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European Medicines Agency

Final programming document 2019-2021

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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

EMA priority areas: Brexit, and relocation of the Agency

The UK's decision to leave the European Union (EU) following the 2016 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, but it must continue complying with its legal role and performing its activities on time and to the same high level of quality despite both the loss of 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 the Agency's day-to-day activities. It is important in this respect that the new host Member State will fully comply with its commitments as stated in the offer to host EMA.

More significantly, the Agency and the wider EU regulatory 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 some 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 EU regulatory network as a whole, and will require capacity building and re-distribution of the workload among the Member States. In addition, the EU regulatory network may lose access to some specific expertise, which requires further steps to be taken to ensure the quality of the scientific output is not affected. Furthermore, the inevitable staff losses suffered by EMA due to relocation may have significant consequences not only for the Agency but also for the EU regulatory network and this could negatively impact EMA's role in the protection of public and animal health in the EU.

Taking into account the latest EMA staff survey performed in June 2018, conducted to inform the Agency's recruitment strategy to compensate for staff loss, as well as further direct feedback from staff, the end of September 2018 status on staff intention to relocate indicates that a relocation of EMA to the Netherlands could result, in a best-case scenario, in EMA losing some 24% of its total workforce. Although this would allow the Agency to stay operational throughout the transition period, nevertheless there will be important disruption to its daily work. It is also possible that some specific functions may experience significant staff attrition even when the overall staff loss at the Agency level remains manageable. Consequently, actual staff loss will need to be closely monitored to ensure continuity of operations.

Preparations for Brexit consequences

Organisational and operational aspects

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

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

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

Each area of activity is divided into various work streams.

EMA Brexit preparedness and implementation

Work streams include:

- Scientific committees procedures and inspections, which focus 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.
- Brexit preparedness business continuity plan (BCP) which has been developed to address a situation where a "business as usual" scenario is no longer possible. The BCP covers prioritisation of EMA activities in order to free-up the resources needed to prepare for Brexit, particularly the relocation, and to address potential staff loss.
- Staff relocation and support, which 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, its key stakeholders and the wider public.

EMA-Dutch Authorities collaboration for relocation to Amsterdam

The Agency and the Dutch Authorities have put in place a dedicated joint governance structure to steer and oversee the relocation to Amsterdam project, with plans to progress activities within the work streams as follows:

- The new permanent building.
- The temporary building.
- Staff relocation.
- Financial and legal aspects.
- External communication.
- Removal and logistics.

Preparations to date

During 2016-2018 the Agency has undertaken considerable work to address the Brexit impact on the Agency's operations, including but not limited to:

- Completing an initial impact assessment, identifying also the key risks that the Agency would be facing in this environment.
- Preparing the Agency's requirements for the new location, including infrastructure requirements, technical specifications for the new premises, and other factors critical to operations of the Agency, and sharing this information with the interested Member States as well as the EU Institutions.
- Hosting Member State visits to EMA and EMA site visits to candidate host countries upon request from a candidate host Member State.
- Undertaking further analyses of the impact of the decision for the Agency to relocate to the Netherlands.
- Liaising with representatives from the new host city of Amsterdam and the government of the Netherlands following the Council decision of the new EMA seat on 20 November 2017.
- Preparing for the relocation of the Agency's data centres to Hamburg.
- 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 Netherlands.
- Conducting several staff surveys, to gauge the potential staff losses in view of their impact on the Agency's operations and assess potential remedial actions.
- Developing a dedicated Brexit recruitment and selection strategy to address the potential staff loss, including a job and competency mapping to support succession planning.
- Developing and implementing a dedicated EMA Brexit preparedness BCP, to address situations where a "business as usual" scenario is no longer possible.
- Putting in place supporting measures to maximise staff retention and to facilitate the relocation of staff to Amsterdam in addition to the support provided by the Dutch authorities.
- Working with the Member States to address the workload issues arising from the loss of UK expertise and agreeing on the re-distribution. Conducting surveys with the Member States to establish the capacity and training needs.
- Issuing communications and preparing guidance for the pharmaceutical industry, to ensure companies have the correct information and take the necessary steps to be able to operate in the EU 27, ensuring continued availability of their medicines to EU citizens.

Future work

Work on preparing for the relocation and mitigating negative implications of these changes is now intensifying in view of the imminent move of the Agency to Amsterdam and the approach of the date on which the UK leaves the EU. The resource requirements for the move itself, with all the ensuing changes both technical and administrative, together with the resources needed to handle the regulatory changes due to Brexit, will put a considerable strain on the Agency in 2019.

The following Brexit related activities are foreseen for 2019-2020, in order to finalise preparations for and execute the actual move of the Agency to the temporary building and from the temporary building to the permanent building:

Work stream	Activity	2019	2020
Work stream 1: Relocation preparedness	Continue in collaboration with the Dutch Authorities the implementation of the Memorandum of Understanding/ Host State Agreement and monitor such implementation	x	x
	Finalise the necessary procurement procedures enabling EMA operation in Amsterdam	x	
	Initiate and monitor the contractual activities related to the existing providers of services	x	x
	Implement the staff retention and relocation support measures	x	
	Prepare for and carry out the transfer of knowledge on IT systems and programmes	x	
	Implement the plan for relocating EMA to the temporary premises in close collaboration with the Dutch Authorities	x	
	Implement the plan for the new definitive building and work with the Dutch Authorities on the new premises' development project	x	
	Support the Dutch Authorities in the preparation of a plan for relocating EMA to the permanent premises and monitor the implementation of such plan	x	x
	Execute the relocation of the Agency to the temporary premises including move of the archives	x	
	Move the Agency's staff from the temporary to the permanent building in Amsterdam	x	x
	Prepare for and implement changes stemming from the physical relocation, e.g. changes of contact details on all Agency templates	x	x
Work stream 2: Operational and financial preparedness	Finalise redistribution of work on evaluation and monitoring of medicines with NCAs	x	
	Establish and conduct with the NCAs the training identified through the capacity and training surveys through the EUNTC	x	x
	Prepare Q&As and guidance documents for	x	

Work stream	Activity	2019	2020
	pharmaceutical industry on the Brexit-related changes to marketing authorisations		
	Handle the additional, Brexit-related post-authorisation applications	x	
	Identify remedies to address supply shortages resulting from the impact of Brexit on the availability of centrally authorised products	x	x
	Draft and implement the next phases of the EMA Brexit preparedness BCP as need arises	x	
	Implement additional business continuity measures during the relocation period in 2019	x	
	Develop and implement additional business continuity measures for the relocation from the temporary to the permanent building	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	Undertake any recruitments necessitated by staff loss	x	x
	Prepare for operational activities related to relocation of staff including interaction with the Dutch authorities	x	
Work stream 4: Communication	Provide timely and targeted communication to the EU regulatory network, stakeholders and pharmaceutical industry	x	x
	Provide timely communication to staff and contractors	x	x
	Ensure adequate communication on the operation of EMA to relevant decision-makers and citizens in the Netherlands/Amsterdam	x	x
Project coordination	Undertake efficient coordination of the overall project relating to the EMA relocation to the Netherlands and the Brexit impact on EMA operations, including robust budgeting	x	x
FORECAST FTE WORKLOAD		62 FTEs	12 FTEs

Impact on the Agency's activities

EMA'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 level of 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. To enable the Agency to prepare for the physical move to the new EMA premises in Amsterdam and its impact on the Agency's operations, the Agency implemented the first phase of its BCP in May 2017, ensuring delivery of its highest priority activities while temporarily scaling back or suspending lower priority activities. A further set of EMA activities, including medium priority activities, were temporarily affected as of January 2018.

The Agency implemented phase 3 of the BCP on 1 October 2018 in order to safeguard core activities related to the evaluation and supervision of medicines, while the Agency is intensifying its preparations for the physical move to Amsterdam in March 2019 and is coping with significant staff loss, primarily relating to its short-term contract staff. Phase 4 of the BCP will start as of 1 January 2019 to address further staff loss and to cope with the critical period relating to the physical move itself. The staff loss will be closely monitored and the situation will be reviewed in the second quarter of 2019 at which time the Agency will review the priorities, the measures and the work to be undertaken in the second half of 2019.

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 EU 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 the EU and would also jeopardise production and distribution of medicines in the EU.
- Category 2, medium priority activities (subdivided in 2A and 2B), either strategic activities or other core activities not captured in category 1, which include various initiatives aimed at promoting availability of medicines as well as some political priorities of the EU, for example, EMA's contribution to the fight against antimicrobial resistance or the Agency's interactions with Health Technology Assessment (HTA) bodies. These medium priority activities will be maintained for as long as possible, workload and staffing situation permitting, in order to safeguard the development of new medicines.
- Category 3 activities are the lowest priority and cover governance and support activities, such as corporate governance, audits, participation in and organisation of meetings and conferences.

Some activities, for instance, 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 suspended or reduced, with the understanding that a reduced output should continue to adhere to the same high standards, although it may result in a reduction of volume or a delay in the time to achieve the agreed deliverables.

EMA approach towards the 2019 and 2020 work programme

On the basis of the end of September 2018 knowledge of anticipated staff loss for 2019 and 2020, 2019 will be a year of transition for EMA, whilst the Agency will strive for 2020 to be the year of paving the way for the future.

The first half of 2019 will require EMA to focus on category 1 activities; only critical category 2A and 2B activities will be maintained, albeit downsized as needed. No new activities will be undertaken during the first two quarters of 2019. All other activities remain temporarily suspended or reduced. During the crucial period around the physical relocation from London to Amsterdam (anticipated to be from mid-February to mid-March 2019) specific arrangements will apply since a high disruption to the normal working pattern of EMA staff is forecast. Consequently, during this time period the focus will only be on category 1 and Brexit related activities.

The Agency aims to gradually restore previously suspended/reduced activities as of the 2nd half of 2019. This will be undertaken by first drawing up a list of priorities for further consideration. Where relevant and feasible, a reflection on longer term sustainability will take place before restoring the prioritised activities. In the 2nd half of 2019 the Agency will also start preparing for the next 5 year strategy (2020-2025) in collaboration with the EU regulatory network. In such next 5 year strategy EMA will put particular emphasis on its Regulatory Science Strategy as well as on its Corporate ICT Strategy.

The work programme for 2020 should, on condition that the Agency can fully restore its overall workforce, result in a lifting of the previously temporarily suspended/scaled back activities, revised as necessary to achieve longer term fit-for-purpose applications/processes/tools and thus further increasing the efficiency of the Agency's operations.

The list of activities temporarily suspended or reduced, as described below, 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 (an exception is made for IAS and ECA audits, legally required audits and 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 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 MNAT pre- and post-authorisation e-submissions programme All missions relating to reduced activities *All legal requirements are maintained*

Priority level	Temporarily suspended activities	Temporarily reduced activities
Category 2 (medium prioritised activities)	Development of the European medicines web portal; Development of extranet & intranet functionality Interaction with pre-accession countries to support 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 Proactive publications of clinical data under Policy 0070 All missions relating to suspended activities	Interaction with patients, healthcare professionals & academia reduced with the exception of: • A webinar for PCWP/HCWP Q1 2019 on Brexit preparedness; Interaction with industry stakeholders reduced except for: • Webinars for industry stakeholders in January 2019 and June 2019 to update on Brexit related activities; Transparency, information, and non-product related communication: • Reduced to exceptional participation in conferences and meetings with stakeholders; • reduce production of brochures / info-sheets / leaflets • reduce number of workshop reports giving priority to category 1 and 2A activities • reduction in exhibition services • reduce translations by 50%, prioritising those legally required Training to stakeholders and NCAs that are not essential to support capacity building for Brexit, or to implement new legislation (e.g. clinical trials) Product-specific focus of engagement on geriatrics rather than general guidance Training in areas such as GxP, general pharmacovigilance and quality topics All guidelines development, including consultative meetings with stakeholders, including GVPs except those that will meet an urgent public/animal health need, are needed in the context of Brexit or for implementation of new/revised legislation; Reduction of the number of meetings of the working parties and of QRD working group, NRG and GXP IWGs to those meetings that are product-related 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 FDA and PMDA • Reduced support for visiting experts • Activities related to international reliance

Priority level	Temporarily suspended activities	Temporarily reduced activities
		• Only exceptional participation at DIA, TOPRA, RAPS and limited to 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 to outcome of projects will be reviewed. • Engagement in advisory boards of new IMI projects and follow up to existing IMI projects will be reviewed on a case-by-case basis and overall 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 2019–2021

Multiannual objectives

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

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

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

The current integrated Network strategy covers the time period to 2020 and guides the EMAs multi-annual work-programming. Anticipating a new EMRN strategy to 2025 the EMA has initiated a reflection on its regulatory science engagement priorities through 2018 which following a public consultation is expected to be finalised by the end of 2019. This reflection is expected to constitute a key building block of the EMRN strategy to 2025 which will then drive future multi-annual work programmes including a cascade to individual scientific committee and working party work-plans.

Theme 1: Contributing to human health

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

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

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

Theme 3: Optimising the operation of the network

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

Theme 4: Contributing to the global regulatory environment

Theme 4: Contributing to the global regulatory environment	
Objective 1: Assure product supply chain and data integrity	Main areas of work: supply chain and data integrity, information sharing
Objective 2: Convergence of global standards and contribution to international fora	Main areas of work: harmonisation of standards and approaches, contribution to international cooperation mechanisms, use of animals in medicines development
Objective 3: Ensure best use of resources through promoting mutual reliance and work-sharing	Main areas of work: work-sharing, information sharing and increasing reliance on European assessments
Objective 4: Support training and capacity building and promote the EU regulatory model	Main areas of work: non-EU regulators' training and capacity building

Multiannual work programme

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

Theme 1: Contributing to human health

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

NR – not reduced 2B activity

RA – reduced 2B activity

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	2A Activity suspended first half of 2019	- 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	2A None – activity maintained	- number and proportion of TATFAR actions implemented (where EMA has a role) - level of completion of the actions
		1.1-3	Contribute to implementation of the next phase of the EC Action Plan on antimicrobial resistance, and other action plans such as the WHO Global action plan and OIE strategy	2016	2019	2A None – activity maintained	- actual contribution to EU institutions activities including EP - contribution to WHO led initiatives -contribution to initiatives related to clinical trials networks and other funded projects, e.g. IMI - completion level and/or rate of

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							implementation of actions in the action plan(s)

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

Public health needs and priorities	Ensure needs of specific populations are met, including elderly, children, patients with rare diseases and others	1.1-4	Contribute to Global Action Against Dementia (GAAD)	2015	2019	2B NR None - completed	- implementation of the actions in the GAAD
		1.1-5	Implement the geriatrics strategy	2011	2020	2B NR Activity suspended first half of 2019	Level of strategy implementation: proportion of actions implemented - Frailty reflection paper [completed] - Pilot review of outcomes [completed]
		1.1-6	Support innovation, early dialogue and research for paediatric medicines	2007	2021	2A Restricted to activities addressing public health needs in 2019	- support to early engagement with developers of paediatric medicines (continue common commentaries with the FDA, other pre-submission interactions) completed (ongoing) - number of scientific workshops / expert meetings to support innovation in paediatric medicines - 1 Accelerate multi stakeholder forum - 1 EC/EMA multi stakeholder workshop - 1 Enpr-EMA working group meeting (In planning for October 2018) - 1 Enpr-EMA annual workshop

		1.1-7	Scientific and regulatory contribution enhancing drug safety in pregnancy	2015	2019	2B RA Activity suspended first half 2019	- delivery of the GVP special populations III: pregnant and breastfeeding women
		1.1-8	Strengthen scientific evaluation of orphan designation criteria by COMP at the time of MAA	2015	2020	1A None – completed	- publication/availability of additional guidance on the evaluation of significant benefit - publication of orphan maintenance assessment reports

Public-health emergencies	Enhance ability to respond quickly to public-health emergencies	1.1-9	Facilitate early introduction of appropriate treatments or preventive measures	2015	2020	1A Early interaction 2B RA International None – activity maintained	- interactions with developers in early phase (pre-Scientific advice) to Scientific advice and Marketing authorisation applications -international collaboration including clinical study design and emergency use
		1.1-10	Improve Health Threats plan and update post-health-threat activity completion (e.g. Ebola, Zika etc.)	2015	2018	2B RA None - completed	- action plan developed and process for rapid answers set up: [completed] - number of 'lessons' implemented from the 'lessons learned' [completed]

Supply issues and availability of new and well-established medicines	Minimise risk and impact of shortages due to manufacturing problems and quality defects	1.1-11	Implement revised action plan regarding medicinal product supply shortages caused by manufacturing/good manufacturing practice compliance problems, including - 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	2A None – activity maintained	- implementation of the action plan: level of completion of initiatives and proportion of initiatives implemented
		1.1-12	Develop formal collaboration with WHO in the area of supply disruptions	2017	2021	2B RA Restricted to support / collaborate with the HMA / EMA Taskforce on availability in first half of 2019.	- formal agreement with WHO - number of cases worked in collaboration
		1.1-13	Support to the European Observatory on the supply of medical radioisotopes	2017	2020	2B RA Restricted to exchanges on product specific issues in first half of 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
		1.1-14	Consolidate information on compliance issues and quality defects	2017	2020	2B RA Suspended first half of 2019	- system of warning letters in case of GMP non-compliance issues implemented - completed - improvements implemented in the coordination/handling of quality defects across the network

	Address the threat posed by illegal medicines supply chains	1.1-15	Continue to support the implementation of the Falsified Medicines Directive	2011	2019	2A None - completed	- number of cases supported/coordinated by EMA in relation to falsified medicines in the supply chain [completed]
		1.1-16	Streamline process for reporting of suspected falsified medicines in the supply chain by MAHs	2011	2019	2A None - completed	- implementation of the revised form for reporting quality defects and suspected falsified medicines – completed according to mid-year activity line 112 [completed]
		1.1-17	Strengthen communication within the network, including with WGEO	2014	Continuous	1A None - completed	- timely sharing of relevant information related to illegal supply chain as it is notified to EMA – sharing of information within the network and WGEO has been implemented and is an ongoing activity. [completed]
	Facilitate/support availability of already approved medicines	1.1-18	Contribute to the work of the EMA/HMA Joint task force on availability of authorised medicines for human and veterinary use (TF AAM)	2016	2021	2A None - Activity maintained first half 2019	- 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	Reduce time–to-patient of novel medicines through	1.2-1	Integrate 'adaptive pathways' concept into formal EMA scientific	2014	2020	1A Activity suspended in 2019	- number of scientific advice procedures with proactive and

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
	optimised use of existing and new assessment approaches within existing regulatory frameworks		advice procedures				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	1A None - completed	- number/increase in PRIME products that received scientific advice - time from request to final response, compared with other products and with previous period [completed]
		1.2-3	Develop/enhance collaboration with EUnetHTA, HTAN as well as HTA/pricing and reimbursement bodies in the area of parallel regulatory-HTA scientific advice, including contribution to specific deliverables in EUnetHTA Joint Action 3	2010	2020	2A None – activity maintained	- 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
acc ess	Support effective and efficient conduct of pharmacovigilance	1.2-4	Implement planned access and analysis of real-world data	2016	Contin uous	2B RA Restricted to activities directly related to product support in first half of 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	2016	Contin uous	2B RA None – Activity maintained	- patient registries actually used for novel medicines implemented and activity is now a routine

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			Action 3				activity (core business)
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	2B RA stakeholder interaction or 1A Activity restricted to activities directly related to product support in 2019	- processes to capture such values and preferences developed and implemented - increased number of cases where patient and healthcare professional 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	2020	1A Activities are entered in 1.7 projects	- availability of functional IT tools/systems
		1.3-2	Update guidelines and inspection-related procedures in accordance with the new legal requirements	2014	2018*	2B RA guidelines or 2A implementation new legislation None - completed	- level of completion or availability of updated guidelines/processes

*Audit of the system is planned to take place in 2019; depending on successful completion of the audit the system could be ready to go live in 2020.

