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Executive Director

Work programme 2017

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[1] Project added to 2017 work programme, chapter 4: Support and governance activities

Mission

The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

Legal role

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

The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

Principal activities

Working with the Member States and the European Commission as partners in a European Medicines Regulatory Network, the European Medicines Agency:

- provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;

- applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;

- implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;

- provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;

- recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;

- involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;

- publishes impartial and comprehensible information about medicines and their use;

- develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level.

Guiding principles

- We are strongly committed to public and animal health.

- We make independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in our field.

- We support research and innovation to stimulate the development of better medicines.

- We value the contribution of our partners and stakeholders to our work.

- We assure continual improvement of our processes and procedures, in accordance with recognised quality standards.

- We adhere to high standards of professional and personal integrity.

- We communicate in an open, transparent manner with all of our partners, stakeholders and colleagues.

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

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Part I: General context

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

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

EMA priority areas and key influences

The Agency operates in a constantly changing and evolving environment. Factors such as developments in the pharmaceutical industry, globalisation, growing complexity of medicines development, stakeholder requirements for transparency and key legislation changes all impact the Agency's work.

The activities and initiatives planned in this work programme should be considered in the context of the current political environment resulting from the outcome of the UK referendum of 23 June 2016.

No Member State has ever left the EU so there is no precedent for this situation. As a result, EMA is exposed to a level of uncertainty around the seat and operations of the Agency. Currently, the UK Government intends to trigger Article 50 of the Treaty on the Functioning of the EU by the end of March 2017. This would mark the start of a minimum of two years of formal negotiations. In this context, Member States are also likely to decide whether the Agency will relocate. Therefore, EMA must prepare for a possible relocation and a potentially significant loss of staff and expertise.

The Agency will continue to carry out its mission to protect public health. However, the evolving situation may require a shift in priorities and focus. As the scale of impact on EMA becomes known, the Agency may need to review its work programme to postpone less urgent activities to guarantee the continued delivery of its core operations.

In this climate, EMA is undertaking general preparedness planning to assess the steps needed to ensure continuity of its business operations. As part of these efforts, the Agency is looking at possible measures in the event of relocation to compensate for the potential loss of UK experts in the assessment of medicines, to attract and retain highly qualified staff, and to ensure that scientific recommendations and supervision of medicines can continue to be delivered on time and to the same high level of quality the Agency's stakeholders have come to expect.

Fulfilling legislative obligations in the context of evolving workload and increasingly complex environment

The Agency is a demand-driven organisation. Developments in the pharmaceutical industry and the number of medicinal products on the market strongly influence the volumes of pre-authorisation

activities, initial marketing applications and related activities in the post-authorisation stage. The Agency sees stable, increasing trends in these activities.

Scientific-advice requests and follow-up activities show positive trends over the last years. In March 2016, the Agency launched its priority medicines scheme (PRIME) and started providing early and enhanced scientific and regulatory support to developers of promising new medicines that target unmet medical need. A continuously growing portfolio of authorised products on the market translates into additional workload in post-authorisation, pharmacovigilance and supervision activities.

As a result of finalisation of implementation of the pharmacovigilance legislation in 2017, the coordinating role of the Agency in the monitoring of all EU medicines is increasing. Among the recent new tasks are the introduction of single assessment for nationally authorised products (PSUSAs) in 2015, the ongoing implementation of public hearings in 2016-2017, and management of signals submitted by the pharmaceutical industry from Q3 2017. The Agency expects that the volume of PSUSAs will continue to increase over the next few years.

The Clinical Trials Regulation (EU) 536/2014 was published in May 2014, and requires the Agency, in collaboration with the European Commission (EC) and Member States, to develop the systems necessary for its implementation. In 2017, an audit of the EU Portal and Database will take place and, on the basis of the audit report, the EMA Management Board will confirm whether the EU Portal and Database have achieved full functionality. According to the adopted delivery timeframe, the Regulation will then become applicable by October 2018, following which the Agency will be tasked with maintaining these systems and providing support to stakeholders.

The discussions leading to the revision of the EU veterinary medicines legislation are expected to continue in the coming years, with the legislation expected to be adopted by 2018. Until then, the Agency will focus on ensuring that the existing legal framework is used as effectively as possible and will carry out the necessary preparations for the entry into effect of the revised legislation.

Efficiency is the key to sustainable delivery of regulatory activities and to coping with increasing responsibilities, volumes and complexity of science, procedures and activities. This is particularly important with continued economic pressures on the Member States, and regulatory authorities being required to cut costs while delivering their responsibilities. EMA, like other EU agencies, is required to reduce the number of posts by 10% during 2014-2020[2]. At the same time, legislative changes in scientific (e.g. pharmacovigilance, clinical trials, veterinary) and corporate areas (evolving financial and staff regulations, procurement procedures, responsibilities in areas of handling of competing interests, auditing and fraud-prevention), growing complexity of science and interactions, and increasing product portfolio are all expanding the responsibilities of medicines regulators in Europe.

The Agency continuously seeks to improve internal processes and is implementing its process-performance management system to further increase efficiencies and optimise operations. As part of supporting the work of the NCAs, the Agency is delivering telematics systems, both to implement legal requirements and help achieve operational excellence. An EU Network Training Centre was established in 2016, to facilitate regulatory capacity-building across Europe.

Support to innovation and addressing scientific advancement

Advancements in science and technology are redefining the scientific basis of disease, expanding the possibilities for medicines development and use, and increasing demands on regulatory advice and

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[2] Communication from the Commission to the European Parliament and the Council. Programming of human and financial resources for decentralised agencies 2014-2020;
http://ec.europa.eu/budget/library/biblio/documents/fin_fwk1420/COM_2013_519_en.pdf

assessment. Emerging new technologies, personalised medicines, new advanced therapies, combination and borderline products all contribute to the increasing complexity of medicines.

The availability of sustainable, high-quality scientific and regulatory expertise will be a critical success factor in addressing the progress in regulatory science. Therefore, strengthening capacity and capability development across the network through the aforementioned Network Training Centre, supporting the work of the innovation network, and enriching expertise through outreach to academia will remain an important part of the Agency's agenda.

At the same time, the face of the pharmaceutical industry is evolving, with a high number of small or medium-sized enterprises (SMEs) as well as academia undertaking the early stages of medicines development. Recent initiatives have reinforced the regulatory support on offer to medicines developers. There is a constant need for continuous improvement of our processes and approaches to ensure that prospective medicines reach their patients in such an environment.

Timely access to promising medicines

The ever-increasing expectations of patients, animal owners and healthcare professionals to have promising medicines available at the earliest appropriate opportunity, in combination with the continuous need for flexible and fast reaction to arising public-health threats (many zoonotic), requires exploring flexible licencing pathways and a lifespan approach to medicines. The Agency launched its PRIME scheme in 2016, providing early and reinforced regulatory and scientific advice to priority medicines, and is committed to working in collaboration with the European Commission and the STAMP expert group on the development and implementation of tools to further improve timely access to medicines for patients.

Maintaining the quality of scientific assessment and ensuring the safety of medicines remains paramount, and introducing a more comprehensive approach to planning and generation of post-authorisation data is an important component in these efforts.

Collaboration with HTA bodies and payer organisations as downstream decision-makers will further increase, and contribute towards treatment options becoming available to patients. This concerns all phases of the life-cycle, from horizon scanning, through planning for data generation, at the market entry phase and during post-authorisation evidence generation. Continuation of scientific and technical cooperation with EUnetHTA Joint Action 3, which runs from 2016 to 2020, particularly through the deliverables of the relevant work packages, is envisaged.

The availability of veterinary medicines in general, and in particular vaccines against emerging infectious animal disease with relevance for human health or which are of major economic significance in terms of animal production, is of concern. To facilitate the availability of veterinary medicines, the Agency will pursue a number of initiatives detailed in this programming document that fall within its own mandate and will, at the same time, work closely with the Network to deliver shared initiatives with this objective, such as the HMA/EMA Task Force on Availability and the Action Plan on Availability of Veterinary Vaccines.

Enhancing international cooperation

The globalisation of pharmaceutical activities results in an increasing number of manufacturing and clinical-trial activities being conducted outside the EU. This, coupled with the complexity of international supply chains, presents challenges to ensure adherence to the required clinical-trial and manufacturing standards, to ensure data integrity, and to manage the risks of supply chain and counterfeit operations.

To ensure that medicines tested and manufactured outside the EU meet the EU requirements, the Agency and NCAs will continue and strengthen their collaboration with international partners in relation to work-sharing and collaborative inspections, information exchanges and greater mutual reliance, as well as harmonisation of standards and building regulatory capacity, especially in countries where manufacturing and clinical trials take place. With regard to standards in veterinary medicines, a particular focus will be on fostering the VICH Outreach programme, which aims to extend uptake of VICH guidelines to countries with less developed regulatory systems.

In the global arena, regulators worldwide are also increasingly recognising the potential and need to create synergies, avoid duplications and use global regulatory resources more effectively. Here, the Agency continues its collaboration with non-EU competent authorities and regulators to increase work-sharing in various domains, and reliance on each other's inspection and assessment activities, develop exchanges of information on products throughout their lifecycle, cooperate on activities in particular areas of interest, and build capacity and capability of regulators in candidate and potential candidate countries,as well as countries with less developed systems (including through the Network Training Centre). Work to optimise use of Article 58 of Regulation EC (No) 726/2004 remains an important item on the Agency's agenda.

Addressing public-health priorities

Antimicrobial resistance (AMR) is a global health crisis, as recognised by the development of a Global Action Plan for AMR by the World Health Organization (WHO). The Food and Agriculture Organisation of the United Nations and the World Organisation for Animal Health (OIE) have also created similar, related plans in terms of their strategy on AMR and prudent use of antimicrobials. Efforts to combat AMR will remain high on the Agency's agenda and will include providing the necessary support to the European Commission Action Plan on AMR, to the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) as well as to the WHO, OIE and other international initiatives. The Agency will continue to cooperate closely with other EU institutions, particularly ECDC and EFSA, adopting the 'One Health' approach. The approach will encompass developing or updating relevant guidelines (including paediatric aspects), and balancing the need to assure the continued availability of antimicrobials in veterinary medicines with the need to minimise the risk to man from their use in animals whilst contributing to effort to develop alternative approaches to the use of such medicines in managing infectious disease in animals.

Alongside known problems such as antimicrobial resistance, new diseases and issues emerge that need addressing. Societal trends, including an aging population, polypharmacy and comorbidity, and new and redefined diseases such as dementia, will become more of a public-health burden. The Agency will implement its geriatric strategy and engage in a number of activities related to dementia and Alzheimer's disease. The Agency will also continue its work to facilitate the development of medicines for rare diseases and identify areas in need of further research.

To address shortages and ensure availability of authorised medicines, the Agency will continue promoting proactive risk-management by manufacturers and marketing-authorisation holders, and instil controls to ensure product quality and supply continuity. Since the availability of medicines goes beyond supply issues, the Agency will also support additional measures that can address the wider aspects of availability using existing fora with NCAs.

The Agency will also be improving its public-health crisis-response mechanisms, building on the past experience of pandemic influenza and the work on Ebola and Zika.

Veterinary medicines

Ensuring the adequate availability of a wide range of high-quality, safe and effective veterinary medicines remains the highest priority for regulators within the European Union. The European Commission has proposed ambitious changes to the legal framework for veterinary medicines, designed to ensure that legislation is adapted over the next few years to the particular needs of the veterinary domain, where this is needed. Novel therapies that were previously seen only in the human domain are starting to make their way into veterinary medicine, and the Agency will need to harness the expertise of the network to develop or adapt regulatory requirements to make the European market attractive for this type of product. Identifying if there is a need to develop specific regulatory approaches to facilitate the authorisation of novel products that represent alternative to the use of antimicrobials will be an area of particular focus. Work will continue on facilitating access to the market for products for minor use in major species or for use in minor species (MUMS), providing fee reductions for those products considered of most benefit to animal or public health. Particular attention will be given to tackling the challenges that exist in bringing new vaccines to market and in ensuring that authorised vaccines are available to deal rapidly with incursions of exotic disease, the risk of which has increased substantially in recent years.

Finally, the Agency will also improve on the procedures for management of incidents relating to veterinary medicines within the EU that have the potential to create crisis situations in terms of animal or public health or lack of availability. This objective will be achieved through close cooperation with the Network through the European Surveillance Strategy Group, taking into account recent experience and considering in particular how to improve communication around crises within the Network and with stakeholders. The experience gained in managing shortages in supply of essential human medicines will be reviewed to adapt existing systems or to develop new approaches specifically designed to minimise the impact of problems in the supply chain of essential veterinary medicines.

Stakeholder involvement and transparency

With a multitude of stakeholders involved from the early stages of development through to patients accessing and using medicines, the Agency continuously works to interact with and involve stakeholders in the regulatory processes in the best ways possible. Patients, consumers, animal owners and healthcare professionals demand high levels of transparency, and more and better information to support their decision-making. Society wants to see the outcomes of clinical trials, pharmacovigilance and other stages of the medicines lifecycle. All aspects of the work of the Agency, from the initial evaluation through to post-authorisation monitoring, are becoming subject to more intense scrutiny by stakeholders and the community as a whole.

Following the implementation of relevant legislative provisions, patients and healthcare professionals are represented in the corporate governance of the Agency, Management Board and certain scientific committees. In addition, the Agency closely cooperates with its various stakeholders, including healthcare professionals' organisations, patients and consumers' organisations, scientific and academic societies, and the pharmaceutical industry.

To ensure that stakeholders' relations are guided by key principles of transparency, independence and appropriate interaction, formal frameworks for interacting with patients, healthcare professionals, the pharmaceutical industry and academia have been developed and are currently being implemented. These frameworks collectively offer a platform for exchange and multi-stakeholder dialogue at the European level.

Capturing patient values and preferences in the benefit-risk assessment of medicines, and understanding better the clinical use of medicines once on the market, will contribute to the quality of the scientific opinions we adopt. The implementation of public hearings will allow the Agency to reach

out to civil society, allowing citizens to voice their views, while further transparency initiatives will promote a better understanding of the decision-making process.

Part II: Multiannual programming 2017–2019

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 fact that about 75 percent[3] of new diseases that have affected humans over the past decade have been caused by pathogens originating from animals or products of animal origin and the continued emergence of new pathogens reinforce the need for a 'One Health' approach between those regulating human and veterinary medicines.

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

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

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

Theme 4: Contributing to the global regulatory environment	
	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

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

Theme 1: Contributing to human health

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

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	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	Critical/ urgent	- 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	2018	High	- 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 AMR, the WHO Global action Plan, OIE strategy and other action plans such as the "G8"	2016	2018	High	- actual contribution to WHO - completion level and/or rate of implementation of actions in the action plan(s)

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

	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	2017	High	- implementation of the actions in the GAAD - increased number of new medicines for dementia
Public health needs and priorities		1.1-5	Implement the geriatrics strategy	2011	2019	Medium	- level of strategy implementation - proportion of actions implemented - deliverables completed (guidelines, pilot outcomes, GVP module)
		1.1-6	Support innovation, early dialogue and research for paediatric medicines	2007	2019	Medium	- increased support to early interaction with developers of paediatric medicines (number of early interactions, expanded common commentaries with the FDA, other pre-submission interactions) - number of scientific workshops / expert meetings to support innovation in paediatric medicines
		1.1-7	Scientific and regulatory contribution enhancing drug safety in pregnancy	2015	2017	High	- delivery of the GVP module on ″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	2018	High	- publication/availability of additional guidance on the evaluation of significant benefit
		1.1-9	Foster research and data generation in the areas of public health needs	2015	2020	Medium	- relevant and adequate programmes initiated

Public-health emergencies	Enhance ability to respond quickly to public-health emergencies	1.1-10	Facilitate early introduction of appropriate treatments or preventive measures	2015	2019	High	- time between starting point (e.g. application/request for advice) and EMA response (e.g. approval of medicine/SA letter)
		1.1-11	Improve Health Threats plan and update post-health-threat activity completion (e.g. Ebola, Zika etc.)	2015	2016	Medium	- action plan developed and process for rapid answers set up - number of 'lessons' implemented from the 'lessons learned' - rate of completion of post-health-threat activities
Supply issues and availability of new and well-established medicines	Minimise risk and impact of shortages due to manufacturing problems and quality defects	1.1-12	Implement revised action plan regarding medicinal product supply shortages caused by manufacturing/good manufacturing practice compliance problems, including - harmonised definition (criteria) of shortages - develop metrics for shortages - best practices on communication of shortages - review impact of implementation of tools developed by industry	2017	2019	High	- implementation of the action plan: level of completion of initiatives and proportion of initiatives implemented
		1.1-13	Develop formal collaboration with WHO in the area of supply disruptions	2017	2019	Medium	- formal agreement with WHO - number of cases worked in collaboration
		1.1-14	Support to the European Observatory on the supply of medical radioisotopes	2017	2019	High	- timely input provided to facilitate implementation by the regulatory network of the transition from the use of

						highly enriched uranium to low enriched uranium in the production of radiopharmaceuticals
		1.1-15	Consolidate information on compliance issues and quality defects	2017	2019	Medium	- system of warning letters in case of GMP non-compliance issues implemented - improvements implemented in the coordination/handling of quality defects across the network
	Address the threat posed by illegal medicines supply chains	1.1-16	Continue to support the implementation of the Falsified Medicines Directive	2011	2019	High	- number of cases supported/coordinated by EMA in relation to falsified medicines in the supply chain
		1.1-17	Streamline process for reporting of suspected falsified medicines in the supply chain by MAHs	2011	2019	High	- implementation of the revised form for reporting quality defects and suspected falsified medicines
		1.1-18	Strengthen communication within the network, including with WGEO	2014	2019	High	- timely sharing of relevant information related to illegal supply chain as it is notified to EMA
		1.1-19	Review collaboration with EDQM in the framework of the sampling and testing programme to include increased number of APIs and parallel distribution medicinal products	2016	2018	High	- criteria for inclusion of APIs and parallel distribution medicinal products in the sampling and testing programme agreed and reflected in new contract with EDQM
	Facilitate/support availability of already approved medicines	1.1-20	Support and contribute to Member States' efforts in addressing issues that limit access to already authorised medicines	2016	2020	Medium	*To be confirmed, based on the reflection paper (to be finalised in 2016)*

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

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
Early access to medicines	Reduce time–to-patient of novel medicines through optimised use of existing and new assessment approaches within existing regulatory frameworks	1.2-1	Integrate 'adaptive pathways' concept into formal EMA scientific advice procedures	2014	2018	Medium	- number of development proposals following the adaptive pathways concept in scientific advice
		1.2-2	Provide reinforced regulatory and scientific advice for priority medicines (PRIME)	2014	2017	Critical/ urgent	- number/increase in PRIME products that received scientific advice - time from request to final response – compared with other products and with previous period
		1.2-3	Develop/enhance collaboration with EUnetHTA, HTAN as well as HTA/pricing and reimbursement bodies in the area of parallel regulatory-HTA scientific advice, including contribution to specific deliverables in EUnetHTA Joint Action 3	2010	2019	High	- 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
	Support effective and efficient conduct of pharmacovigilance	1.2-4	Implement planned access and analysis of real-world data	2016	2020	High	- availability and use of tools and processes for analysing real-world data
		1.2-5	Conduct planned surveillance using patient registries, also in collaboration with EUnetHTA Joint Action 3	2016	2019	High	- patient registries actually used for novel medicines

	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	High	- 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
Benefit-risk assessment							

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	Priority	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	2018*	Critical/ urgent	- availability of functional IT tools/systems
		1.3-2	Update guidelines and inspection-related procedures in accordance with the new legal requirements	2014	2018*	High	- level of completion or availability of updated guidelines/processes

* According to the timeframe adopted by the EMA Management Board, audit of the IT systems will take place in 2017, leading to the regulation becoming applicable by October 2018.

