocation plans and their impact on P&SMS phase 1 plan*	
Identity and access management 2 **[continues]**	n/a	2017	2018	• Onboarding EudraVigilance organisations in OMS and establishing a common process for managing the EV organisations lifecycle • Standardise the way EudraVigilance users register, so that they rely on the EMA registration portal • Standardise the way the users request access to EudraVigilance, so that they are supported by the EMA registration portal • Standardise the way the user access is approved, provisioned and verified by configuring specific workflows in the EMA registration portal	€126,161
Online programme					
Extranet **[suspended]**		Q1 2014	2020	• *Project on hold until Q3 2019*	-
Intranet **[suspended]**	n/a	Q1 2014	2020	• *Project on hold until Q3 2019*	-
European medicines web portal **[suspended]**	• Regulation (EC) 726/2004 • Regulation (EC) 1235/2010, art.26	Q1 2014	2020	• *Project on hold until after Q2 2019*	-
Corporate website **[continues]**	n/a	Q1 2014	2018	• Delivery of the new EMA corporate website using the DIGIT NextEuropa Platform (NE-CMS) • Preparation of training materials and delivery of training to stakeholders • Preparation of user guidance documentation • Implementation of communication plan	€488,671

Programme / Project	Legal basis	Start date	End date	Deliverables 2018	Budget 2018
Standalone projects					
SA-REPS, phase 1 – Orphans (previously - SIAMED systems integration phase I) **[continues]**	n/a	2017	2018	• Delivery of the CRM platform to support Orphan Drugs processes • Enable CRM capability for the Agency (operating model and competency centre setup) • Data migration complete • Decommissioning of current Orphan Drugs database • Integration with the Agency's core systems (e.g. SPOR, Identity and Access Management) • Training complete	€304,664
SA-REPS, phase 2 **[continues subject to budget availability]**	n/a	2018	2018	• Definition of a CRM roll-out strategy and roadmap • Delivery of the analysis and design documentation for the selected processes • Configuration of the CRM platform to integrate with the selected processes • Preparation of training materials and delivery of training to stakeholders • Delivery of CRM platform for selected processes	€696,679

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, as well as management of cash resources and ex ante verification of transactions.
- **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 support and training, 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 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 an 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 of 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

A new Regulation on data protection (Regulation EU 679/2016, the GDPR) will be applicable as of 25 May 2018 for all private and public organisations. Regulation (EC) No 45/2001, which is currently applicable to the EU institutions, agencies and bodies, including EMA, will be repealed and as a result, a new GDPR-like Regulation will apply to EMA.

The new EU data protection legislation will entail new obligations and responsibilities for EMA as Data Controller and it will affect the governance aspects of implementing the accountability principle. Procedures for the notification of data breaches to the competent supervisory authorities and data subjects will need to be adopted. Data protection by design and by default will need to be implemented in new projects and solutions already during the planning phase. Risk checks of new data processing operations will need to be conducted, and training sessions will need to be offered to staff on the new rules.

Workload indicators

	Results			Forecasts
	2015	2016	2017	2018
n/a				

Performance indicators

	Results			Targets
	2015	2016	2017	2018
Posts on the Agency establishment plan filled	98%	98%	98%	97%
Revenue appropriations implemented	98.7%	100%	96%	97%
Expenditure appropriations implemented	95.8%	96%	93%	97%
Payments against appropriations carried over from year N-1	94%	96%	89.9%	97%
The maximum rate of carryover to year N+1, of total commitments within the title				
Title 1	0.9%	1%	1%	1%
Title 2	7.6%	8%	11.8%	15%
Title 3	26.9%	27%	28.1%	25%
Payments made within 30 days' time	99.7%	99%	97.3%	98%
Availability of Telematics/corporate IT systems and corporate website (% of time)		100%	99.8%	98%
Energy consumption (change in % per workstation)	+5.1%	-19.6%[1]	-5%	-1%
Water consumption (change in % per workstation)	+2.9%	-52.8%[1]	+13%[2]	-5%
Paper consumption (change in % per workstation)	-38.2%	-22.7%[1]	-13%	-4%
Non-recyclable waste produced in restaurant and kitchenette (change in % per workstation)	-12.9%	-46.0%[1]	+13%[3]	-5%
Recyclable waste produced (change in % per workstation)	n/a	-26.3%[1]	+10%[3]	+2%
Recycling rate (change in % per workstation)		-5.2%[1]	-4%	+2%
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)	+1.0%	+1.4%	n/a[4]	+2%
Overall net CO_2 emissions (per workstation)	+0.2%	-10.2%[1]	n/a[4]	+1%

[1] in 2016, the number of workstations increased, following the addition of the 10th floor.
[2] fault in the grey water re-use system increased the need of fresh water
[3] increase in recyclable waste due to the increase in the Agency' activity and disposal of equipment in preparation for the relocation
[4] no data available since July 2017, as the new travel agent does not provide such information

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	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	~~2018~~ 2020	End date extended, to consider Brexit implications
	3.2-5	Implement a competency management framework	2017	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	
		Implement the new EU data protection legislation	2018	continuous	New legislation entailing new responsibilities for EMA affecting the governance process, including adoption of new procedures, which will impact new projects and solutions already during the planning phase.