Innovation	Facilitate translating innovation into medicinal products	1.3-3	Streamline interaction with academia	2016	2020	2B RA stakeholders or 2A innovation None – activity maintained	- 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	2A None – activity maintained	- 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	2A Restricted to activities directly related to product support in first half of 2019	- number of research areas/opportunities identified
		1.3-6	Explore opportunities to reduce regulatory and administrative burden	2017	2020	2A Activity suspended in 2019	- number of opportunities identified and implemented, including those raised through stakeholder platform meetings
		1.3-7	Strengthen collaboration and integration across the Network and with academia to facilitate translation of innovation into medicinal products, through involvement of academia in early dialogue procedures (ITF, Innovation network, SA, paediatric procedures, PRIME, orphan designation)	2016	Continuous	2A Restricted to observer status in first half of 2019	- increase in the number of early dialogue procedures involving academia

	Provide adequate regulatory support to innovation stemming from SMEs and academia	1.3-8	Review existing support measures and explore additional supportive measures to incentivise innovation by SMEs	2016	2020	2A Restricted to activities directly related to product support in the first half of 2019	- 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	1A None- activity maintained (pilot phase extended for Brexit reasons)	- implementation of required processes
		1.4-2	Ensure EU network is ready for the new EudraVigilance functionalities, including centralised reporting and the new data format	2016	2018	1A None - completed	- number of NCAs/MAHs trained on new functionalities completed – training of MS will continue
		1.4-3	Explore the potential use of real-world databases, electronic healthcare records and 'big data'	2016	2020	2A innovation/emerging technologies Restricted to activities directly related to HMA Big Data taskforce	- number of new data sources used in regulatory activities/decision-making – the inventory of the electronic healthcare data is completed.
Transparency	Increase access to data for delivery of regulatory activities	1.4-4	Take forward discussion on making available individual patient data (IPD) from clinical trials to assessors	2016	2020	SUSPENDED 2B RA Activity suspended in first half of 2019	- 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	2014	2020	2B RA Activity suspended	- availability of clinical trial data/information

			Trials Regulation regarding the transparency and availability of clinical trial data				
		1.4-6	Improve provision of information to patients and prescribers [completed]	2011	2017	None - completed	- 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	2A Activities suspended	- number of environmental risk assessment supported by EMA in initial marketing authorisation Assessment Report

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

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

Area	Medium-term objective	No	Initiative(s)	Start	End	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	2022	2A None – activity maintained	- 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] - training available in EU NTC
	Support development and availability of veterinary	2.1-2	Identify and implement EMA contribution to the EU Network	2016	2022	2A Activities suspended first	- increased number of pre-submission requests and

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
	medicines		Strategy to 2020 in the area of promoting availability of vaccines within the EU			half of 2019	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 - reflection paper on promoting availability of veterinary vaccines in emergency situation published
		2.1-10	Participate in the HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use	2016	2022	2A None – activity maintained	- completion of actions assigned to EMA concerning veterinary medicines in the joint EMA/HMA task force on availability of authorised medicines for human and veterinary use
	Explore ways to limit attrition of existing products	2.1-3	Develop with the network a strategy and action plan to support retention on the market of long-used veterinary antimicrobials	2016	2020	2A None – activity maintained	- pilot project on extrapolation of data on existing antimicrobials to promote their retention on the market
	Explore new ways for specific sectors to improve availability	2.1-4	Cooperate with FishMed Plus coalition to increase availability of medicines for use in aquaculture	2016	2022	2A Restricted to promote access to the Agency's Innovation Task Force	- 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

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							availability of medicines for use in aquaculture
		2.1-11	Explore with relevant stakeholders approaches to best use of existing and new antiparasitic veterinary medicine so as to minimise development of antiparasitic resistance	2016	2022	2A Activities suspended first half of 2019	- 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 reflection paper on anthelmintic resistance
Innovation	Promote innovation and use of new approaches in the development of veterinary medicines	2.1-5	Evaluate the impact of measures recently put in place to support innovation (ADVENT, ITF) and implement improvements in measures to support innovation	2016	2022	2A Activities reduced to promoting access to the Agency's Innovation Task Force	- 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	2022	2B RA None – activity maintained	- 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	2B RA None - completed	- 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 animal husbandry included in the 10-year review programme (long-used substances)	2015	2022	1A None- activity maintained	- role of EMA confirmed with the European Commission for establishment of MRLs for biocidal substances
		2.1-9	Provide technical support to the European Commission in drafting implementing acts specified in Regulation 470/2009	2016	2018	2B RA None - completed	- recommendations and implementing acts sent to the EC [completed] - “other provisions” in Regulation (EC) 37/2010 reviewed [completed]

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	None - completed	- advice provided to the European Commission on request in a timely and accurate manner [completed]
		2.2-2	Put in place the revised EMA processes and IT systems as envisaged in the revised legislation	2015	2021	2A Activity suspended in first half of 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)
		2.2-9	Provide technical support to the European Commission in drafting implementing and delegated acts specified in the new veterinary legislation	2019	2021	2A None – activity maintained	- recommendations and implementing acts sent to the EC
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	2B RA Activity suspended first half of 2019	- 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	2B RA Guidance 1A signal detection None – activity maintained	- 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 [completed]
		2.2-5	Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species	2016	2020	2B RA Activity suspended in 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	2022	1A None – completed	- existing Incident Management Plan tested and updated in light of testing and experience [completed] - continuous monitoring and update in light of experience
Qu alit	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	2016	2020	2B RA guidance 2A EUNTC Activity restricted to	- templates for assessors finalised [completed] - high-quality assessment reports

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
of sci			CVMP assessment reports, including training in cooperation with EU NTC			consider and develop training in cooperation with EU NTC in areas identified by CVMP to build network assessment capacity"	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	2019	2B RA Suspended activity first half of 2019.	- 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 implementation of new veterinary regulation)

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

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
Ant imi	Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	2.4-1	Engage with the EC and Member States to identify and, where possible, prioritise the referral of antimicrobials and other classes of products for which the conditions of use need to be both harmonised and aligned with the principles of prudent and	2010	2020	2A Suspended first half 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)
			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	2A None - maintained	- 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	2A None - completed	- methodology approved by the steering group [completed] - guidance on methodology published [completed]
		2.4-4	Provide advice to stakeholders on prudent and responsible use of veterinary antimicrobials	2015	2019	2B RA/2A Activity suspended first half of 2019	- reflection paper on aminoglycosides published [completed] - reflection paper on extended-spectrum penicillins published
		2.4-5	Provide scientific advice to the EC on optimising the use of antimicrobials in veterinary medicine	2015	2022	1A None - maintained	- 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 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

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							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 - third report with EFSA and ECDC on consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals prepared
Risk to the environment	Effectively manage risks to the environment arising from the use of veterinary medicines	2.4-6	Develop a strategic approach to persistent bioaccumulative and toxic substances within the authorisation procedure for veterinary medicinal products	2014	2022	2B RA Activity suspended first half of 2019	- 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	2022	2B RA Activity suspended first half of 2019	- finalised guideline on risk assessment of veterinary medicinal products in groundwater [completed] - 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 environment	2015	2022	2A Activity suspended first half of 2019	- 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	2A None – activity maintained	- 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)
Regul	Ensure 'fit-for-purpose' scientific capability of the network	3.1-1	Conduct horizon-scanning to ensure understanding of and preparedness for emerging	2016	Continuous	2B NR Activity to develop a regulatory science strategy	- inventory of needs available - mapping of expertise versus needs available

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			technologies in medicines, and identify gaps in expertise			has been suspended first half of 2019, remaining activities are maintained	
		3.1-2	Deliver curricula for competence development on the basis of the identified needs	2016	Continuous	2A None – activity maintained	- action plan available - number of curricula drafted - continuous activity
		3.1-3	Develop a catalogue of training material through the EU Network Training Centre	2016	2019	2A None – activity maintained	- 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	2A None-activity maintained	- 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-authorisation	2016	2020	1A None- activity maintained	- increase in the number of MNAT procedures - implementation level of the identified improvements
		3.1-6	Implement the multinational assessment team approach post-authorisation in a phased approach	2016	2019	1A None –activity maintained	- increase in the number of MNAT procedures - implementation level of the identified improvements
ry cap		3.1-7	Enhance outreach for academic expertise for services provided to	2017	2019	2A Suspended first half of 2019	- implementation of the framework of interaction with academia

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			EMA, in particular as regards innovation of medicines				
Scientific and regulatory expertise	Strike an optimal balance between ensuring impartiality/independence of experts and securing the best possible scientific expertise	3.1-8	Undertake annual review of the EMA independence policies to identify room for improvement to strike such balance	2016	continuous	1A Suspended first half of 2019	- 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 system	Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	3.2-1	Undertake a continuous review and improvement of the centralised procedural management	2016	2020	2A Activity suspended first half 2019	- processes maintained /updated using an agreed methodology - key interfaces with network and industry enhanced (as demonstrated using surveys, workshops, etc.) [completed] - increased efficiency of the processes [completed]
		3.2-2	Undertake a continuous review and improvement of the EMA support to scientific committees/working parties/expert groups	2016	2021	2B RA guidelines 1A committees Restricted to review and implement optimised operations in first half 2019	- increased productivity of the committees - optimised product support and guideline generation activities, following revision of the working

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							party utilisation
		3.2-3	Undertake a revision of the operation of the EU pharmacovigilance system for human medicines	2017	2020	2A Restricted to providing input to the commission review of the pharmacovigilance tasks of EMA and NCAs	- 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	3 None - maintained	- integrated planning and reporting system introduced
		3.2-5	Ensure EMA has the right capabilities to deliver its mission	2016	2020	1A None - maintained	- 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	2A Restricted to implement new legislation maintained	- number of analyses conducted - number of contributions to the EC made
		3.2-7	Participate in the BEMA exercise as per the agreed BEMA cycle	2016	2020	3 Activity suspended in 2019	- participation undertaken as per the agreed BEMA cycle - review of quality-management framework undertaken and resulting actions implemented
		3.2-8	Provide regular training to BEMA assessors	2016	2020	3 Activity suspended in 2019	- 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	None - completed	- data-gathering initiative conducted as per the action plan [completed]

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
		3.2-10	Contribute to external evaluation of the current fee regulation	2016	2018	2A None – completed	- 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[1]	2016	2020	1A None – no activities in blue table	- 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 2C None – no activities in blue table	- access provided to clinical data - European Medicines Web Portal operational [suspended] - improved provision of data and analytical capability
Quality of scientific outputs	Strengthen the quality of the scientific review processes	3.2-14	Achieve common standards of scientific quality across the network	2016	2019	2B RA Activity suspended first half of 2019	- 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	2B RA Activity suspended in first	- revised procedure and harmonised standards for

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

						half of 2019	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	2019	1A Activity suspended first half of 2019	- utilisation of the effects table in pilot post-authorisation procedures – pilot completed - explore B/R modelling (CHMP activity) is still ongoing

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	2B RA/1A Activity maintained	- framework strategy for external communication approved and implemented, supported by annual communication plans
		3.3-2	Implement an Agency-wide structure for public hearings	2016	2020	1A Report on lessons learned suspended first half of 2019	- public hearings for safety-related referrals implemented and lessons learned incorporated
		3.3-3	Upgrade the EMA corporate website	2016	2020	2A None - maintained	- EMA corporate website upgraded
		3.3-4	Develop and implement a social media strategy	2016	2020	2B RA Activity suspended first half of 2019	- implementation level of the approved strategy
		3.3-5	Expand the range of digital and multimedia communication tools	2016	2020	2B RA Activity suspended first half	- increased production of material with new communication tools

						of 2019	

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	2B RA Activity suspended in 2019	- 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 and stakeholders	2016	2021	2B RA Activity suspended in 2019	- biennial perception survey implemented and analysed
		3.3-8	Explore additional ways to assess the impact of EMA communications [completed]	2016	2017	None - completed	- dedicated workshop with HCIN planned and organised [completed]
		3.3-9	Advance the development of the European Medicines Web Portal	2016	2021	2C Activity suspended in 2019	- 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	2B RA Activity suspended in 2019	- 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	2C None completed in 2018	- final output from ADVANCE project available – final report expected to be published by end 2018 - contribution to the Joint Action on Vaccination led by France and DG Santé, in accordance with the work programme of the Joint Action
		3.4-2	Strengthen cooperation with other EU agencies in areas of common interest, taking into account memoranda of understanding where they exist	2016	2020	2A None – activity suspended in 2019	- mapping of areas of common interest completed - 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	None - completed	- extended scope achieved and implemented - number of medicinal products/APIs included in the sampling and testing programme Contract was renewed taking into account above indicators - completed

Collaboration with stakeholders	Increase collaboration with civil-society representatives	3.4-4	Involve patients, healthcare professionals and academia more, to further integrate clinical practice and real-life experience of disease and its management along a medicine's lifecycle	2016	2020	2B RA/1A Activity reduced in 2019 to product related involvement	- 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	2B RA/1A Activity suspended in 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	2B RA Activity reduced in first half of 2019 to Brexit and Category 1 and 2A activities.	- 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	None - completed	- timely sharing of relevant product information related to GMP inspections, quality defects and shortages – activity has been implemented and has become a routine activity – completed.
	Improve knowledge and understanding of data integrity, and implications for regulatory decision-making	4.1-2	Develop guidance on data integrity in collaboration with PIC/s	2017	2020	2B RA Activity suspended in 2019	- draft guidance published
		4.1-3	Develop joint communication and training in collaboration with the FDA	2016	beyond 2020	2B RA None – completed	- 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 the EudraGMDP Planning module [completed]	2016	2017	None - completed	- 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	None -completed	- increased coverage of GMP inspections in third countries, using fewer network resources – completed – see midyear report line 111
		4.1-6	Implement a risk-based approach to PMF inspections	2012	beyond 2020	None - completed	- implementation level of the risk-based approach to PMF inspections completed according to mid-year

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
							report line 115

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	1A Activity suspended first half of 2019	- Network approach to inspections and training collaboration agreed, with particular focus on China and India – implemented and is now a continued activity - agreed procedures for cooperation
		4.2-2	Invite non-EU regulators to relevant training activities and to observe GCP and GMP inspections	Continuous	Continuous	2B RA Restricted to specific inspections requested in 2019	- increase in number of non-EU inspectors participating in relevant training activities – implemented and is now a continued activity - increase in number of non-EU observers participating in inspections
	Facilitate effective information-sharing by using international electronic standards	4.2-3	Implement first iteration of international electronic standards within the EU, and extend to non-EU countries	2012	2020	2B RA Restricted to product specific exchanges	- 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	2020	2B RA Activity suspended first half 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	2016	2020	2B RA Activity suspended first half	- EU systems and approach presented at international training

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			uptake of VICH standards by non-VICH countries			2019	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 2B RA Activity suspended first half 2019	- 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	2B RA Activities suspended in 2019	- mechanism to ensure participation and feedback through pharmaceutical committee and HMA agreed
Use of animals in medicines	Minimise use of animals in medicines research and development activities	4.2-9	Contribute to the development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch-testing of veterinary vaccines and other relevant areas	2014	2017	2B RA None - completed	- completed guidelines on applying 3Rs [completed 2017]

		4.2-10	Improve the guidance available on regulatory acceptance of 3R principles in testing approaches	2014	2018	2B RA None – completed	- availability of up-to-date guidance [completed]

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

Area	Medium-term objective	No	Initiative(s)	Start	End	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	2020	1A None – activities maintained	- 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	2B RA Restricted to product specific issues in first half of 2019	- GCP initiative with PMDA established - pharmacovigilance inspection initiative with FDA established
		4.3-6	Leverage the technical, procedural and scientific advancements resulting from the EU pharmaceutical legislation to improve convergence with other regions	2017	beyond 2020	2B RA Activities restricted to product related activities	- 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	2B RA Activities suspended in 2019	- document on good-reliance practices - increased cooperation with FDA on generics
		4.3-4	Improve existing mechanisms for sharing and exchanging information with other regulators on products throughout their	2017	beyond 2020	2B RA Restricted to exchange on product specific issues in first half of 2019	- agreement on template for sharing confidential information

Area	Medium-term objective	No	Initiative(s)	Start	End	BREXIT implications	Performance indicator(s)
			lifecycle				
		4.3-5	Explore opportunities to leverage resources in other areas and increase reliance of other regulators on European assessments and outputs	2017	continuous	2B RA Activities suspended in 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	2B RA Activity suspended first half 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	2B RA Activity suspended first half 2019	- increased number of participants from developing countries / non-EU regulators

Resource outlook

Overview

The priority in 2019 will be managing resources to ensure the successful relocation of the Agency, while ensuring that scientific recommendations and supervision of medicines can continue to be delivered on time and to the same high level of quality, taking into account the loss of the UK expertise and the anticipated staff loss at the Agency. Business continuity will need to be maintained within an environment where it is expected that 20% or more of the workforce will not relocate, with a consequent challenge to ensure that critical knowledge and skills are transferred and retained. In addition to staff loss, the relocation tasks and workload described in detail in Part I of this document will require around 62 FTEs in 2019. The Agency is requesting that a pool of up to a maximum of an additional 40 'Brexit' contract agent is approved exceptionally from 2019 for a limited period of three years. This will provide limited risk mitigation to ensure that relocation tasks are carried out successfully, and knowledge transfer from experienced to new staff is secured.

During 2019 the Agency will also take steps to prepare for the future (2020-2025 strategy), with particular emphasis on Regulatory Science Strategy and Corporate ICT Strategy. In a sense, 2019 will be a year of transition while 2020 will be the year of returning to 'cruising speed' but also paving the way for the future. From the second half of 2019, activities that have been reduced or suspended/reduced will be gradually in line with the priorities identified in the Network strategy to 2020, but only after reflection on the most efficient way to achieve longer term fit-for-purpose applications, processes and tools. Equally, the Agency will continue to work on workforce planning from a strategic perspective, to ensure the right competencies are in place to meet the needs of the Agency and its stakeholders both now and in the future, and to maximise the use of scarce resources.