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
Innovation	Facilitate translating innovation into medicinal products	1.3-3	Streamline interaction with academia	2016	2019	Medium	- 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	2015	2019	Medium	- 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

			and downstream decision makers				facilitated following regulatory assessment, as part of Joint Action 3 / work package 4
		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	High	- number of research areas/opportunities identified
		1.3-6	Explore opportunities to reduce regulatory and administrative burden	2016	2020	Medium	- number of opportunities identified and implemented
	Provide adequate regulatory support to innovation stemming from SMEs and academia	1.3-7	Review existing support measures and explore additional supportive measures to incentivise innovation by SMEs	2016	2020	High	- increasing use of the available support measures/incentives
		1.3-8	Involve academia in early dialogue procedures (ITF, Innovation network, SA, Paediatric procedures, PRIME, orphan designation)	2016	2017	High	- increase in the number of early dialogue procedures involving academia

Objective 4: Strengthen regulatory capability and transparency

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	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	2018	High	- 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	High	- number of NCAs/MAHs trained on new functionalities

Transparency	Increase access to data for delivery of regulatory activities	1.4-3	Take forward discussion on making available individual patient data from clinical trials	2016	2018	Medium	- draft reflection paper prepared and endorsed by the Management Board
		1.4-4	Explore the potential use of real-world databases, electronic healthcare records and 'big data'	2016	2020	High	- number of new data sources used in regulatory activities/decision-making
	Increase transparency of the work of the network	1.4-5	Implement clinical data policy and provisions of the Clinical Trials Regulation regarding the transparency and availability of clinical trial data	2014	2019	Critical/ urgent	- availability of clinical trial data/information
		1.4-6	Improve provision of information to patients and prescribers	2011	2017	High	- better information to patients
		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	2019	Medium	- level of acceptance/implementation of new benefit-risk template in 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	Priority	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	2017	High	- increased number/proportion of MUMS marketing-authorisation applications and MUMS products on the market - publication of the revised MUMS/limited markets guidelines
	Support development and availability of veterinary medicines	2.1-2	Identify and implement EMA contribution to the EU Network Strategy to 2020 in the area of promoting availability of vaccines within the EU	2016	2020	High	- increased number of pre-submission requests and submissions of MAAs for vaccines in general and those against transboundary diseases in particular - completion of actions assigned to EMA/CVMP in the Joint EMA/HMA Action Plan on Availability of Veterinary vaccines
		2.1-10	Participate in the HMA/EMA Task Force on Availability of authorised medicines for human and veterinary use	2016	2020	High	- completion of actions assigned to EMA 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	2017	Medium	- 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	Provide CVMP feedback on gap analysis from the FishMed Plus coalition on availability of fish medicines	2016	2020	Medium	- regulatory activities initiated to address identified gaps in the availability of fish medicines
		2.1-11	Explore with relevant stakeholders	2016	2020	Medium	- reflection paper on antiparasitic

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
			approaches to best use of existing and new antiparasitic veterinary medicine so as to minimise development of anthelmintic resistance				resistance developed and published
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	2019	High	- 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	2019	High	- increased number of applications for innovative medicines - guidance on 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	2016	High	- first draft of guideline on genotoxic 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	2017	High	- 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	2016	2017	High	- recommendations and implementing acts sent to the EC

			implementing acts specified in Regulation 470/2009				

Objective 2: Promote 'Better Regulation'

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	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 co-decision process for the new veterinary legislation	2014	2019	High	- advice provided to the European Commission on request in a timely and accurate manner
		2.2-2	Put in place the revised processes and IT systems envisaged in the revised legislation	2015	2019	Critical/ urgent	- IT systems and processes implemented - practical approaches to harmonisation of the SmPCs of veterinary medicinal products developed with the Network

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
Veterinary pharmacovigilance	Support efficient and effective conduct of pharmacovigilance	2.2-3	Publish information to the general public on the surveillance of centrally authorised veterinary products on the market	2016	2020	High	- annual pharmacovigilance bulletin published
		2.2-4	Strengthen signal-detection for veterinary medicines by developing an approach for ensuring quality control and verification of product data in the EU database of veterinary medicines, and linking these data to adverse event information in the EudraVigilance veterinary data warehouse	2016	2019	High	- data on nationally authorised products supplied for use in EudraVigilance - data quality controlled and linked to adverse event information in the data warehouse - approach defined to develop and deliver a replacement database for EVVet 2 - VICH-compliant database fully operational
		2.2-5	Revise the reflection paper on promoting pharmacovigilance reporting	2016	2017	Low	- increase in reporting of adverse reactions in food-producing species,

							following the publication of the revised reflection paper
			to address adverse events in food-producing species				following the publication of the revised reflection paper
		2.2-6	Ensure effective procedures are in place to manage incidents and crises relating to Veterinary Medicinal products	2016	2018	High	- existing Incident Management Plan tested and updated in light of testing and experience - continuous monitoring and update in light of experience

Quality of scientific output	Provide high-quality and consistent scientific outputs of the EMA	2.2-7	Finalise the development and promote the uptake of the revised guideline, procedures and templates for CVMP assessment reports	2016	2018	Medium	- templates for assessors finalised - high-quality assessment reports received
	Ensure efficient operation of procedures within the Veterinary Medicines Division	2.2-8	Review operational procedures within the Veterinary Medicines Division	2016	2017	High	- improved performance metrics introduced, demonstrating an improvement in performance

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, development of advice that can support the work in Council and Parliament in relation to revision of the veterinary legislation)

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

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
Antimicrobial resistance	Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	2.4-1	Engage with the EC and Member States to identify and, where possible, prioritise the referral of antimicrobials and other classes of products for which the conditions of use need to be both harmonised and aligned with the principles of prudent and responsible use, including in relation to environmental issues	2010	2019	Critical/ urgent	- agreed list of priority and antimicrobial substances for referral to CVMP
		2.4-2	Refine and continue data collection on the consumption of antimicrobials in veterinary medicine	2010	Continuous	High	- 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	2017	High	- methodology approved by the steering group
		2.4-4	Provide advice to stakeholders on prudent and responsible use of veterinary antimicrobials	2015	2018	High	- draft reflection paper on aminoglycosides published for consultation (in 2016) - draft reflection paper on extended-spectrum penicillins published for consultation (in 2017)
		2.4-5	Provide scientific advice to the EC on optimising the use of antimicrobials in veterinary medicine	2015	2016	High	- EMA-EFSA opinion on how to reduce the need for antimicrobials in food-producing species published on EFSA and EMA website - plan for follow up actions to the

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
-							recommendations in the above EMA-EFSA opinion drafted - second report with EFSA and ECDC on consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals prepared - opinion on indicators regarding surveillance of antimicrobial resistance and antimicrobial consumption in 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	2017	Medium	- first draft of document published for consultation/adoption
		2.4-7	Develop a guideline on risk assessment of veterinary medicinal products in groundwater	2013	2018	High	- finalised guideline adopted by CVMP
		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 water	2015	2018	High	- 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	Medium	- 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	Priority	Performance indicator(s)
Regulatory capability and capacity	Ensure 'fit-for-purpose' scientific capability of the network	3.1-1	Conduct horizon-scanning to ensure understanding of and preparedness for emerging technologies in medicines, and identify gaps in expertise	2016	Continuous	High	- inventory of needs available - mapping of expertise versus needs available
		3.1-2	Deliver curricula for competence development on the basis of the identified needs	2016	2017	Medium	- action plan available - number of curricula drafted
		3.1-3	Develop a catalogue of training material through the EU Network Training Centre	2016	2019	Medium	- training material catalogue developed - number of training courses - 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	Medium	- 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	Medium	- 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	Medium	- increase in the number of MNAT procedures - implementation level of the identified improvements
		3.1-7	Enhance outreach for academic	2017	2019	Medium	- implementation of the framework of

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
			expertise for services provided to EMA, in particular as regards innovation of medicines				interaction with academia
Scientific and regulatory expertise	Strike an optimal balance between ensuring impartiality/independence of experts and securing the best possible scientific expertise	3.1-8	Undertake annual review of the EMA independence policies to identify room for improvement to strike such balance	2016	2020	Medium	- 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	Priority	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	High	- processes maintained /updated using an agreed methodology - key interfaces with network and industry enhanced (as demonstrated using surveys, workshops, etc.) - increased efficiency of the processes
		3.2-2	Undertake a continuous review and improvement of the EMA support to scientific committees/working parties/expert groups	2016	2020	High	- increased productivity of the committees - optimised product support and guideline generation activities, following revision of the working party utilisation
		3.2-3	Undertake a revision of the operation of the EU pharmacovigilance system	2017	2020	High	- process improvements/efficiency gains implemented in the areas of ADR

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
			for human medicines				reporting, signal management and incident management
		3.2-4	Improve the efficiency of EMA corporate support activities	2016	2017	Medium	- integrated planning and reporting system introduced
		3.2-5	Ensure EMA has the right capabilities to deliver its mission	2016	2020	High	- 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	Medium	- 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	Medium	- 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	Medium	- 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	2015	2017	High	- data-gathering initiative conducted as per the action plan
		3.2-10	Contribute to external evaluation of the current fee regulation	2016	2017	High	- 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	High	- IT systems/solutions delivered and in operation
		3.2-12	Establish and improve EMA information services	2016	2020	High	- information services operated with processes that are monitored and

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
							continuously improved
		3.2-13	Share information on medicines within the network and with stakeholders	2016	2020	High	- access provided to clinical data - European Medicines Web Portal operational - improved provision of data and analytical capability

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
Quality of scientific outputs	Strengthen the quality of the scientific review processes	3.2-14	Achieve common standards of scientific quality across the network	2016	2018	High	- 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	2019	High	- revised procedure and harmonised standards for guideline development and revision - number of new/revised guidelines
		3.2-16	Improve the benefit-risk methodology and expand it to post-authorisation updates	2016	2017	High	- utilisation of the effects table in pilot post-authorisation procedures

Objective 3: Ensure effective communication of and within the network

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
Building/ maintaini	Run necessary communication initiatives to support achieving strategic goals	3.3-1	Develop and implement a five-year EMA communication strategy	2016	2020	High	- framework strategy for external communication approved and implemented, supported by annual communication plans

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
		3.3-2	Implement an Agency-wide structure for public hearings	2016	2020	High	- public hearings for safety-related referrals implemented and lessons learned incorporated
		3.3-3	Upgrade the EMA corporate website	2016	2020	High	- EMA corporate website upgraded
		3.3-4	Develop and implement a social media strategy	2016	2020	High	- implementation of the approved strategy
		3.3-5	Expand the range of digital and multimedia communication tools	2016	2020	High	- increased production of material with new communication tools
Cross-EU communication about medicines	Ensure effective and consistent communication about medicines	3.3-6	Review and improve as needed the information on medicines for stakeholders, in particular information for patients and healthcare professionals	2016	2020	High	- 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	2020	High	- biennial perception survey implemented and analysed
		3.3-8	Explore additional ways to assess the impact of EMA communications	2016	2020	High	- dedicated workshop with HCIN planned and organised
		3.3-9	Advance the development of the European Medicines Web Portal	2016	2020	High	- European Medicines Web Portal launched

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
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	High	- crisis communication strategy endorsed and implemented - report on coordination of safety announcements finalised and improvements implemented

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

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	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	High	- availability and implementation of framework - number of benefit-risk profile updates achieved - final output from ADVANCE project - final proposals to the EC
		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	Medium	- 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	Medium	- extended scope achieved and implemented - number of medicinal products/APIs included in the sampling and testing programme

Collaboration with stakeholders	Increase collaboration with civil-society representatives	3.4-4	Involve patients, HCPs and academia more, to further integrate clinical practice and real-life experience of disease and its management along a medicine's lifecycle	2016	2020	High	- 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	Medium	- 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	High	- 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	Priority	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	High	- timely sharing of relevant information related to GMP inspections, quality defects and shortages
	Improve knowledge and understanding of data integrity, and implications for regulatory decision-making	4.1-2	Develop guidance on data integrity in collaboration with PIC/s	2017	2018	High	- draft guidance published
		4.1-3	Develop joint communication and training in collaboration with the FDA	2016	2018	High	- 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	2016	2017	High	- information on planned GMP inspections systematically introduced in the existing EudraGMDP planning module by inspectorates
		4.1-5	Develop a procedure for the coordination of inspections in third countries, to make best use of network resources	2017	2019	Medium	- increased coverage of GMP inspections in third countries, using fewer network resources
		4.1-6	Implement a risk-based approach to PMF inspections	2012	2018	Medium	- implementation level of the risk-based approach to PMF inspections

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

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	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	High	- Network approach to inspections and training collaboration agreed, with particular focus on China and India - agreed procedures for cooperation
		4.2-2	Invite non-EU regulators to relevant training activities and to observe GCP and GMP inspections	Continuous	Continuous	High	- increase in number of non-EU inspectors participating in relevant training activities - increase in number of non-EU observers participating in inspections
		4.2-3	Leverage the technical, procedural and scientific advancements resulting from the EU pharmaceutical legislation to improve convergence with other regions	2017	2019	High	- 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
	Facilitate effective information-sharing by using international electronic standards	4.2-4	Implement first iteration of international electronic standards within the EU, and extend to non-EU countries	2012	2019	High	- implementation plan agreed - increase in the number of international partners using the standards
	Promote uptake of harmonised standards for veterinary medicines at international level	4.2-5	Consider international scientific approaches for the establishment of MRLs for harmonisation purposes	2016	2019	Medium	- a report on the outcome of discussions with Codex Alimentarius presented to the CVMP
		4.2-6	Participate in training events that raise awareness and enhance uptake of VICH standards by non-VICH countries	2016	2019	Medium	- EU systems and approach presented at international training events

Compliance with global standards	Contributing to European and international initiatives and collaborations regarding environmental friendliness	4.2-7	Implement a structured approach to environmental management, with objective-setting and monitoring, with a target to reduce the carbon footprint of the Agency's activities	2016	2017	Medium	- 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	2019	Medium	- mechanism to ensure participation and feedback through pharmaceutical committee and HMA agreed
Use of animals in medicines development	Minimise use of animals in medicines research and development activities	4.2-9	Contribute to the development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch-testing of veterinary vaccines and other relevant areas	2014	2020	Medium	- completed guidelines on applying 3R
		4.2-10	Improve the guidance available on regulatory acceptance of 3R principles in testing approaches	2014	2017	Medium	- availability of up-to-date guidance

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

Area	Medium-term objective	No	Initiative(s)	Start	End	Priority	Performance indicator(s)
Efficient use of global resources	Expand work-sharing and mutual-reliance initiatives	4.3-1	Support the Commission with the establishment of a Mutual Recognition Agreement with the US	2016	2018	High	- principles of 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	High	- GCP initiative with PMDA established - pharmacovigilance inspection initiative with FDA established
	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	2019	Medium	- document on good-reliance practices
		4.3-4	Improve existing mechanisms for sharing and exchanging information with other regulators on products throughout their lifecycle	2017	2019	Medium	- agreement on template for sharing confidential information
		4.3-5	Explore opportunities to leverage resources in other areas and increase reliance of other regulators on European assessments and outputs	2017	2019	Medium	- 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	Priority	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	High	- 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	2018	Medium	- increased number of participants from developing countries / non-EU regulators

Part III: Work programme 2017

Structure of the work programme

The work programme is a reflection of the European Medicines Agency's (EMA) priorities and main focus areas for 2017. It describes the objectives and activities planned for 2017. The document consists of four parts:

1. **Human medicines evaluation activities**. This chapter covers all Agency activities specifically related to the human medicines area. These are split into pre-authorisation, initial evaluation, post-authorisation, pharmacovigilance and referrals sections. Any other activities within the human medicines area are covered in the last section of this chapter.

2. **Veterinary medicines evaluation activities**. This chapter covers all activities done in regard to veterinary medicines evaluation and monitoring, and has a similar structure to the human medicines chapter.

3. **Horizontal activities**. These are business activities that span both human and veterinary areas, and enable and support the evaluation activities. These cover committee coordination, inspections, partner and stakeholder relationship management, and data management.

4. **Corporate governance and support activities**. These are non-business specific corporate support functions and activities — finance, human resources, quality management, and others — which exist in all organisations and are performed to ensure continuous operation of the Agency.

Each section is structured as follows:

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

- **Drivers**. This is a reflection of the key trends, initiatives and events that are expected to influence the Agency's focus and activities in 2017.

- **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 2017, 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 (temporary agents, contract agents and national experts) in full-time equivalents, and not the allocation and number of posts.