Resources

Area of activity[1]	Financial resources (cost, thousand Euro)		Human resources (FTEs)		Of which Human resources – Brexit preparedness (FTEs)	
	2017[1]	2018	2017	2018	2017	2018
Governance, quality management and internal audit	6,305	7,433	29	33	n/a[4]	12
Finance	4,741	5,002	24	27	n/a[4]	3

Area of activity[1]	Financial resources (cost, thousand Euro)		Human resources (FTEs)		Of which Human resources – Brexit preparedness (FTEs)	
	2017[1]	2018	2017	2018	2017	2018
Information technology	9,633	14,372	52[3]	75	n/a[4]	27
Human resources	6,699	10,406	37	64	n/a[4]	29
Infrastructure services	2,215	3,292	15	20	n/a[4]	7

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

[2] Figures based on the 2017 provisional accounts

[3] Additional 30 FTE in ICT services working on projects are allocated to the relevant sections of the work programme

[4] EMA ORP BCP was developed in March/April 2017, and at the time of preparing the activity-based budget for 2017, no staff was earmarked for Brexit activities

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 2018-2019. The deliverables for 2019 provide a high-level overview and will be detailed during the preparation of the final work programme 2019.

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 2018	Budget 2018
Standalone projects					
Data centre strategy implementation **[continues]**	n/a	2017	2018	• Lessons learned • Project closure	€13,382
Data centre relocation **[continues]**	n/a	2017	2019	• Relocation of the Agency's two existing data centres to a new location in the EU27 • Delivery of two functioning data centres connected to the	€4,526,793

Programme / Project	Legal basis	Start date	End date	Deliverables 2018	Budget 2018
				Agency's existing headquarters in London and its future headquarters • Design and implementation of technical changes to allow the data centres to operate in the required target configuration • Transportation, fit-out and commissioning of the data centres in their new location. • 'Remote hands' support to be in place for both data centres • Implementation of a 'desktop as a service' solution for off-site IT support, development and maintenance	
e-recruitment (Success factors) **[continues]**	n/a	2017	2018	• Delivery of a new recruitment platform for EMA • More efficient and less labour-intensive recruitment and onboarding of staff • Preparation of training materials and delivery of training to stakeholders • Preparation of user guidance documentation • Implementation of communication plan	€77,658
IT applications maintenance transition **[continues]**		2017	2018	• Transformation of applications maintenance operations from current in-house to future off-site / fixed price model	€2,016,559

Annexes

Annex 1: Activity based budget 2018

Work programme chapters	Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	* Total expenditure	
	€'000	€'000	€'000	€'000	€'000	€'000	%
	Title 1	Title 2 & Budget Item 3105	Budget item 3000	Article 301	Articles 302, 303 & Item 3003		
1 Evaluation activities for human medicines	**58,513**	**31,883**	**10,525**	**119,165**	**6,362**	**226,449**	**70%**
1.1 Pre-authorisation activities	12,986	4,219	4,306	20,124	4	41,640	13%
1.2 Initial evaluation activities	12,477	3,345	1,765	14,207	888	32,682	10%
1.3 Post-authorisation activities	13,610	7,431	1,310	71,596	1,716	95,664	30%
1.4 Referrals	925	252	283	-	272	1,732	1%
1.5 Pharmacovigilance activities	14,273	8,470	1,721	13,238	3,472	41,175	13%
1.6 Other specialized areas and activities	4,241	8,165	1,139	-	11	13,557	4%
2 Evaluation activities for veterinary medicines	**5,708**	**1,950**	**1,974**	**4,054**	**425**	**14,111**	**4%**
2.1 Pre-authorisation activities	351	115	217	245	-	929	0%
2.2 Initial evaluation activities	2,143	602	740	1,252	165	4,903	2%
2.3 Post-authorisation activities	1,277	703	444	2,557	207	5,187	2%
2.4 Arbitrations and Referrals	450	108	157	-	53	768	0%
2.5 Pharmacovigilance activities	617	198	-	-	-	815	0%
2.6 Other specialized areas and activities	870	224	416	-	-	1,510	0%
3 Horizontal activities and other areas	**23,971**	**7,966**	**3,990**	**4,222**	**1,786**	**41,934**	**13%**
3.1 Committee coordination	3,196	924	958	-	-	5,078	2%
3.2 Inspection and Compliance	4,050	1,760	672	4,222	-	10,703	3%
3.3 Partners and Stakeholders	6,903	1,671	2,287	-	1,316	12,178	4%
3.3a Transparency and access to documents	2,759	732	44	-	-	3,535	1%
3.3b Information	4,759	2,398	-	-	470	7,626	2%
3.4 International activities	2,304	481	29	-	-	2,814	1%
4 Corporate Governance and Support activities	**30,962**	**9,113**	**425**	**-**	**5**	**40,505**	**13%**
4.1 Governance, quality management and internal audit	5,172	1,836	425	-	-	7,433	2%
4.2 Finance	3,948	1,049	-	-	5	5,002	2%
4.3 Information technology	11,487	2,885	-	-	-	14,372	4%
4.4 Human resources	7,855	2,551	-	-	-	10,406	3%
4.5 Infrastructure services	2,499	793	-	-	-	3,292	1%
Total	**119,153**	**50,913**	**16,914**	**127,441**	**8,578**	**322,999**	**100%**

* It excludes costs related to Brexit 14,762

Total Budget for 2018 337,761

Annex 2: Financial resources

Table 1 – Expenditure

Expenditure	2017		2018	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1	€ 106,792,756	€ 106,792,756	€ 125,550,000	€ 125,550,000
Title 2	€ 49,364,129	€ 49,364,129	€ 56,267,000	€ 56,267,000
Title 3	€ 151,667,701	€ 151,667,701	€ 155,944,000	€ 155,944,000
Title 9	€ 0	€ 0	€ 0	€ 0
Total expenditure	**€ 307,824,586**	**€ 307,824,586**	**€ 337,761,000**	**€ 337,761,000**

Table 2 – Revenues

Revenues	2017	2018
	Revenue estimated by the agency[1]	Budget estimate
EU contribution	€ 28,473,150	€ 32,521,000
Other revenue	€ 288,887,276	€ 305,240,000
Total revenue	**€ 317,360,425**	**€ 337,761,000**

1) Data as per provisional accounts of January 2018

Budget outturn

The European Medicines Agency monitors its budget closely throughout the year, with the aim to achieve a high execution rate on the budget by year end. Most of the Agency's income is self-generated through fee charges, for which the timing of the submission of applications is not under its control. At the same time, the revenue can only be registered in the budgetary accounts once the cash is received on the Agency's bank account. This demand-driven process makes for uncertainty for revenue.