The Agency will endeavour to cope with the additional budgetary challenges within the budgetary envelope originally approved by the budgetary authority and fee revenue. It 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. Relocation-driven costs are budgeted at €30.6 million in 2019, with a further provision of €14.4 million to mitigate the risk of exceptional costs (a total of €45.0 million in 2019). Preliminary figures for 2020 estimate there will be a need for a further €43.0 million relocation-driven cost.

Financial resources

Revenues from fees and charges are expected to fall by €7.3 million (-2.4%) in 2019 compared with 2018 budget, totalling €297.2 million, before growing again in 2020 by €14.2 million (+4.8). The relatively small decrease in 2019 is considered to be as a result of one-off timing factors and short-term operational challenges faced by the pharmaceutical industry when responding to the Brexit environment, and there are no indications of any fundamental changes or trends concerning the pattern of marketing authorisation and post-authorisation applications. Nevertheless, the Agency will

carry out regular reviews of fee forecasts and maintain contact with the pharmaceutical industry to monitor early indications of possible fluctuations in the applications submitted.

Revenue from the EU/EEA contribution for 2019 is budgeted at €35.5 million, €6.5 million below the EU Multi-annual Financial Framework level of €42 million originally requested by the Agency, in line with the decision of the budgetary authority to reduce it. Of the overall contribution, €14.5 million is funded by the positive balance of the EMA budget outturn in 2017, leaving €21.0 million to be funded out of new 2019 credits from the EU budget (compared to the EU Multi-annual Financial Framework level of €42.0 million). Out of this funding, €15.7 million is earmarked as a special contribution to fund fee reductions for applications for orphan medicinal products, leaving €5.4 million (under 2% of total budget) to contribute to the funding of the non-fee financed general public health activities at EMA. For the preliminary draft 2020 budget, the EU contribution is budgeted in line with the EU Multi-annual Financial Framework ceiling.

Due to the factors described above, overall revenue from 2018 budget to 2019 budget decreases by €4.8 million, or 1.4%. In 2020, revenues are expected to increase by €36.5 million overall, with €14.2 million generated by additional fee income, €7.3 million by EU contribution (in line with the Multi-annual Financial Framework), plus one-off assigned revenue of €15 million from a one-time financial incentive provided by the Dutch Authorities to be used to support the building fitting-out costs of the new premises in Amsterdam.

Budgetary expenditure, as with revenue, is equally planned to decrease by €4.8 million (-1.4%) in 2019, and then increase by €36.5 million in 2020 (including the €15 million fitting out costs mentioned above). These figures include €45.0 million of Brexit-related relocation costs in 2019 and €43.0 million of further Brexit-related costs in 2020.

The 2019 Brexit costs are broken down into: €21.9 million 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 up to 40 additional contract agent FTEs to cope with additional relocation workload and knowledge transfer; €8.4 million in Title II, primarily covering IT costs, removal and archiving costs, and legal and consultancy fees; and €200K in Title III.

In addition the 2019 budget includes provisions totalling €14.4 million 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 final settlement in line with the negotiation directives of the Council cited above.

The 2020 Brexit costs are broken down into: €6.9 in Title I, of which the main element is staff relocation support measures and the cost of 40 additional contract agent FTEs to cope with additional relocation workload and knowledge transfer; €17 million in Title II, primarily covering the physical infrastructure aspects of the relocation (of which €15 million is financed by the financial incentive provided by the Dutch Authorities). In addition the 2020 budget includes provisions totalling €19.1 million 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 2020, using similar assumptions as described above for 2019.

It should be noted that neither the 2019 or 2020 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 a request for additional funding through an amending budget.

Finally, it should also be noted that both 2019 and 2020 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 Appendix 1 of this document for a more detailed Activity Based Budget analysis of how human and financial resources are allocated to the activities of the Agency in 2019 and 2020.

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 remain at 591 in 2019, to fully comply with these requirements, taking into account the 3 additional posts authorised by the Budgetary Authority for 2016. EMA is requesting 11 additional fee-financed posts in 2020 to compensate for additional fee-financed workload.

For 2019, the Agency had requested 193 FTE (full time equivalent) contract agents (CAs) and 30 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 previously (+9 CAs and -9 SNEs). Taking into account the exceptional ‘Brexit’ challenges facing the Agency in 2019 and 2020, EMA is also requesting approval to employ up to a maximum of an additional 40 contract agents for a three year period to ensure a smooth relocation and knowledge transfer transition. These additional resources would be funded within the existing budget allocations, as the significant staff loss due to relocation is will create at least an average 5% staff vacancy rate throughout the 2019-2020 transition period (average loss of 42 TA and CA FTEs).

New tasks

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

Growth of existing tasks

The tasks related to the relocation of the Agency as described in Part I of this document will bring a significant additional workload for EMA staff. Other activities are also increasing as a result of changes of legislation, for example the implementation of the new veterinary legislation and the general data protection legislation.

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

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 level of 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. During 2019 the Agency will operate under a 'scaled down' "business as usual" scenario in many areas (in line with its business continuity plans), whilst coping with both the physical move to the new EMA premises in Amsterdam and the estimated loss of 20% of the workforce.

However, the evolving situation may require a further shift in priorities and focus. As the relocation proceeds, 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

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

Establishment plan

Year	Management Board request	EC proposal	Adopted by Budgetary Authority
2013	611	611	611
2014	611	599	599

Year	Management Board request	EC proposal	Adopted by Budgetary Authority
2016	636	599	602
2017	596	596	596
2018	591	591	591
2019	602	591	591
2020	602	tbc	tbc

Implementation of agreed 5% staff cuts

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

Part III: Work programme 2019

EMA's priority with respect to Brexit is to ensure that the assessment and supervision of medicines continues to be delivered on time and to the same high level of 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, whilst 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 2019 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 2019, and for those entries that are either temporarily reduced or suspended during this time, the respective note has been added.

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 2019. It describes the objectives and activities planned for 2019. The document consists of four parts:

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.

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.

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.

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 2019.

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 2019, 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 2019 is added at the end 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[2].

1.1. Pre-authorisation activities

Activity areas

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

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

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

[2] Reference: *1.4. Referrals*

completed, the EMA verifies their compliance with key elements contained in the agreed PIPs. The Agency also issues decisions on requests for modification of a previously agreed PIP. An agreed PIP leads to information on the paediatric use of medicines being included in a centralised or national marketing-authorisation procedure (for new or already authorised medicinal products), or in a paediatric-use marketing authorisation (PUMA) for off-patent products.

Classification and certification of advanced therapy medicinal products (ATMPs). The Agency issues a scientific recommendation, after consultation with the European Commission, on whether a given product based on genes, cells or tissues, falls, on scientific grounds, within the definition of an advanced therapy medicinal product (ATMP classification). The Agency also carries out a scientific evaluation of quality data and, when available, non-clinical data, for advanced therapy products under development by small and medium-sized enterprises. Subject to this evaluation, the Agency may issue a certificate confirming the extent to which the available data comply with the standards that apply for evaluating a marketing-authorisation application (ATMP certification).

Innovation and emerging therapies. The Agency provides a platform to support and facilitate innovation in medicines development through its Innovation Task Force (ITF) and its co-chairmanship of the EU Innovation Network.

The ITF serves as a discussion platform for early dialogue with applicants, identifying scientific, legal and regulatory issues of emerging therapies and technologies, providing advice on product eligibility for EMA scientific services and procedures, as well as scanning the horizon, exchanging information and establishing networks to develop and maintain expertise in the field. The ITF works closely with our partners within the network, academic specialists and the EU network of Innovation and Technology Forum Offices. The ITF also collaborates with the European institutions and international partners on ITF procedures. The Agency has also set up the Modelling and Simulation Working Group (MSWG), which provides specialist input in the assessment of modelling and simulation methodologies in the context of scientific advice, PIPs and MAA procedures.

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

Supporting the development of medicines for specific target populations. In addition to the aspects linked to the development of medicines for children (see above), this includes increasing focus on geriatric patients and pregnant and lactating women. Changes in the world's demographic composition draw increasing attention to the health needs of the very-old and frail population. The Agency encourages research and development of medicines for a real-life population, with a particular emphasis on areas of unmet need, such as frailty, on formulations and packaging adapted to the ageing population, and on challenges posed by co-morbidities and multiple medications.

Drivers

n/a

Workload indicators

	Results			Forecast
	2016	2017	2018	2019
Scientific advice/protocol assistance pre-submission meetings	117	118	97	139
Scientific-advice and protocol-assistance requests, of which:	582	630	634	708
Parallel scientific advice with international regulators requests	6	3	2	5
Joint scientific advice with HTA bodies requests	23	29	27	34
Scientific advice for PRIME products	4	28	36	26
Protocol assistance	126	159	168	175
Novel technologies qualification advice/opinions	14	19	9	24
PRIME eligibility requests received	84	81	57	100
Scientific advice finalised	439	490	444	563
Protocol assistance finalised	122	156	170	167
Orphan medicines applications, of which:	329	260	236	275
Parallel orphan applications with international regulators	96	55	0[3]	0
Submitted applications on the amendment of an existing orphan designation	4	2	1	5

[3] Following IRIS implementation common applications no longer used

	Results			Forecast
	2016	2017	2018	2019
Oral explanations for orphan designation	87	80	86	95
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	549	630	669	500
Finalised procedures for compliance check on PIPs	73	67	96	70
Annual reports on paediatric deferred measures processed	189	197	270	170
EMA paediatric decisions processed	369	402	407	350
Requests for classification of ATMPs	60	46	55	50
Innovation Task Force briefing meetings	41	33	22	25
Innovation Task Force Art 57 CHMP opinion requests	2	0	5	1

Performance indicators

	Results			Target
	2016	2017	2018	2019
Scientific advice/protocol assistance procedures completed within regulatory timeframes	99.5%	100%	100%	100%
PRIME eligibility requests assessed within regulatory timeframe			100%	100%
Orphan designation opinions delivered within the legal timeframe	100%	100%	96%	100%
PDCO opinions sent to applicants within legal timelines	99.5%	99.75%	99.9%	100%
Increase in scientific-advice requests	14%	8%	0.6%	7%

	Results			Target
	2016	2017	2018	2019
SME requests for SA (% of total SA requests)	30%	31%	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 2A	Reduced activity in 2018-2019 to high level EMA presence in IMI scientific Committee, with no proactive identification of new research topics. Proposed priority for Q3/Q4 2019
		Identify recurring topics from ITF discussions with the highest potential benefit in terms of driving science and innovation	2015	After 2020 2A	Suspended in 2019. Not a proposed priority for Q3/4 2019.
		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 2A	Suspended in 2019. Not a proposed priority for Q3/4 2019.
	1.3-8	Reinforce collaboration via EU innovation Network	2018	2020	Suspended in Q1/Q2 2019. Proposed priority

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		with academia and research hospitals that could benefit most of the innovation offices regulatory support		2A	for Q3/Q4 2019.
	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 2B	Maintained in Q1/Q2 2019. Proposed priority for Q3/4 2019.
	3.2-2	Establish a platform for project-specific engagement with developers, to optimise activities during the development phase.	2017	2020 2B RA	SUSPENDED in 2019. Not a proposed priority for 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 2B RA	All activities directly related to product support are maintained in Q1/Q2 2019; non-product support activities are suspended in Q1/Q2 2018. Proposed priority for Q3/Q4 2019.
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 2A	Activities maintained in Q1/Q2 2019 are those addressing public health needs (e.g. molecular targets in paediatric oncology) and operational improvement (e.g. simplification of compliance check). All other activities are suspended in Q1/Q2 3019. Proposed priority for Q3/Q4 2019
		Contribute to the activities of the International Neonatal Consortium (INC)	2015	2020 2A	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
					Annual C-Path meeting suspended
		Contribute scientifically to methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders	Before 2015	2020 2A	Suspended in Q1/Q2 2019. Not a proposed priority for Q3/Q4 2019.
	1.3-5	Review the experience with the "Orphan Notice" and interaction with stakeholders	2017	2019 2B RA	Maintained in Q1/Q2 2019. Proposed priority in Q3/Q4 2019.
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 2A	Maintained in Q1/Q2 2019. Proposed priority in Q3/Q 2019.
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	Activity restricted to activities directly related to product support in Q1/Q2 2019. Proposed for priority in Q3/Q4 2019.
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 2A	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019
		Prepare for implementation of Medical Devices and In vitro Diagnostics Legislation, in relation to the implementation of the new consultation	2017	2020 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		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			
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	2020 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
Ensure and run highly effective and efficient processes to deliver pre-authorisation activities	3.2-2	Review and implement optimised operations for all functions supporting medicines' development, including knowledge management.	2017	2019 1A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q42019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	41,640	36,102
Human resources (FTEs)	87	81
Of which Human resources – Brexit preparedness (FTEs)	1	1

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 on which a committee’s opinion is based is documented in an assessment report, which is made publicly available as a European public assessment report (EPAR).

Drivers

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

Increasing stakeholder expectations that medicines should be available to treat various conditions, and the continuing need for flexible and fast reaction to new public-health threats, highlight the importance of maintaining the quality of scientific assessments while contributing to faster patient access to medicines on the market. To improve the use of existing 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
	2016	2017	2018	2019
Number of MAA pre-submission meetings	85	63	71	60
Initial evaluation applications, of which:	114	90	84	102
New non-orphan medicinal products	41	32	31	53
New orphan medicinal products	27	19	17	28
Similar biological products	12	17	9	18
Generic, hybrid and abridged products	31	15	23	13
Scientific opinions for non-EU markets (Art 58)	0	1	1	3
Paediatric-use marketing authorisations	1	2	0	1
Number of granted requests for accelerated assessment	12	9	11	10
Number of consultations of SAGs / Ad-hoc expert groups in the context of MAAs	8	15	13	24
Reviews on the maintenance of the orphan designation criteria at MAA stage	20	24	45	40

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Applications evaluated within legal timeframes	99%	100%	100%	100%
Average assessment time for new active substances and biosimilars	197.2	175.7	205.3	205
Average clock-stop for new active substances and biosimilars	136.1	136.9	195.2	180
% of requests granted for accelerated assessment	48%	63%	46%	70%
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment	43%[1]	58%	44%	75%
% of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice	63%	69%	68%	80%
Labelling review of the English product information Annexes for new MAAs and line extensions by Day 10 and Day 140 of the evaluation process	97%	95%	96%	90%
% of therapeutic guidelines progressed to next step or finalised (vs planned)[3]		60%	70%[1]	70%[1]
% of early background summaries drafted and sent to assessment teams (vs planned)		100%	100%	100%
% of outcomes/results of workshops on therapeutic objectives published on EMA website		90%	100%	100%

[1] 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	
Provide high quality, robust, scientifically sound and consistent scientific assessments	3.2-14	Strengthen the support in clinical pharmacology and non-clinical aspects to centrally authorised products along their life-cycle	Before 2016	2020	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 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 2B RA	Activity reduced in Q1/Q2 2019 to e-PI. Proposed for priority 2019.
Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	1.3-4	Support activities stemming from Joint Action 3/work package 4, by providing relevant information from regulatory assessment to HTA bodies for relative effectiveness assessments	2015	2020 2A	Maintained in Q1/Q2 2019. Proposed for priority for Q3/Q4 2019.
Provide high quality, robust, scientifically sound and consistent scientific assessments	3.2-15	Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: Improve the structure and information on benefit/risk in the EPAR by including the effects table and implement new templates and guidance. Explore feasibility of using a more explicit approach in describing value-judgments in the benefit risk assessment.	2018	After 2020	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
Provide high quality, robust, scientifically sound and consistent scientific assessments	3.2-15	Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: Increase patients' involvement in assessment work and support the IMI PREFER project.	2018	After 2020	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Provide high quality, robust, scientifically sound and consistent scientific assessments	3.2-15	Develop the scientific assessment further and improve communication on the benefit/risk ratio of medicines: Explain the rationale for single-arm trials-based approvals to the public and explore the need for wider discussion of such approvals.	2018	2019	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	32,682	26,764
Human resources (FTEs)	76	75

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 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
	2016	2017	2018	2019
Variations applications, of which:	6,204	6,267	6,716	6,563
Type-IA variations	3,019	3,080	3,433	3,207
Type-IB variations	2,000	2,054	2,164	2,144
Type-II variations	1,185	1,133	1,119	1,212
Line-extensions of marketing authorisations	25	21	20	18

	Results			Forecasts
	2016	2017	2018	2019
PASS scientific advice through SAWP	2	1	3	2
Number of consultations of SAGs / Ad-hoc expert groups in the context of post-authorisation activities	6	15	13	12
Renewal applications	107	94	90	100
Annual reassessment applications	25	19	22	28
Transfer of marketing authorisation applications	35	47	377	100
Article 61(3) applications	216	234	258	200
Post Authorisation Measure data submissions	1,016	795	812	900
Plasma Master File Annual update and variation applications	19	22	19	18

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Post-authorisation applications evaluated within the legal timeframes	99%	99%	99%	99%
Average assessment time for variations that include extension of indication	165	162	157	180
Average clock-stop for variations that include extension of indication	73	67	66	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	2020	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/4 2019.
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	2020	Suspended in Q1/Q2 2019. Not proposed priority for Q3/4 2019.
Strengthen the quality of the scientific review process	3.2-16	Improve the benefit-risk methodology and expand it to post-authorisation updates	2016	2019	Suspended in Q1/Q2 2019. Proposed priority for Q3/4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	95,664	88,094
Human resources (FTEs)	94	79
Of which Human resources – Brexit preparedness (FTEs)	1	1

1.4. Referrals

Activity area

Referrals are initiated for centrally and nationally authorised products, either in cases where there is concern over the safety or benefit-risk balance of a medicine or a class of medicines, disagreement among Member States on the use of the medicine, a Community interest, or in order to obtain harmonisation within the Union of the conditions of authorisation for products already authorised by Member States. In a referral, the Agency conducts scientific assessment of a medicine (or class of medicines) and makes a recommendation for a harmonised position across the EU. Depending on the type of procedure, the outcome will be implemented by the Member States or the European Commission will issue a decision to all Member States reflecting the measures to take to implement the Agency's recommendation.

Referrals can be started by the Commission, any Member State, EMA or by the marketing-authorisation holder that markets the medicine.

Drivers

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

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

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

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

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Pharmacovigilance referrals started	8	7	2	8
Non-pharmacovigilance referrals started	10	3	15	8

Performance indicators

	Results			Targets
	2016	2017	2018	2019
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	
Development of a common understanding with the Network on the best use of Referrals	3.2-1	The need to develop a common understanding within the Network on the best use of referrals was adopted by HMA in November 2017 (referrals roadmap). Working groups have been formed with the relevant Committees (PRAC, CHMP and CMDh). An agreement on deliverables for 2018 has been reached in Q1-Q2 2018. It is expected that by Q4 2018 a mapping of the outcomes of key PhV referrals will have been	2017	2020 1A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		developed; together with an analysis of efficacy driven referrals with focus on mature products.			

Resources

	2018	2019
Financial resources (cost, thousand Euro)*	1,732	1,220
Human resources (FTEs)*	6	6

* Excludes resources related to pharmacovigilance referrals

1.5. Pharmacovigilance and epidemiology activities

Activity area

Pharmacovigilance covers the science and activities relating to the detection, assessment, understanding and prevention of adverse drug reactions (ADRs) or any other medicine-related problem.