Information on the main **projects** planned for 2017is added at the end of the relevant sections of the work programme. The delivery of IT solutions for the Agency and the European medicines regulatory network is described as part of the projects falling under human medicines, veterinary medicines and horizontal activities.

1. Evaluation activities for human medicines

The European Medicines Agency supports and facilitates development of human medicines, evaluates these medicines through scientific committees, and advises the European Commission on their marketing authorisation, as well as monitoring the safety, quality and benefit-risk balance of authorised medicines. It also develops scientific guidelines to facilitate the development of medicines and to protect public health.

The Agency performs the scientific evaluation of applications for EU marketing authorisations for medicines that fall under the scope of the 'centralised procedure', and provides its scientific opinion to the Commission. The Agency is not involved in the assessment of nationally authorised medicines, except regarding pharmacovigilance activities under the new legislation, or to solve disagreements between two or more Member States.

1.1. Pre-authorisation activities

Activity areas

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

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

- **Designation of orphan medicines** and related maintenance procedures. To foster the availability of medicines for rare diseases, the Agency gives its opinion on the designation of medicinal products as orphan products and on maintenance of this status at the time of marketing authorisation. The designation status granted by the European Commission allows sponsors and marketing-authorisation holders to benefit from a number of important incentives designed to encourage the development of products which, for economic reasons, would otherwise not be pursued.

- **Development of medicines for children**. To improve the availability of medicinal products specifically authorised for children, the Agency issues decisions on paediatric investigation plans (PIPs), with or without deferrals, or where justified agrees to waivers. When the studies or measures are completed, 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, of advanced therapy products under development by small and medium-sized enterprises. Subject to this evaluation, the Agency may issue a certificate confirming the extent to which the available data comply with the standards that apply for evaluating a marketing-authorisation application (ATMP certification).

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

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

Drivers

Medicines development continues to become more individualised and oriented towards prevention, targeted drugs and adaptation of treatment to the individual's characteristics and needs. The continuous evolution of state-of-the-art knowledge and technologies in drug development, new ways of integrating development and use of medicines and medical devices, and development of new approaches for safety testing will all contribute to increasing the complexity of scientific advice and other Agency activities. Following closely these developments and ensuring the preparedness of the regulatory system will therefore be important.

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

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

phase, including better connection of product-specific reviews across the various scientific committees and working parties, should be explored.

Collaboration with HTA bodies and payer organisations as downstream decision-makers will further increase, to facilitate that treatment options become available to patients. This concerns all phases of the lifecycle, from horizon scanning, through planning for data generation, at the market entry phase and during post-authorisation evidence generation. Continuation of scientific and technical cooperation with EUnetHTA Joint Action 3, particularly through the deliverables of the relevant work packages, is envisaged.

In addition, an increase is expected in the number of requests for regulatory-science input in a number of EU health-research initiatives, especially those covering areas of great medical need, such as dementia, antimicrobial resistance, infectious diseases and psychiatric disorders, those affecting the elderly and neonates, and pregnancy-related conditions.

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Scientific advice/protocol assistance pre-submission meetings	137	89	117	115
Scientific-advice and protocol-assistance requests, of which:	551	510	582	570
Parallel scientific advice with international regulators requests	2	3	6	3
Joint scientific advice with HTA bodies requests	11	30	23	26
Post-authorisation scientific advice	122	89	148	118
Scientific advice for PRIME products	n/a	n/a	4	7
Protocol assistance	113	137	126	122
Novel technologies qualification advice/opinions	22	20	14	15
PRIME eligibility requests received	n/a	n/a	84	150
Scientific advice finalised	432	386	439	430
Protocol assistance finalised	101	139	122	121
Orphan medicines applications, of which:	329	258	329	317
Parallel orphan applications with international regulators	109	86	96	95
Submitted applications on the amendment of an existing orphan designation	0	1	4	5
Oral explanations for orphan designation			87	85
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	485	515	549	500
Finalised procedures for compliance check on PIPs	85	67	73	90
Annual reports on paediatric deferred measures processed	157	172	189	170
EMA paediatric decisions processed	344	319	369	350
Requests for classification of ATMPs	28	61	60	50
Innovation Task Force briefing meetings	27	35	41	35
Innovation Task Force Art 57 CHMP opinion requests	5	0	2	4

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Scientific advice/protocol assistance procedures completed within regulatory timeframes	99%	100%	99.5%	100%
Products included in PRIME scheme (% of applications)			17.9%	20%
Orphan designation opinions delivered within the legal timeframe		100%	100%	100%
PDCO opinions sent to applicants within legal timelines	99.7%	99.7%	99.5%	100%
Increase in scientific-advice requests	17%	-8%	14%	0%
SME requests for SA (% of total SA requests)		32%	30%	30%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	End
Facilitate research and development of new medicines	1.3-5	Identify areas in need of further research and communicate it to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects	Before 2015	After 2017
		Identify recurring questions in areas of highest potential benefit from science and innovation and develop the relevant Q&A or regulatory guidance documents	2015	After 2018
		Based on the horizon scanning activities and gaps identified, organise workshops with key opinion leaders and innovators, and involving NCAs, to address specific areas for innovation	Q2 2016	After 2017
	1.3-8	Strengthen collaboration and integration across the Network and with academia to facilitate translation of innovation into medicinal products, including through the work undertaken by the Innovation Network	2016	Continuous
	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 2018
	3.2-2	Establish a platform to review and explore opportunities for optimising activities and procedures during the development phase	2017	After 2018
Ensure needs of specific populations are met, including elderly, children, patients with	1.1-8	Hold an industry platform meeting focused on changes to the interpretation of the orphan legislation due to the new Notice from the EC	2017	2017

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
rare diseases and others		Implement the revised interpretation of the orphan legislation (via the Notice), including update guidance documents and website	Q3 2016	Q2 2017
		Optimise applicant submissions for maintenance of orphan designation through introduction of pre-assessment review meetings	Q3 2016	Q2 2017
	1.1-5	Implement EMA geriatric medicines strategy	2015	2017
	1.1-6	Provide feedback to the EC regarding their 10-year report on the paediatric regulation. Ensure interaction with FDA and other regulators regarding future scientific and regulatory challenges	2016	2018
		Contribute to the activities of the International Neonatal Consortium (INC)	2015	After 2018
		Complete EMA contribution to FP-7 financed projects Inspire, Asterix and Ideal on small population research methodology, and foster dissemination and application of the project results	2015	2017
		Contribute scientifically to methodological aspects of drug development for paediatric rare diseases, particularly for rare inborn metabolic disorders	Before 2015	After 2018
	1.1-6 3.1-3	Develop and provide up-to-date training in Paediatric Medicines development for the EU-NTC. Develop and implement strategy for regular update of the training	2016	2017
	1.1-8	Complete the pilot of rare disease cluster with FDA and conduct lessons learnt	2016	2017
Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product lifecycle	1.2-3	Contribute to the activities of EUnetHTA under Joint Action 3, particularly to selected activities in work packages 4 (joint production) and 5 (evidence generation), including exploring opportunities for collaboration through observership at relevant discussions	Before 2015	2020
	1.2-3	Develop and deliver a joint EMA/EUnetHTA work plan covering the areas from horizon scanning, pre-and post-licensing evidence generation as well as market entry	2016	2020
Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal	1.2-2	Build Network capacity to support accelerated development pathways (including PRIME), with a focus on quality aspects on critical development path	2016	2018

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
frameworks, including through collaboration with international partners		Provide scientific leadership to the ADAPT-SMART project	Before 2016	2017
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 legislation	Before 2015	2017
		Develop implementation strategy on companion diagnostics legislation and related guidance documents for the industry	2015	2017
Provide high quality, efficient and consistent support to medicines development	1.3-5	Perform an in-depth review of quality data needed to support the development of a biosimilar medicinal product in a targeted way	2016	2017

Resources

	2017
Financial resources (cost, thousand Euro)	36,091
Human resources (FTEs)	90

1.2. Initial evaluation activities

Activity areas

Initial evaluation refers to the process of **scientific assessment of medicines submitted for centralised marketing authorisation**. It also covers the provision of scientific opinions, in cooperation with the World Health Organization (WHO), on medicinal products for human use that are intended exclusively for markets outside of the European Union (so-called Article 58 applications).

The Agency coordinates and performs (through its committees) the scientific evaluation of applications for marketing authorisation, including risk-management plans, and issues opinions that form the basis for the European Commission's decision to grant an EU-wide marketing authorisation.

The opinions are based on balancing a medicine's desired effects ('benefits') against the undesired effects ('risks'). Weighing the benefits and risks of a medicine is based on evaluation of a large amount of data relating to quality, safety and efficacy of a medicine. Scientific guidelines are developed to guide applicants with regard to the requirements for demonstrating quality, safety and efficacy of a medicine.

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

Drivers

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

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

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

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

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

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Number of MAA pre-submission meetings	57	102	85	50
Initial evaluation applications, of which:	100	111	114	114
New non-orphan medicinal products	38	36	41	50
New orphan medicinal products	21	25	27	25
Similar biological products	3	12	12	13
Generic, hybrid and abridged products	37	37	31	25
Scientific opinions for non-EU markets (Art 58)	1	1	0	0
Paediatric-use marketing authorisations	0	1	1	1
Number of granted requests for accelerated assessment			12	15
Number of consultations of SAGs / Ad-hoc expert groups in the context of MAAs	14	7	8	10
Reviews on the maintenance of the orphan designation			20	25

	Results			Forecasts
	2014	2015	2016	2017
criteria at MAA stage				

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Applications evaluated within legal timeframes	100%	100%	99%	100%
Average assessment time for new active substances and biosimilars		200.7	197.2	205
Average clock-stop for new active substances and biosimilars		138.4	136.1	180
% of requests granted for accelerated assessment			48%	70%
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment			43%	70%
% of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice		82%	63%	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%	90%
% of comments on product information submitted during assessment procedure and taken on-board by assessors				90%
% of therapeutic guidelines progressed to next step or finalised (vs planned)				70%
% of early background summaries drafted and sent to assessment teams (vs planned)				100%
% of outcomes/results of workshops on therapeutic objectives published on EMA website				100%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Provide high quality, robust, scientifically sound and consistent scientific assessments of marketing authorisation applications	3.2-15	Continuously improve the tools (guidance, and databases) available to EMA staff supporting scientific evaluation activities of the committees	Before 2015	After 2017
	3.2-1	Monitor the conduct of pre-submission meetings and continue optimisation towards improved support for the later evaluation	2015	2017
Embedding pharmacovigilance planning in clinical guidelines	3.2-15	Develop and maintain guidance and other tools (training material, checklist, metrics)	2016	2017

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
and improve quality of risk management review and better use of resources		embedding pharmacovigilance planning in clinical guidelines, supporting risk management planning and stakeholder interaction		
Ensure and run highly effective and efficient processes to deliver initial evaluation activities	3.2-14	Streamline and strengthen the process of input by Quality Working Party and other quality of medicines working groups to the relevant parts of assessment report	2015	After 2017
	3.2-1	Optimise and embed in the Agency the process performance management system with strong customer focus on quality, simplification and regulatory procedural excellence	2016	2018
		Improve guidance and provide internal and external trainings to ensure regulatory procedural consistency	2016	2107
		Establish an internal system of knowledge sharing with the aim of providing consistent regulatory advice to the NCAs and MAHs	Q1 2106	2017
		Deliver workflow/case management solutions to reduce the Agency's and Network's administrative burden and facilitate collaboration using online tools	2017	2019
		Develop regular interactions with industry, HTAs and HCPs to promote the operations of the evaluation activities and engage with industry in their optimisation	2015	2017
		Create a platform for collaboration with NCAs to understand level of satisfaction and identify improvement opportunities	2017	2018
		Simplify the handling of generic applications, to increase the capacity whilst maintaining quality	2017	2018
Provide high quality, robust, scientifically sound and consistent product information	3.3-6	Develop and maintain guidance and other tools (training material, checklist, metrics or labelling review guide) supporting SmPC review	Before 2015	After 2017
		Develop tools for improved oversight of labelling development during the lifecycle, supporting consistent and evidence-based reviews	2017	2018
	3.3-7	Analyse external requests regarding the contents of approved SmPC and provide consistent response	2016	2017
Increase reliance of other	4.3-4	Implement collaborations with FDA on	2016	2018

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
regulators on European assessment and output		pharmaceutical quality through setting up a new cluster, with focus on innovation		
Ensure appropriate representation in relevant fora, to ensure convergence of standards	4.2-8	Contribute to ICH activities on starting materials (ICH Q11 Q&As on starting materials) and lifecycle management (ICH Q12 on lifecycle management guideline)	2015	2017
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	After 2017

Resources

	2017
Financial resources (cost, thousand Euro)	35,312
Human resources (FTEs)	87

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 organic 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
	2014	2015	2016	2017
Variations applications, of which:	6,006	5,999	6,204	6,270
Type-IA variations	2,969	2,864	3,019	2,773
Type-IB variations	1,886	1,980	2,000	2,228
Type-II variations	1,151	1,155	1,185	1,269
Line-extensions of marketing authorisations	16	14	25	15
PASS scientific advice through SAWP	n/a	1	2	5
Number of consultations of SAGs / Ad-hoc expert groups in the context of post-authorisation activities			6	12
Renewal applications			107	62
Annual reassessment applications			25	26
Transfer of marketing authorisation applications			35	53
Article 61(3) applications			216	190
Post Authorisation Measure data submissions			1016	900
Plasma Master File Annual update and variation applications			19	17

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Post-authorisation applications evaluated within the legal timeframes	100%	99%	99%	99%
Average assessment time for variations that include extension of indication	175	160	165	180
Average clock-stop for variations that include extension of indication	90	65.5	73	90
% of submitted risk management plans peer reviewed by the Agency as part of the extension of indication and line	100%	100%	100%	100%

	Results			Targets
	2014	2015	2016	2017
extensions				

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 Start	End
Provide high quality, robust, scientifically sound and consistent scientific assessments of post-authorisation changes to marketing authorisations		Strengthen the support in clinical pharmacology and non-clinical aspects to centrally authorised products along their life-cycle	Before 2016	After 2017
	3.2-1	Develop/improve guidance and quality standards for each procedure and deliver internal trainings to ensure regulatory procedural consistency	Q1 2016	2017
		Establish an internal system of knowledge sharing with the aim of providing consistent regulatory advice to the NCAs and MAHs	Q1 2016	2017
		Develop a knowledge sharing system, including for experts, to capture and share the knowledge gained through the initial evaluation and product lifecycle in order to harmonise approaches	2017	2019
Ensure and run highly effective and efficient processes to deliver post-authorisation activities	3.2-1	Optimise and embed in the Agency the process performance management system with strong customer focus on quality, simplification and regulatory procedural excellence	Q1 2016	2018
		Implement identified improvements to handling procedures for CAPs and NAPs	2016	2017
		Develop and implement a simplified work-sharing procedure for the evaluation of active substance master files used in submissions in centralised and decentralised procedures	2017	2018
		Optimise processes that include interactions among multiple Committees	2017	2018
		Create a platform for collaboration with NCAs to understand level of satisfaction and identify improvement opportunities	2017	2018
Further promote use of scientific advice throughout the lifecycle of the product, including further development	1.3-6	Analyse the impact of scientific advice on the likelihood of obtaining a positive opinion for extensions of indication	2017	2018

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
of authorised medicines (e.g. extensions of indications, post-authorisation safety and efficacy studies)				
Foster research and data generation in the areas of public health needs	1.1-9	Promote research activities in the area of direct oral anticoagulants (DOACs), thereby using high quality data, information and knowledge to enhance benefit-risk monitoring of the authorised DOACs	2016	2017

Resources

	2017
Financial resources (cost, thousand Euro)	90,196
Human resources (FTEs)	92

1.4. Referrals

Activity area

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

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

Drivers

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

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

recognised as value added, and will continue to be sought where applicable to best inform these decisions.

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

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Pharmacovigilance referrals started	7	5	8	8
Non-pharmacovigilance referrals started	11	16	10	12

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Referral procedures managed within the legal timelines	100%	100%	100%	100%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Provide high quality, robust, scientifically sound and consistent scientific assessments of referrals	3.2-1	Develop and improve guidance and provide internal training to ensure regulatory procedural consistency	2016	2017
Ensure and run highly effective and efficient processes to deliver assessment of referrals	3.2-1	Optimise and embed in the Agency a process performance management system with strong customer focus on quality, simplification and regulatory procedural excellence	2016	2018
		Create a platform for collaboration with NCAs to understand level of satisfaction and identify improvement opportunities	2017	2018
		Review and rationalise the involvement of multiple Committees in the evaluation of safety issues in the post-authorisation phase	2017	2018
		Implement identified improvements to handling procedures for CAPs and NAPs	2016	2018

Resources

	2017
Financial resources (cost, thousand Euro)*	2,006

	2017
Human resources (FTEs)*	8

* 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

There is increasing realisation that pharmacovigilance plays a critical role through the lifecycle of medicines. This includes the importance of early pre-authorisation planning of data collection for when products are released onto the market and the reliance placed on pharmacovigilance systems for the monitoring of products and the rapid detection of and action taken on emerging safety issues. Therefore the Agency will further support the planning and operation of pharmacovigilance and risk management to help fulfil the unmet medical needs of patients.

Having finished implementing the pharmacovigilance legislation in 2017, the coordinating role of the Agency in the monitoring of all EU medicines has increased. This means the volume of data and

information, as well as number of safety issues to be managed and procedures run, will continue to increase over the next few years. For example, PSUR procedures are forecast to remain at high levels (up to 889 in 2017) while in Q3 2017 the pharmaceutical industry will have new access to the EudraVigilance database and by law will have to send validated signals to the EMA for confirmation and subsequent management, constituting new work for the Agency.

Regulatory sciences provide the evidence to support process improvement in pharmacovigilance and in 2017 regulatory science results will become available (for example from the ADVANCE and WEBRADR projects) and existing results that have demonstrated efficiency gains will be fully implemented (notably for signal detection based on the EU PROTECT project). In addition, the availability of new IT tools will further support the conduct of pharmacovigilance. Such evidence-based process improvements and roll-out of IT (including the new EudraVigilance functionalities) help deliver better pharmacovigilance and to respond to calls for simplification.