As for 2017 appropriations, the Agency achieved an implementation rate of its expenditure budget of 92.92%, matched by an implementation rate of its revenue budget of 95.80% (based on cash receipts against recovery orders from 2017 and earlier). Taking account of the overall budget volume, unused carry-overs, assigned revenue and exchange rate variances, this resulted in a final budgetary outturn of EUR 14,468,303.00 (4,56% of total revenue), and an actual net implementation rate of 95,44%.

Cancellation of appropriations

The European Medicines Agency has not introduced differentiated appropriations. Therefore, the commitment appropriations equal the payment appropriations for the current budget (C1+R0). Amounts carried over can in full be regarded as payment appropriations (C2 for amount carried-over non-automatically and C8 for amounts carried over automatically).

Cancellation of commitment appropriations

Cancellation of commitment and payment appropriations on 2017 current budget (C1)

For 2017, the majority of cancelled C1 appropriations relate to provisions made for salaries, allowances and weightings (chapter 11), building and IT infrastructure, (chapters 20 and 21) as

well as overestimation of meeting and business consultancy expenditure (articles 300 and 303) and rapporteur expenditure (item 3010).

Cancellation of assigned payment appropriations for 2017 (R0)

All amounts committed were used in full. No further appropriations remain.

Cancellation of payment appropriations

Cancellation of payment appropriations carried over from 2016 to 2017 (C8)

The cancellation of payment appropriations carried-over (€4,350,907.86 of a total of €43,032,304.83) represents a rate of 10.11,%, an increase from the previous year's rate of 4,46%.

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 31/12/2015	Authorised under EU budget for 2016	Actually filled as of 31/12/2016	Authorised under EU budget for 2017	Actually filled as of 31/12/2017	Autorised under EU budget for 2018	Actually filled as of 31/12/2018[1]	Draft budget for 2019	Envisaged in 2020	Envisaged in 2021
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	333	343	337	340	334	340		425	425	425
	AST	254	259	250	256	249	251		177	177	177
	AST/SC	0	0	0	0	0	0		0	0	0
Total		**587**	**602**	**587**	**596**	**583**	**591**	**0**	**602**	**602**	**602**
CA FG IV		55	58	55	63	57	85		89	89	89
CA FG III		20	14	15	17	16	25		25	25	25
CA FG II		81	73	73	78	72	70		70	70	70
CA FG I		0	0	0	0	0	0		0	0	0
Additional CA[2]		0	0	0	0	0	20		40	40	20
Total CA[3]		**156**	**145**	**143**	**158**	**145**	**200**	**0**	**224**	**224**	**204**
SNE[3]		33	40	36	45	36	39		35	35	35
Total TA+CA+SNE		**776**	**787**	**766**	**799**	**764**	**830**	**0**	**861**	**861**	**841**

1) To be completed in January 2019
2) Additional staff to cover Brexit-related additional work (FTE)

Table 2 - Multiannual staff policy plan

Category and grade	Establishment plan in EU budget 2016		Filled as of 31/12/2016[1]		Modifications in 2016 in application of flexibility rule		Establishment plan in voted EU budget 2017		Modifications in 2017 in application of flexibility rule		Establishment plan in voted EU budget 2018		Establishment plan 2019		Establishment plan 2020	
	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		4		2				4				3		2		2
AD 14		6		6				6				7		8		9
AD 13		9		9				11				11		14		14
AD 12		42		39				40				43		46		46
AD 11		38		37				40				43		41		47
AD 10		44		44				43				41		44		39
AD 9		37		37				42				45		48		53
AD 8		54		54				53				59		75		82
AD 7		54		54				61				65		82		81
AD 6		37		37				37				23		54		48
AD 5		18		18				3				0		11		4
Total AD	**0**	**343**	**0**	**337**	**0**	**0**	**0**	**340**	**0**	**0**	**0**	**340**	**0**	**425**	**0**	**425**
AST 11		2		2				2				2		2		2
AST 10		5		5				6				7		8		8
AST 9		7		7				7				6		5		6
AST 8		16		16				16				16		13		13
AST 7		19		17				19				22		21		22
AST 6		39		39				43				42		13		11
AST 5		43		42				43				46		21		28
AST 4		49		49				52				57		55		66
AST 3		47		46				45				46		39		21
AST 2		32		27				23				7		0		0
AST 1		0		0				0				0		0		0
Total AST	**0**	**259**	**0**	**250**	**0**	**0**	**0**	**256**	**0**	**0**	**0**	**251**	**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**
Total	**0**	**602**	**0**	**587**	**0**	**0**	**0**	**596**	**0**	**0**	**0**	**591**	**0**	**602**	**0**	**602**

Annex 4: Risks

The European Medicines Agency operates in a risk environment of growing uncertainty. To assist the Agency in visualising, assessing and mitigating the risks that threaten delivery of its mission, the Agency has developed a sustainable process to identify, assess and manage risks across the organisation, to ensure achievement of key organisational objectives and to avoid surprises. This process is aligned with the principles of the IRM standard and the Agency-wide risk management manual, and consists of identifying, assessing and mitigating enterprise risks through the following process:

- Risk identification; where the key risks to the Agency achieving its strategic objectives are identified. Significant risks identified here are then selected for further assessments.
- Risk assessment; where the likelihood and potential impact of each of the identified risks is identified.
- Risk mitigation. Based on the results of the Assessment phase, primary risk owners for each key risk and its relevant sub-components are identified, and potential mitigating activities are documented.