The Agency coordinates the EU pharmacovigilance system that connects the systems of each national competent authority, and operates pharmacovigilance processes that support both the EU pharmacovigilance system and the recommendations and opinions of the EMA committees on the benefits and risks of medicines. Pharmacovigilance activities are integrated with many aspects of the Agency's processes, including evaluation (for centrally authorised procedures), post-authorisation referrals, inspections and data-management, and therefore related items are found also in those sections of this document.

The area covers:

- management of adverse drug reaction reports, periodic safety update reports (PSURs), risk-management plans and oversight of post-authorisation studies;

- cooperation with NCAs in the management of safety signals for centrally authorised products and nationally authorised products, and of emerging safety issues and (safety) incidents;

- coordination of safety communications;

- publication of lists of products, including EU reference dates (for PSURs), products under additional monitoring and withdrawn products;

- coordination of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), which builds capacity in the delivery of post-authorisation studies;

- development and maintenance of good pharmacovigilance practices (GVP) and standards for the system, as well as development and implementation of evidence-based process improvements and updates to GVP.

Drivers

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

Regulatory sciences provide the evidence to support process improvements in pharmacovigilance. New regulatory science results have become available (for example from the ADVANCE and WEBRADR projects) and process improvements that have demonstrated efficiency gains will be implemented. In addition, the availability of new IT tools further supports the conduct of pharmacovigilance and preparation for better tracking of safety signals and product incidents will be prioritised in 2019. Such evidence-based process improvements and optimal use of IT (including the new EudraVigilance functionalities) help deliver more effective and efficient pharmacovigilance.

The increasing role of information technology in health-related matters, including new data sources, methodologies and technologies, as well as the use of e-health records and databases, mobile communications and social media by consumers and healthcare professionals, offers unprecedented opportunities to access and analyse real-world data to support decision-making of the EMA scientific committees. Such real world data complements more traditional data sources notably clinical trials. The work of the HMA/EMA joint big data task force will continue to develop the approach of European Regulators in this area and the EMA Regulatory Science Strategy will include access to and analysis of real world data at its core.

Society wants to see the impact of pharmacovigilance and calls for ever increasing transparency and engagement with patients and healthcare professionals. This will drive a number of work items, including work to measure the impact of pharmacovigilance (based on the PRAC Impact strategy).

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Number of signals peer-reviewed by EMA	2076	2,062	2,204	1,800
Number of signals assessed by PRAC	48	43	74	35
PSURs (standalone CAPs only) started	518	555	554	555
PSUSAs started	243	365	327	264
Number of imposed PASS protocol procedures started	12	6	17	20
Number of imposed PASS result procedures started	3	6	8	15
Number of emerging safety issue notifications received	21	21	8	10
Number of notifications of withdrawn products received	118	302	413	430
Cumulative number of products on the list of products to be subject to additional monitoring	301	336	351	320
Number of Incident Management Plans triggered	7	4	11	9
Number of non-urgent information (NUI) or Rapid Alert (RA) notifications submitted through EPITT	49	61	44	55
Number of external requests for EV analyses	34	32	17	20
Number of MLM ICSRs created	8,495	14,193	13,275	12,000

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Periodic Safety Update Reports (PSURs standalone CAPs only) assessed within the legal timeframe	100%	100%	100%	100%
Periodic Safety Assessment Reports (PSUSAs result procedures) assessed within the legal timeframe	100%	100%	100%	95%
Protocols and reports for non-interventional imposed post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%	100%
Reaction-monitoring reports supplied to the lead Member State monthly	97%	97%	95%	94%
PRAC recommendations on signals and translation of labelling changes in EU languages published	100%	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	ongoing	Ongoing 1A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	1.2-4 3.2-3	To provide input into EC 2019 report on EU network pharmacovigilance	2019	Ongoing 2A	Maintained Q12019
	3.3-2	Conduct a lessons-learned exercise after one year experience of public hearings	Q1 2017	2020	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
				2B RA	
	1.4-1	Finalise (2019) GVP product- or population-specific considerations III on pregnant and breastfeeding women post public consultation in Q1 2019.	2018	2019 2B RA with except	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Conduct public consultation and finalise GVP product- or population-specific considerations V on geriatric population	2019	2020 2B NR	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		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	2019	2020 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
Maximise benefits to public health promotion and protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through the use of high-quality data, information and knowledge	1.2-4	Build and maintain capacity for EU Network analysis of epidemiological data	2016	2020 2B RA	Reduced to support to the EMA/HMA task force on Big Data in Q1/Q2 2019. Proposed for priority for Q3/Q4 2019.
		Develop and maintain inventory to facilitate access to data on real-world data	2016	2020 2B NR	Reduced to maintenance activities in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Initiate at least four EMA studies on real world evidence data	2016	Continuous 2B NR	Reduced to initiating EMA studies on real world evidence data at the request of PRAC in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Review the scientific advice process for post-authorisation studies, to identify possible process	2016	2020	Suspended in Q1/Q2 2019. Not proposed for

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
		improvement opportunities		2A	priority for Q3/Q4 2019.
	1.2-5	Based on evaluation of the options and feasibility provide support to the use of registries for targeted products on the EU market from learnings from the pilot process.	Before 2016	Continuous 2B RA	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Implement the recommendations from 2017 guidance on key principles for use of registries from a regulatory perspective	Before 2016	2019 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	1.4-1 3.2-3	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 1A	Pilot maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Resources

	2018	2019	2020
Financial resources (cost, thousand Euro)*	41,175	32,598	39,101
Human resources (FTEs)*	106	96	109

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

1.6. Other specialised areas and activities

Activity area

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

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

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

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

Public health threat preparedness. The 2009 influenza pandemic led to a review of the cross-European strategy for pandemic preparedness. In 2016 the Agency reviewed its pandemic preparedness plan and transformed it into a wider-ranging preparedness plan for emerging health threats. The Agency continuously works, in collaboration with NCAs, the EC and ECDC, to implement improvement actions to ensure high level of coordinated cross-European preparedness to act upon public health threats.

Drivers

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

The Clinical Trials Regulation published in May 2014 requires the Agency to develop the systems necessary for its implementation, in collaboration with the EC and the Member States. The audit of the EU Portal and Database is planned in 2019. Dependent on successful completion of the audit and review by the EMA Management Board around the end of 2019, the system could be ready to go live later in 2020.

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Herbal monographs, new[4]	8	4	4	3
Herbal monographs, reviewed[5]	n/a	n/a	7	12
Herbal monographs, revised	9	8	15	4
List entries	2	0	0	1

Performance indicators

	Results			Targets
	2016	2017	2018	2019
n/a				

[4] when the assessment does not lead to a monograph, a public statement is published
[5] when after review of new data no change in monograph/LE is required, an addendum to the existing assessment report is published

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	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority in Q3/Q4 2019.
Promote application of harmonised international standards	4.2-5	Provide technical and scientific contribution to the development of ICH safety guidelines (Carcinogenicity assessment document evaluation for ICH S1)	Before 2015	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority in Q3/Q4 2019.
Effectively manage risks to the environment arising from the use of human medicines	4.2-6	Collaborate with the EC on the roadmap “Strategic approach to pharmaceuticals in the environment” and update EMA guideline on environmental risk assessment (ERA). Participate in EC cross-service group on medicines in the environment	2018	2020 2A	Suspended in Q1/Q2 2019. Not proposed for priority in Q3/Q4 2019.
Promote responsible use of antibiotics in human and veterinary medicine adopting a 'One Health' perspective*	1.1-1	Establish and run cross-Agency Task Force on anti-microbial resistance. Provide proposals and implement them for EMA activities to address antimicrobial resistance.	2015	2020	Suspended in Q1/Q2 2019. Proposed for priority for Q3/Q4 2019.
Enhance ability to respond quickly to public-health emergencies	1.1-9	Collaborate with international stakeholders on the clinical study design and emergency use of medicines in case of a public health emergency and interact with medicines developers in the early stages of the development to facilitate early introduction of appropriate treatments or preventive measures.	2015	2020	Maintained in Q1/Q2 2019. Proposed for priority for Q3/Q4 2019.
Contribute to European and	1.1-2	To implement actions assigned to EMA as part of	2016	2019	Maintained in Q1/Q2 2019. Proposed priority

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
international initiatives and collaborations in the area of AMR		the third implementation period of the TATFAR initiative			for Q3/Q4 2019.
Contribute to European and international initiatives and collaborations in the area of AMR	1.1-3	Contribute to implementation of the next phase of the EC Action Plan on antimicrobial resistance, and other action plans such as the WHO Global action plan and OIE strategy	2016	2019	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
Enhance ability to respond quickly to public-health emergencies	1.1-9	Contribute to Joint Action on Vaccines and EC vaccines task force on vaccines (action the plan from the Council Recommendations on vaccination). This includes activities related to support R&D of vaccines including dialogue with NITAGs; discussion with EC and ECDC on platform for B/R monitoring of vaccines.	2018	2020	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	13,557	9,399
Human resources (FTEs)	26	16

1.7. Projects

Projects outlined in Annex 10

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[6] 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

[6] 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-yearly basis.

Support development of emerging therapies and technologies. To proactively identify scientific, legal and regulatory issues of emerging therapies and technologies, the Agency provides a discussion platform for early dialogue with applicants within the context of the Innovation Task Force, and has also established the Ad hoc experts group on Veterinary Novel Therapies (ADVENT) to create guidance in this area.

Vaccine availability. Vaccination is one of the most effective tools for preventing animal diseases and for promoting animal health and welfare, safe food production and public health. Despite their importance, there are often challenges to ensuring that suitable veterinary vaccines are available in a timely manner on the European Union (EU) market. The European Medicines Agency (EMA) and its partners in the European medicines regulatory network have agreed and are implementing an action plan to help increase the availability of veterinary vaccines in the EU.

Drivers

In 2019, the focus in terms of pre-authorisation activities will remain on promoting access to market of veterinary products, particularly those based on novel technologies, those indicated for MUMS/limited markets and vaccines.

The ADVENT (established in 2015), will continue in 2019 its work on developing and delivering guidance in accordance to its work plan.

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

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

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Innovation Task Force briefing requests	4	7	5	4
Scientific advice requests received	18	17	25	15
Requests for classification as MUMS/limited market, of which	25	25	32	25

	Results			Forecasts
	2016	2017	2018	2019
Re-classification requests	6	8	5	5

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Scientific advice procedures completed within set timeframes	100%	100%	96%	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 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Develop training material on the latest revision of MUMS guidelines on data requirements and other guidance	2018	2020 2A	Suspended in Q1/Q2 2019. Not proposed for priority in Q3/Q4 2019.
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 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	2.1-6	Develop and publish Q&As developed by ADVENT in priority areas for technologies that are new to	Before 2016	2019 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
		veterinary medicine			
		Develop an action plan on specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials, to control infectious diseases in animals	2017	2019 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
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	2022 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
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	2020 2A	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Develop a reflection paper on promoting availability of veterinary vaccines in emergency situations	2016	2020 2A	Suspended in Q1/Q2 2019. No priority for Q3/Q4 2019.
	2.1-4	Provide advice and input to address gaps in availability identified in the FishMed Plus Coalition where relevant to CVMP activities	2017	2022 2A	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	3.2-15	Revise guideline on anticoccidials used for the therapy of coccidiosis	2017	2020 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Revise guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne	2015	2020 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		diseases			
		Revise Note for guidance on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use	2015	2021 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
		Develop a concept paper for revision of SmPC guideline for anthelmintics	2016	2020 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	929	710
Human resources (FTEs)	2	3

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, monitoring and fine tuning of streamlined business processes will continue in 2019, to provide increased harmonisation and efficiency in procedures.

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Initial evaluation applications	21	17	15	14
New MRL applications	6	3	3	3
MRL extension and modification applications	1	3	2	2
MRL extrapolations	0	0	0	1
Art 10, Biocides	0	0	0	0
Review of draft Codex MRLs	5	0	5	0

Performance indicators

	Results			Targets
	2016	2017	2018	2019
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	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health	2.1-8	Finalise, in collaboration with ECHA and the EC, the procedure for the establishment of MRLs of biocidal substances used in animal husbandry, included in the 10-year review programme (long-used substances)	2015	2021 2A	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
	2.1-7	Review the approach on genotoxic substances in the establishment of MRLs and authorisation of veterinary medicinal products.	2015	2019 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
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 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	4,903	3,064
Human resources (FTEs)	15	12

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 Q1-Q2 2019 when marketing authorisation holders are obliged to move activities such as manufacturing (including batch release) and pharmacovigilance responsibilities away from UK-based companies and furthermore to transfer MAs away from UK-based MA holders.

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Variations applications, of which:	410	446	589	367
Type I A variations	243	238	330	191
Type I B variations	126	130	147	125
Type II variations	41	78	112	51
Line extensions of marketing authorisations	3	5	1	3
Transfers of marketing authorisations			17	25

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Post-authorisation applications evaluated within the legal timeframes	100%	100%	99.9%	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	2.2-8	Revise and update post-authorisation procedural	2018	2019	Suspended in Q1/Q2 2019. Proposed priority

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
post-authorisation procedures		guidance		2B RA	for Q3/Q4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	5,187	4,433
Human resources (FTEs)	11	10
Of which Human resources – Brexit preparedness (FTEs)	1	1

2.4. Arbitrations and referrals

Activity area

The Agency conducts referral and arbitration procedures.

Arbitration procedures are initiated for nationally authorised products because of disagreement between Member States (e.g. in granting a variation or a marketing authorisation), or when over the years Member States have adopted different decisions for some medicines and discrepancies need to be harmonised.

Referrals are initiated regarding centrally and nationally authorised products to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by Member States, or in cases where there is a Community interest, or in cases where there are other safety-related issues. In a referral, the Agency conducts a scientific assessment of a medicine (or class of medicines) and makes a recommendation for a harmonised position across the EU. Depending on the type of procedure, the outcome will be implemented by the Member States or the European Commission will issue a decision to all Member States reflecting the measures to take to implement the Agency's recommendation.

Drivers

The Agency expects fewer referral procedures compared with 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 2019-2020. Some of these referrals might be triggered by the European Commission as part their Action plan against the rising threats from antimicrobial resistance (AMR), and as a result of the advice provided to the Commission in 2014 on the risks to human health that may arise from the use of antimicrobials in veterinary medicine.

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Arbitrations and Community referral procedures initiated	7	1	5	3

Performance indicators

	Results			Targets
	2016	2017	2018	2019
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	2.4-1	Provide the EC with CVMP recommendation on prioritisation developed in 2017, for the EC to	2018	2021 2A	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
the use of antibiotics in veterinary medicine		consider the need for further referrals			

Resources

	2018	2019
Financial resources (cost, thousand Euro)	768	372
Human resources (FTEs)	3	2

2.5. Pharmacovigilance activities

Activity area

Pharmacovigilance covers the science and activities relating to the detection, assessment, understanding and prevention of adverse reactions to medicines or other medicine-related problems. Pharmacovigilance aims to ensure that post-authorisation monitoring and effective risk-management are continuously applied to veterinary medicines throughout the EU.

The Agency coordinates the EU pharmacovigilance system and constantly monitors the safety of medicines in Europe, and takes action if information indicates that the benefit-risk balance of a medicine has changed since authorisation. The Agency provides advice to ensure safe and effective use of veterinary medicinal products.

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

- management and assessment of adverse event (AE) reports;
- management and assessment of periodic safety update reports (PSURs).

Drivers

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

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Periodic safety-update reports (PSURs)	175	161	158	160
Total AERs, of which:	38,162	50,885	66,844	60,000
Adverse-event reports (AERs) for CAPs	18,419	26,671	35,835	30,000
Adverse-event reports (AERs) for NAPs	15,257	24,214	31,009	30,000

Performance indicators

	Results			Targets
	2016	2017	2018	2019
PSURs evaluated within the established timeline	98%	98%	99%	90%
AERs for CAPs monitored within the established timelines	96%	98%	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 these data to adverse event reports for CAPs and non-CAPs, to allow signal detection	Before 2016	2019 1A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	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	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
	2.2-6	Ongoing monitoring of incidents, evaluation of lessons learned and update of the incident management plan (IMP) and process in light of experience	2016	Continuous 1A	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	2.2-3	Publish the veterinary pharmacovigilance annual bulletin	2019	Continuous 1A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Develop and implement criteria for proactive risk communication concerning CAPs	2018	2021 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	815	1,080
Human resources (FTEs)	4	5

2.6. Other specialised areas and activities

Activity area

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

Implementation of new veterinary regulation. The Agency will provide support to the European Commission in drafting the implementing and delegated acts specified in the new veterinary regulation adopted in 2018.

Antimicrobial resistance. The Agency adopts a 'One Health' approach in the area of antimicrobial resistance, whereby there is close and integrated cooperation between those working in the human and veterinary fields. In the veterinary area, attention is focused in particular on ensuring the continued availability of antimicrobials for treatment of infectious disease in animals, while recognising the need to preserve the efficacy of certain critically important antimicrobials for human use.

International harmonisation of requirements for authorisation of veterinary medicines. Research and development of veterinary medicines being a global activity, harmonised authorisation requirements will benefit both the animal health industry and European competitiveness.

Drivers

The new veterinary regulation was adopted on in 2018 and aims to promote availability of veterinary medicines and to reduce the administrative burden for both industry and applicants: it will have a significant impact on the work of the Agency. In the upcoming years the Agency will face a period of intense workload preparing for the implementation of the new provisions that will come into effect in 2021, both in terms of adapting the work of the

Agency to the new requirements of the legislation and in providing advice to the Commission with respect to the various implementing provisions that will apply. In addition, the new regulation foresees an expanded role for IT systems to support and promote effective and efficient working. The Agency will need to work with the Commission and with the Network to develop the strategy by which these systems can be developed and deployed.