The increasing role of information technology in health-related matters, including new data sources, methodologies and technologies, as well as the use of e-health records and databases, mobile communications and social media by consumers and healthcare professionals, offers unprecedented opportunities to access and analyse real-world data to support decision-making of the EMA scientific committees. Such real world data complements rather than replaces more traditional data sources, notably clinical trials. Building on the real world data work that has already been done to support PRAC signals and referrals, there is a need to build the capacity to support decision-making across the EMA committees.

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 in 2017 including enhanced web-presentation of EudraVigilance data for the general public, the conduct of public hearings, and work to measure the impact of pharmacovigilance (based on the PRAC Impact Strategy adopted in January 2016).

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Number of signals peer-reviewed by EMA	2,030	2,372	2,372	1,800
Number of signals validated by EMA	34	61	61	35
PSURs (standalone CAPs only) started	520	512	518	521
PSUSAs started		268	243	368
Number of imposed PASS protocol procedures started	32	31	12	25
Number of imposed PASS result procedures started		2	3	15
Number of emerging safety issue notifications received	19	34	21	35
Number of notifications of withdrawn products received		160	118	168
Cumulative number of products on the list of products to be subject to additional monitoring		261	301	281
Number of Incident Management Plans triggered			7	9
Number of non-urgent information (NUI) or Rapid Alert (RA) notifications submitted through EPITT			49	55
Number of external requests for EV analyses			34	50
Number of MLM ICSRs created			8,495	9,000

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Periodic Safety Update Reports (PSURs standalone CAPs only) assessed within the legal timeframe		100%	100%	100%
Periodic Safety Assessment Reports (PSUSAs result procedures) assessed within the legal timeframe		98.5%	100%	95%
Protocols and reports for non-interventional imposed post-authorisation safety studies assessed within the legal timeframe	100%	98.4%	100%	100%
Reaction-monitoring reports supplied to the lead Member State monthly	100%	100%	97%	100%
PRAC recommendations on signals and translation of labelling changes in EU languages published			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	
			Start	End
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes and services	1.2-4	Coordinate data collection and analysis to measure pharmacovigilance impact as feedback to improve processes, and to provide input into the EC report on EU network pharmacovigilance tasks in 2018	ongoing	ongoing
	3.4-1	Support ECDC in the delivery of the vaccine risk/benefit blueprint as anticipated in the IMI ADVANCE project through providing the governance and code of conduct for such studies and regulatory support, as required	2016	2019
	1.2-4 1.4-4	Present learnings from codeine study to PRAC as a proof of concept for the collaborative approach on collection and analysis of real-world data, and initiate further network studies	2016	2017
	1.4-2	Revise as necessary guidance and Q&As on medication errors	2016	2017
	3.3-2	Conduct a lessons-learned exercise after one year experience of public hearings	Q1 2017	After 2018
	1.4-1	Publish final ADR and signal management GVP module and prepare for public consultation on GVP modules on pregnancy, paediatrics, PSURs and geriatrics	2016	2018
	3.2-1	As part of implementing the PSUR Roadmap,	2015	2017

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
		conduct a consultation with the pharmacovigilance stakeholders on the Explanatory note for the GVP VII on PSURs and deliver a joint NCA/Industry training on preparing and assessing PSURs		
		Optimise administration of the EURD list by moving it to an appropriate IT platform, developing close collaboration with the network and developing risk-based criteria to determine periodicity and granularity of PSUSA scope of procedures	2015	2018
Maximise benefits to public health promotion and protection by enhancing benefit-risk monitoring of authorised medicines and pharmacovigilance decision-making through use of high quality data, information and knowledge	1.2-4	Build capacity for EU Network analysis of epidemiological data	2016	2020
		Develop inventory to facilitate access to data on real-world data	2016	2020
		Consult on mechanism for joint industry funding of studies. Initiate at least 4 EMA studies on real world evidence data	2016	2020
		Review the scientific advice process for post-authorisation studies to identify possible process improvement opportunities	2016	2020
	1.4-4 1.4-2	Continue leadership of work package for WebRADR on governance aspects of social media monitoring	Before 2016	2018
	1.2-5	Evaluate the options and feasibility to provide increased support to use of registries for targeted products on the EU market from learnings from the pilot process	Before 2016	2019
	1.4-1	Implement business process to receive and manage industry reported safety signals	Before 2016	After 2018

Resources

	2017
Financial resources (cost, thousand Euro)*	47,091
Human resources (FTEs)*	117

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

The Clinical Trials Regulation published in May 2014 requires the Agency to develop the systems necessary for its implementation, in collaboration with the EC and the Member States. In 2017, an audit of the EU Portal and Database will take place and, on the basis of the audit report, the EMA Management Board will confirm if the EU Portal and Database have achieved full functionality. According to the adopted delivery timeframe, the Regulation will then become applicable by October 2018.

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Herbal monographs, new	11	14	8	5
Herbal monographs, revised	5	3	9	15
List entries	1	0	2	1

Performance indicators

	Results			Targets
	2014	2015	2016	2017
n/a				

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe Start	End
Implement the Clinical Trials Regulation (EU) No 536/2014*	1.3-2	Finalise the new and revised guidelines related to the implementation of the Clinical Trials Regulation, considering as applicable the comments received during public consultation	2015	2017
Support high level of coordinated cross-European preparedness to act upon public health threats	1.1-11	Issue specific working procedures on handling emerging health threats, in line with the new structure and plan	2015	After 2017
Facilitate development of new antibiotics for treatment of multi-resistant bacteria, including through enhanced international cooperation	3.2-15	Provide scientific support to writing a new guideline on paediatric aspects of new antibiotics and to revision of SmPCs for already approved antibiotics	2016	2018
Strengthen the quality of the scientific review processes	3.2-14	Establish a pragmatic approach setting European standards for herbal combination products	2016	2018
Promote application of harmonised international standards	3.2-15	Provide technical and scientific contribution to the development of an addendum to the ICH guideline E9 statistical principles in clinical trials, and the finalisation of the ICH guideline E17 on multi-regional clinical trials	Before 2015	2017
		Provide technical and scientific contribution to the development of ICH safety guidelines (Carcinogenicity assessment document evaluation for ICH S1)	Before 2015	After 2017
Ensure needs of specific populations are met, including	1.1-7	Develop and implement EMA strategy for medicine safety in pregnancy	2016	After 2018

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
elderly, children, patients with rare diseases and others				

* For information on the IT systems required by the Clinical trials regulation, please see section 1.7. Projects

Resources

	2017
Financial resources (cost, thousand Euro)	13,790
Human resources (FTEs)	23

1.7. Projects

In order to support the Agency's work and achievement of set objectives, a number of programmes and projects will be undertaken. The table below details the main projects, their timelines and deliverables that the Agency will pursue in 2017. The main projects in 2017 will be related to:

- **Pharmacovigilance**. The main focus will be on building and implementing the enhanced EudraVigilance system to deliver adverse drug reaction (ADR) and signal-management capability for the network in 2017.

- **Clinical trials**. In August 2017, an audit of the EU Portal and Database will take place enabling the Clinical Trials Regulation to become applicable by October 2018. Following the audit, improvement of the system will continue.

- **eCollaboration**. The focus in 2017 will be on finalising the eCTD v4.0 standard, and implementing the single entry point for electronic submissions for the network through integration of the EMA's gateway and the CESP.

Programme / Project	Legal basis	Start date	End date	Deliverables 2017
Pharmacovigilance programme				
EudraVigilance auditable requirements	- Directive 2001/83/EC, art.107 - Regulation (EC) 726/2004, art.24 - Commission implementing regulation (EU) 520/2012, art.18, 23, 25-28 and chapter V	Q4 2013	2018	- Audit of new EudraVigilance system - PRAC recommendation on the EV system audit results - Agency move to simplified reporting - Mandatory reporting of non-serious cases in EudraVigilance - Data submission to WHO - Switch of eRMR functionalities
EudraVigilance critical requirements	- Directive 2001/83/EC, art.107 - Regulation (EC) 726/2004, art.24 - Commission implementing regulation (EU) 520/2012, art. 23, 25 and 26	Q4 2013	-	Project on hold until after 2018

Programme / Project	Legal basis	Start date	End date	Deliverables 2017
Clinical Trials programme				
EU portal and clinical trials database	• Regulation (EC) 536/2014, art.80-82	Q3 2014	2018	• Delivery of fully functional system (i.e. EU portal and database) ready for audit • Initiation of audit of EU portal and database • Preparation of training materials and delivery of training to stakeholders • Preparation of user guidance documentation • Implementation of communication plan
Safety reporting	• Regulation (EC) 536/2014, art.40-43	Q4 2014	2019	• Final business case completed for approval • Integration of safety reporting business requirements for the data warehouse with the EU portal and database requirements and EudraVigilance data warehouse
EudraCT and EU Portal	• Regulation (EC) 536/2014, art.80-82, 98	2017	2019	• Initial business case completed for approval • Design completed • Final business case completed for approval
eCollaboration programme				
eCTD 4 pre-project activities	n/a	2017	2017	• Environmental analysis to examine available eCTD4 tools • Impact assessment to provide an estimation of cost for adapting the EMA systems to eCTD4
Single submission portal and integration (external project activities)	n/a	Q3 2016	2018	• Provide centralised business subject matter expertise for integration of the human initial marketing authorisation application form in the CESP via the existing EUTCT, and EMA master data and controlled terminology
Standalone projects				
AddValue: raising the standard of scientific output	n/a	Q3 2015	2017	• Support tools and processes aimed at obtaining consistently high standards of scientific quality and robustness for key EMA scientific outputs, focussing on the marketing authorisation application assessment report • Support tools and processes to ensure consistency of assessment and decision-making throughout the process, along the life-cycle and across medicinal products • Standards for scientific quality of assessment reports with a special focus on how to best document the scientific rationale behind decisions • Mechanisms for continuous improvement of assessment reports

Programme / Project	Legal basis	Start date	End date	Deliverables 2017
				• Recommendations for feasible approaches to increase the involvement of patients and the integration of their values into the body of assessment work (methodologies for benefit-risk evaluation and graphical representation)

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[4] 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 to applicants submitting applications for products for limited markets. Products for food-producing species that are classified as MUMS are eligible for incentives, to encourage development of products that would otherwise not be developed in the current market conditions. Product eligibility 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 recently put in place the Ad hoc group on Veterinary Novel Therapies (ADVENT) to create guidance in this area.

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[4] 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'

Drivers

In 2017, the focus in terms of pre-authorisation activities will remain on promoting access to market of veterinary products, particularly those based on novel technologies and those indicated for MUMS/limited markets.

Following the first years of operation of the ADVENT group, the work on delivering guidance according to its work plan will continue in 2017.

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 during 2017 and beyond.

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

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Innovation Task Force briefing requests	2	2	4	4
Scientific advice requests received	31	27	18	25
Requests for classification as MUMS/limited market	29	27	25	24

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Scientific advice procedures completed within set timeframes	97%	100%	100%	100%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			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	Q1 2017	2017
		Inform stakeholders of the revised MUMS guidelines	2015	2017
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	After 2018
		Implement any improvements identified as a result of 2016 evaluation of the impact of	Q1 2017	After 2018

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
		measures recently put in place to support innovation (ADVENT, ITF)		
	2.1-6	Publish Q&A developed by ADVENT in priority areas for technologies that are new to veterinary medicine (including cell-based therapies, monoclonal antibodies for veterinary use)	Before 2016	After 2018
		Explore the scope for developing specific regulatory approaches to facilitate authorisation of alternatives to antimicrobials to control infectious disease in animals	2017	2018
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners	2.1-5	Explore ways to promote the uptake of parallel scientific advice with the FDA, as part of pre-submission advice	Before 2015	After 2018
Support development and availability of veterinary medicines	2.1-2	Implement EMA contribution to the EU Network Strategy to 2020 in the area of promoting availability of vaccines within the EU, with particular emphasis on vaccines against transboundary diseases and diseases with limited markets	2016	2020

Resources

	2017
Financial resources (cost, thousand Euro)	1,310
Human resources (FTEs)	2

2.2. Initial evaluation

Activity area

Initial evaluation refers to the process of scientific assessment of applications for veterinary medicines submitted for marketing authorisation through the centralised procedure. The following activities are included in this domain.

- **Initial evaluation**. The initial evaluation phase includes pre-submission discussions with future applicants, scientific evaluation of applications, and issuing an opinion to the European Commission. The Commission grants the marketing authorisation, following which the Agency publishes a European public assessment report (EPAR).

- **Establishment of MRLs**. The use of veterinary medicinal products in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. Before a veterinary

medicinal product can be authorised, the safety of its residues must be evaluated. The Agency establishes 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.

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 continuous interest in the industry in developing new veterinary medicines for food-producing animals.

Streamlined business processes will be implemented in 2017 to provide increased harmonisation and efficiency in procedures.

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Initial evaluation applications	12	10	21	24
New MRL applications	4	4	6	2
MRL extension and modification applications	2	3	1	2
MRL extrapolations	2	1	0	1
Art 10, Biocides	0	0	0	2
Review of draft Codex MRLs	5	0	5	0

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Procedures completed within legal timeframes	100%	100%	100%	100%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Provide high quality and consistent scientific outputs of the EMA	2.2-7	Finalise development of revised guideline, procedures and templates for CVMP assessment reports and provide training on these	Before 2015	2017
Ensure the establishment of	2.1-9	Provide technical support to the European	Before	2018

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
MRLs supports the safe use of veterinary medicines in regard to their impact on human health		Commission in drafting implementing acts specified in Regulation 470/2009	2015	
	2.1-7	Review the approach on genotoxic substances in the establishment of MRLs and authorisation of veterinary medicinal products	2015	2017
	2.1-8	Finalise, in collaboration with ECHA and 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	After 2017

Resources

	2017
Financial resources (cost, thousand Euro)	4,840
Human resources (FTEs)	16

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 internal procedures for variations for veterinary products will continue to be reviewed alongside other business processes, taking into account the best practice developed in the management of procedures for human medicines applications in the Agency.

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Variations applications, of which:	340	373	410	355
Type I A variations	175	196	243	180
Type I B variations	118	116	126	130
Type II variations	47	61	41	45
Line extensions of marketing authorisations	6	3	3	5

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Post-authorisation applications evaluated within the legal timeframes	100%	100%	100%	100%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Ensure efficient delivery of post-authorisation procedures	2.2-8	Implement improvements identified in the review of post-authorisation procedures	2017	2018

Resources

	2017
Financial resources (cost, thousand Euro)	5,384
Human resources (FTEs)	11

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 the same intense workload that has been experienced for referrals in recent years to continue. This will be managed through streamlined business procedures that will be implemented in 2017.

Referrals concerning individual antibiotics or classes of antibiotics that are particularly important for use in human medicine will continue to be a priority area in 2017-2018. A number of these referrals are expected to 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
	2014	2015	2016	2017
Arbitrations and Community referral procedures initiated	7	7	8	8

Performance indicators

	Results			Targets
	2014	2015	2016	2017
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	
			Start	End
Facilitate prudent and responsible use of antimicrobials and other classes of products	2.4-1	Engage with the EC and Member States to identify and, where possible, prioritise referral of antimicrobials and other classes of products for which the conditions of use need to be both harmonised and aligned with the principles of prudent and responsible use, including in relation to environmental issues	2016	2017

Resources

	2017	2018
Financial resources (cost, thousand Euro)	669	719
Human resources (FTEs)	2	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 still with considerable scope for simplification and reduction of duplication through improved cooperation within the EU regulatory network. In addition to providing technical support to the European Commission with respect to future changes that are envisaged in the proposals for new legislation, the Agency will work with the NCAs to develop improved IT tools to underpin the current and future pharmacovigilance systems of the network. This work is all the more important in view of the fact that it is at least four years before new legislation could become applicable.

In 2015 the Agency established the Common European Database of veterinary medicinal products, based on EudraPharm, and efforts will continue in 2017 to work with Member States to populate this database with high-quality data on nationally authorised products.

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Periodic safety-update reports (PSURs)	158	159	175	160
Total AERs, of which:	28,404	31,467	38,162	30,000
Adverse-event reports (AERs) for CAPs	11,878	14,387	18,419	13,500

Performance indicators

	Results			Targets
	2014	2015	2016	2017
PSURs evaluated within the established timeline	97%	99%	98%	90%
AERs for CAPs monitored within the established timelines	95%	98%	96%	95%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes	2.2-4	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	2018
		Revise the surveillance strategy for centrally authorised products to link signal detection and PSURs and ensure better use of pharmacovigilance resources	2015	2017
	2.2-5	Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species	Before 2016	2017
	2.2-6	Revise the process for incident management plans in light of the lessons-learned from a simulation exercise and a recent experience	2016	2017
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	2.2-3	Publish the veterinary pharmacovigilance annual bulletin	Q1 2017	2017

Resources

	2017
Financial resources (cost, thousand Euro)	2,371
Human resources (FTEs)	9

2.6. Other specialised areas and activities

Activity area

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

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

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

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

Drivers

The revision of the EU veterinary medicines legislation is expected to impact the Agency's activities once the legislation is adopted. Discussions are expected to continue in the next years, with the legislation expected to be adopted by 2018. Therefore, the Agency will continue providing technical support to the EC with respect to discussions in Parliament and Council on their proposal for revision of the veterinary legislation, including on amendments to the framework for authorisation of innovative veterinary medicines, simplification of post-authorisation maintenance of veterinary products, pharmacovigilance and other aspects. Planning for changes within the Agency that will arise as a result of the implementation of the revised legislation started in 2015 and will continue in 2017.

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 imminent 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 will work to implement the recommendations that fall under its scope.

Following 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, the Agency will continue to provide input during 2016-2017 in measures initiated by the Commission, such as additional advice, referrals and the production of guidance documents, including jointly 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. Daily Defined Doses Animals). The Agency is looking to improve the web tool for reporting of data to ESVAC.