Significant risks are then reviewed by the EMA Executive Board, which acknowledges the risks and validates the action plans, to further mitigate these risks.

Risks are assessed and reported at a residual level, i.e. taking into account controls and mitigations that are already in place. Risks are reported consistently on a 6x6 matrix (likelihood x consequence), and only the risks with residual risk rate of 16 or above (significant risks) are discussed by the Executive Board, indicating that the acceptable residual risk rate is 1 to 15.

The significant risks that could potentially impact achievement of the Agency's objectives, and respective mitigating actions and controls that successfully reduce the risks to an acceptable level (those already in place as well as those planned to be implemented in 2018-2019), are outlined in the tables below. These risks, should they materialise and the consequences, should they not be appropriately managed, would result in operational, reputational, legal or financial implications for the Agency and achievement of its objectives.

Table 1 – Operational activities

Risk	Mitigating actions and controls
Product assessment – procedure management	
Lack of experts having the required competences and expertise	In place: • Legal requirements, e.g., regarding composition for CxMPs • Appointment process for CxMP, working party and SAG members • Management Board review of CHMP, CVMP and PRAC competencies • Criteria for competence and expertise of committee members and alternates for CHMP, CVMP, PRAC, HMPC PDCO, COMP and CAT • Defined roles and responsibilities of experts and committees • Establishment of specialised forums for experts (including SAGs) • Proactive search for expertise from academia/learned societies • Possibility for expert witnesses having a limited controlled role • Joint EMA-HMA training strategy

Risk	Mitigating actions and controls
Product assessment – Applicant fraud	
Incorrect scientific opinion due to infringement of compliance involving data fraud by applicant or third party supplying data	In place: • Cross-Agency infringement action group • Procedures for implementing Penalties Regulation • Standards for documentation of investigations and ensuing procedures to ensure integrity of any future infringement procedures • Processes for taking regulatory action • EMA policy on handling of information from external sources, disclosing alleged improprieties concerning EMA activities related to the authorisation, supervision or maintenance of human or veterinary medicinal products • Established contact point for anybody with suspicious evidence of misconduct to bring information to the attention of EMA, if necessary, in confidence (reporting@ema.europa.eu) In progress: • Active publication of clinical trials data post authorisation • Process for triage of cases and decision-making (with Head of Department, CxMP, supervisory authorities, EC, third country regulators etc.) on further action • Increased transparency to third parties through access to documents encouraging reporting of infringements
Inspections	
Risk of substandard data and information which can impact on scientific opinions on medicinal products due to the framework for compliance with GMP/GCP/GLP/PhV from non EU countries not meeting EU standards	**For GMP** In place: • The ICH process • Third countries policies/work programmes (Mutual Recognition Agreements, • Agreement on Conformity Assessment and Acceptance of Industrial Products • EC/EMA bilateral relations with other third countries, and exchange of inspections information and reports, in particular non-compliance cases • GMP pilot programme on active pharmaceuticals ingredients and joint GMP inspections for finished products (pilot) • GMP inspections project with ICMRA (in progress) • Listing of third countries APIs and written statement • EMA-FDA GMP initiative in the area of GMP inspections (ongoing) • Reduction of duplication of inspections with consequent resource saving, leading to wider range of sites being inspected at global level • Better use of information from other authorities and the use of such information for the triggering of inspections (Inspection agreements with international partners) • Planning module for GMP inspections available in EudraGMP **For GCP** In place: • The ICH process • GCP Inspection Policy (expansion of routine inspections for third countries) • Third countries policies/work programmes • EC/EMA bilateral relations with other third countries and exchange of inspections information and reports, in particular non-compliance cases • EMA GCP Working Group on acceptability of third country clinical trials established – Ethics Advisory Group • Guidance on the acceptability of third country clinical trials • International cooperation through training and capacity-building activities for inspectors (ongoing activity) • EMA-FDA GCP initiative in the area of GCP inspections (ongoing)

Risk	Mitigating actions and controls
	• Request for certain information to applicants through the Q&A of inspections included in the pre-submission guideline • Inspection validation of the MAA • Reduction of duplication of inspections with consequent resource saving, leading to wider range of sites being inspected at global level In progress: • Capacity building activities **For GLP** In place: • The OECD programme • Validation process of MAAs feeds into the decision on inspections (site selection) • Request for certain information to applicants through the Q&A of inspections included in the pre-submission guideline • Promoting the verification of the GLP status of sites at the time of the Clinical trial application, rather than MAA. **For PhV** In place: • The ICH programme • Inspection programmes • PhV inspectors working group • Planned international cooperation • International cooperation through training activities • Cooperation between EMA and Member States on inspections in third countries • Informal network of PhV inspectors to enable capacity building • Better use of information to focus the scope of the inspections on the issues of most concern
Need for an inspection not identified or inspection not carried out on time	In place: • Relevant SOPs/WINs are in place to identify the need for an inspection, to ensure that the inspection is carried out on time, and to cover the handling of quality defects • Relevant external guidance document available • Contracts in place with NCAs, specifying the expertise of the staff involved and the timeframes for the procedures
Pharmacovigilance	
Lack of additional post-marketing authorisation data on human medicines to proactively identify, qualify and quantify risks related to use of authorised medicines	In place: • Launch of post-authorisation studies, using ENCePP network • Independence, transparency and methodological standards of ENCePP studies ensured • Implementation of pharmacovigilance legislation (PASS and PAES) • 'Best evidence' procedure to support PRAC discussions In progress: • EMA studies conducted using longitudinal patient record databases (in-house and commissioned studies) • Registries initiative • Real world evidence
Inability of the Agency to effectively conduct veterinary pharmacovigilance, if suitable IT system is not developed to replace EVVet2	In place: • Review of the Agency's requirements for IT, related to pharmacovigilance of veterinary products *Creation and maintenance of single EU product database now included in SPOR scope.*