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

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

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

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

In 2015, an updated strategy for the next five years was developed and adopted for the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). 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
	2016	2017	2018	2019
n/a				

Performance indicators

	Results			Targets
	2016	2017	2018	2019
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	2019 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	2.1-11	Develop a reflection paper on resistance in ectoparasites	2015	2020 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Contribute to EU position for the revision of VICH guidelines on anthelmintics (GL7, 12-16 and 19-21)	2016	2020 2B RA	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 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 2A	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	2.2-9	Provide technical support to the European Commission in drafting implementing and delegated acts specified in the new veterinary	2019	2021 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
		legislation			
	2.1-10	Contribute to the EMA/HMA task force on availability of authorised human and veterinary medicines	2016	2020 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	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 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
Provide high-quality and consistent scientific outputs	3.2-15	Revise guideline on summary of product characteristics for antimicrobials	2017	2020 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 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 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 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 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 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	2021 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
Contribute to minimising the risk to man and animals from the use of antibiotics in	2.4-4	Finalise the reflection paper on aminoglycosides and publish for consultation the reflection paper on extended-spectrum penicillins	2015	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
veterinary medicine in 2018-2019					
	2.4-3	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 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	1.1-2	Implement actions assigned to EMA as part of the third implementation period of the TATFAR initiative	2018	2019 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	1.1-3	Contribute to implementation of the next phase of the EC action plan on antimicrobial resistance, the WHO global action plan, OIE strategy and other action plans (such as the G8)	2018	2019 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 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	2010	Continuous 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 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	2019 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Finalise in cooperation with EFSA and ECDC the third report on consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-	2019	2021 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		producing animals prepared			
Effectively manage risks to the environment arising from the use of veterinary medicines	2.4-7	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	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
		Develop a reflection paper on the potential risks associated with the use of veterinary medicinal products in aquaculture	2018	2019 2B RA	Suspended in Q1/Q2 2019. Proposed for priority for Q3/Q4 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	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
	2.4-8	Provide advice to the European Commission to assist the preparation of their strategy on managing pharmaceuticals in environment.	2013	2022 2A	Suspended in Q1/Q2 2019. Proposed for priority for Q3/Q4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	1,510	490
Human resources (FTEs)	6	3

2.7. Projects

Projects outlined in Annex 10

3. Horizontal activities and other areas

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

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

3.1. Committees and working parties

Activity area

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

The activities within this domain include the following:

Scientific Coordination Board. The Scientific Coordination Board (SciCoBo) is composed of the chairs of the scientific committees, CMDh and the Scientific Advice Working Party, as well as members of the Agency's senior management. The SciCoBo has a strategic role and a coordination role which are closely linked. Strategically, it is responsible for identifying key priorities where new or enhanced engagement is essential to the continued success of the Agency’s mission and consequently essential to shape and influence the vision for the next EU medicines agencies network strategy. It analyses trends in science, technology and regulatory science tools captured by horizon scanning with a view to generating and overseeing implementation of the EMA regulatory science strategy. Regarding its coordination role, it ensures there is sufficient coordination between the committees, to increase the robustness and predictability of the outcomes of benefit-risk assessments, by having consistent standards set for the development of medicines across the whole product lifecycle.

Committees Secretariat. The Committees Secretariat provides organisational, secretarial and budget management for the operation of the Agency's scientific committees, as well as necessary technical, legal and regulatory support to the committees. It includes coordinating adequate

scientific support and leadership across the Agency's divisions, as well as ensuring coordination and communication across scientific committees, working parties and scientific advisory groups, and facilitating interactions between these groups. In addition, the Committees Secretariat coordinates work-plan proposals and prioritisation, according to the impact of work on committees and strategic priorities set in the work programme of the Agency.

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

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

Scientific guideline development. To facilitate the development of medicinal products and guide applicants in their medicines' development planning, the Agency, through its working parties, prepares and reviews guidelines on a variety of scientific topics relevant for the development of medicines. The guidelines take into consideration the latest scientific developments and the knowledge derived from product assessments within the Agency, and contain detailed requirements for the demonstration of quality, safety and efficacy for specific diseases or conditions. They are consulted upon with stakeholders, adopted by the Agency's scientific committees and made available on the Agency's public website. Transfer of the knowledge accumulated from medicines evaluation through state-of-the-art recommendations of the guidelines is a key activity of the Agency.

Meeting management. Meeting management encompasses the organisation of EMA meetings, conferences, workshops and training courses, including those under the EU enlargement programme. The Agency organises travel and accommodation arrangements for delegates, while also providing assistance with logistical and administrative issues.

Drivers

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

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

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

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

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Number of reimbursed meetings	441	529	408	348
Committee meetings	71	71	71	88
Trainings[1]	21	30	29	33
Workshops	66	35	33	6
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)	283	396	273	221
Number of virtual meetings (audio-, video- and web-conferences)	4,969	4,802	4,793	6,799
Number of reimbursed delegates	7,972	8,743	7,214	6,500
Number of non-reimbursed delegates	1,724	1,464	1,064	1,000

[1] includes EU Network training centre meetings.

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Delegate satisfaction with meeting support services	n/a	n/a[1]	n/a	
Up-to-date electronic declarations of interests submitted by committee members prior to participating in a scientific committee meeting	99%	100%	99%	100%
First-stage evaluations of conflicts of interests for committee members completed	100%	100%	100%	100%

	Results			Targets
	2016	2017	2018	2019
prior to 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%	99%	100%	100%

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

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	3.2-1	Support the activities of the HMA Regulatory Optimisation Group (ROG) to simplify and optimise the processing of Type IA variations	2017	2020	Suspended in 2019.
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 2A	SUSPENDED in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Resources

	2018	2019
Financial resources (cost, thousand Euro)	5,078	9,597
Human resources (FTEs)	25	65

3.2. Inspections and compliance

Activity area

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

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

Harmonisation of inspection standards and practices. The Agency contributes to the harmonisation of inspection standards and practices within the European Union and with international partner authorities.

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

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

Certificates. The Agency issues certificates of medicinal products, in accordance with WHO requirements, in order to support the work of health authorities outside the European Union, especially in developing countries. Certificates are issued by the Agency, on behalf of the European Commission, to confirm the marketing-authorisation status and GMP compliance of the manufacturing sites of products authorised by the Commission through the centralised procedure, or of products for which a marketing-authorisation application has been submitted to the Agency.

Parallel distribution. Parallel distribution is the distribution of a centrally authorised medicinal product from one Member State to another by a pharmaceutical company, independent of the marketing-authorisation holder. The Agency checks compliance of products distributed in parallel with the conditions laid down in Union legislation on medicinal products and the marketing authorisation of the product.

Mitigation of supply shortages. Past years saw cases of global supply shortages of medicines caused by quality defects or GMP non-compliance. This has led to development of recommendations to minimise the risks of such shortages occurring in the future, as well as mitigate the impact of shortages that do occur. The Agency continues to promote proactive risk-management by manufacturers and marketing-authorisation holders and, within its scope, instilling controls to ensure product quality and supply continuity.

Drivers

Increasing numbers of manufacturing sites located and clinical trials conducted outside the EU will continue to be a trend. As a result, increased focus on ensuring the medicines tested and manufactured outside the EU meet the EU requirements will drive efforts to develop and strengthen collaboration with international partners regarding collaborative inspections, information exchange, capacity-building and greater mutual reliance. The newly implemented mutual recognition agreement with the US FDA will have a significant impact on the organisation of inspections, exchange of information on their conduct and 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.

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.

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

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
GMP inspections	548	314	332	150
GLP inspections	0	0	1	1
GCP inspections	121	136	140	130

	Results			Forecasts
	2016	2017	2018	2019
Pharmacovigilance inspections	8	15	20	12
PMF inspections	124	83	84	85
Notifications of suspected quality defects	181	161	147	200
Notifications of GMP non-compliances[1]	17	23	25	20
Medicinal products included in the sampling and testing programme	48	58	53	78
Standard certificate requests received	3,787	4,023	3,703	3,750
Urgent certificate requests received	487	531	1,069	500
Parallel distribution initial notifications received	2,850	2,639	2,304	2,300
Parallel distribution notifications of change received	1,847	1,975	2,184	2,200
Parallel distribution notifications of bulk changes received	8	6	11	11
Parallel distribution annual updates received	3,815	3,798[2]	6,000[3]	5,400

[1] previously: "Other GMP inspections related notifications"

[2]excludes approximately 1,900 notifications received in 2017 but processed in 2018

[3]estimated final figure

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Inspections conducted within established regulatory timeframes	100%	100%	100%	100%
Standard certificates issued within established timelines (10 working days)	91.6%	64.2%	0%[7]	90%
Average days to issue standard certificate	7	10.3	27.3	10
Urgent certificates issued within established timelines (2 working days)	100%	100%	99%	100%

[7] Backlog delay

	Results			Targets
	2016	2017	2018	2019
Parallel distribution initial notifications checked for compliance within the established timeline	99%	96%	97%	90%
Additional GCP inspections addressed through information exchange on inspections carried out by international partners	34%	39%	38%	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 Start	Timeframe End	BREXIT implications
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 2B RA	Activity restricted to exchange on product specific issues in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	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	2020 2B RA	Activity restricted to exchange on product specific issues in Q1/Q2 2019. Proposed priority for Q3/Q4 2019
	4.1-5	Monitor and review effect of implementing EudraGMDP rules for planning module on cooperation with Member States in coordinating third-country inspections	2017	2020 2B RA	Activity restricted to exchange on product specific issues in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019.
Minimise risk and impact of	1.1-14	Provide regulatory support to the work of the EU	2014	2020	Activity restricted to exchange on product

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
shortages due to manufacturing problems and quality defects		Observatory, to facilitate the transition from high enriched uranium to low enriched uranium		2B RA	specific issues in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	1.1-20 1.1-12 1.1-11	Support and collaborate with the EMA/HMA task force on the availability of authorised human and veterinary medicines	2017	2019 2A	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019
Improve application of equivalent standards of good manufacturing and clinical practice throughout the world	4.2-1	Support training activities in India and China, including establish a panel of European inspectors available to participate in capacity-building workshops in these countries	Continuous	Continuous 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 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	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019
Support capacity building of non-EU regulators	4.4-1	Deliver training and capacity-building for inspectors and assessors from international regulators	Before 2016	Continuous 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019
Expand work-sharing and mutual-reliance initiatives	4.3-1	Coordination of Joint Audit Programme in support to the implementation and extension of the EU US MRA.	2016	2019	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019

Resources

	2018	2019
Financial resources (cost, thousand Euro)	10,703	9,230
Human resources (FTEs)	37	34

3.3. Partners, stakeholders, communication and transparency

Activity area

Activities covered in this area include the following:

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

Stakeholder interactions with patients, healthcare professionals, industry organisations and academia. The interactions involving patients and healthcare professionals range from information and consultation to participation in the scientific activities of the Agency and its committees, and review of information intended for the public. The Agency is also developing its collaboration with academia, with a particular focus on innovation in medicines, such as qualification of biomarkers and new methodologies.

Micro, small and medium-sized enterprises. The Agency has an office specifically dedicated to supporting smaller companies, the SME Office. It provides eligible SMEs with access to various incentives and regulatory assistance, including fee reductions, administrative and procedural support, as well as assistance with translations of the product-information documents submitted in applications for marketing authorisation. 1893 SMEs were registered with the Agency at the end of 2017.

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

Information and transparency. The Agency places high importance on the transparency, openness and efficiency of its interactions with partners and stakeholders. The Agency maintains and manages specific communication and information exchange platforms, and provides up-to-date information to its stakeholders, partners and the general public on its work and outputs as well as important subject matters and developments, including lay-language summaries on medicines and regulatory outcomes. This information is also shared within the European regulatory network in advance of publication in order to ensure that consistent messages on medicines are available to citizens across the EU. In addition to the activities described above, public access to documents and information is provided in accordance with Regulation (EC) No 1049/2001, and the number of requests for access to documents and information is continuously increasing.

Communication activities. The Agency's communication activities aim at supporting the Agency's mission of protecting public and animal health and the achievement of its strategic priorities. The Agency produces a wide variety of communication materials including for example press releases, infographics, videos distributed via a range of channels with its corporate website, ema.europa.eu, as the main channel. The Agency fosters productive relationships with the media, both general and specialist, through the provision of press materials, organising media interviews and press conferences, and responding to journalists' queries. The Agency's social-media activities include communication via a Twitter account and regular updates on LinkedIn and YouTube. The Agency has put in place a dedicated, centralised service to respond to queries received from patients, healthcare professionals and academia.

Drivers

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

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

Academia, SMEs and public-private partnerships are an increasingly important source of innovation in medicines. The ongoing work within the European medicines regulatory network to strengthen early support for innovative medicines, teamed with the roll-out of further funding opportunities, such as the SME 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 development and delivery of training in the priority areas for capacity increase in the Network which included the results of the 2018 HMA survey and consultation of the EMA committees and SciCoBo. These priorities particularly aim to deliver capacity needed because of the increase in workload for NCAs caused by the UK's withdrawal from the EU.

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Requests for SME qualification	582	553	487	751
SME status renewal requests	1,185	1335	1,334	1,617
Number of cases of patient/consumer engagement[1] in EMA activities	750	950	493	400
Number of cases of healthcare professionals engagement[2] in EMA activities	399	450	212	200
New scientific, regulatory and telematics curricula developed	8	0	2	1
Number of training events advertised to the EU Network	140	100	60	60
Number of reimbursed training events to the EU Network	25	20	8	8
Number of messages circulated via 'Early Notification System'	380	383	440	400
Number of EMA communications pro-actively sent to stakeholders	172	144	175	150
Number of EPAR summaries and EPAR summaries updates published	283	299	343	300
Number of summaries of orphan designation published	240	168	169	200
Access to documents, requests received	823	865	822	850
Access to documents, documents released	2,876	2,807	2,422	2,700
Requests for information received	4,843	6,735	7,554	5,500
Number of documents published on EMA website	7,369	6,736	4,840	7,000
Number of pages published and updated on EMA website	4,790	3754	6,307	4,000
Number of press releases and news items published	197	181	183	80
Requests for interviews and comments by media representatives	2,149	1,862	1,517	1,800
Number of reports, brochures, leaflets laid out or printed	25	60	85	30

[1] these include any interaction that a patient, consumer or carer may have with the agency, such as, acting as a committee/working party member, reviewing a package

leaflet or being invited to a SAG meeting or any other activity which entail engagement from both sides. The figures represent number of interactions (not patients, as the same patient may be involved several times, within different activities at the Agency)

[2] these include any interaction a healthcare professional may have with the EMA, in addition to those occurring with healthcare professionals nominated by the national agencies

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Satisfaction level of patients and consumers	97%	n/a	n/a[1]	n/a[1]
Satisfaction level of healthcare professionals	n/a	n/a	n/a[1]	n/a[1]
Satisfaction level of SMEs	94%	93%	95%	80%
Response to ATD within set timelines	97%	96%	96%	90%
Response to RFI within set timelines	98%	98%	97%	95%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI	77%	81%	85%	75%
Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	14	8	7	7
Number of users registered to the EU NTC Learning Management System	2,117	3583[2]	4,424	4600
Number of NCA experts registered to the EU NTC Learning Management System	1,225	2668[2]	3,480	3600
Satisfaction level of partners/stakeholders with EMA communications as per “EMA perception survey for communication”	n/a	82%	n/a	n/a[1]
Average rating given to pages on corporate website during the year	3.6	3.3	3.1	3.5

[1] No survey due to BCP

[2]Higher than expected activity seen signing up to the EU NTC learning system due to 'registration drivers' in HPRA, BfArM, AEMPS, AIFA, PEI and ANSM.

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
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 2B RA	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019 Focus on priority areas: - Support entry of academia to PRIME, OD (link to ERN) and SA including fee incentives. - Support to scientific publication strategy
	3.4-6	Publish annual report on EMA interactions with industry associations	Q4 2019	Continuous 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019 A biennial report covering 2018-2019 will be finalised in 2020
	3.4-4	Publish annual report on EMA interactions with patients, consumers, healthcare professionals, and their organisations	Q4 2019	Continuous 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019 A biennial report covering 2018-2019 will be finalised in 2020
	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 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019
Further develop support to, and strengthen stakeholder relations with SMEs	1.3-8	Implement the action plan arising from the 10-year report on the implementation of the SME Regulation	2016	2020 2A	All activities directly related to product support are maintained in Q1/Q2 2019; non-product support activities are suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019
Further strengthen Agency's transparency and open data	1.4-3	Complete the reflection paper on providing access to individual patient data	Q3 2017	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
commitments	1.4-5	Assess implementation of the policy on publication of clinical data and publish annual report	2019	Continuous 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019
		Hold regular discussions in the technical group on anonymisation of clinical data	Q2 2017	2019 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019 No meetings in 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 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019
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	2019 1A	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	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 2020 1A	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019. Launch of second phase in 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 capability of the EU Network	2017	Continuous 2A	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Develop in collaboration with the Network, the EU Medicines Agencies Network Strategy to 2025	2019	2020 2A	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	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 2A	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
		Work with the Network to prioritise training needs	2018	Continuous 2A	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

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 2A	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	1.3-8	Strengthen collaboration among the EU Innovation offices on regulatory challenges identified to promote harmonisation and consistency	2017	2020 2A	Reduced to observer status in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	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 2A	Reduced to observer status in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
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 2A	Reduced to observer status in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
Provide stakeholders and partners with consistent, high-quality, timely, targeted and accessible information on Agency 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	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019
	3.3-6 3.3-7	Implement user-testing for EMA communication products which target the general public	Before 2016	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019
	3.3-10	Run a pilot to test and improve the crisis communication plan	2017	2020 1A	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019
	3.3-7	Carry out an EMA perception survey to better	2019	2020	Suspended in Q1/Q2 2019. Not proposed for

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	Timeframe End	BREXIT implications
		understand communication opportunities and challenges, and review the Agency's communication products and tools, as per the results of the survey		2B RA	priority for Q3/Q4 2019
	3.3-3	Improve the corporate website by adding new tools and features, such as tools to improve search, search-engine optimisation, accessibility, analytics and others	2017	2020 2A	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	3.3-1	Develop and implement an annual communication plan, in line with the framework strategy for external communication	2016	2020 2B RA	Maintained for Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	3.3-4	Continue development and implementation of a social media strategy, including consolidation of social media channels and growth in followership	2016	2020 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019
	3.3-5	Develop new digital and multimedia communication tools	2016	2021 2B RA	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019
Improve provision of and access to strategic information resources	3.3-11	Implement Information Literacy Programme	2017	2020 3	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019 with the exception of 2 trainings for new staff in 2019
	3.3-12	Proactive development and provision of InfoCentre collection and services including e.g. journals, eBooks and databases that address the changing needs of the Agency	2017	2020	2B RA Activity reduced to all relevant resources are purchased, reviewed, maintained and made accessible in 2019
	3.3-13	Support open access publication of relevant scientific articles (Open access requests reviewed and approved as necessary, payment procedure initiated)	2017	2020	2B RA Maintained for Q1/Q2 2019. Proposed for priority for Q3/Q4 2019
	3.3-14	Develop pilot to measure reach of open access	Q3/Q4	Q3/Q4	Suspended in Q1/Q2 2019. Not proposed for

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
		publications (Assessment on the methods to measure the impact of open access publications completed)	2019	2020	priority for Q3/Q4 2019

Resources

Area of activity	Financial resources (cost, thousand Euro)		Human resources (FTEs)		Of which Human resources – Brexit preparedness (FTEs)	
	2018	2019	2018	2019	2018	2019
Partners and stakeholders	12,178	7,904	41	40	4	4
Transparency and access to documents	3,535	2,960	19	17	0	0
Information	7,626	7,231	40	40	1	1

3.4. International activities

Activity area

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

Regular exchanges of information on products, guidelines, policies, approaches and other activities take place across the lifecycle of the product and in all therapeutic and product areas.