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 actively to its implementation. A particular focus will be 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
	2014	2015	2016	2017
n/a				

Performance indicators

	Results			Targets
	2014	2015	2016	2017
n/a				

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Support increased availability of veterinary medicines	2.1-3	Set up a pilot project to evaluate how existing data on antimicrobials can be extrapolated to promote retention on the market	2016	2017
	2.1-4	Provide CVMP feedback on gap analysis from the FishMed Plus coalition on availability of fish medicines	2016	2020
	2.1-11	Finalise reflection paper on anthelmintic resistance	2013	2017
		Develop a reflection paper on resistance in ectoparasites	2017	2019
		Contribute to EU position for the revision of VICH guidelines on anthlemintics (GL7, 12-16 and 19-21)	2016	2020
	2.2-1	Provide necessary input to the European Commission during the co-decision process for new veterinary legislation	Before 2015	After 2018
	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	After 2018
	2.1-10	Contribute to the EMA/HMA task force on	2016	2020

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
		availability of authorised human and veterinary medicines		
	2.4-9	In cooperation with the European Surveillance Strategy Group finalise revision of the Incident Management Plan for veterinary medicines and develop systems to facilitate management of shortages and ensure the adequate supply of essential veterinary medicines	2017	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	After 2018
	4.2-5	Consider international scientific approaches for the establishment of MRLs for harmonisation purposes	Before 2015	After 2018
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	2.4-4	Finalise the reflection paper on aminoglycosides and publish for consultation the reflection paper on extended-spectrum penicillins	2015	2018
	2.4-5	Work with the European Commission to publish the outcome and follow up to the joint EMA-EFSA opinion on how to reduce the need for antimicrobials in food-producing species	2015	2017
		Prepare a second report in collaboration with EFSA and ECDC on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals	2016	2107
		Prepare an opinion on indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals	2016	2017
	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	Before 2015	2017
	2.4-3	Publish a harmonised methodology for measurement of use of antimicrobials per species	2016	2017
		Publish reports on existing systems within the EU for collection of data on use of antimicrobials in chickens and cattle	2016	2017
Minimise the use of animals in	4.2-10	Improve the guidance available on regulatory	2014	2017

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
medicines research and development activities		acceptance of 3Rs (replacement, reduction, refinement) testing approaches		
	4.2-9	Contribute to development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch testing of veterinary vaccines and other relevant areas	Before 2015	2017
Effectively manage risks to the environment arising from the use of veterinary medicines	2.4-7	Develop a guideline on risk assessment of veterinary medicinal products in groundwater	2013	2018
	2.4-8	Provide advice to the European Commission to assist the preparation of their strategy on managing pharmaceuticals in water	2013	2018
	2.4-6	Develop a strategic approach to persistent bioaccumulative and toxic (PBT) substances within the authorisation procedure for veterinary medicinal products	2014	2017

Resources

	2017
Financial resources (cost, thousand Euro)	1,922
Human resources (FTEs)	7

2.7. Projects

To support the Agency's work and achievement of the set objectives, a number of programmes and projects specifically related to veterinary medicines will be undertaken. The table below details the main veterinary-specific projects, their timelines and deliverables that the Agency will pursue in 2017.

The main veterinary-specific projects in 2017 will relate to the veterinary IT programme and implementation of veterinary legislation. The cross-Agency projects that relate to both human and veterinary medicines (e.g. SPOR, e-Submission including common repository) are described in the project section of the Horizontal activities' chapter (section 3.6).

Programme / Project	Legal basis	Start date	End date	Deliverables 2017
Veterinary IT programme				
EudraVigilance veterinary v3.0	• Regulation (EC) 726/2004, art.57(d)	2017	2018	• Report and outcome of requirements and options analysis • Development of initial business case for approval
Veterinary Change Programme				
Veterinary business process	• New veterinary legislation (under drafting)	Q2 2016	2017	• Finalising implementation based on final business case to release capacity and enhance preparedness for implementation of new veterinary legislation

Programme / Project	Legal basis	Start date	End date	Deliverables 2017
Governance/potential centralisation of functions	• New veterinary legislation (under drafting)	2017	2020	• Development of initial business case for approval • Finalisation of design phase

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. 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 impact and role of the Scientific Coordination Board in ensuring optimal interaction between the committees regarding development standards, robustness of benefit-risk assessment and utilisation of scientific resources across the network will also increase.

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
	2014	2015	2016	2017
Number of reimbursed meetings	397	437	441	500
Committee meetings			71	71
Trainings			21	73
Workshops			66	62
Others (working groups, working parties, ad hoc expert meetings, SAG etc.)			283	294
Number of teleconference meetings (audio, video and web)	3,215	4,273	4,969	5,500
Number of reimbursed delegates	7,488	8,226	7,972	9,500

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Delegate satisfaction with meeting support services	n/a	93%	n/a	90%
Up-to-date electronic declarations of interests submitted by committee members prior to participating in a scientific committee meeting	100%	99%	99%	100%
First-stage evaluations of conflicts of interests for committee members completed prior to their participation in the first committee meeting after the submission of a new or updated declaration of interests	100%	100%	100%	100%
Ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts database	94%	100%	100%	90%

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Optimise the current regulatory framework by ensuring efficiency of the existing regulatory operations	1.3-4	Explore opportunities for collaboration and work with HTA organisations by providing support to the development and revision of methodological and disease-specific guidelines	Before 2015	2018
	3.2-2	Improve alignment of committee work plans with the EMA work programme	2016	2017
		Implement policy on coordination between committees – with particular focus on coordination between scientific committees and the SAWP	2016	2017
		Implement transparency initiatives relating to committee communications, including agendas, minutes, meeting highlights	2016	2017
		Conduct a survey to capture the needs and expectations of stakeholders (committee members, NCA support staff) regarding the committee secretariat	2016	2017
		Optimise automatic population of agendas and minutes using available databases and design business intelligence reports to respond to the needs of the Network	2016	2017
Ensure 'fit-for-purpose' scientific capability of the network	3.1-1	Establish an EMA regulatory science observatory and develop a horizon-scanning process and methodology	2017	2017
		Develop a regulatory science strategy, addressing evolution in science, technology and regulatory tools for human and veterinary	2017	2017

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
		medicines		
Improve collaboration and communication between committees, working groups and SAGs to increase quality, efficiency and consistency of outputs	3.2-1	Analyse involvement of scientific advisory groups in evaluation activities to identify gaps and improve guidance	2015	After 2017
Provide up-to-date, timely state-of-art guidance documents on relevant topics of medicines' development	3.2-15	Provide administrative and scientific support to the drafting/revision of Biostatistics Working Party guidelines on clinical and quality topics	2015	2018

Resources

	2017
Financial resources (cost, thousand Euro)	4,351
Human resources (FTEs)	22

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.

Increasing complexity and globalisation of the medicines supply chain will also contribute to information exchange and closer, more streamlined cooperation among authorities, to ensure product and data integrity, and continuity of the medicines supply chain.

Parallel distribution is seeing increase across the three procedures – initial notifications, annual updates and notifications of change. The increase in notifications of change is driven by the growing number of safety updates to centrally authorised products.

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

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

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
GMP inspections	420[2]	567[2]	548	200
GLP inspections	0	1	0	1
GCP inspections	66	86	121	125
Pharmacovigilance inspections	20	14	8	14
PMF inspections	-[3]	-[3]	124	45
Notifications of suspected quality defects	147	164	181	200
Notifications of GMP non-compliances[1]		18	17	60
Medicinal products included in the sampling and testing programme	46	48	48	48
Standard certificate requests received	3,338	3,221	3,787	3,500
Urgent certificate requests received	535	785	487	480
Parallel distribution initial notifications received	2,492	2,838	2,850	3,350
Parallel distribution notifications of change received	1,295	2,096	1,847	2,200
Parallel distribution notifications of bulk changes received	9	13	8	11
Parallel distribution annual updates received	2,339	4,550[4]	3,815[5]	5,100

[1] previously: "Other GMP inspections related notifications"
[2] includes PMF inspections
[3] included in GMP inspections results
[4] includes 560 parallel distribution annual update notifications that were received in 2014 but processed in 2015
[5] excludes approximately 1000 notifications received but not processed in 2016

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Inspections conducted within established regulatory timeframes	100%	100%	100%	100%
Standard certificates issued within established timelines (10 working days)	30.4%	91%	91.6%	90%
Average days to issue standard certificate	13.7	7	7	10
Urgent certificates issued within established timelines (2 working days)	100%	100%	100%	100%
Parallel-distribution notifications checked for compliance within the established timeline	97%	99%	99%	90%
Additional GCP inspections addressed through information exchange on inspections carried out by international partners	29%	46%	34%	35%
Additional routine GMP re-inspections of manufacturing sites addressed through exchange of information with international partners	8%	14%	19%	10%
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	End
Increase efficiency, consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities	4.3-2	Strengthen collaboration on GCP and pharmacovigilance compliance and inspections activities in areas of particular interest, based on mutual reliance with trusted international partners, in particular those with confidentiality agreements in place (e.g. FDA and Japan)	Before 2016	2018
		Continue to provide support to EC on negotiations work to establish a mutual reliance framework with US FDA	Before 2015	2017
	4.3-2 4.3-4	Set up a pilot phase with FDA on sharing information on pharmacovigilance inspections	2015	2018
	4.1-5	Implement EudraGMDP instruction rules for planning module to enable increased cooperation with Member States in coordinating third-country inspections	2017	2018
Minimise risk and impact of shortages due to manufacturing problems and quality defects	1.1-17	Implement the new form for reporting quality defects/suspected falsified medicinal products and start compiling information received, to analyse root causes for quality defects	2015	2019
	1.1-14	Provide regulatory support to the work of the EU Observatory to facilitate the transition from high enriched uranium to low enriched uranium	2014	2019
	1.1-20	Support and collaborate with HMA on the availability of medicines initiative	2017	2019
	1.1-15	Develop a new procedure within the Compilation of Union Procedures for issuance of warning letters by Member States in case of non-compliance issues through the GMDP IWG	2017	2019
Ensure quality of medicines wherever they are manufactured	4.1-4	Monitor and report on the use of EudraGMDP planning module by inspectorates	2016	2017
	4.1-6	Publish risk-based approach to GMP inspection for plasma master file inspections	2017	2018
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
Improve knowledge and understanding of data integrity	4.1-2	Develop a draft guidance for industry on data integrity with the GMDP IWG and in	2017	2018

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
and implications for regulatory decision-making		collaboration with PIC/s		
Address the threat posed by illegal supply chains of medicines	1.1-16	Review the practical use of the existing Rapid Alert mechanism for transmission of information related to stolen and falsified medicines	2017	2019
Support capacity building of non-EU regulators	4.4-1	Deliver training and capacity-building for inspectors and assessors, including international regulators	Before 2016	2018
Strengthen collaboration with EDQM	3.4-3 1.1-19	Review collaboration with EDQM to enable the updated contract to be signed	2017	2018

Resources

	2017
Financial resources (cost, thousand Euro)	15,886
Human resources (FTEs)	41

3.3. *Partners, stakeholders, communication and transparency*

Activity area

Activities covered in this area include the following:

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

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

- **Micro, small and medium-sized enterprises**. The Agency has an office specifically dedicated to supporting smaller companies, the SME Office. It provides eligible SMEs with access to various incentives and regulatory assistance, including fee reductions, deferrals and conditional exemptions, administrative and procedural support, as well as assistance with translations of the product-information documents submitted in applications for marketing authorisation. Around 1,450 SMEs are registered with the Agency.

- **EU Network Training Centre**. This is a joint EMA/HMA initiative to harmonise training in Europe through implementing a common online platform for scientific and regulatory training, accompanied by a training strategy, curriculum and methodology.

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

- **Communication activities.** The Agency's communication activities aim at supporting the Agency's mission of protecting public and animal health and the achievement of its strategic priorities. The Agency uses 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 has put in place a dedicated, centralised service to respond to queries received from patients, healthcare professionals and academia. The Agency's social-media activities include communication via a Twitter account and regular updates on LinkedIn and YouTube.

Drivers

The process of regulating medicines is becoming increasingly 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.

Increasingly complex environment of operations and interactions emphasises the need for EMA to increase its visibility in this space 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 a prerequisite for any outreach activities by 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 the 10 years of experience accumulated within the SME Office. There will also be a need to offer assistance to SMEs in the areas of pharmacovigilance and clinical-data transparency.

Proactive publication of clinical reports (submitted as part of marketing-authorisation applications and applications for line extensions/extensions of indication) under the 2014 EMA policy on publication of clinical data for medicines for human use started in 2016. SMEs are provided with specific support to

meet the policy's requirements. In 2017, the Agency will monitor the implementation of the policy and publish a report.

An independent communication perception survey conducted on behalf of the Agency in 2015 highlighted the need to produce more targeted communications using a wider range of tools and platforms, as well as to further engage with different groups of users via electronic communication channels and via social media. This is particularly pertinent in the area of medicine-related information. The increasing involvement of and demand from key stakeholders, including patients and healthcare professionals, for easily usable and reusable up-to-date information requires the use of simplified messages and more user-friendly communication tools and platforms. Recent user research confirms that patients are taking ever greater control of healthcare decisions and choices, basing these choices on a range of online information sources.

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 is 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.

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
Requests for SME qualification	499	793	582	650
SME status renewal requests	813	994	1,185	1,400
Number of cases of patient/consumer engagement[1] in EMA activities	633	743	750	700
New scientific, regulatory and telematics curricula developed	n/a	1	8	0
Number of training events advertised to the EU Network	n/a	105	140	170
Number of reimbursed training events to the EU Network	n/a	7	25	25
Number of messages circulated via 'Early Notification System'	317	310	380	400
Number of EMA communications pro-actively sent to stakeholders	135	138	172	200
Number of EPAR summaries and EPAR summaries updates published	260	340	283	300
Number of summaries of orphan designation published	218	230	240	250
Access to documents, requests received	416	701	823	850
Access to documents, documents released	1,771	2,972	2,876	2,500
Requests for information received	4,625	4,573	4,843	4,800
Number of documents published on EMA website	4,858	7,154	7,369	7,000
Number of pages published and updated on EMA website	2,201	2,911	4,790	3,500
Number of press releases and news items published		190	197	150
Requests for interviews and comments by media representatives	2,384	2,268	2,149	2,000
Number of reports, brochures, leaflets laid out or printed		7	25[2]	6

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Satisfaction level of Patient and Consumers' Organisations	95%	n/a	n/a[1]	n/a
Satisfaction level of SMEs	80%	92%	94%	80%
Response to ATD within set timelines		94%	97%	90%
Response to RFI within set timelines		97%	100%	97%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI		81.7%	77%	70%
Number of NCAs that have opened their training for inclusion in EU NTC Learning Management System	n/a	6	14	20
Number of users registered to the EU NTC Learning Management System	n/a	n/a	2,117	3,000
Number of NCA experts registered to the EU NTC Learning Management System	n/a	n/a	1,225	1,600
Satisfaction level of partners/stakeholders with EMA communications as per "EMA perception survey for communication"	n/a	80%	n/a	80%
Key messages included in media articles generated by EMA press releases:				
At least 1 key message		100%	100%	95%
At least 2 key messages		100%	51%	70%
Quote included		60%	0%[2]	60%
Average rating given to pages on corporate website during the year			3.6	3.0

[1] the results not yet available, but will be finalised during Q1 2017
[2] no monitoring was done for quotes

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Enhance cooperation within European medicines regulatory network	3.1-1	Conduct horizon-scanning to identify emerging trends at an early stage and to ensure appropriate expertise is available and improve regulatory preparedness, including through supporting the work undertaken by the Innovation Network and EU Network Training Centre	2015	2017
	3.2-9	Complete the data-gathering initiative for	2016	2017

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
		non-fee generating activities		
Strengthen stakeholder relation 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	2018
	3.4-6	Conduct a survey to monitor the interaction with industry associations	2017	2017
		Publish an annual report on EMA's interaction with industry associations	Q4 2017	2017
	3.4-4	Publish an annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations	Q4 2017	After 2018
	3.4-5	Implement recommendations to promote GPs interactions with EMA	2016	2018
	1.2-6	Propose and agree additional processes to capture patient views and preferences within benefit/risk evaluations at CHMP, following the outcome of the pilot phase of patient involvement in CHMP oral explanations and the research projects on elicitation of patient preferences	2016	2017
		Explore most optimal way to report patient input and values in the relevant assessment reports, in line with the EMA AddValue project	2016	2017
Further develop support to and strengthen stakeholder relations with SMEs	1.3-7	Implement action plan arising from 10-year report on the implementation of the SME Regulation	2016	2018
		Deliver high quality guidance and systems for optimal use of available regulatory tools for SMEs (EU e-SME application) to facilitate efficient and effective access to support measures	2016	2017
Further strengthen Agency's transparency and open data commitments	1.4-3	Complete the reflection paper on providing access to individual patient data	2016	2018
	1.4-5	Publish the clinical data under phase I of the policy on publication of clinical data	2017	2017
		Assess implementation of the policy on publication of clinical data and publish a report	Q3 2017	Q4 2017
		Establish a technical group on anonymisation of patient data and hold regular discussions	Q2 2017	2018
	1.4-5 1.4-6	Finalise the transparency road map following public consultation on the draft roadmap	2016	2018
	1.4-7	Conduct public consultation and finalise the	2016	2017

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
		revised policy on access to documents		
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	2020
	3.1-6	Implement the first phase of the multinational assessment team approach post-authorisation	2016	2019
Ensure 'fit-for-purpose' scientific capability of the network	3.1-3	Work with NCAs to include training courses in NTC learning management system and promote use of NTC courses, to maximise the use of the EU NTC learning management system	2015	2019
	3.1-2	Review and update existing curricula to ensure provision of up-to-date training, and further develop new curricula in various areas of identified needs	2015	2017
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	After 2017
	1.4-6 3.3-6	Implement and maintain up-to-date 'product-related communication guidance' on 'what' and 'when' EMA publishes information on products	2016	2017
		Implement a framework for communicating the scientific output of EMA scientific committees	2016	2017
	3.3-6 3.3-7	Implement user-testing for EMA communication products which target the general public	Before 2016	After 2017
	3.3-10	Run a pilot to test and improve the crisis communication plan	2017	After 2018
	3.3-8	Organise workshop with HCIN to explore additional ways to assess impact of EMA communications	2017	2017
	3.3-7	Carry out an EMA perception survey to better understand communication opportunities and challenges, and review the Agency's communication products and tools as per the results of the survey	2017	After 2017
	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	2016	After 2017
	3.3-5	Develop new digital and multimedia communication tools	2016	After 2017

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
	3.3-1	Develop and implement an annual communications plan, in line with the framework strategy for external communication	Q1 2017	2017
	3.3-4	Implement a social media strategy	Before 2016	After 2017

Resources

Area of activity	Financial resources (cost, thousand Euro) 2017	Human resources (FTEs) 2017
Partners and stakeholders	11,241	38
Transparency and access to documents	4,831	21
Information	3,137	14
Communication	6,771	28

3.4. International activities

Activity area

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

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

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

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

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

Drivers

The global nature of medicines development and research continues to be a key driver of the Agency's international collaborative activities. The increasing complexity of supply chains, combined with ever-expanding manufacture outside the EU, presents additional oversight challenges, increasing risks of falsification and concerns about data integrity.