Risk	Mitigating actions and controls
Lack of an agreed and consistent approach for the evaluation of benefit-risk balance for mature (old) products	In place: • Peer-review of reports • Strengthened input from specialists during evaluation Planned: • Discussion with Committees at strategic review and learning meetings • Reflection with Committees on the approach
Procedure management – resources	
Lack of Agency resources for the introduction of the new PSUSA procedure	In place: • Documented procedure for management of PSUSA procedures • Redistribution of workload across the different procedural teams • PSUR repository for management of PSURs • Existence of quality-controlled reliable source of data about products on the EU market and MAHs (e.g. Art 57 of Regulation (EU) No 1235/2010) (Human) In progress: • Operational validation of the article 57 database Planned: • Initiation of ICT tools, i.e. inclusion of NAPs into SIAMED
Lack of Agency resources to support the management of procedures (reliance on interims)	In place: • Documented procedures for managing different types of procedures • Optimised organisational design to maximise resource utilisation • Reduced resource allocation to other non-core fee generating tasks, projects (e.g. e-submission, workflow tool) and initiatives • Training to interim staff • Use of SIAMED templates In progress: • Change request for SIAMED to automate procedure tracking and improve management of procedures

Table 2 – Support activities

Risk	Mitigating actions and controls
Data management – data protection and security	
Accidental leak of confidential information to external parties by internal employees, interims, trainees or contractors with access to EMA information systems	In place: • EMA Security Policy adopted (including 3 annexes related to IT Security) and continuously reviewed • Security officer and dedicated Information security service • IT tools including adequate security measures to protect confidential data (e.g. BitLocker and encryption) • IT security measures to manage access to data (e.g. access rights management) • Declaration of confidentiality and conflicts of interests for staff and for IT contractors • Complementing the internal log reviews with an independent log reviews • Annual checks to validate the control of access to database by system/data owner (i.e. SIAMED) • Security tools against data leak (EudraLink to secure package, End point security (media encryption)) • USB restriction on laptops In progress: • Security strategy

Risk	Mitigating actions and controls
Intentional leak of confidential information to external parties by internal employees, interims, trainees or contractors with access to EMA information systems	In place: • Data-access management • Firewall system in place to protect the information systems • Antivirus system in place • Datacentre access limited to relevant resource • Access control lists to restrict contractors' data access • Checklist to manage contractors' access to IT systems that have not been added to the SAP HR system • Data-encryption tools to allow data transfer between parties outside the EMA network (e.g. via an encrypted USB stick) • Passwords are required to be updated every 6 months • USB restriction on laptops Planned: • Data logs activated on all systems (where possible) and red flags set up and actively monitored • Proactive markings on sensitive documents • Each new system account given appropriate level of access and necessary access restrictions applied • Access rights reviewed on regular basis to ensure that permissions are appropriate
Sensitive and/or confidential data intentionally accessed or removed from EMA premises by external suppliers	In place: • Security awareness training • Code of conduct • CCTV • Access control • Printing control • Confidential waste stored in locked confidential bins
Financial, legal and reputational damages for the Agency in case of data-protection failure	In place: • Identification of systems to be notified and regular management review • Data protection Regulation (EC) 45/2001 • Data protection implementing rules • Data Protection function within the Agency • Appointment of data protection officer (DPO) • Notification procedures from data controllers to DPO • Notification procedures from DPO to European Data Protection Supervisor (EDPS) • Register of data processing • Training programme for existing members of staff and new comers • Data protection microsite on intranet
Data management – data quality	
Data required for scientific and regulatory procedures and decision-making is of poor quality, incomplete, inaccurate and/or lacks integrity	In place: • Validation of data entry in SIAMED and EudraVigilance • Data manager/stewards functions with defined roles and responsibilities • Data analytics tool (SAS) and processes for monitoring data quality • Ensure that the data management activities have enough human skilled resources (e.g. to SIAMED OBIEE support) • Governance structure for data management • Centralised activity in single department responsible for data governance and information assets • Design and maintain core data (SIAMED) reports and templates In progress: • Data cleaning of existing data to ensure reference quality level • Agency quality standard and reference for data based on ISO standards • Single trusted, identifiable master copies of substances, referentials, organisations and products data available as service