Specific collaborative projects, such as provision of parallel scientific advice (human and veterinary) with the FDA, qualification of novel methodologies, joint collaboration on orphan medicines, biosimilars, paediatric and advanced therapies, and in the area of nanomedicines. The potential for further international work-sharing has led to additional cooperation activities, particularly in the areas of inspections, pharmacovigilance and signal-detection, as well as in transatlantic efforts to combat antimicrobial resistance and on generic medicine evaluation.

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

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

Drivers

The global nature of medicines development and research continues to be a key driver of the Agency's international collaborative activities. In 2019, these activities will be affected by the restrictions imposed by the decision by the UK to withdraw from the EU; the restrictions will mean that priorities only *might* be implemented. The priorities in terms of global development are to ensure and maintain supply chain and data integrity as both have a direct effect on patient safety. This will mean focusing on GMP and GCP inspections, in particular in the context of the implementation of the MRA with the US FDA. 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 training to raise standards of our main partners India and China as major producers of medicines (in particular APIs, and generics).

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

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

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

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
Interactions with FDA	n/a	654	584	700
Interactions with PMDA/MHLW	n/a	138	122	200
Interactions with Health Canada	n/a	91	175	90
Interactions with Membership organisations	n/a	104	118	100
Interactions with any other stakeholders	n/a	498	734	500
Answers to membership organisations' speaker requests	n/a	125	103	100
Number of information and/or document exchanges	n/a	929	920	750
Number of teleconferences organised	n/a	166	172	150

Performance indicators

	Results			Targets
	2016	2017	2018	2019
n/a				

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
Ensure best use of resources through promoting mutual reliance and work-sharing	4.2-3	Optimise Article 58 scientific opinion activities, including enhance collaboration with WHO and concerned regulators	2015	Ongoing 2B RA	Activity restricted to product specific issues in Q1/Q2 2019. Proposed priority for Q3/Q4.
Promote convergence of global standards and	4.2-8	Provide assistance to candidate countries, to align their standards and practices with those	2016	2020 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019

Medium-term objective	MAWP initiative	Activity description	Timeframe		BREXIT implications
			Start	End	
contribution to international for a		established in the European Union, and to further foster their integration process			
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 2B RA	Activity restricted to specific inspections requested in Q1/Q2 2019. Proposed priority in Q3/Q4 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 2B RA	Activity restricted to support to topic lead for Q1/Q2 2019. Proposed priority for Q3/Q4.
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[8]	2016	Continuous 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019
		Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU	2017	Ongoing 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019
		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 2B RA	Suspended in Q1/Q2 2019. Not proposed for priority for Q3/Q4 2019

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

Resources

	2018	2019
Financial resources (cost, thousand Euro)	2,814	2,546
Human resources (FTEs)	11	11

3.5. Information management

Activity area

Information-management activities aim to establish and manage information as a key asset to support sound decisions and provide reliable information on medicines for the promotion and protection of human and animal health in compliance with European pharmaceutical legislation. This involves the delivery and operation of efficient and effective data and information-management services and increasing the Agency's information-processing capacity, and requires management of in-house and outsourced information and technology services. The 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, the EMA and medicines regulatory authorities in Member States. This activity covers the support and coordination of the Telematics governance and the delivery and maintenance of shared data, IT systems and infrastructure. The list of Telematics services can be found here.

Drivers

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

Successfully relocate EMA's operations outside the United Kingdom - in the context of the UK's withdrawal from the EU, once the arrangements have been clarified, EMA will, as required, amend access to networks, information systems and data bases under its control to ensure that permissions and access rights granted to United Kingdom participants in the European Medicines Agency are withdrawn at the end of any agreed transition period. EMA will amend all programmes as necessary to reflect the cessation of United Kingdom participation in the activities of the Agency, including the relevant financial arrangements. In the context of the relocation of the Agency to Amsterdam, EMA will amend all programmes as necessary to operate in the new location, including, for example, necessary changes to security and financial systems. 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, 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 premises, 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 reducing 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 the clinical trials and the pharmacovigilance legislation and subject to increase in capacity the new veterinary legislation.

Deliver, upgrade and maintain effective and secure 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 governance and management frameworks (COBIT5, ITIL) 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. Effective functioning of the Telematics governance framework will be essential 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 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. To ensure sustainability of the information services it provides it is essential that EMA dedicates the necessary resources to upgrading its IT to meet required technical and information security standards.

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.

	Result			Forecast
	2016	2017	2018	2019
Number of Telematics information services provided by EMA	22	23	25	25
Number of ongoing Telematics IT projects where EMA is the delivery organisation	13	11	3	14
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	6	5	5	5

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Satisfaction of EMA internal and external users	94%	94%	91.92%	80%
Availability of corporate/Telematics IT systems and corporate website	100%	99.3%	98.11%	98%

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

	* 2018	2019
Financial resources (cost, thousand Euro)		11,160
Human resources (FTEs)	25 (for information only)	24

* Up to 2018 the resources for Information management were allocated to the relevant activities and chapters throughout this work programme.

3.6. Projects

Projects outlined in Annex 10

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 for and is responsible for the preparation and implementation of the Agency’s anti-fraud strategy and the related action plan.

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.

Quality- and risk-management and internal-control coordination. Quality-management includes both the integrated quality-management activities and risk-management within the Agency. Risk-review is conducted annually, with risks being assessed at a residual level, i.e. taking into account controls and mitigations already in place. Conducting self-assessments (as part of the EU Agencies benchmarking programme), annual reviews of sensitive functions and ex post controls also falls within this area, as does maintaining a register of exceptions.

Internal audit. Internal audit reviews and evaluates risk-management, governance and internal-control processes at the Agency, to provide to the Executive Director and the Management Board independent and objective assurance and consulting services designed to add value and improve the Agency's operations.

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

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

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

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

Emergency and crisis management. These activities relate to crisis management of emergency events (both product and non-product related) with policy, political, reputational consequences for the Agency, or important public-health related events.

Drivers

n/a

Workload indicators

	Results			Forecasts
	2016	2017	2018	2019
n/a				

Performance indicators

	Results			Targets
	2016	2017	2018	2019
Posts on the Agency establishment plan filled	98%	98%	98.3%	97%
Total AT staff recruited against vacant posts		15	29	42
Staff turnover rate (staff leaving against total no. of staff TA & CA)		4.1%	4.57%	10%
Time to fill position from vacancy notice to establishment of reserve list:				
Standard procedure		>3 months	85% < 3 months	<3 months
Medium procedure		>4 months	100% < 4 months	<4 months
Large procedure		>6 months	76% < 6 months	<6 months
Revenue appropriations implemented	94%	94%	92%	97%
Expenditure appropriations implemented	96%	93%	91%	97%
Payments against appropriations carried over from year N-1	96%	90%	91%	97%
The maximum rate of carryover to year N+1, of total commitments within the title				
Title 1	1%	1%	1%	1%
Title 2	8%	12%	16%	15%
Title 3	26%	27%	31%	25%
Payments made within 30 days' time	99%	99%	97%	98%

	Results			Targets
	2016	2017	2018	2019
Availability of Telematics/corporate IT systems and corporate website (% of time)	100%	99.3%	98.11%	98%
Energy consumption (change in % per workstation)[1]	-19.6%[1]	-5%	-3%	n/a
Water consumption (change in % per workstation)[1]	-52.8%[1]	13%	-7%	n/a
Paper consumption (change in % per workstation)[1]	-22.7%[1]	-13%	-8%	n/a
Non-recyclable waste produced in restaurant and kitchenette (change in % per workstation)[1]	-46.0%[1]	13%	-5%	n/a
Recyclable waste produced (change in % per workstation)[1]	-26.3%[1]	10%	-22%	n/a
Recycling rate (change in % per workstation)[1]	-5.2%[1]	-4%	3%	n/a
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)[1]	+1.4%	n/a	-6%	n/a
Overall net CO_2 emissions (per workstation)[1]	-10.2%[1]	n/a	-14%	n/a

[1] results only for current premises at 30 Churchill Place in London, UK. The Agency is expected to relocate during 2019.

Due to UK exit of the EU and EMA's two-stage relocation to Amsterdam the environmental performance indicators cannot be estimated. During 2019-2021 EMA will occupy three buildings; 30 Churchill Place in London between Jan-Feb 2019, Spark building Mar-Nov 2019 and EMA building Dec 2019 to 2021. To provide meaningful environmental targets, at least one base year of gathering data with regular building occupancy is required and therefore it is envisaged that the new environmental indicators will be set up only for 2022.

The following aspects related to the relocation do not allow the estimation of the environmental indicators:

- *Performance indicators such as water and electricity consumption are dependent on building design and will change with each relocation;*
- *Streams of waste segregation are not fully known at this stage e.g. oil collection, coffee cups recycling, segregation of recyclable waste, and consequently the volumes cannot be estimated;*
- *The occupancy in Spark building and in the first year in EMA building might vary due to the amount of staff relocating and teleworking;*
- *Delegates and staff travel will change due to the relocation from the UK to the Netherlands;*
- *The occupancy of 30 Churchill Place in Jan-Feb 2019 will be significantly reduced due to a high proportion of staff teleworking.*

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	2020 3	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	3.2-5	Implement a competency management framework	2017	2020 3	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
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 1A	Suspended in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
	3.1-8	Implement the action plan of the anti-fraud strategy	2019	2020	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.
Implementation of new GDPR legislation	4.1	Enhance the protection of personal data in all aspects of the Agency work	2018	Continuous 1B	Maintained in Q1/Q2 2019. Proposed priority for Q3/Q4 2019.

Resources

Area of activity[1]	Financial resources (cost, thousand Euro)		Human resources (FTEs)		Of which Human resources – Brexit preparedness (FTEs)	
	2018	2019	2018	2019	2018	2019
Governance, quality management and internal audit	7,433	6,096	33	32	12	10
Finance	5,002	3,397	27	27	3	3
Information technology	14,372	12,331	75	58	27	17
Human resources	10,406	8,324	64	60	29	19

Area of activity[1]	Financial resources (cost, thousand Euro)		Human resources (FTEs)		Of which Human resources – Brexit preparedness (FTEs)	
	2018	2019	2018	2019	2018	2019
Infrastructure services	2,454	2,039	15	15	7	5

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

Projects

Projects outlined in Annex 10

Annexes

Annex 1: Activity based budget 2019

Work programme chapters	Full Time Equivalence			Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	Total expenditure	
	* Total FTEs	Business as usual	Brexit preparedness	€'000	€'000	€'000	€'000	€'000	€'000	%
	TA, CA & National Experts			Title 1	Title 2 & Budget Item 3105	Budget item 3000	Article 301	Articles 302, 303 & Item 3003		
1 Evaluation activities for human medicines	353	351	2	45,287	20,347	5,938	115,804	6,801	194,176	68%
1.1 Pre-authorisation activities	81	80	1	10,592	2,095	2,982	20,426	7	36,102	13%
1.2 Initial evaluation activities	75	75	0	10,549	1,566	1,062	12,705	882	26,764	9%
1.3 Post-authorisation activities	79	78	1	9,558	6,067	208	70,835	1,425	88,094	31%
1.4 Referrals	6	6	0	746	125	72	-	277	1,220	0%
1.5 Pharmacovigilance activities	96	96	0	11,577	4,146	958	11,838	4,079	32,598	11%
1.6 Other specialized areas and activities	16	16	0	2,264	6,349	656	-	130	9,399	3%
2 Evaluation activities for veterinary medicines	36	35	1	4,255	1,079	715	3,687	413	10,149	4%
2.1 Pre-authorisation activities	3	3	0	363	67	67	212	-	710	0%
2.2 Initial evaluation activities	12	12	0	1,494	255	255	912	147	3,064	1%
2.3 Post-authorisation activities	10	9	1	1,164	415	74	2,562	219	4,433	2%
2.4 Arbitrations and Referrals	2	2	0	198	37	91	-	47	372	0%
2.5 Pharmacovigilance activities	5	5	0	676	236	168	-	-	1,080	0%
2.6 Other specialized areas and activities	3	3	0	360	70	61	-	-	490	0%
3 Horizontal activities and other areas	231	226	5	30,005	14,127	1,193	4,450	854	50,629	18%
3.1 Committee coordination	65	65	0	7,728	1,325	544	-	-	9,597	3%
3.2 Inspection and Compliance	34	34	0	3,638	1,111	31	4,450	-	9,230	3%
3.3 Partners and Stakeholders	40	36	4	5,990	806	503	-	605	7,904	3%
3.3a Transparency and access to documents	17	17	0	2,236	704	21	-	-	2,960	1%
3.3b Information	40	39	1	5,008	1,968	7	-	248	7,231	3%
3.4 International activities	11	11	0	2,279	222	45	-	-	2,546	1%
3.5 Information Management (incl. EU Telematics)	24	24	0	3,126	7,991	43	-	-	11,160	4%
4 Corporate Governance and Support activities	191	137	54	24,098	7,892	192	-	5	32,186	11%
4.1 Governance, quality management and internal audit	32	22	10	4,760	1,144	192	-	-	6,096	2%
4.2 Finance	27	24	3	2,850	542	-	-	5	3,397	1%
4.3 Information technology	58	41	17	7,949	4,382	-	-	-	12,331	4%
4.4 Human resources	60	41	19	6,809	1,515	-	-	-	8,324	3%
4.5 Infrastructure services	15	10	5	1,729	309	-	-	-	2,039	1%
Total	811	749	62	103,645	43,445	8,037	123,941	8,072	287,140	100%

* FTEs are calculated as follows:	
Temporary Agents	591
Contract Agents (193 FTEs business as usual + 40 Brexit related)	233
Seconded National Experts	30
Total Staff	854
5% vacancy rate	- 43
Estimated FTEs for 2019	811

Brexit related expenditure	45,819
Budget 2019	332,959

Annex 2: Financial resources

Table 1 – Expenditure

Expenditure	2018[1][2]		2019		2020	
	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations	Commitment appropriations	Payment appropriations
Title 1	€ 112,518,178	€ 112,518,178	€ 125,638,000	€ 125,638,000	€ 122,569,000	€ 122,569,000
Title 2	€ 51,297,560	€ 51,297,560	€ 46,234,000	€ 46,234,000	€ 64,169,000	€ 64,169,000
Title 3	€ 144,221,104	€ 144,221,104	€ 146,663,000	€ 146,663,000	€ 163,619,000	€ 163,619,000
Title 9	€ 0	€ 0	€ 14,424,000	€ 14,424,000	€ 19,102,000	€ 19,102,000
Total expenditure	€ 308,036,841	€ 308,036,841	€ 332,959,000	€ 332,959,000	€ 369,459,000	€ 369,459,000

[1] 2018 includes under title 3 an amount of EUR 1.5 million which will be carried forward non-automatically to 2019

[2] Data as per provisional accounts of January 2019

Table 2 – Revenues

Revenues	2018[1]	2019	2020
	Outturn	Budget estimate	Preliminary budget estimate
EU contribution	€ 32,951,580	€ 35,497,000	€ 42,811,000
Other revenue	€ 284,129,545	€ 297,462,000	€ 326,672,000
Total revenue	€ 317,081,125	€ 332,959,000	€ 369,483,000

[1] Data as per provisional accounts of January 2019

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	0
	AST	0	0	0	0	0	0	0	0	0	0
	AST/SC	0	0	0	0	0	0	0	0	0	0
TA	AD	333	343	337	340	334	340	338	365	401	436
	AST	254	259	250	256	249	251	243	226	201	177
	AST/SC	0	0	0	0	0	0	0	0	0	0
Total		587	602	587	596	583	591	581	591	602	613
CA FG IV		55	58	55	63	57	85	60	52	52	52
CA FG III		20	14	15	17	16	25	33	131	131	131
CA FG II		81	73	73	78	72	70	66	10	10	10
CA FG I		0	0	0	0	0	0	0	0	0	0
Additional CA[2]		0	0	0	0	0	0	0	40	40	40
Total CA[3]		156	145	143	158	145	180	159	233	233	233
SNE[3]		33	40	36	45	36	39	32	30	30	30
Total TA+CA+SNE		776	787	766	799	764	810	772	854	865	876
Structural service providers[4, 5, 6]		132		148		125		114			
occasional replacement[7]		40		59		67		66			
Fee related staff			567		616		546		560	567	574
			72.0%		77.1%		67.4%		65.6%	65.6%	65.6%
Non-fee[8] related staff			220		183		264		294	298	302
			28.0%		22.9%		32.6%		34.4%	34.4%	34.4%
TOTAL			787		799		810		854	865	876

1) completed in January 2019

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

3) FTE

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

5) Structural service providers for EMA include (2018 FTEs): Reception (6), Security (8), Building maintenance (4), Cleaning (13), Catering (26), Reprographics and mail services (7), IT service desk (16), IT maintenance and support - 'time&means' contracts only (34). Excludes project-related consultancy work.

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

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

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

Table 2 - Multiannual staff policy plan

Category and grade	Establishment plan in voted EU budget 2017		Filled as of 31/12/2017		Modifications in 2017 in application of flexibility rule		Establishment plan in voted EU budget 2018		Filled as of 31/12/2018		Modifications in 2018 in application of flexibility rule		Establishment plan in draft EU budget 2019		Establishment plan 2020		Establishment plan 2021	
	Officials	TA	Officials	TA	Officials	TA	Officials	TA	Officials	TA	Officials	TA	Officials	TA	Officials	TA	Officials	TA
AD 16		0						0		0				0		0		0
AD 15		4		3				3		3				3		3		3
AD 14		6		6				7		6				7		8		9
AD 13		11		11				11		11				11		12		13
AD 12		40		35				43		42				43		44		45
AD 11		40		40				43		43				43		47		51
AD 10		43		43				41		41				43		44		45
AD 9		42		42				45		45				43		46		52
AD 8		53		53				59		59				59		67		79
AD 7		61		61				65		65				65		80		103
AD 6		37		37				23		23				37		50		36
AD 5		3		3				0		0				11		0		0
Total AD	0	340	0	334	0	0	0	340	0	338	0	0	0	365	0	401	0	436
AST 11		2		2				2		2				2		2		2
AST 10		6		6				7		7				7		7		7
AST 9		7		7				6		5				7		8		6
AST 8		16		16				16		16				16		19		18
AST 7		19		18				22		22				22		15		2
AST 6		43		43				42		39				27		15		17
AST 5		43		39				46		43				35		39		43
AST 4		52		52				57		57				57		52		54
AST 3		45		44				46		46				46		44		28
AST 2		23		22				7		6				7		0		0
AST 1		0		0				0		0				0		0		0
Total AST	0	256	0	249	0	0	0	251	0	243	0	0	0	226	0	201	0	177
AST/SC1																		
AST/SC2																		
AST/SC3																		
AST/SC4																		
AST/SC5																		
AST/SC6																		
Total AST/SC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	0	596	0	583	0	0	0	591	0	581	0	0	0	591	0	602	0	613

Annex 4: Human resources policies

A - Recruitment policy

Officials

The Agency does not have any posts for officials.