At the same time, the similarity of tasks and objectives of regulators worldwide leads to increasing awareness of the need to avoid duplication and use global regulatory resources more effectively. As a result, and particularly in resource-limited settings, there is enhanced willingness for regulators to work collaboratively, and the EU regulatory network is seen as an effective model.

Realisation of the need for greater strategic oversight and common international approaches to the protection of public health requires mechanisms to build greater trust and confidence in other regulatory systems. To achieve this, an international coalition of medicines regulatory authorities (ICMRA) is being established, to which the Agency contributes through its active membership and support for the virtual secretariat.

Reforms to ICH – now called the International Council for Harmonization – came fully into force in 2016, allowing for a broader global membership and strengthening ICH as the leading platform for global pharmaceutical regulatory harmonisation. VICH is subject to an updated strategy and a particular focus will be to foster the VICH Outreach programme, which aims to extend uptake of VICH guidelines to countries throughout the world with less developed regulatory systems. The Agency plays an important role in supporting the European Commission by coordinating the EU expertise and contribution to the work of ICH and VICH.

Alongside enhanced cooperation in the field of inspections and supply-chain continuity, the Agency will additionally support efforts to increase international work-sharing in these and other areas, as well as support convergence of international practices and work within international organisations to encourage better and more effective use of global regulatory resources.

The Ebola and Zika outbreaks exemplified the need to support the strengthening of regulatory systems to protect global public health, as set out in the 2014 World Health Assembly resolution WHA67.20. The EMA contributes to the WHO work on regulatory-systems strengthening, including through its activities within the Article 58 framework and a pilot programme on collaborative registration of medicines in resource-constrained countries.

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
n/a				

Performance indicators

	Results			Targets
	2014	2015	2016	2017
n/a				

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Ensure best use of resources through promoting mutual reliance and work-sharing	4.3-3	Implement and review the IGDRP information-sharing pilot to the centralised procedure	Before 2016	2017
		Optimise Article 58 scientific opinion activities, including enhance collaboration with WHO and concerned regulators and develop additional communication tools	2015	ongoing
Promote convergence of global standards and contribution to international fora		Provide assistance to candidate countries, to align their standards and practices with those established in the European Union and to further foster their integration process	2016	2018
	1.1-4	Finalise the guideline on dementia	2016	2018
		Contribute to global dementia activities/programme in collaboration with other partner agencies, the EC and international organisations	2016	2018
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
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	Ongoing	ongoing
Support training and capacity building of non-EU regulators	4.4-2	Increase the number of opportunities for non-EU regulators, in particular those of candidate and potential candidate countries, to participate in scientific and regulatory training activities	2016	ongoing
		Explore and foster opportunities for the EU Network to contribute to scientific and regulatory training events organised outside the EU	2017	ongoing
		In collaboration with the WHO, increase non-EU regulators' awareness of scientific and regulatory training opportunities offered by the EU Network through the WHO training platform	2016	ongoing

Resources

	2017
Financial resources (cost, thousand Euro)	3,844

	2017
Human resources (FTEs)	14

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. 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 EMA currently delivers and maintains 23 EU Telematics services:
  - EU electronic application form (eAF), eSubmission portal, Common Repository for Centrally Authorised Products for electronic regulatory submissions, and PSUR repository to facilitate the exchange of information on the safety of authorised medicines;
  - SIAMED dashboard (centrally maintained procedure management tracking database);
  - Eudra Common Directory (ECD), EU Controlled Terminology (EUTCT), EudraPharm for Human medicinal products, EudraPharm for veterinary medicinal products), Art 57 database (product database of EudraVigilance system) for storing master data;
  - EudraCT for clinical trials;
  - EudraVigilance systems for human and veterinary medicines, Medical Literature Monitoring services for collection of adverse drug reactions;
  - the EudraVigilance and clinical trials data warehouses for analysis;
  - EudraGMDP for the management of GMP inspections in the EU;
  - EudraLink (secure file sharing) and EudraMail (e-mail services) for collaboration;

- EudraNet (secure network for the EU regulatory network) and submission gateway (for transmission of submissions and adverse drug reactions) infrastructure components;

- Referential Management Service and Organisations Management Service.

The portfolio will be further expanded in the future with the delivery of projects such as the EU portal and database for clinical trials as well as the Product and Substance Management Services for human and veterinary medicines.

Drivers

Increasingly, digital technologies are becoming key enablers for the regulation of medicines. The EU, for example, requires centralised information technology for pharmacovigilance and clinical trials. Further demands are expected from the upcoming revision of EU legislation on veterinary medicines. Generally, there is a growing need for establishing interconnected information systems to manage and share information on medicines among regulators within the EU and globally. This relies on unequivocal identification of medicinal products according to international standards enforced by EU law.

To fulfil its role, the EMA provides information and information systems to numerous partners and stakeholder groups with growing and different needs and demands. For instance, the work of EU medicines agencies and the Commission requires new or extended information-technology services; individually, EU agencies operate differently, which needs to be taken into account when implementing the EU Telematics strategy; the EU network of experts needs the right information at the right time and solutions that facilitate their work; the pharmaceutical industry is facing rising costs of regulation and expects information systems that help them meet their regulatory requirements more efficiently; cost-efficiency is particularly important for promoting the availability of veterinary medicines; patients and healthcare professionals demand timely access to information on medicines so they can make their own decisions. Globalisation of medicines requires that we share more information with regulatory authorities worldwide; academic sponsors also rely on EMA's information services, and this information is also important to further academic research. Therefore, the need to cater for a wide range of needs has an impact on how the EMA's information services are designed and provided.

The ever-increasing role of information technology in health-related matters, including growing use of e-health records and databases, mobile communication and social media by consumers and healthcare professionals, demands that surveillance and analytics methods evolve accordingly. New approaches to allow timely access to novel medicines will rely on real-time post-authorisation monitoring and data-driven decision-making based on patient outcomes. Methods to gain insights from data and information technology are progressing at an exponential pace. A robust and agile information-technology infrastructure, partnered with new capabilities to manage data, is required to allow the Agency to reap the benefits of this growing presence and role of technology.

To date, EMA has developed, hosted and curated its information-management estate on an infrastructure owned by EMA in London. In the context of the potential relocation of the Agency to another country, EMA will consider moving towards the use of cloud services[5], following a robust impact assessment shared with the Management Board. Taking due account of the necessity for data protection and information security, this could mean outsourcing some services and activities to external suppliers, and could include data centre operations, hosting and maintenance of systems and data, etc.

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[5] Cloud services in this context are defined as IT services provided to multiple customers, over the internet, on a pay-as-you-go basis. This includes, for example, private, public or hybrid cloud, as well as Infrastructure as a Service (IaaS), Platform as a Service (PaaS), and Software as a Service (SaaS).

Workload indicators

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

	Results			Forecasts
	2014	2015	2016	2017
Number of Telematics information services provided by EMA	16	20	22	23
Number of ongoing Telematics IT projects where EMA is the delivery organisation	19	18	13	8
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	15	11	6	6

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Satisfaction of external customers of Telematics information services provided by EMA (% satisfied & very satisfied)	n/a	n/a	94%	80%
Satisfaction of EMA internal customers of information services (% satisfied & very satisfied)	n/a	n/a	94%	80%

Additional objectives and activities

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

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Share information on medicines within the network and with stakeholders	3.2-12	Improve and establish systems and processes to ensure timely access to clinical data	Before 2016	2017
Establish and improve EMA information services	3.2-12	Finalise implementation of the Enterprise Architecture function, including processes and artefacts	2016	2017

Resources

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

3.6. Projects

To support the Agency's work and achievement of its set objectives, a number of programmes and projects will be undertaken. The table below details the main projects, along with their timelines and deliverables that the Agency will pursue in 2017. The main projects in 2017 will relate to the following:

- **Data integration.** This programme aims to deliver ISO-compliant systems for substance management, product management, organisations management and referential management, supported by appropriate standards and security framework which when integrated with core regulatory processes across Europe result in operational efficiencies and excellence in the evaluation and supervision of medicines.

- **Clinical data publication**. This is a project to implement the Agency's policy on publication of clinical data for medicines for human use in accordance with the agreed stepwise approach, as part of wider transparency initiatives.

Programme / Project	Legal basis	Start date	End date	Deliverables 2017
Data integration programme				
Referentials management service	• Regulation (EC) 520/2012, art.25 and 26 • Pharmacovigilance fees regulation 658/2014	Q1 2015	2017	• System go live
Organisations management services		Q1 2015	2017	• System go live
Substances and products management services (including veterinary Union database)	• Regulation 726/2004, art.57(2) • Regulation (EC) 520/2012, art.25 and 26 • Draft veterinary regulation, art.51 • Clinical trials regulation 536/2014, art.8193) • Pharmacovigilance fees regulation 658/2014, art.7 • Art.4 of Guideline on e-prescriptions dataset for electronic exchange under cross-border Directive 2011/24/EU	2017	2018	• EU implementation roadmap for ISO IDMP compliant substance and product management services and operating model for regulators and pharmaceutical industry • Design of ISO IDMP compatible data management solution for human and veterinary products • Design of a data management solution for substances
ISO IDMP	• Regulation (EC) 520/2012, art.25 and 26	Q4 2013	2017	• Contribute to the ISO process for finalisation of IDMP standards and technical specifications • Complete updating of documentation based on ISO ballot comments
Online programme				
Extranet		Q1 2014	-	• Project on hold until after 2018
Intranet	n/a	Q1 2014	-	• Project on hold until after 2018
European medicines web portal	• Regulation (EC) 726/2004 • Regulation (EC) 1235/2010, art.26	Q1 2014	2018	• Develop preliminary business case for approval • Begin work on interface design • Develop implementation plan to

Programme / Project	Legal basis	Start date	End date	Deliverables 2017
				publish Article 57 database online
Corporate website	n/a	Q1 2014	2019	• Analyse feasibility of outsourced development, build and hosting of the corporate website
Standalone projects				
Identity and access management 2	n/a	2017	2017	• Analysis and design documentation for the on-boarding of selected applications • Configuration of the identity governance solution to integrate with the selected applications and roll-out in production • Communication and knowledge transfer material
SIAMED systems integration phase I	n/a	2017	2018	• Functional and non-functional specifications defined • System and business use cases developed • Data architecture defined • SIAMED architecture designed • Implementation plan • Change management and communication plan
Publication of clinical data for medicinal products for human use	n/a	2014	2017	• Develop workflow and case management tool
Rationalising working parties	n/a	Q1 2015	2017	• Redesign the architecture and governance • Revise the work plan development process • Revise the guidelines lifecycle process • Revise the rules of engagement with interested parties • Continue with operations harmonisation • Develop and roll out a communication plan

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 and corporate planning, 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, link to the budget) and the subsequent monitoring and reporting activities.

- **Finance**. Finance refers to budget processes (planning, monitoring and reporting), 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.** IT provides and maintains required IT solutions to support the EMA's corporate activities and services 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, 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, General Court or Civil Service Tribunal. The EMA's legal service deals regularly with European Commission representatives on the Agency's core activities, and also provides advice and support, among other things, on the implementation of new legislation and legal scrutiny of scientific opinions.

- **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

The Agency is subject to an increasing number of legal challenges resulting from an increasing number of procedures, scientific developments, and the scientific and regulatory complexity of issues with which the Agency deals.

Environmental awareness is increasing in all areas of society, with growing pressure on businesses to show environmental consideration and corporate social responsibility. There is also a growing trend towards using electronic communication, such as electronic submissions, instead of paper-based communication.

Workload indicators

	Results			Forecasts
	2014	2015	2016	2017
n/a				

Performance indicators

	Results			Targets
	2014	2015	2016	2017
Posts on the Agency establishment plan filled	97%	98%	98%	97%
Revenue appropriations implemented	96%	98.7%	100%	97%
Expenditure appropriations implemented	94%	95.8%	96%	97%
Payments against appropriations carried over from year N-1	97%	94%	96%	97%
The maximum rate of carryover to year N+1, of total commitments within the title				
Title 1	1%	0.9%	1%	1%
Title 2	23%	7.6%	8%	15%
Title 3	28%	26.9%	27%	25%
Payments made within 30 days' time	98%	99.7%	99%	98%
Availability of Telematics IT systems (% of time)		99.4%	100%	98%

		Results			Targets
		2014	2015	2016	2017
Availability of corporate IT systems (% of time)			100%	100%	98%
Availability of corporate website (% of time)			99.7%	100%	98%
Change in energy consumption (per workstation)		n/a[1]	+5.1%	-19.6%[2,3]	-1%
Change in water consumption (per workstation)		n/a[1]	+2.9%	-52.8%[2,3]	0%
Change in paper consumption (per workstation)		n/a[1]	-38.2%	-22.7%[2,3]	-2%
Change in non-recyclable waste produced in restaurant and kitchenette (per workstation)		n/a[1]	-12.9%	-46.0%[2,3]	-5%
Change in recyclable waste produced (per workstation)		n/a[1]	n/a	-26.3%	-1%
Change in recycling rate (per workstation)		n/a[1]		-5.2%[2,3]	+1%
Change in carbon emissions from work-related travel (including delegates, missions, trainings and candidates)		n/a[1]	+1.0%	+1.4%	0%
Overall net CO_2 emissions (per workstation)		n/a[1]	+0.2%	-10.2%[2,3]	0%

[1] 2014 data not comparable due to the move to the new building
[2] provisional results
[3] in 2016, the number of workstations increased, following the addition of the 10th floor

Additional objectives and activities

Medium-term objective	MAWP initiative	Activity description	Timeframe	
			Start	End
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	3.2-4	Implement identified actions to align the Agency's quality management system with the new ISO 9001:2015 standard	2017	2017
		Develop and implement a framework for integrated planning and monitoring activities	2017	2018
		Review corporate support processes to identify opportunities for efficiency gains	2017	2018
	3.2-5	Develop a competency management framework, including necessary processes and systems	2017	2017
		Implement a competency management framework	2017	2019
Maintain high level of independence, integrity and transparency in all aspects of Agency's work	3.1-8	Conduct the annual review of the Agency's handling of independence	Q3 2017	2017
		Implement the antifraud action plan	2016	2017
		Review and update the Agency's antifraud strategy	2017	2017
Align the agency with the highest European standards in environmental performance	4.2-7	Receive EMAS certificate and conduct external audit of the implemented standard	Q3 2017	2018
Ensure continuity and quality of the Agency's operation		Conduct an impact assessment of the outcome of the UK referendum on EU membership	2017	2017
		Prepare business continuity scenarios and relevant action plans	2017	2018

Resources

Area of activity[1]	Financial resources (cost, thousand Euro) 2017	Human resources (FTEs) 2017
Governance, quality management and internal audit	6,791	29
Finance	4,985	24
Information Technology[2]	10,191	52
Human resources	6,764	37
Infrastructure services	2,330	15

[1] Legal services resources allocated to relevant activities throughout the work programme
[2] Additional 30 FTEs in ICT services working on projects (mainly pharmacovigilance) are allocated to the relevant sections of the work programme

Projects

To support the Agency's work and achievement of its set objectives, a number of programmes and projects will be undertaken. The table below details the main projects the Agency will pursue in 2017, along with their timelines and deliverables.