Risk	Mitigating actions and controls
	Planned: • Data-quality control level based on risk assessment of individual data assets • Data-quality monitoring and data-quality processes
Data management – document management	
Loss of information due to inadequate document management system and processes	In place: • EMA records-management policy and business classification scheme • Rolling programme to develop RM processes and procedures and education • Basic back-up procedures undertaken on shared drives, Outlook and document management system • Awareness and training session on document/records management best practices • Procedure on Core Master File Product (SOP 1004 on Core master files of medicinal products for human and veterinary use following the centralised and referrals procedures) In progress: • KPIs to monitor compliance with EMA records management policy • Identification of data-set owners and definition of clear roles and responsibilities Planned: • Records management embedded in redesigned human medicines evaluation processes • Ex post controls on compliance with SOP 1004 for product related EMA core documents • Compliance assessment of Agency's document/records management IT systems • Automatic assignment of retention policy and classification • Reporting tools in the document management system to automate monitoring and control measures
IT development and management	
Loss of knowledge due to contractors leaving the Agency	In place: • Reducing reliance on contractors for critical skills and knowledge (e.g. solution architecture, data architecture, system administrators) In progress: • Review of IT operating model to insource further critical skills and knowledge Planned: • Outsourcing less critical skills and services, managed by strict contracts and SLAs • Documenting most critical applications
Recruitment	
Staff planning and recruitment do not cover the needs of the Agency in order to achieve its objectives	In place: • The Agency's management meets at least four times a year (quarterly EXB meetings) to identify future competencies needed and adequate staff levels to meet the Agency's objectives. The EXB sets up the resource plan, which is then monitored throughout the year. In addition, other ad hoc meetings are set throughout the year to discuss particular resource needs • Two separate reports are downloaded from the SAP HR system with all the staff information, and a comparison is done between the reports in order to mitigate any discrepancy on numbers, and to assure that the Agency does not go above the establishment plan. A separate database with all the staff levels is updated daily. This creates a three-layer system which improves the quality of the data. Afterwards, a monthly report is produced comparing the staff levels expected, the actual staff levels, and any deviation from the plan, which is then sent out to the

Risk	Mitigating actions and controls
	head of Administration division, head of HR, head of Strategic planning and budget, and HR business partners • Monthly meetings between the Resource planning coordinator and HR business partners to monitor actual staff levels compared to the plan. These meetings also set the basis for planning of potential resignations, retirements and resource planning for part-time, maternity and unpaid leave covers • Fortnightly recruitment planning meetings between Head of Talent Acquisition, Head of HR, Head of Staff Matters and HR business partners to go through the recruitment planning • Bi-monthly salary budget meetings between Resource Planning Coordinator and Salary officers • Quarterly budget meetings between Resource Planning Coordinator and Budget team • Fortnightly meetings between Resource Planning Coordinator and Head of Strategic planning and Budget • Fortnightly meetings between Resource Planning Coordinator and Head of Administration In progress: • Coordinated planning entity to include resource planning in cooperation with recruitment and management, competence identification and ABB
Inadequate recruitment procedures due to substandard IT tools	In place: • Manual control • Ex-post control In progress: • Talent recruitment tool implementation
Procurement	
Failure to deliver timely procurement and obtain value for money	In place: • Adequate/realistic planning, based on a solid methodology in order to justify and optimize procurement procedures, launched and aligned with budget planning • Clear assignment of responsibilities is defined at the outset of a procurement procedure when defining the business case for capital expenditure. All procurement procedures are performed in close cooperation with procurement control office • Clear definition of needs, including justification (e.g. ex-ante evaluation of needs for new projects or expenditure, a cost/benefit analysis, justification for outsourcing, etc.) • Systematic conduct of a lessons learned exercise at the time when a procurement decision is made. A debriefing is also conducted by procurement control office on any procurement over €60,000 to identify improvements • Regular monitoring of planned deadlines and reporting (e.g. monitoring tools in place, deadline management, quality assurance, etc.) • Procurement procedures included in the scope of the enhanced ex post controls under Article 46 of the Financial regulation
Lack of contract management competencies, processes and tools may impact continuity of services	In place: • Sourcing request system tracking requests • Templates • Weekly, monthly and three months in advance reporting to requestors In progress: • Awareness/training sessions to contract managers requestors/programme/project managers
Tenders are late and/or specifications are poor due to delays in the allocation of relevant staff and/or	In place: • Tenders are managed through a harmonised approach, based on project management practices and using Microsoft Projects tool; plans (including timelines) and resource plans are created

Risk	Mitigating actions and controls
insufficient capacity of allocated staff to dedicate sufficient time to complete tender documentation and progress evaluation activities	• Staff is formally allocated to run tender procedures • Staff allocated to tender procedures to be released from other conflicting priorities in order to dedicate sufficient capacity to ensure the tender is run smoothly In progress: • Increase business involvement and understanding, skills and capacity to perform this task
Finance - Revenue collection and Treasury management	
Loss on currency exchange rate fluctuations	In place: • Decision of the Accounting officer on the management of the Agency's cash and currency exposure • Regular budget monitoring, EUR revaluation of GBP denominated commitments, inclusion of salaries realised exchange rate difference in the budget result, and inclusion of unrealised exchange rate difference in the year end account balance with EC • Disclosure of liquidity, solvency and market risks in Section 11 of the Agency's annual accounts
Clinical data publication	
Non-compliance of MAHs/pharmaceutical industry with the policy	In place: • Consultation with stakeholders in context of particular procedures In progress: • Identification of non-compliance scenarios and remedial actions to be taken Planned: • Annual report on implementation experience, including details of non-compliance
Delay in establishing a dedicated, proactive publication team	In place: • Recruitment of staff members to create the team • Training of new team on process and specifically redaction consultation phase • Establishment of business process In progress: • Automated workflow tool
Not meeting expectations with stakeholders	In place: • Tagging (with text) Protection of Personal Data (PPD) and Commercially Confidential Information (CCI) differently in the text • Communication strategy including targeted interactions with stakeholders • Introducing a colour scheme to identify PPD from CCI In progress: • Establishing technical anonymisation group Planned: • Review of experience six months after implementation of the policy, resulting in lessons learned, remedial actions and continuous interactions with stakeholders
Stakeholder relationships	
Insufficient resources to implement legally required activities to meet expectation of stakeholders	In place: • Long-term strategy (Network strategy 2016-2020) • Programming process (Programming document, MAWP) • Portfolio management process • ABB/ABC/ABM (activity based budget) • Priorities setting and resources allocation (EXB meetings)
Failure to meet stakeholder expectations	In place: • Framework for interaction with patients and consumers • Framework for interaction with healthcare professionals • Framework for interaction with academia