Temporary agents

The Agency employs temporary agents on long-term employment. Staff employed on these posts hold temporary agent contracts and carry out administrative or operational tasks.
The entry grades for recruitment are:

Assistant	AST 3
Administrator, Scientific or Administrative	AD5, AD6
Administrator (scientific or administrative) with specialisation	AD8
Head of Service	AD6/(AST6 if internal procedure)
Head of Department	AD9/AD10
Head of Division	AD12
Advisor	AD13

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

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

Contract agents

The Agency also employs contract agent staff. The category of contract staff can be employed for a period up to five years with a possible renewal of up to a further five years. Any further renewal will be for an indefinite period. Contract staffs at the Agency are employed in function groups II, III and IV.

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

Trainees
The Agency has a traineeship program in place and employs around 70 trainees annually. The Agency is currently reviewing the traineeship program for 2019 in light of the EMA's relation to Amsterdam.

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

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

Key tasks assigned	Tender procedure	Contract duration
Reception/switchboard	Restricted procedure; Contract no EMEA/2012/53/IS; Contract start: 29.11.2013	4 years This contract has been extended until 30 March 2019, based on the exceptional circumstances related to Brexit.
IT service desk	Restricted procedure; Contract no EMEA/2013/09/ICT; Contract start: 02.04.2014	4 years This contract has been extended until 30 March 2019, based on the exceptional circumstances related to Brexit.

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

B - Appraisal of performance and reclassification / promotions

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

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

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

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

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

Year	2015 actual	2016 actual	2017 actual	2018 actual	2019 estimate
Number of reclassifications (TAs)	74 = 22% on average of eligible staff	78= 17% on average of eligible staff	94 = 25% on average of eligible staff	119 = 32% on average of eligible staff	Max percentage of eligible staff according to Annex I Staff Regulations

Table 1 - Reclassification of temporary staff / promotion of officials

Category and grade	Staff in activity at 01/01/2016		How many staff members were promoted / reclassified in 2017		Average number of years in grade of reclassified / promoted staff members	Staff in activity at 01/01/2017		How many staff members were promoted / reclassified in 2018		Average number of years in grade of reclassified / promoted staff members
	Officials	TA	Officials	TA		Officials	TA	Officials	TA	
AD 16										
AD 15		2					1			
AD 14		1					1			
AD 13		10		1	6.0		10		1	10
AD 12		27		1	12.0		27		2	5.71
AD 11		25		1	8.0		24		3	2.66
AD 10		31		7	4.1		31		7	5.71
AD 9		34		2	5.0		35		8	5.25
AD 8		52		6	7.1		52		11	4.81
AD 7		57		14	5.4		56		14	4.85
AD 6		67		13	4.0		73		18	5.04
AD 5		15		7	4.8		19		2	2.33
Total AD	0	321	0	52		0	329	0	66	
AST 11										
AST 10		3					3			
AST 9		3					3			
AST 8		4		2	5.2		4			
AST 7		13		1	4.0		12		1	4
AST 6		22		2	3.6		21		4	3.5
AST 5		32					30		8	4.87
AST 4		35		7	4.4		35		10	4.4
AST 3		69		18	4.4		75		14	3.8
AST 2		35		6	4.3		34		9	3.33
AST 1		45		6	5.9		37		7	4.44
Total AST	0	261	0	42		0	254	0	53	
AST/SC1										
AST/SC2										
AST/SC3										
AST/SC4										
AST/SC5										
AST/SC6										
Total AST/SC	0	0	0	0		0	0	0	0	
Total	0	582	0	94		0	583	0	119	

Table 2 - Reclassification of contract staff

Function group	Grade	Staff in activity at 01/01/2016	How many staff members were reclassified in 2017	Average number of years in grade of reclassified members	Staff in activity at 01/01/2017	How many staff members were reclassified in 2018	Average number of years in grade of reclassified members
CA IV	18						
	17	1			1		
	16	2			2		
	15	2			5		
	14	35	7	2.21	36	10	3.86
	13	16	3	3.44	10	1	3.75
CA III	12						
	11						
	10	1			2		
	9	12	1	8.16	8	1	3.87
	8	5	1	3.58	5	2	3.31
CA II	7						
	6	7			13	1	5.00
	5	39	7	3.13	40	7	2.66
	4	33	10	3.03	21	7	3.32
CA I	3						
	2						
	1						
Total		153	29		143	29	

C - Mobility policy

Internal mobility

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

Year	2014	2015	2016	2017	2018	2019 estimate
Internal vacancy announcements/calls for expression of interest and internal selection procedures	16	11	12	10	25	15

Mobility between the agencies

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

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

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

D - Gender and geographical balance

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

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

Gender balance

Contract Type[1]	Men	Women	Total
Temporary Agents	198	383	581
Contract Agents	34	136	170
National Experts	11	19	30
Total	243	538	781
Trainees	12	38	50
Visiting experts	3	2	5
Grand total	258	578	836

1) Data as of 31/12/2018

Status 31/12/2018	Category AD				Category AST				TA/CA - all grades			
	Men		Women		Men		Women		Men		Women	
Ratio TA	165	49%	171	51%	33	13%	212	87%	198	34%	383	66%
Ratio CA	19	28%	50	72%	15	15%	86	85%	34	20%	136	80%
Total	184	45%	221	55%	48	14%	298	86%	232	31%	519	69%

Geographical balance

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

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

Status 31/12/2018	Temporary Agents			Contract Agents	National experts	Trainees	Visiting experts	Total
	AD	AST	Total					
Austria	7	2	9	3	0	0	0	12
Belgium	16	2	18	4	0	0	0	22
Bulgaria	4	3	7	8	0	2	0	17
Croatia	2	0	2	2	2	3	0	9
Cyprus	0	0	0	1	0	0	0	1
Czech Republic	2	13	15	5	0	0	0	20
Denmark	5	6	11	0	0	0	0	11
Estonia	0	8	8	2	0	0	0	10
Finland	5	7	12	1	1	1	0	15
France	56	26	82	13	0	6	0	101
Germany	30	15	45	5	1	0	1	52
Greece	22	11	33	13	1	4	0	51
Hungary	4	14	18	8	0	0	0	26
Ireland	13	2	15	1	3	1	0	20
Italy	45	22	67	26	5	8	0	106
Latvia	2	5	7	2	0	0	0	9
Lithuania	2	8	10	5	1	0	0	16
Luxembourg	0	0	0	0	0	0	0	0
Malta	0	0	0	0	0	0	0	0
Netherlands	2	4	6	2	2	0	0	10
Norway	0	1	1	0	0	0	0	1
Poland	8	26	34	14	1	1	0	50
Portugal	20	7	27	8	3	5	0	43
Romania	9	4	13	13	1	6	0	33
Slovakia	3	13	16	6	0	0	0	22
Slovenia	0	1	1	2	0	0	0	3
Spain	41	27	68	20	3	13	0	104
Sweden	6	3	9	3	2	0	0	14
United Kingdom	32	15	47	3	3	0	1	54
Other	0	0	0	0	1	0	3	4
Total	336	245	581	170	30	50	5	836

E – Schooling

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

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

Pre-school and after school care for children

The Agency introduced in 2007 an Executive Decision under social measure for a contribution which covered full-time or part-time crèche costs.

In 2014 the Executive Decision has been amended to cover pre-educational costs for children up to the age of 5, *in line with the principle and rationale of the support required* as per Staff Regulations. The Executive decision covers nurseries/pre-educational establishments in the UK, and the maximum reimbursement is based on actual UK costs. The total household income is considered to establish the amount of the contribution, therefore the financial contribution of the other parent, whether the couple is married or not, is taken fully into account. The amount deducted as the parental financial contribution follows the Commission's approach and methodology and that of other agencies'.

During the years the rules has been into force it is noted an increase in costs reimbursement due the growing population of EMA staff children.

Following the official decision to relocate the Agency's seat to the Netherlands in 2019, EMA's commitment is to provide appropriate social measures for its staff during the period of relocation of the Agency. The policy has now expanded and will offer to staff relocating to the Netherlands support with a contribution to children day-care, including childminders, and pre and after school care costs in the Netherlands.

The Executive Decision is in line with the same principles of the Commission's. An increase in the children's population is expected which will benefit of this measure in the Netherlands.

Budget year	Total cost to Agency, EUR	Average payment per child, EUR
2014 (94 children, actual)	293,555	3,123
2015 (122 children, actual)	426,915	3,499
2016 (117 children, actual)	415,740	3,553
2017 (133 children, actual)	483,233	3,633
2018 (140 children, estimate)	478,368	3,987
2019 (220 children, *estimate:* 200 NL – 20 in UK)	753,000	3,422
2020 (220 children, *estimate:* 200 NL – 20 in UK)	840,000	3,818

Schooling

Staff do not have access to a European School in the UK and it has not proved possible to establish a European School for the Agency's staff. The distance to the previous European School in Culham was more than 100km, but this school has been closed.
The financial support offered to other EU staff having access to the European School system is considerable, as well as the important opportunity for their children to be educated in a linguistically suitable manner that is consistent with social support for staff employed by EU institutions and agencies.

The average financial support for a child attending a European School is approx. £11,300 per annum. The Agency's staff merit the same extent of social support for educational costs and the same system of advantages as offered to staff employed under the Staff Regulations in other locations. Article 1d(6) of the Staff Regulations prohibits discrimination and promotes equal opportunity, linking both principles to legitimate objectives in the general interest in the framework of staff policy. The current and new Staff Regulations enshrine principles of non-discrimination and proportionality in their execution, e.g. Articles 1d(6) and 1e. Article 1e refer to access to measures of a social nature, and the European School system falls within this concept. Article 1d(6) of the Staff Regulations supports the principle of non-discrimination and proportionality in linking both principles to "legitimate objectives in the general interests in the framework of staff policy". The lack of a European School in London is an obstacle to such fairness. The financial support offered to staff through the European School system is considerable as well as the important opportunity for their children to be educated in a linguistically suitable manner that is consistent with social support for staff employed by EU institutions and agencies.

Taking into account the spirit of the Staff Regulations, the absence of a European School in the UK, the preferred option to use educational institutions providing multilingual education and the complex local geographical situation, the Agency established an educational contribution as a top-up of the ceiling indicated in Art. 3 of Annex VII of the Staff Regulations. In acknowledgement of the Commission's recommendation, the Agency did set up direct agreements with schools attended by the children of EMA staff. The service agreements with the schools have been concluded by individual pupil, and amount to 282 (from January 2018 to December 2018). The Agency's staffs currently use 99 schools across London.

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

Budget year	Total cost to Agency, EUR	Average payment per child, EUR*
2014 (209 children, actual)	875,713	4,190
2015 (222 children, actual)	1,241,300	5,591
2016 (252 children, actual)	1,474,858	5,853
2017 (281 children, actual)	1,530,786	5,448
2018 (282 children, estimate)	2,243,422	7,955
2019 (163 children, estimate)	1,041,522	6,389
2020 (20 children, estimate)	67,153	3,534

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

Following the official decision to relocate the Agency’s seat to the Netherlands in 2019, EMA’s commitment is to provide appropriate social measures for its staff during the period of relocation of the Agency, and with regards to educational support in particular for children in the last 2 years of their A-levels.

The Agency is currently still in the process to support staff to find adequate school places for their children in the Netherlands which cannot all be met by the two European schools which are both more than 50 km away from the future office location of the Agency.

Exceptional education allowance

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

Annex 5: Building policy

Current building(s)

	Name, location and type of building	Other comments
	30 Churchill Place, London, E14 5EU	The building is a multi-tenanted office building and EMA occupies parts of the basement, ground and promenade levels and level 1 through to level 10
Surface area (in m^2)	26,450	
of which office space	18,448	
of which non-office space	8,002	
Annual building charges	GBP 15.7 million	
of which rent	GBP 12,301,584.50	
of which estimated building service charges	GBP 2,235,000.00	
of which estimated estate service charges	GBP 950,000.00	
of which business rates	GBP 225,000.00	
Type and duration of rental contract	Rental agreement of 25 years' duration with no break clause; term commencement is 1 July 2014	With the exit of the United Kingdom from the EU and relocation of the Agency to a new host MS, the contractural arrangements with the current landlord are under discussion.
Host country grant or support	Reduction in business rates	
Present value of the building	Not applicable	

Building projects in the planning phase

[If applicable: information on building policy, expected evolution of surface area, and description of building projets in planning phase which are already identified]

Building projects submitted to the European Parliament and the Council

There are no building projects in the planning phase identified for the Agency's current London premises for 2018.

It is currently not certain if building projects or dilapidations for the current premises will be required for 2019 and 2020. Once known, the relevant information will be provided to the budget authority.

[If applicable: information on building projects likely to have significant financial implications which will be submitted to the EP and the Council shortly, as well as final terms and costs of building projects previously submitted, ina ccordance with Article 203 of the Financial Regulation]

Following on the outcome of the procedure leading to a decision on the relocation of the EMA, and once the necessary details are known, the Agency will have to submit the building project for the relocation to a new host member state, which is likely to have significant financial implications. To comply with the relevant artide of the Financial Regulation regarding the building project procedure, the present building declaration does not include this scenario. The decision on the Agency's new location was taken at the General Affairs Council (Art.50) on 20 November 2017. While we have now started the building project procedure, darification is still being sought from the new host country and city to ensure that submission to the budget authority can take place as soon as possible, in order not to hold up the overall relocation process.

Building project under planning phase:

The NL government offered the Agency a fully fitted and furnished premises (EMA Building) to be constructed (charged at rent of EUR 280/m2 plus 40 m2 for maintenance) as well as an incentive of EUR 18 million for fit-out enhancements of the future permanent building and/or an overall reduction of the annual lease. The Agency agreed with the Dutch government use this incentive to contribute EUR 15 million to fit-out costs and EUR 3.0 million to obtain yearly rent reductions of EUR 150,000 over the 20-year duration of the lease (January 2020 – December 2039). For details please see the Information note to the budgetary authority EMA/749315/2017;

The NL government will provide a temporary building (SPARK Building) at no rental cost to the Agency for the interim period from 1st of January 2019, whilst the final premises are being constructed and fitted out, expected to be delivered on 15th November 2019;

There is currently no certainty if building projects or dilapidations for the current premises will be required for 2019-2020. Once known, the relevant the relevant information will be provided the budget authority.

Annex 6: Privileges and immunities

a) FIRST 3 MONTHS OF 2019 (until official move to the NL) – old UK regime

Agency privileges	Privileges granted to staff	
	Protocol of privileges and immunities / diplomatic status	Education / day care
Agency has diplomatic status	Staff do not pay national taxes on their Union salary	UK European School is 103 km from Agency's location and therefore not suitable for Agency's staff. In 2008 the Agency introduced a model for payment of part of the school fees
Agency can recover value added tax, insurance premium tax and airport departure tax from the host country	Non-resident staff (Temporary Agents or Contract Agents who have been in the UK for less than 6 months prior to take up employment at the EMA) can buy a tax-free vehicle from a UK supplier within the first 12 months of taking up service subject to payment of residual value added tax on its sale. Not applicable to UK nationals	Agency does not have a day care facility but provides financial contribution using the same rules as EC for nursery contribution to European School kindergarten
Agency pays reduced business rates (equivalent of Council tax) and reduced charge for fibre optic cable usage	Non-resident staff (Temporary Agents or Contract Agents who have been in the UK for less than 6 months prior to take up employment at the EMA) can register their car with diplomatic plates (2 per household if the staff member is married, 1 otherwise) and therefore be exempt from road tax. Not applicable to UK nationals	
Agency has exmption from excise duty for alcohol used/consumed at the Agency	Non-resident staff (Temporary Agents or Contract Agents who have been in the UK for less than 6 months prior to take up employment at the EMA) can also request a UK diplomatic driving permit. Not applicable to UK nationals. The permit is only valid to drive in the UK	
Exemption from paying for TV licenses at the Agency premises	Non-resident staff (Temporary Agents or Contract Agents who have been in the UK for less than 6 months prior to take up employment at the EMA) can apply for a FCO identity card. However, this card does not confer any special rights	
Exemption from employer's liability insurance in UK	Non-resident staff (Temporary Agents or Contract Agents who have been in the UK for less than 6 months prior to take up employment at the EMA) can apply for a FCO identity card. However, this card does not confer any special rights	

b) FROM 01.04.2019 ONWARDS – new regime applicable in the NL

Agency privileges Privileges granted to staff

Agency privileges	Protocol of privileges and immunities / diplomatic status	Education / Day care
Agency has the most extensive legal capacity accorded to legal persons under the laws of the Host State (the Netherlands)	Staff (including Dutch nationals) do not pay national taxes on their EU salary.	There are two European Schools in the Netherlands both located > 50km (but <60km) from the Agency's future seat in Amsterdam
Agency's premises, property and assets are inviolable, as well as Agency's archives	The Head of the Agency and the members of his/her household are accorded the same privileges and immunities as accorded by the Netherlands to heads of diplomatic missions in accordance with the Vienna Convention.	Staff have access to Dutch national childcare benefit (kinderopvangtoeslag) on the same terms as Dutch nationals or other persons with the right to live and work in the Netherlands
In case of interruption or threatened interruption of public services in the Agency's premises, the Agency is accorded the priority given to essential agencies and organs of the Host State (the Netherlands)	Certain EMA staff members are conferred with a status which equates to the same privileges and immunities as members of the diplomatic staff under the Vienna convention of 1961.	Staff have no access to Dutch national child allowance/benefit (kinderbijslag)
Absence of restriction for Agency's financial assets (funds, currency, cash or securities), and immunity from legal proceedings in the Host State (the Netherlands) – including immunity from search, seizure, requisition, confiscation, expropriation and any other form of interference	All other EMA staff are conferred with a status which equates to the same privileges and immunities as member of the administrative and technical staff of the diplomatic missions under the Vienna convention of 1961.	
The Agency, its assets, income and other property are exempt from all direct taxes		

Agency privileges	Protocol of privileges and immunities / diplomatic status	Education / Day care
The Agency is exempt from the following indirect taxes: import and export taxes and duties; motor vehicle tax; tax on passenger motor vehicles and motor cycles; value added tax paid on goods and services supplied on a recurring basis or involving expenditure totalling € 225 or more; excise duties included in the price of alcoholic beverages and hydrocarbons such as fuel oils and motor fuels; real property transfer tax; insurance tax; energy tax; and tax on water mains. The Agency is also exempt from any other indirect taxes or duties of a substantially similar character as the ones mentioned above, enacted by the Netherlands after the signature of the seat agreement.		
The Agency is exempt from all custom duties, prohibitions and restrictions on import and export in respect of goods and publications intended for its official use.		

Annex 7: Evaluations

Article 86 of Regulation (EC) 726/2004 report on the experience of the operation of EU marketing authorisation procedures

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

The latest evaluation of the Agency took place in 2009, and resulted in a European Commission report that was published in January 2010. The Agency’s follow up to the recommendations from this report has been described in detail in the Programming Document 2018-2020 (version circulated to the Management Board of 13-14 December 2017).

In 2017 the European Commission started preparing for the next evaluation and in 2018 it selected Ernst & Young to perform a study on the operation of centralised procedure (CP) and decentralised and mutual recognition procedures (MRP/DCP) for the authorisation and monitoring of medicinal products for human use during the period 2009-2017. The contractor is expected to deliver its analysis to the European Commission by June 2019, while a formal Commission report is to be delivered to the European Parliament and to the Council by mid-2020.