Programme / Project	Legal basis	Start date	End date	Deliverables 2017
Standalone projects				
Data centre strategy implementation	n/a	2017	2018	• Initial business case based on known information • As-is technical configuration M. Data Base • Plan to migrate low-risk services to the Cloud • Plan for major move in 2018 and/or 2019 • List of technical requirements / resources to trigger procurement processes • Migrate some (low-risk) IT services to the Cloud
IT delivery lifecycle (P3i methodology	n/a	2017	2017	• Processes, workflows, templates, tools and related guidance for all IT roles involved in IT projects, in line with the EMA's P3i methodology and IT governance • Models for adaptation based on delivery approach • Integration with the portfolio, programme and project management layers of EMA's P3i methodology
Application maintenance relocation	n/a	Q4 2017	Q4 2018	• Preparation of final business case • Launch of fixed price contract • Start of systems documentation and knowledge transfer process

Annexes

Annex 1: Activity based budget 2017

Chapter	Staff expenditure	Infrastructure, IT and project exp.	Meeting exp. (incl. overhead)	Evaluation Service (NCAs)	Other operational expenditure	* Total expenditure	
	€'000	€'000	€'000	€'000	€'000	€'000	%
	Title 1	Title 2 & Budget Item 3105	Budget Item 3000, 3001 & 3003	Budget Item 3010	Remainder of Title 3		
1 Evaluation activities for human medicines	**63,474**	**37,158**	**9,311**	**107,285**	**7,257**	**224,485**	**70%**
1.1 Pre-authorisation activities	13,617	4,054	3,384	15,034	2	36,091	11%
1.2 Initial evaluation activities	13,923	3,719	1,732	15,013	926	35,312	11%
1.3 Post-authorisation activities	14,106	9,218	1,098	64,491	1,283	90,196	28%
1.4 Referrals	1,052	277	370	-	307	2,006	1%
1.5 Pharmacovigilance and epidemiology activities	16,524	11,556	1,629	12,748	4,634	47,091	15%
1.6 Other specialized areas and activities	4,252	8,334	1,098	-	105	13,790	4%
2 Evaluation activities for veterinary medicines	**6,861**	**3,334**	**1,934**	**3,820**	**547**	**16,496**	**5%**
2.1 Pre-authorisation activities	399	135	434	342	-	1,310	0%
2.2 Initial evaluation activities	2,413	609	327	1,321	171	4,840	2%
2.3 Post-authorisation activities	1,498	1,347	178	2,157	204	5,384	2%
2.4 Arbitrations and referrals	295	67	136	-	172	669	0%
2.5 Pharmacovigilance activities	1,125	884	362	-	-	2,371	1%
2.6 Other specialized areas and activities	1,132	293	497	-	-	1,922	1%
3 Horizontal activities and other areas	**25,563**	**10,539**	**4,980**	**7,587**	**1,392**	**50,061**	**16%**
3.1 Committee coordination	2,749	865	737	-	-	4,351	1%
3.2 Inspections and compliance	4,748	2,534	1,017	7,587	-	15,886	5%
3.3a Partners and stakeholders	6,235	1,439	2,577	-	991	11,241	3%
3.3b Transparency and access to documents	3,173	1,424	233	-	-	4,831	1%
3.3c Information	2,271	514	-	-	352	3,137	1%
3.3d Communication (corporate)	3,514	3,208	-	-	49	6,771	2%
3.4 International activties	2,874	554	417	-	-	3,844	1%
4 Corporate governance and support activities	**23,241**	**7,533**	**280**	**-**	**6**	**31,061**	**10%**
4.1 Governance, quality management and internal audit	5,076	1,436	280	-	-	6,791	2%
4.2 Finance	3,347	1,631	-	-	6	4,985	2%
4.3 Information technology	8,277	1,914	-	-	-	10,191	3%
4.4 Human resources	4,759	2,005	-	-	-	6,764	2%
4.5 Infrastructure services	1,783	547	-	-	-	2,330	1%
Total	**119,140**	**58,564**	**16,505**	**118,692**	**9,202**	**322,103**	**100%**

Total budget for 2017:		**322,103**

Annex 2: Financial resources

		2015 (outturn)[1]		2016 (outturn)[2]		2017 (budget)[3]	
		€ '000	% of total	€ '000	% of total	€ '000	% of total
	Revenue						
100	Revenue from services rendered	251,490	82.7%	272,588	89.3%	285,140	88.5%
200	General EU contribution	18,669	6.1%	2,038	0.7%	4,323	1.3%
201	Special EU contribution for orphan medicinal products	13,212	4.3%	12,769	4.2%	11,802	3.7%
300	Contribution from EEA / EFTA	554	0.2%	56	0.0%	398	0.1%
600	External assigned revenue	17,559	5.8%	15,276	5.0%	6,611	2.1%
700	Correction of budgetary imbalances	1,499	0.5%	1,950	0.6%	12,767	4.0%
5+9	Other	1,135	0.4%	421	0.1%	1,062	0.3%
	TOTAL REVENUE	**304,119**	100.0%	**305,099**	100.0%	**322,103**	100.0%
	Expenditure[4]						
	Staff						
11	Staff salaries and allowances	94,091	31.9%	91,821	30.9%	112,104	34.8%
12	Expenditure relating to staff recruitment	0	0.0%	0	0.0%	230	0.1%
13	Duty travel	623	0.2%	683	0.2%	856	0.3%
14	Socio-medical infrastructure	783	0.3%	865	0.3%	665	0.2%
15	Training	5,105	1.7%	5,647	1.9%	1,160	0.4%
16	External services	528	0.2%	472	0.2%	4,085	1.3%
17	Receptions and events	137	0.0%	56	0.0%	40	0.0%
18	Staff insurances	2,382	0.8%	11,186	3.8%	0	0.0%
	Total Title 1	**103,651**	35.1%	**110,729**	37.3%	**119,140**	37.0%
	Building/equipment						
20	Investment in immovable property, renting of building and associated costs	30,263	10.3%	22,529	7.6%	21,630	6.7%
21	Information and communication technology	16,522	5.6%	15,502	5.2%	20,692	6.4%
22	Movable property and associated costs	1,337	0.5%	1,284	0.4%	954	0.3%
23	Current administrative expenditure	1,145	0.4%	847	0.3%	1,223	0.4%
24	Postage	108	0.0%	93	0.0%	97	0.0%
25	Other meetings	46	0.0%	152	0.1%	373	0.1%
26	Restaurant and catering	0	0.0%	0	0.0%	751	0.2%
27	Information and publishing	0	0.0%	0	0.0%	1,445	0.4%
28	Business consultancy and audit services	0	0.0%	0	0.0%	5,777	1.8%
	Total Title 2	**49,422**	16.7%	**40,407**	13.6%	**52,942**	16.4%
	Operational expenditure						
300	Meetings	7,993	2.7%	7,924	2.7%	9,349	2.9%
301	Evaluation of medicines	107,952	36.6%	114,509	38.6%	118,692	36.8%
302	Translations	3,742	1.3%	3,759	1.3%	4,483	1.4%
303	Studies and consultants	8,151	2.8%	6,570	2.2%	4,300	1.3%
304	Publications	138	0.0%	152	0.1%	0	0.0%
305	Community programmes	0	0.0%	0	0.0%	0	0.0%
31	Expenditure on business related IT projects	14,106	4.8%	12,962	4.4%	13,197	4.1%
	Total Title 3	**142,082**	48.1%	**145,877**	49.1%	**150,021**	46.6%
	TOTAL EXPENDITURE	**295,154**	100.0%	**297,013**	100.0%	**322,103**	100.0%

[1] as per final accounts of 01/06/2016
[2] as per provisional accounts of 24/01/2017
[3] as adopted by the Management Board on 14/12/2016
[4] the budget nomenclature has changed in 2017 to ensure full comparability with that of the European Commission. The net effect of this change amounts to €849,000 being moved from title I to title II and €6,758,000 being moved from title III to title II

Annex 3: Human resource needs and establishment plan

Category and grade	Authorised for 2015		Occupied as of 31/12/2015			Authorised for 2016		Occupied as of 31/12/2016			Authorised for 2017	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts
				Grade filled	Actual grade				Grade filled	Actual grade		
AD 16	-	0	-	0	0	-	0	-	0	0	-	0
AD 15	-	4	-	3	2	-	4	-	2	1	-	4
AD 14	-	6	-	5	1	-	6	-	6	1	-	6
AD 13	-	9	-	9	10	-	9	-	9	10	-	11
AD 12	-	42	-	41	24	-	42	-	39	27	-	40
AD 11	-	37	-	36	22	-	38	-	37	25	-	40
AD 10	-	40	-	39	33	-	44	-	44	31	-	43
AD 9	-	36	-	36	33	-	37	-	37	35	-	42
AD 8	-	52	-	51	51	-	54	-	54	52	-	53
AD 7	-	52	-	51	50	-	54	-	54	56	-	61
AD 6	-	36	-	36	77	-	37	-	37	74	-	37
AD 5	-	26	-	26	20	-	18	-	18	18	-	3
Total AD	*0*	*340*	*0*	*333*	*323*	*0*	*343*	*0*	*337*	*330*	*0*	*340*
AST 11	-	2	-	2	0	-	2	-	2	0	-	2
AST 10	-	5	-	5	3	-	5	-	5	3	-	6
AST 9	-	7	-	6	2	-	7	-	7	3	-	7
AST 8	-	16	-	16	5	-	16	-	16	4	-	16
AST 7	-	19	-	18	14	-	19	-	17	12	-	19
AST 6	-	39	-	38	19	-	39	-	39	21	-	43
AST 5	-	42	-	42	33	-	43	-	42	30	-	43
AST 4	-	49	-	49	33	-	49	-	49	35	-	52
AST 3	-	43	-	41	65	-	47	-	46	78	-	45
AST 2	-	37	-	37	34	-	32	-	27	34	-	23
AST 1	-	0	-	0	56	-	0	-	0	37	-	0
Total AST	*0*	*259*	*0*	*254*	*264*	*0*	*259*	*0*	*250*	*257*	*0*	*256*
AST/SC1	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC2	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC3	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC4	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC5	-	0	-	-	0	-	0	-	-	0	-	0
AST/SC6	-	0	-	-	0	-	0	-	-	0	-	0
Total AST/SC	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Grand subtotal	*0*	*599*	*0*	*587*	*587*	*0*	*602*	*0*	*587*	*587*	*0*	*596*
Grand total	599		0	587	587	602		0	587	587	596	

Contract agents	2015		2016		2017
	Actual FTE as of 31/12/2015	Actual headcount as of 31/12/2015	Actual FTE as of 31/12/2016	Actual headcount as of 31/12/2016	Planned FTE
FG IV	55	55	55	54	63
FG III	20	18	15	15	17
FG II	81	80	73	74	78
FG I	0	0	0	0	0
Total	156	153	143	143	158

National experts	2015		2016		2017
	Actual FTE as of 31/12/2015	Actual headcount as of 31/12/2015	Actual FTE as of 31/12/2016	Actual headcount as of 31/12/2016	Planned FTE
Total	33	35	36	38	45

Annex 4: Risks

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

- Risk identification: This phase consists of facilitated sessions with all middle and senior managers across all areas of the organisation. In these sessions, managers are asked to identify what they view as the key risks to the Agency achieving its strategic objectives. From these sessions, significant risks are selected for further assessment.

- Risk assessment: In this phase, managers identify the likelihood and potential impact of each of the identified risks.

- Risk mitigation: Based on the results of the assessment phase, primary risk owners for each key risk and its relevant sub-components are identified and potential mitigating activities are documented in accordance with the procedures laid out by the Agency-wide risk management manual.

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

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

The significant risks that could potentially impact achievement of the Agency's objectives and respective mitigating actions and controls that successfully reduce the risks to an acceptable level (those already in place as well as those planned to be implemented in 2017-2018) are outlined in the tables 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 and achievement of its objectives.

Table 1 – Operational activities

Risk	Mitigating actions and controls
Product assessment – procedure management	
Incorrect scientific opinions due to lack of required competences and expertise of experts	In place:
	• Legal requirements regarding expertise and competence
	• Appointment process for CxMP, working party and SAG members
	• Management Board review of CHMP, CVMP and PRAC competencies
	• Criteria for competence and expertise of committee members and alternates for CHMP and PRAC
	• Defined roles and responsibilities of experts and committees
	• Establishment of specialised forums for experts (including SAGs)
	• Proactive search for expertise from academia/learned societies
	• Possibility for expert witnesses having limited controlled role
	• Revised policy on CoI to improve balance between reducing risk for CoI and

Risk	Mitigating actions and controls
	using best available expertise
	• Joint EMA-HMA training strategy

Product assessment – Conflict of interests / independence

Risk	Mitigating actions and controls
NCA experts participating in the assessment work at the level of national agencies influence the outcome due to a failure to disclose conflicts of interests	In place: • Legal requirements for independence • Contractual arrangements and memorandum of understanding with NCAs • Agreement by HMA that EMA standards should be the minimum standards applied at NCAs
Experts attending and providing advice or opinions during EMA committees, working parties and other groups, influence the outcome due to a failure to disclose conflicts of interests	In place: • Legal requirements for independence • EMA code of conduct • Framework for decision-making process at CxMP • Policy on handling competing interests of scientific committee members and experts • Check of interests declared by members and experts participating in meetings • Publication of e-DoIs and e-CVs of committee members and experts on Agency website • Breach-of-trust procedures on conflicts of interests for scientific committee members and experts • Comparing e-CVs and e-DoIs to uncover discrepancies regarding conflicts of interests • KPIs to monitor competing interests declared • Guidance on the handling of declarations of interests in case of a scientific committee member/other (scientific) forum member's intention to become an employee in a pharmaceutical company • Annual review of independence policies • Re-activation of the Declaration of Interests evaluation Advisory group Planned: • Improvements to the Experts database to incorporate DoI evaluation forms and overview of involvement of the experts

Product assessment – Applicant's manipulation of data

Risk	Mitigating actions and controls
Incorrect scientific opinion due to infringement of compliance involving data manipulation by applicant or third party supplying data	In place: • Cross-Agency infringement action group • Increased transparency to third parties through access to documents, encouraging reporting of infringements • Procedures for implementation of Penalties Regulations In progress: • Active publication of clinical-trials data post-authorisation • Policy and procedures for handling whistle-blowers/parties raising concerns • Triage of cases procedure Planned: • Policy and procedures on EMA activities relating to prevention, detection, investigation and action relating to infringement

Inspections

Risk	Mitigating actions and controls
Risk of substandard data and information, and resulting negative impact on the scientific opinions on medicinal products due to non-compliance of third-country companies with EU standards for GMP, GCP, GLP and GVP for centrally and nationally authorised products	**For GCP** In place: • The ICH process • GCP Inspection Policy (expansion of routine inspections for 3rd countries) • Third countries policies/work programmes • EC bilateral relations with other 3rd countries and exchange of inspections information and reports, in particular negative cases • EMA GCP Working Group on acceptability of 3rd country clinical trials established • Guidance on the acceptability of 3rd country clinical trials • International cooperation through training and capacity-building activities

Risk	Mitigating actions and controls
	for inspectors (ongoing activity)
	• EMA-FDA GCP initiative in the area of GCP inspections (ongoing)
	• Request for certain information to applicants through the Q&A of inspections included in the pre-submission guideline
	• Inspection validation of the MAA
	• Reduction of duplication of inspections with consequent resource saving leading to wider range of sites being inspected at global level
	In progress:
	• Informal network of GCP inspectors to enable capacity-building
	For GLP
	In place:
	• The OECD programme
	• Validation process of MAAs feeds into the decision on inspections (site selection)
	• Request for certain information to applicants through the Q&A of inspections included in the pre-submission guideline
	• Promoting the verification of the GLP status of sites at the time of the Clinical trial application rather than MAA.
	For PhV
	In place:
	• The ICH programme
	• Inspection programmes
	• PhV inspectors working group
	• Implementation of new legislation (Regulation (EU) No 1235/2010 and Directive 2010/84/EU)
	• Planned international cooperation
	• International cooperation through training activities
	• Cooperation between EMA and Member States on inspections in 3rd countries
	In progress:
	• Informal network of PhV inspectors to enable capacity-building
Pharmacovigilance	
Lack of additional post-marketing authorisation data on human medicines to proactively identify, qualify and quantify risks	In place:
	• Launch of post-authorisation studies using ENCePP network
	• Independence, transparency and methodological standards of ENCePP studies ensured
	• Implementation of pharmacovigilance legislation (PASS and PAES)
	• 'Best evidence' procedure to support PRAC discussions
	In progress:
	• Longitudinal patient record databases used for EMA studies (in-house and commissioned studies)
	• Registries initiative
	• Real-world evidence monitoring
Inability of the Agency to effectively conduct veterinary pharmacovigilance if suitable IT system is not developed to replace EVVET2	In place:
	• Maintain expertise and knowledge in house to ensure EVVet 2 can continue to operate until a replacement system is developed
	Planned:
	• Replace existing technology for EVVet 2 with more modern technology as a first step to a complete revision/replacement of the system

Table 2 – Support activities

Risk	Mitigating actions and controls
Data management – data protection and security	
Accidental leak of confidential information to external parties by internal employees, interims, trainees or contractors with access to EMA information systems	In place: • IT security policies and strategy implemented and continuously reviewed • Security officer and dedicated information security service • IT tools including adequate security measures to protect confidential data • IT security measures to manage access to data • Declaration of confidentiality and conflicts of interests for staff and for IT contractors • Annual checks to validate the control of access to database by users • Security tools against data leak (EudraLink to secure package, End point security) • USB restriction on laptops Planned: • Security road map project
Intentional leak of confidential information to external parties by internal employees, interims, trainees or contractors with access to EMA information systems	In place: • Policy and procedures in place • Data-access management • Datacentre access limited to relevant resource • Access control lists to restrict contractors' data access; checklist to manage contractors' access to IT systems • Data-encryption tools to allow data transfer between parties outside the EMA network • USB restriction on laptops Planned: • Data logs activated on all systems (where possible) and red flags set up and actively monitored • Proactive markings on sensitive documents • Each new system account given appropriate level of access and necessary access restrictions applied • Access rights reviewed on regular basis to ensure permissions are appropriate
Sensitive and/or confidential data intentionally accessed or removed from EMA premises by external suppliers	In place: • Security awareness training • Code of conduct • CCTV • Access control • Printing control • Confidential waste stored in locked confidential bins Planned: • Guidance on 'clear desk policy'
Financial, legal and reputational damages for the Agency in case of data-protection failure	In place: • Identification of systems to be notified and regular management review • Data protection Regulation (EC) 45/2001 • Data protection implementing rules • Data Protection function within the Agency • Appointment of data protection officer (DPO) • Notification procedures from data controllers to DPO • Notification procedures from DPO to EDPS • Register of data processing in place • Training programme for existing members of staff and new comers • Data protection microsite on intranet • Regular bi-lateral meetings scheduled between Executive director and DPO
Data management – data quality	
Data required for scientific and	In place:

Risk	Mitigating actions and controls
regulatory procedures and decision-making is of poor quality, incomplete, inaccurate and/or lacks integrity	• Validation of data entry in SIAMED and EudraVigilance • Data analytics tool and processes for monitoring data quality • Centralised activity in single department responsible for data governance and information assets In progress: • Data cleaning of existing data to ensure reference quality level • Agency quality standard and reference for data based on ISO standards • Single trusted, identifiable master copies of substances, referentials, organisations and products data available as service • Data cleaning of existing data to bring up to reference quality • Defined roles and responsibilities for all data managers/stewards Planned: • Established Agency quality standard and reference for data based on ISO standards • Single, trusted, identifiable master copies of substances, referentials, organisation and products (SPOR) data available as a service • Data-quality control level based on risk assessment of individual data assets • Data-quality monitoring and data-quality processes • Core data (SIAMED) reports and templates
Data management – document management	
Loss of information due to inadequate document management system and processes	In place: • EMA records-management policy and business classification scheme • Basic back-up procedures undertaken on shared drives, Outlook and document management system • Awareness and training session on document/records management best practices • Procedure on Core Master File Product In progress: • Identification of data-set owners and definition of clear roles and responsibilities Planned: • Records management embedded in redesigned human medicines evaluation processes • Compliance assessment of Agency's document/records management IT systems • Automatic assignment of retention policy and classification • KPIs to monitor compliance with EMA record-management policy • Reporting tools in the document management system to automate monitoring and control measures
IT development and management	
Loss of knowledge due to contractors leaving the Agency	In place: • Reducing reliance on contractors for critical skills and knowledge In progress: • Review of IT operating model to insource further critical skills and knowledge Planned: • Outsourcing less critical skills and services, managed by strict contracts and SLAs • Review of I-Division operating model to insource further critical skills and knowledge
Recruitment	
Staff planning and recruitment do not cover the needs of the Agency in order to achieve its objectives	In place: • The Agency's management meets at least four times a year (quarterly EXB meetings) to identify future competencies needed and adequate staff levels to meet the Agency's objectives. The EXB sets up the resource plan, which is then monitored throughout the year. In addition, other ad hoc meetings are set throughout the year to discuss particular resource needs