Risk	Mitigating actions and controls
	• Framework for interaction with industry stakeholders • SME surveys and other initiatives • Communication perception surveys • Targeted stakeholder meetings • Rudimentary tools including website/media monitoring/google alerts • Involvement of patients and health care professionals
Issues not identified and escalated potentially into a crisis	In place: • Media monitoring • Escalation process to DED-PCM level • MLT rules of procedure (escalation of issues) • Incidence Review Network process • Involvement of stakeholders and partners (in particular HCP and patients) in all EMA's activities

In light of the UK decision to withdraw from the EU, the Agency is conducting impact and risk assessment. Along other aspects, the main risks identified are as follows:

Risk	**Impact**
Loss of UK expertise in the scientific work	UK experts constitute 15% of the Agency's expert base and conduct around 20% of the scientific work. Losing these resources will lead to: • significant increase in workload for EU experts, requiring remedial actions to address workload and capacity aspects; • potential loss of specific expertise, requiring remedial actions to ensure that the quality of scientific output is not affected.
Loss of existing staff and inability to recruit new staff, resulting in loss of professional competencies and knowledge	Due to high uncertainty: • current EMA staff may choose to leave the Agency for other organisations to re-acquire longer-term stability and perspective; • the Agency is not able to provide longer-term stability when recruiting new employees, and as such may fail to attract competent experts to fulfil the roles and tasks.
Currency volatility	High fluctuations of GBP to EUR exchange rate introduce instability in the Agency's cash flow and budget.