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

In terms of scope, the second evaluation study will have to analyse in particular the following five areas: (1) the European Medicines Regulatory Network, with a focus on its evolution across the last 10 years as regards effectiveness and efficiency of the system in delivering its mission; (2) the efficiency and effectiveness of the pre-submission procedures, including how these activities act as promoters of innovation and medicines development and facilitate the access of applicants to marketing authorisations procedures; (3) initial marketing authorisations procedures, with a focus on their sustainability, long term capacity to meet the increasing requirements of the system and aptitude to ensure predictability to applicants; (4) post-marketing authorisation procedures,

including their suitability to deal with future scientific and technical developments, emergency needs and medicines shortages, as well as their efficient use of available resources and operational efficiency; (5) the effectiveness and efficiency of support activities, such as Telematics/digitalisation and communication.

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

As follow up to the Council's conclusions on 'strengthening the balance in the pharmaceutical systems in the EU and its Member States' of 17 June 2016, the European Commission is conducting an evidence-based analysis of the impact of incentives for developers of medicines in the EU on innovation, availability and accessibility of medicines. In the context of this exercise, the following studies regarding the experience with the operation of other pieces of legislation applicable to the Agency have been published or will be published soon:

First, pursuant to the reporting requirement under Article 50(3) of Regulation (EC) No 1901/2006, in October 2017 the European Commission presented to the European Parliament and the Council a comprehensive report on progress made in children's medicines 10 years after the Paediatric Regulation came into force. This study was built on a 10-year report prepared by the Agency and its Paediatric Committee in 2016 (EMA/231225/2015). Second, in line with the Commission's commitment in the context of its Better Regulation agenda to keep existing laws under review, in March 2018 the European Commission started preparing an evaluation of the functioning of the orphan regulation EC No 141/2000 over the period 2006-2017. A study was commissioned to Technopolis Group and ECORYS, to be delivered by June 2019, in order to analyse the impact of the incentives provided in the EU orphan legislation on innovation, availability and accessibility of orphan medicinal products. Third, based on the evidence provided in the two studies above, the European Commission is also planning to publish in late 2019 a Staff Working Document on the orphan and paediatric regulations to assess the functioning of the EU legislation on medicines for special purposes. These and other studies will serve as a basis for the next European Commission to consider the need for possible changes to the EU legislative framework on pharmaceuticals after 2020.

Project and programme evaluations

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

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

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

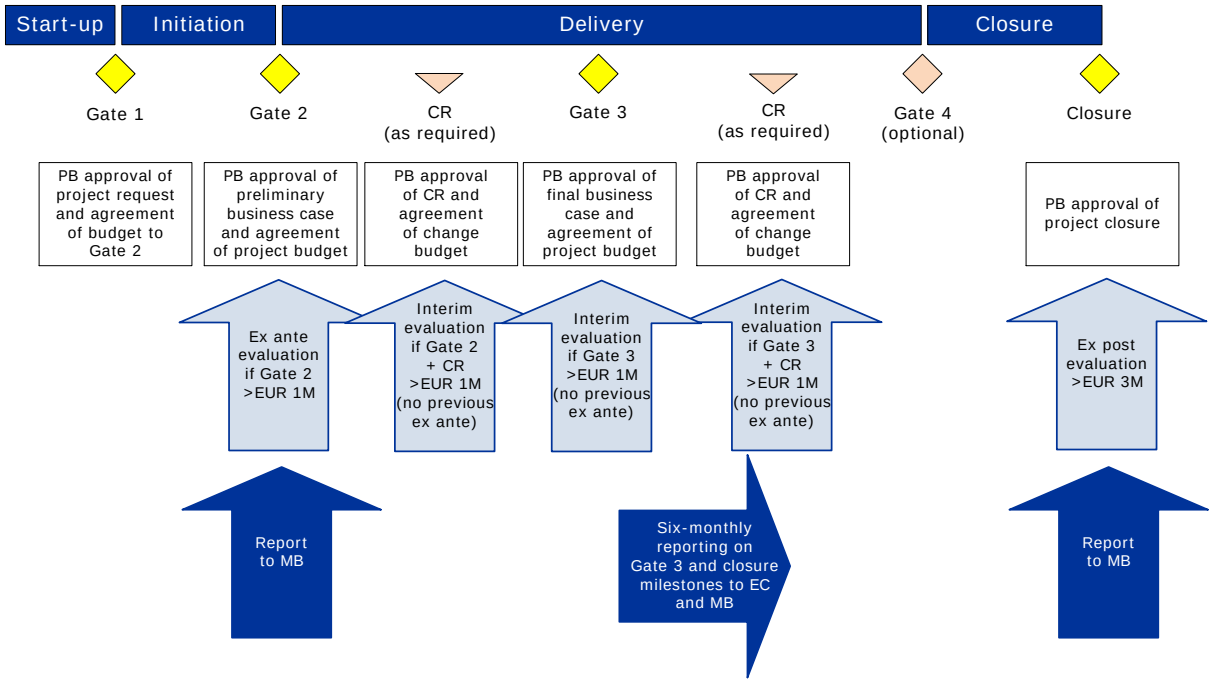
Ex ante evaluations are conducted at Gate 2 of the project procedure on the basis of the preliminary business cases (including cost estimates), before projects and budget expenditure are formally initiated. When the total project costs estimated at Gate 2 exceed EUR 1 million, the evaluation is conducted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

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

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

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

Figure 1. Project oversight and evaluations



Annex 8: Risks

As expected, the most significant risks that could potentially impact the achievement of the Agency's objectives in 2019 are related to 'BREXIT'. The Agency has been continuously assessing these risks since the result of the UK referendum and designed a risk mitigation strategy.

The significant risks and respective mitigating actions are outlined in the table below.

These risks, should they materialise and the consequences not be appropriately managed, would result in operational, reputational, legal or financial implications for the Agency.

Table 1 – Operational activities

Risk	Mitigating actions and controls
Loss of existing staff resulting in loss of professional competencies and knowledge	The Agency has implemented staff support measures aiming to make the transition to our new location as smooth as possible for colleagues who relocate with the Agency. They include entitlements and allowances available in the Staff Regulations or already in place at the Agency, as well as additional provisions put in place for a transitional period. Several new recruitment procedures have been launched in 2018 to replace possible loss of staff.
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; – potential loss of specific expertise. A dedicated ORP subgroup has been set up to evaluate the impact of Brexit on the Agency's core activities and propose remedial actions. The group has been focussing on the following remedial actions: • Redistribution of UK product portfolio. • Distribution of workload for initial marketing-authorisation applications, including reassignment of procedures not yet started but currently assigned to the UK. • Distribution of workload for scientific-advice procedures.

Risk	Mitigating actions and controls
	• Distribution of workload for PRAC procedures, for which the contribution of the CMDh is required concerning nationally authorised medicinal products. • Distribution of workload for initial marketing-authorisation applications and maximum residue limits (MRLs), including reassignment of procedures not yet started but currently assigned to the UK (veterinary medicines). • Distribution of workload for pharmacovigilance procedures for centrally authorised products (veterinary medicines). • Operational adjustments.
Inability to relocate the Agency HQ to the NL by the 29 March 2019	A joint governance structure between EMA and government authorities in the Netherlands has been set up to enable close collaboration between our Agency and the Dutch authorities at national and local levels, and to monitor progress of the relocation.

Annex 9: Procurement plan

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

Activity statement:	Real world evidence data analytics system
Objective:	See Work Programme, heading 1.5
Budget:	€1,000,000
Financial year:	2019-2023
Description of action:	Off-the-shelf platform providing access to and analysis of patient data from different data sources (such as electronic health records and claims data) to perform very rapid evaluation of utilisation patterns, benefits and risks of medicines and impact of regulatory actions.
Type of contract:	Service contract
Number of contracts:	1
Indicative timeframe for contract:	Expected to be signed in 2019
Indicative timeframe for procurement:	Expected to be launched in 2019
Indicative budget for procurement:	€1,000,000
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

Activity statement:	Validation of data sources
Objective:	See Work Programme, heading 1.5
Budget:	€1,000,000
Financial year:	2019-2023
Description of action:	Based on the initial EMA inventory of data sources for longitudinal patient-based studies, the action will consist in the validation of data quality, relevance and completeness of data sources. In the long term it is expected that this activity will contribute to increased interoperability of data sources through guidance, standards and agreement on minimum data sets across borders and disease areas.
Type of contract:	Service contract
Number of contracts:	1
Indicative timeframe for contract:	Expected to be signed in 2019
Indicative timeframe for procurement:	Expected to be launched in 2019
Indicative budget for procurement:	€1,000,000
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

Activity statement:	Effectiveness and pharmacoepidemiology studies
Objective:	See Work Programme, heading 1.5
Budget:	€700,000
Financial year:	2019
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 10
Indicative timeframe for contract:	Expected to be signed in 2019 (approximately 12-18 months each)
Indicative timeframe for procurement:	Expected to be launched in 2019
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

Activity statement:	External service providers for Development, Implementation and Maintenance of Software and Information Systems - ESP-DIMSIS II
Objective:	See Work Programme, heading 3.5
Budget:	€80M of which €38.5M operational and €41.5M administrative

Financial year:	2020-2024
Description of action:	This framework contract will relate to the provision of external service providers for development, implementation and maintenance of software and information systems.
Type of contract:	Framework contract to be implemented by Specific Contracts
Number of contracts:	3 framework contracts are expected to be concluded
Indicative timeframe for contract:	Expected to be signed in 2020
Indicative timeframe for procurement:	Expected to be launched in 2019
Indicative budget for procurement:	€80M of which €38.5M operational and €41.5M administrative
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	3105/2114

Activity statement:	Data management services
Objective:	See Work Programme, heading 3.6
Budget:	€3,000,000
Financial year:	2019-2023
Description of action:	Outsourcing data management and data quality business processes for SPOR data management services, to support EU regulatory processes and facilitate the reliable exchange of medicinal product information.
Type of contract:	Framework contract
Number of contracts:	1
Indicative timeframe for contract:	Expected to be signed in 2020
Indicative timeframe for procurement:	Expected to be launched in 2019
Indicative budget for procurement:	€3,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010; Regulation (EC) 520/2012, Articles 25 and 26.
Budget line:	3030

Annex 10: Projects

In order to support the Agency's work and achievement of set objectives, a number of programmes and projects will be undertaken. The table below details the main projects, their timelines and deliverables that the Agency will pursue in 2019-2020. The deliverables for 2020 provide a high-level overview and will be detailed during the preparation of the final work programme 2020.

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

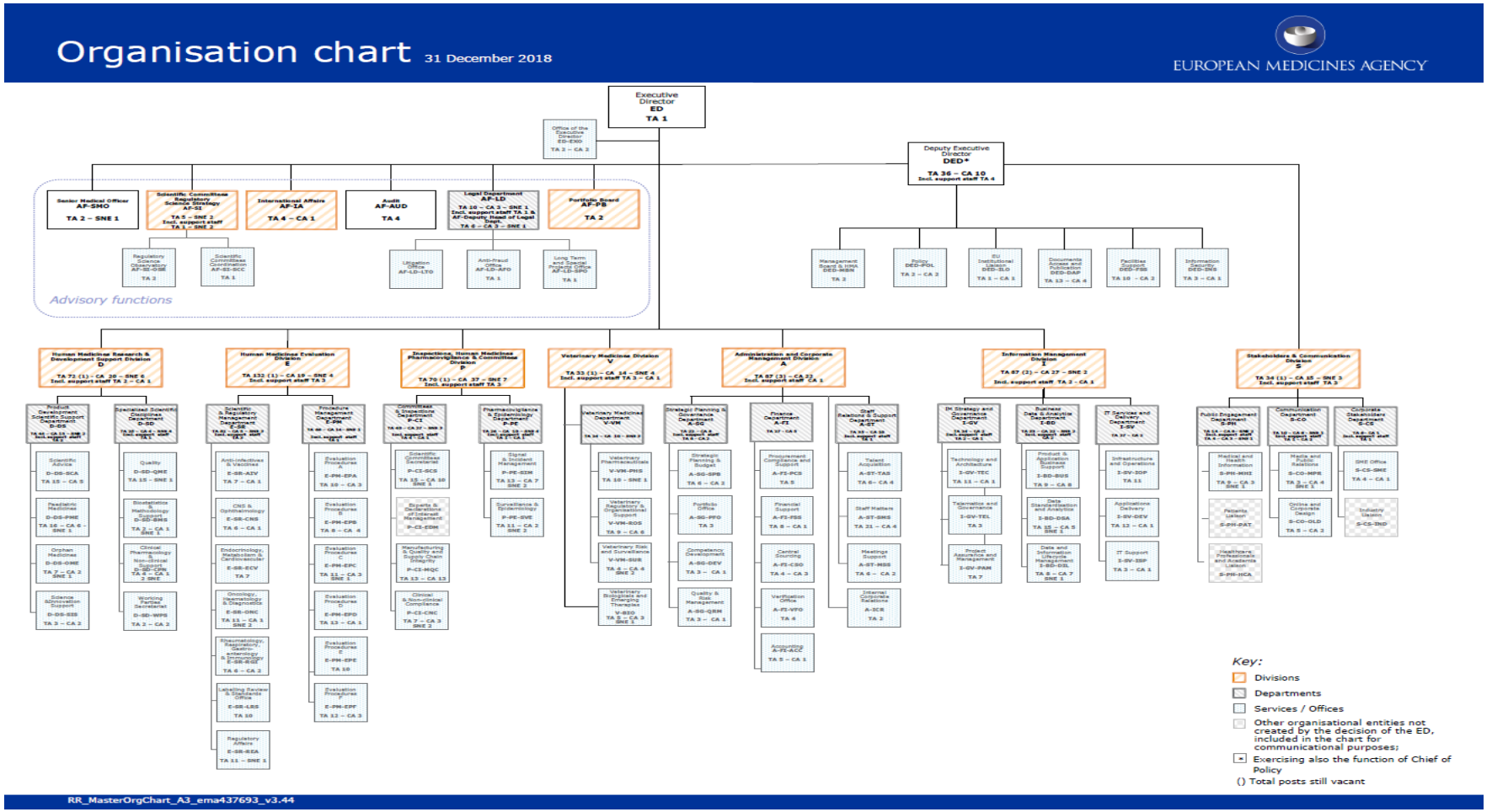
Programme / Project	Legal basis	Start date	End date	Deliverables 2019	Budget 2019
Clinical Trials Programme					€736,364
EU portal and clinical trials database (renamed as "CTIS – Clinical Trials Information System" after merger with SUSAR) [continues]	• Regulation (EC) 536/2014, art.80-82	Q3 2014	2020	• An evolved version of the EU portal and database release for audit • Conduct of independent audit of EU portal and database • Training materials and commence delivery of training to stakeholders • User guidance documentation • Implement a communication plan	€7,629,412
EudraCT & EU Portal (EudraCT legacy) [continues]	• Regulation (EC) 536/2014, art.80-82, 98	2018	2020	• Preliminary business case towards the integration of legacy clinical trials data with the EU Portal and Database system • System and process analysis and design • Final business case • Start of implementation	€1,445,345
e-Submission Programme					
eCTD4 pre-project	n/a	2020	2021	Suspended until 2020	

Programme / Project	Legal basis	Start date	End date	Deliverables 2019	Budget 2019
activities [suspended]					
Single Submission Portal [suspended]	n/a	2020	2021	Suspended until 2020	
Veterinary Change Programme					€174,107
EudraVigilance veterinary v3.0 [continues, subject to budget availability]	• Regulation (EC) 726/2004, art.57(d)	2017	2019	• Initiation of system implementation as a first step towards a Union veterinary pharmacovigilance system • Initiation of testing of 1st release	€1,477,909
New Veterinary Legislation [continues, subject to budget availability]	• New veterinary legislation under drafting	Q1 2019	2021	• Project initiation and analysis of requirements (for one IT component to be identified) • Preliminary business case • Delivery of revised internal governance within the V division of EMA	To be defined
Online Programme					
European Medicines web portal [suspended]	• Regulation (EC) 726/2004 • Regulation (EC) 1235/2010, art.26	2020	2021	Suspended until 2020	
EMA Intranet	n/a	2020	2021	Suspended until 2020	
EMA Extranet	n/a	2020	2021	Suspended until 2020	
Data integration programme					€635,955
Substances and products management services (including veterinary Union database) [temporarily reduced]	• Regulation 726/2004, art.57(2) • Regulation (EC) 520/2012, art.25 and 26	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 • IDD access for substances	€2,956,276

Programme / Project	Legal basis	Start date	End date	Deliverables 2019	Budget 2019
	• Draft veterinary regulation, art.51 • 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				
Administration Digitalisation	n/a	2019	2021	• Provide better tools to overcome manual processing and repetitive tasks • Process and system analysis and design • Start of implementation	€2,000,000
S-REPS Phase 3 SIAMED with Knowledge Management	n/a	2019	2020	• Provide a more integrated business process and Information based on the new IRIS Portal • Better capture and manage the scientific knowledge • Process and system analysis and design • Start of implementation	€2,750,000
Data centre relocation [continues]	n/a	2017	2019	• Execution of move of data centres • Sign-off handover of data centres to normal	€333,038

Programme / Project	Legal basis	Start date	End date	Deliverables 2019	Budget 2019
				run phase	
EMA Move to permanent building	n/a	2019	2019	• Integration of the security IT systems with the new physical security systems of the building	€1,000,000
AM & D Sourcing Project	n/a	2019	2019	• Replacement of IT Framework Contract, which arrives at their end and needs to be replaced	€500,000
Information Classification	n/a	2019	2019	• New policy for information classification	€500,000
GDPR	Regulation (EU) 2016/679	2019	2019	• Check and update of stored data in line with GDPR (General Data Protection Regulation)	€500,000
Upgrade of the Data Analytics infrastructure	n/a	2019	2021	• Design and implement a Data Analytics infrastructure capable of overcoming the critical limitations faced by the current infrastructure	€500,000

Annex 11: Organisational chart



EUROPEAN MEDICINES AGENCY
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Annex 12: Terms and abbreviations

Term / abbreviation	Definition
3Rs	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
AD	administrator category post
ADR	adverse drug reaction
ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe project
ADVENT	ad hoc expert group on veterinary novel therapies
AE	adverse event
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios (Spain)
AER	adverse event report
Agency	European Medicines Agency
AIFA	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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Term / abbreviation	Definition
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
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

Term / abbreviation	Definition
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
ICSR	individual case-safety report
ICT	information and communication technologies
IDD	Informatica Data Director
IDMP	identification of medicinal products
IGDRP	International Generic Drug Regulators Programme
IMI	Innovative Medicines Initiative
INC	International Neonatal Consortium
IPA	Instrument for Pre-accession Assistance
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
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

Term / abbreviation	Definition
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
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
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
S-REPS	scientific and regulatory evaluation procedure support
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

Term / abbreviation	Definition
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