Risk	Mitigating actions and controls
	• Two separate reports are downloaded from the SAP HR system with all the staff information and a comparison is done between the reports in order to mitigate any discrepancy on numbers and assure that the Agency does not go above the establishment plan. A separate database with all the staff levels is updated daily. This creates a three-layer system which improves the quality of the data. Afterwards, a monthly report is produced comparing the staff levels expected, the actual staff levels and any deviation from the plan, which then is sent out to the head of Administration division, head of HR, head of Strategic planning & budget and HR business partners • Monthly meetings between the Resource planning coordinator and HR business partners to monitor actual staff levels compared to the plan. These meetings also set the basis for planning of potential resignations, retirements and resource planning for part-time, maternity and unpaid leave covers • Fortnight recruitment planning meetings between Head of Talent Acquisition, Head of HR, Head of Staff Payments Office and HR business partners to go through the recruitment planning • Bimonthly salary budget meetings between Resource Planning Coordinator and Salary officers • Quarterly budget meetings between Resource Planning Coordinator and Budget team • Fortnight meetings between Resource Planning Coordinator and Head of Strategic planning & Budget • Fortnight meetings between Resource Planning Coordinator and Head of Administration
Procurement	
Failure to deliver timely procurement and obtain value for money	In place: • Adequate/realistic planning, based on a solid methodology in order to justify and optimize procurement procedures launched and aligned with budget planning, three years in advance • Clear assignment of responsibilities is defined at the outset of a procurement procedure when defining the business case for capital expenditure. All procurement procedures are performed in close cooperation with procurement control office • Clear definition of needs, including justification (e.g. ex-ante evaluation of needs for new projects or expenditure, a cost/benefit analysis, justification for outsourcing, etc.) • Systematic conduct of a lessons learned exercise at the time when a procurement decision is made. A debriefing is also conducted by procurement control office on any procurement over €60,000 to identify improvements • Regular monitoring of planned deadlines and reporting (e.g. monitoring tools in place, deadline management, quality assurance, etc.) • Review of procurement planning carried out at least quarterly, follow ups if needed • Procurement procedures included in the scope of the enhanced ex post controls under Article 46 of the Financial regulation
Finance - Revenue collection and Treasury management	
Loss on currency exchange rate fluctuations	In place: • Hedging/other exchange mechanisms • Forward exchange contracts • Treasury policy • Minimum cash flow level kept • Subsidy claimed only as required • Regular meetings with treasure committee
Clinical data publication	
Non-compliance of	In place:

Risk	Mitigating actions and controls
MAHs/pharmaceutical industry with the policy	• Information sessions with industry • Consultation with stakeholders • Issuing of non-compliance statements Planned: • Targeted consultations with stakeholders • Annual report on implementation experience, including non-compliance data
Stakeholder relationships	
Failure to meet stakeholder expectations	In place: • Framework for interaction with patients and consumers • Frameworks for interaction with healthcare professionals • Framework for interaction with academia • SME surveys and other initiatives • Communication perception surveys • Targeted stakeholder meetings • Tools including website/media monitoring/google alerts In progress: • Framework for interaction with industry stakeholders Planned: • Online programme

In light of the outcome of the UK referendum on the EU membership, the Agency is conducting impact and risk assessment. Along other aspects, the main risks identified are as follows:

| Risk	Impact
Loss of UK expertise in the scientific work	UK experts constitute 15% of the Agency's expert base and conduct around 20% of the scientific work. Losing these resources will lead to - Significant increase in workload for EU experts, requiring remedial actions to address workload and capacity aspects - Potential loss of specific expertise, requiring remedial actions to ensure that the quality of scientific output is not affected
Loss of existing staff and inability to recruit new staff, resulting in loss of professional competencies and knowledge	Due to high uncertainty, - Current EMA staff may choose to leave Agency for other organisations in order to re-acquire longer term stability and perspective - The Agency is not able to provide longer term stability when recruiting new employees, and as such may fail to attract competent experts to fulfil In case the Agency would need to relocate, some staff will not be willing to relocate and the Agency may face significant loss of staff/expertise once the new seat becomes know.
Currency volatility	High fluctuations of GBP to EUR exchange rate introduce instability in the Agency's cash flow and budget.

Annex 5: Procurement plan 2017

Activity statement:	**Software for Innovation, Diversity and Evolution**
Objective:	See Work programme 2017, heading 4
Budget:	€ 19,000,000 of which €3,500,000 operational and €15,500,000 administrative
Financial year:	2018-2022
Description of action:	Inter-institutional tender procedure to be run by European Commission (DIGIT) for software purchases
Type of contract:	European Commission tender procedure, Framework Contract implemented by Specific Contracts and Purchase Orders
Number of contracts:	1
Indicative timeframe for contract:	Expected to be signed in 2018
Indicative timeframe for procurement:	Expected to be launched in 2017
Indicative budget for procurement:	€ 19,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2110, B2114, B3105

Activity statement:	**Consultancy services to support the Agency's on-line communications activities**
Objective:	See Work programme 2017, heading 4
Budget:	€ 3,000,000
Financial year:	2018-2022
Description of action:	Consultancy services to support the Agency's on-line communications activities
Type of contract:	Framework contract to be implemented by Specific Contracts
Number of contracts:	1 Framework contract
Indicative timeframe for contract:	Expected to be signed in 2017
Indicative timeframe for procurement:	Expected to be launched in 2017
Indicative budget for procurement:	€ 3,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3105

Activity statement:	**Effectiveness and pharmacoepidemiology studies**
Objective:	See Work programme 2017, heading 1.5
Budget:	€ 10,500,000
Financial year:	2017-2021
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:	Service framework contract with re-opening of competition
Number of contracts:	5
Indicative timeframe for contract:	Expected to be signed in 2018
Indicative timeframe for procurement:	Expected to be launched in 2017
Indicative budget for procurement:	€ 10,500,000
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:	B3030

Activity statement:	**Effectiveness and pharmacoepidemiology studies**
Objective:	See Work programme 2017, heading 1.5
Budget:	€ 1,500,000
Financial year:	2017
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 6
Indicative timeframe for contract:	Expected to be signed in 2017 (approx. 12-18 months each)
Indicative timeframe for procurement:	Expected to be launched in 2017
Indicative budget for procurement:	€ 1,500,000
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:	B3030

Activity statement:	**Hotel service provider**
Objective:	See Work programme 2017, heading 3.1
Budget:	€ 16,300,000
Financial year:	2017-2021
Description of action:	Contract with a hotel service provider to book hotel rooms worldwide for delegates and staff members attending meetings, training sessions and missions
Type of contract:	Service contract with opening tender procedure
Number of contracts:	1
Indicative timeframe for contract:	Expected to be signed in 2017
Indicative timeframe for procurement:	Expected to be launched in 2017
Indicative budget for procurement:	€ 16,300,000
Legal basis:	Articles 56 and 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3000, B1300, B3003

Activity statement:	Travel management company
Objective:	See Work programme 2017, heading 4
Budget:	€ 12,000,000 over 4 years, of which € 10 million operational and € 2 million administrative
Financial year:	2017-2021
Description of action:	Selection of a travel management company to provide travel services for staff members, delegates and candidates attending meetings inside and outside the Agency's premises
Type of contract:	Service contract
Number of contracts:	1
Indicative timeframe for contract:	Commencing in 2017
Indicative timeframe for procurement:	Q1 2017
Indicative budget for procurement:	€ 12,000,000 over 4 years
Legal basis:	Articles 56 and 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B1300, B1850, B3000, B3003

Activity statement:	Scientific e-learning for EMA staff and EU Network Training Centre
Objective:	See Work programme 2017, heading 3.3
Budget:	€ 360,000 over 4 years, of which € 288,000 operational and €72,000 administrative
Financial year:	2016 - 2020
Description of action:	Scientific learning and e-learning for EMA staff and EU Network Training Centre
Type of contract:	Framework contract
Number of contracts:	2
Indicative timeframe for contract:	Commencing in 2017
Indicative timeframe for procurement:	Expected to be launched in 2017, as per DG HR timetable
Indicative budget for procurement:	€ 360,000 over 4 years
Legal basis:	Article 24a of Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and Council Regulation (EC) No 726/2004
Budget line:	B1120, B3003

Annex 6: Organisational chart

EMA organisational chart as of 31/12/2016.
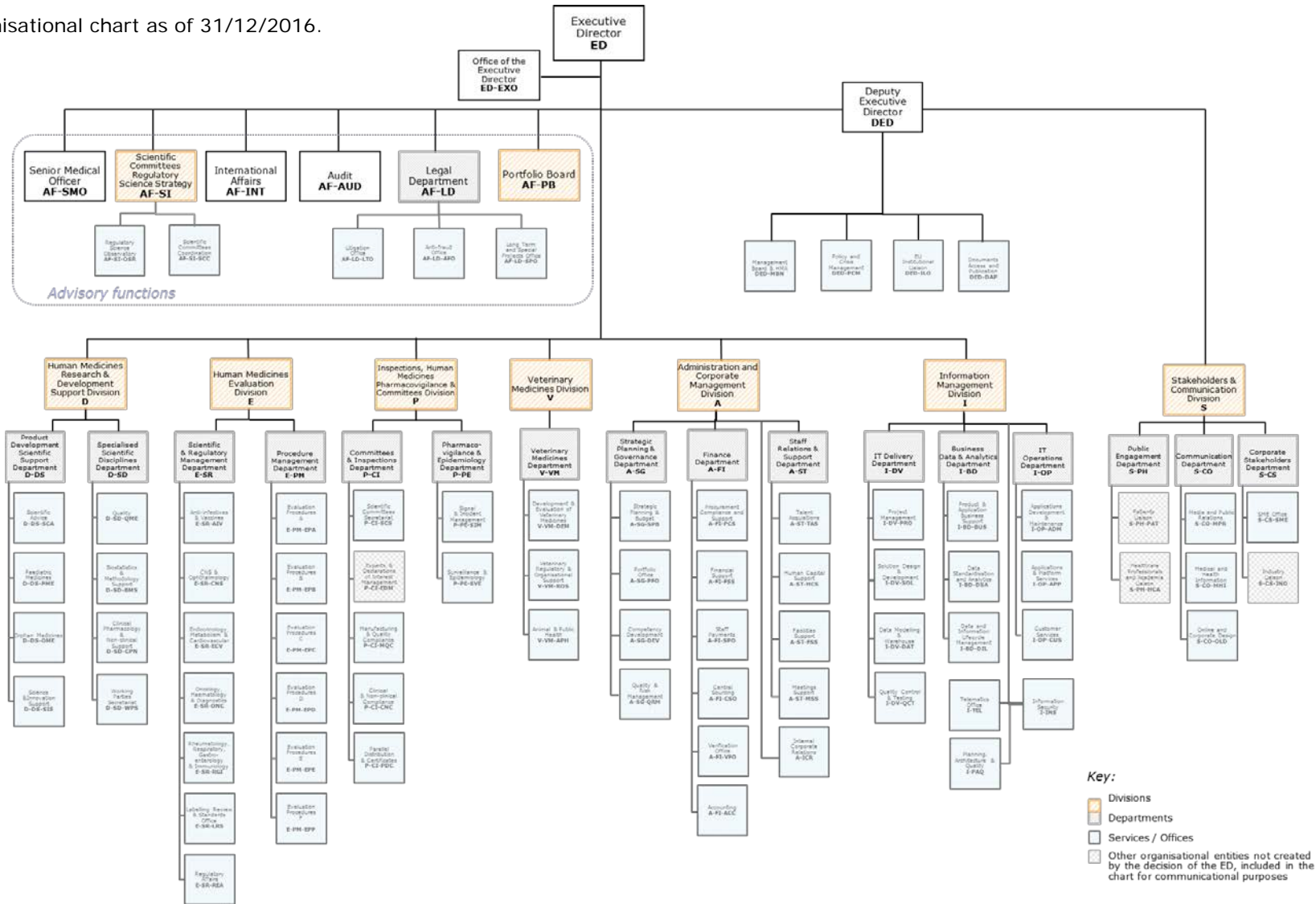
Annex 7: Terms and abbreviations

Term/abbreviation	Definition
3Rs	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
AD	administrator category post
ADAPT SMART	Accelerated development of appropriate patient therapies: a sustainable, multi-stakeholder approach from research to treatment-outcomes; a European public-private collaboration
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
AER	adverse event report
Agency	European Medicines Agency
AMR	antimicrobial resistance
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
BEMA	benchmarking of European medicines agencies
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
CCTV	closed-circuit television, video surveillance system
CESP	Common European eSubmission Platform
CHMP	Committee for Medicinal Products for Human Use
CHMP ORGAM	virtual meeting held to discuss CHMP organisational matters
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CO_2	carbon dioxide
CoI	conflict of interest
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
CVMP	Committee for Medicinal Products for Veterinary Use
CxMP	scientific committee(s) of the Agency
(DG) DIGIT	European Commission's department for informatics
DoI	declaration of interests
DPO	data protection officer
eAF	electronic application form
eCV	electronic Curriculum Vitae
EC	European Commission
ECD	Eudra Common Directory
ECHA	European Chemicals Agency
eCTD	electronic common technical document
ECDC	European Centre for Disease Prevention and Control
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
EFTA	European Free Trade Association

Term/abbreviation	Definition
EMA	European Medicines Agency
EMAS	EU Eco-Management and Audit Scheme
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
eRMR	electronic reaction monitoring report
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
EudraMail	European Union Drug Regulating Authorities email services
EudraNet	European Union Drug Regulating Authorities secure Network for the EU regulatory network
EudraPharm	European Union Drug Regulating Authorities Pharmaceutical Database
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EUnetHTA	European network for health technology assessment
EURD list	EU reference dates, list of active substances and combinations of active substances contained in medicinal products subject to different marketing authorisations, together with the corresponding EU reference dates, frequencies for submission of PSURs and related data lock points
EUTCT	EU Controlled Terminology
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVVet	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance - veterinary
EXB	EMA Executive Board
FDA	United States Food and Drug Administration
FG (I, II, III, IV)	function group (for contract agent staff)
FP-7	7th Framework programme, EU research and innovation funding programme for 2007-2013
FTE	full-time equivalent
G8	Group of Eight – group of eight highly industrialized nations – France, Germany, Italy, the United Kingdom, Japan, the United States, Canada, and Russia
GAAD	Global Action Against Dementia
GCP	good clinical practice
GL	guideline
GLP	good laboratory practice
GMP	good manufacturing practice
GMDP	good manufacturing and distribution practice
GMDP IWG	good manufacturing and distribution practice inspectors working group
GP	general practitioner
GVP	good pharmacovigilance practice
GxP	good practice (clinical, laboratory, manufacturing, distribution, pharmacovigilance etc)
HCIN	Heads of Communication and Information Network (of EU agencies)
HCP	healthcare professional
HL7	Health Level 7
HMA	Heads of Medicines Agencies
Horizon 2020	EU framework programme for research and innovation for 2014-2020
HR	Human Resources
HMPC	Committee on Herbal Medicinal Products
HTA	health technology assessment
HTAN	Health Technology Assessment Network
ICH	International Council for Harmonisation of Technical Requirements for

Term/abbreviation	Definition
	Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	individual case-safety report
ICT	information and communication technologies
IDMP	Identification of Medicinal Products
IGDRP	International Generic Drug Regulators Programme
IMI	Innovative Medicines Initiative
IPRF	International Pharmaceutical Regulators Forum
IRCH	International regulatory cooperation for herbal medicines
IRM	Institute of Risk Management
IT	information technology
ITF	EMA Innovation Task Force
ISO	International Organisation for Standardisation
KPI	key performance indicator
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
MAWP	EMA multiannual work programme
Member State (MS)	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MLM	medical literature monitoring
MNAT	multinational assessment team
MRL	maximum residue limit
MUMS	minor use, minor species products
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
Network strategy	EU Medicines Agencies Network Strategy to 2020
NTC	EU Network Training Centre
NUI	non-urgent information
OECD	Organisation for Economic Cooperation and Development
OIE	World Organisation for Animal Health
OMCL	Official Medicines Control Laboratories
P3i	EMA methodology for portfolio, programme and project management methodology and ITIL (Information Technology Infrastructure Library, set of IT service management practices)
PA	protocol assistance
PAES	post-authorisation efficacy study
Parliament	European Parliament
PAS	Post Authorisation Studies
PASS	post-authorisation safety study
PCO	patients'/consumers' organisation
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIC/s	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency, Japan
PMF	plasma master file
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

Term/abbreviation	Definition
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
SAP	"Systems, Applications & Products", enterprise software to manage business operations and customer relations
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
SPOR	'substances, products, organisations, referentials data' project, now split into projects on 'referentials management service', 'organisations management service' and 'substances and products management services'
STAMP	EC Expert Group on Safe and Timely Access to Medicines for Patients
SWP	Safety Working Party
Strategy	EU Medicines Agencies Network Strategy to 2020
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TGA	Therapeutic Goods Administration, Australia
UEMO	European Union of General Practitioners, organisation for general practitioners and specialists in family medicine in Europe
UK	United Kingdom
US	United States of America
USB	USB flash drive, a data storage device
VAR	variance
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
(Web-)RADR	Recognising Adverse Drug Reactions
WGEO	Working Group of Enforcement Officers of the HMA
WHA	World Health Assembly
WHO	World Health Organization
WONCA	World Organization of Family Doctors
WP	working party