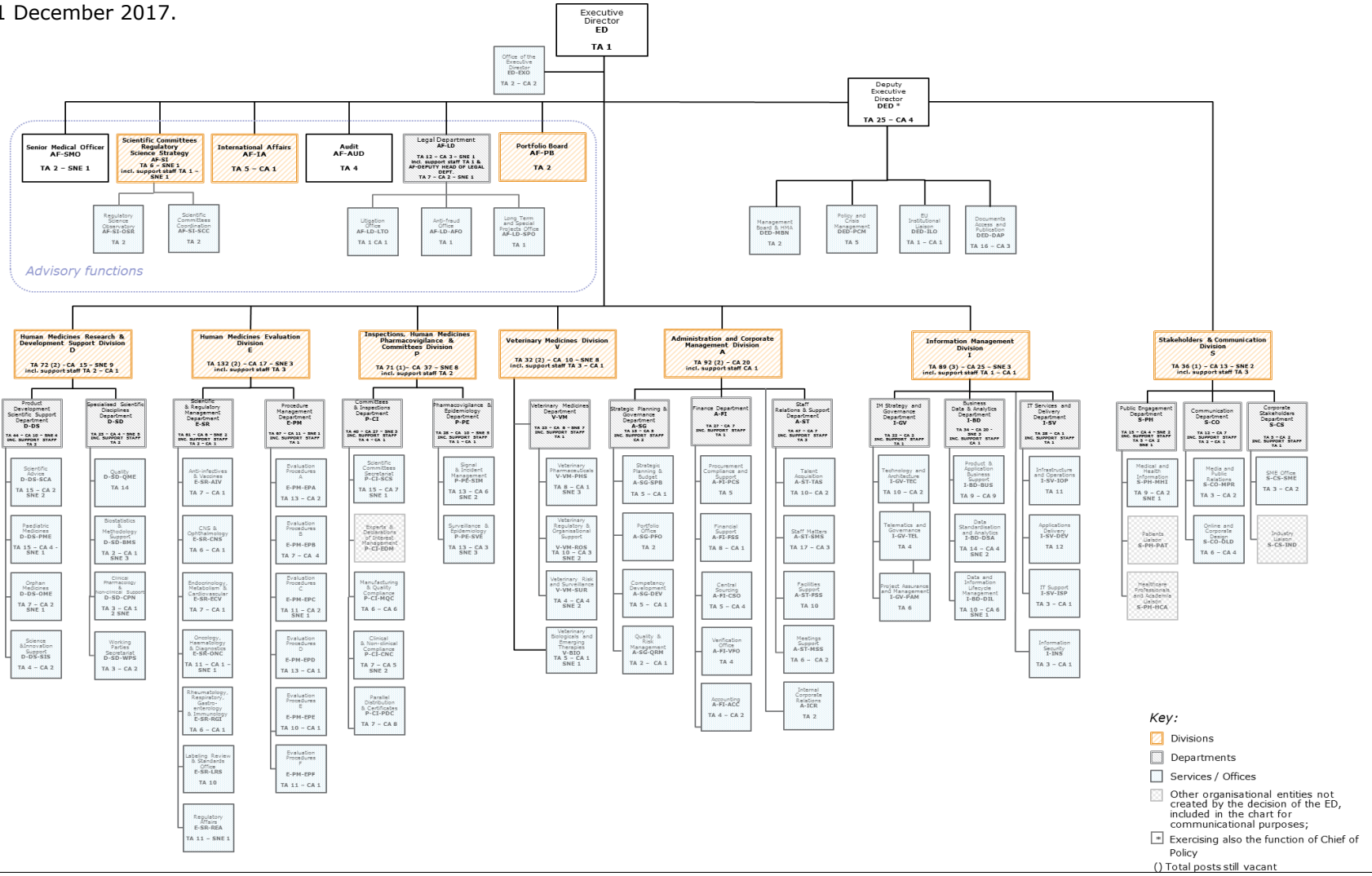
Annex 5: Procurement plan 2018

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

Activity statement:	**Effectiveness and pharmacoepidemiology studies**
Objective:	See Work programme 2018, heading 1.5
Budget:	€ 700,000
Financial year:	2018
Description of action:	Research on utilisation, effectiveness and safety of medicinal products post-authorisation to generate data and information supporting regulatory decision-making, including research on the effectiveness of regulatory measures taken and on the impact of relevant legislation
Type of contract:	Re-opening of competition from existing framework contracts
Number of contracts:	Estimated 4
Indicative timeframe for contract:	Expected to be signed in 2018 (approx. 12-18 months each)
Indicative timeframe for procurement:	Expected to be launched in 2018
Indicative budget for procurement:	€ 700,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010 and Article 31 of Directive 2001/83
Budget line:	3030

Annex 6: Organisational chart

Data as of 31 December 2017.



Annex 7: 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	L'Agenzia Italiana del Farmaco (Italy)
AMR	antimicrobial resistance
ANSM	Agence nationale de sécurité du médicament et des produits de santé (France)
API	active pharmaceutical ingredient
Art	article
AST	assistant category post
AST/SC	secretarial and clerical category post
ATD	access to documents
ATMP	advanced-therapy medicinal product
BCP	business continuity plan
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
CA	contract agent
CADVVA	CVMP ad hoc group on veterinary vaccine availability
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CCI	commercially confidential information
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CO_2	carbon dioxide
COBIT5	Control Objectives for Information and Related Technologies, good-practice business framework for governance and management of enterprise IT
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
CRM	customer relationship management
CT	clinical trial
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	scientific committees of the Agency
DIA	Drug Information Association
DoI	declaration of interests
DPO	Data protection officer
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency

Term/abbreviation	Definition
eCTD	electronic common technical document
EDPS	European Data Protection Supervisor
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
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
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
EudraLink	European Union Drug Regulating Authorities secure file sharing
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
EUTCT	EU Telematics Controlled Terms, a repository and provider of controlled terms in multiple languages for the ongoing exchange of data between information systems and applications throughout the European Medicines Regulatory 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
GLP	good laboratory practice
GMP	good manufacturing practice
GP	general practitioner
GSRS	Global Substance Registration System
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
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
HTA	health technology assessment
HTAN	the HTA network
IAS	Commission's Internal audit service
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities

Term/abbreviation	Definition
ICSR	individual case-safety report
ICT	information and communication technologies
IDD	
IDMP	identification of medicinal products
IGDRP	International Generic Drug Regulators Programme
IMI	Innovative Medicines Initiative
INC	International Neonatal Consortium
IPA	informal network of EU agencies working with pre-accession
IPD	individual patient data
IPRF	International Pharmaceutical Regulators Forum
IRCH	International Regulatory Cooperation for Herbal Medicines
IRM	Institute of Risk Management
ISO	International Organisation for Standardisation
IT	information technology
ITF	Innovation Task Force
ITL	
KPI	key performance indicator
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
MAWP	EMA multiannual work programme
MDM	master data management
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
MSWG	Modelling and Simulation Working Group
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
NUI	non-urgent information
OBIEE	Oracle Business Intelligence Enterprise Edition – a comprehensive business intelligence and analytics platform
OECD	Organisation for Economic Cooperation and Development
OIE	World Organisation for Animal Health
OLAF	European Anti-Fraud Office
OMCL	Official Medicines Control Laboratories
OMS	organisations management service
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
PA	protocol assistance
PAES	post-authorisation efficacy study
Parliament	European Parliament
PAS	Post Authorisation Studies
PASS	post-authorisation safety study
PB	EMA Portfolio Board
PDCO	Paediatric Committee
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
PMDA	Pharmaceuticals and Medical Devices Agency

Term/abbreviation	Definition
PMF	Plasma master file
PPD	protection of personal data
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
PROTECT	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
PSUR	periodic safety-update report
PSUSA	PSUR single assessment
PUMA	paediatric-use marketing authorisation
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
Q&A	questions and answers
RA	rapid alert
RFI	request for information
SA	scientific advice
SAG	Scientific Advisory Group
SA-REPS	scientific and regulatory evaluation procedure support
SAS	Data analytics tool, previously called "Statistical Analysis System"
SAWP	Scientific Advice Working Party
SciCoBo	Scientific Coordination Board
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SLA	service level agreement
SME	small and medium-sized enterprise
SmPC	summary of product characteristics
SNE	seconded national expert
SOP	standard operating procedure
SPOR	Substances, Products, Organisations, Referentials
STAMP	Commission Expert Group on Safe and Timely Access to Medicines for Patients
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
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
WebRADR	Recognising Adverse Drug Reactions
WGEO	HMA Working Group of Enforcement Officers
WHA	World Health Assembly
WHO	World Health Organization
WIN	work instruction
WONCA	World Organization of Family Doctors
WP	working party
xEVMPD	eXtended EudraVigilance Medicinal Product Dictionary