5 July 2016
EMA/92499/2016 Rev. 1[1]
Executive Director

Work programme 2016

[1] Procurement plan added (annex 5)

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Mission

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

Legal role

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

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

Principal activities

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

- provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;
- applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;
- implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;
- provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;
- involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- publishes impartial and comprehensible information about medicines and their use;
- develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level.

Guiding principles

- We are strongly committed to public and animal health.
- We make independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in our field.
- We support research and innovation to stimulate the development of better medicines.
- We value the contribution of our partners and stakeholders to our work.
- We assure continual improvement of our processes and procedures, in accordance with recognised quality standards.

- We adhere to high standards of professional and personal integrity.
- We communicate in an open, transparent manner with all of our partners, stakeholders and colleagues.
- We promote the well-being, motivation and on-going professional development of every member of the Agency.

Table of contents

Structure of the work programme 2016

The 'Work programme 2016' is a reflection of the European Medicines Agency's (EMA) priorities and main focus areas for 2016, and describes the objectives and activities planned for 2016. 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 2016.
- **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 2016, 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 2016 is 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.

EMA priority areas and key influences

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, the EMA works closely with the NCAs. This means the environment trends, workload forecasts and implementation of a number objectives and activities described in this programming document will also impact the national authorities and their work, as well as require their input and support.

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

Evolving workload

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 shows positive trends over the last years. In 2016, the Agency will start providing early and enhanced scientific and regulatory support to medicine developers through the priority medicines scheme (PRIME).

The Agency is finalising implementation of the pharmacovigilance legislation in 2016-2017. Several new tasks have started only in 2015 or are still to commence. Among these are the introduction of single assessment for nationally authorised products (PSUSA) in 2015, the upcoming implementation of public hearings, and management of signals submitted by the pharmaceutical industry from 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. Once the necessary systems are developed and the Regulation comes into application, 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 next years, with the legislation becoming applicable no sooner than 2019. Until then, the Agency will focus on ensuring that the existing legal framework is used as effectively as possible and carry out the necessary preparations for the entry into effect of the revised legislation.

Scientific advancement and changing scene of medicines development

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

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 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 an increasing number of small or medium-sized enterprises (SMEs) undertaking the early stages of medicines development. Reinforcing the support to SMEs to facilitate navigation of the EU regulatory system and simplifying the Agency's approaches, making them more open, flexible and easier to navigate, will be key to ensuring more prospective medicines reach patients in such an environment.

Timely access to promising medicines

The ever-increasing expectations of patients 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, requires exploring flexible licencing pathways and a lifespan approach to medicines. Hence, the main focus areas of the Agency in this respect will include improving utilisation of existing regulatory tools, such as conditional marketing authorisation and accelerated assessment procedures, looking at ways to optimise development pathways and implementing the new priority medicines scheme (PRIME). 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.

Considering the role of health technology assessment (HTA)/pricing and reimbursement bodies in getting innovative medicines to patients, exploring potential synergies and extending and strengthening collaboration with HTA bodies to exchange information around the time of licencing will be another key focus area for the Agency and the NCAs.

Globalisation

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.

Addressing public-health priorities

Antimicrobial resistance (AMR) is a growing issue for both humans and animals. The severity of the issue is also recognised by the development of a global action plan for AMR by the World Health

Organization (WHO), thus highlighting AMR as a global health crisis of similar importance to infectious-disease pandemics. 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, to the transatlantic and WHO initiatives, adopting the 'one health' approach, 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.

Alongside old problems such as antimicrobial resistance, new diseases and issues emerge. 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, identify priority research areas in paediatrics 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.

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. 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. Finally, 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.

Stakeholder involvement and transparency

With a multitude of stakeholders involved from the early stages of development through to patients accessing and using the medicines, the Agency continuously works to interact with and involve stakeholders in the regulatory processes in the best ways possible. This includes development and implementation of frameworks for stakeholder interaction, capturing patient values and preferences in benefit-risk assessment of medicines, implementing public hearings, conducting surveys to better understand and be able to meet stakeholder needs and expectations, and continued cooperation with other EU agencies in the areas of common interest.

Patients, consumers 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. Hence, transparency is one of the Agency's top priorities. Implementation of the policy on publication and access to clinical data will be a significant aspect of the Agency's transparency initiatives in 2016.

Improving the quality and efficiency of regulatory work

Efficiency is the key to sustainable delivery of regulatory activities and to coping with increasing responsibilities, volumes and complexity of 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. The 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 are expanding the responsibilities of medicines regulators in Europe.

The Agency will continue improving internal processes and implementing its process-performance management system to further increase efficiencies and optimise operations. As part of supporting the work of the NCAs, the Agency will deliver telematics systems, both to implement legal requirements and help achieve operational excellence, facilitate capacity-building through the Network Training Centre, and support work-sharing in various domains.

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 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 countries with less developed systems.

[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

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 (MSWG), 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 is expected 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 availability of the required expertise will therefore be important.

The face of the pharmaceutical industry is changing, with an increasing number of small or medium-sized enterprises undertaking the early stages of new medicines development. Ensuring more prospective medicines reach their patients in such an environment requires adapting and simplifying our processes and approaches, making them more open, flexible and easier to navigate for the sponsors, especially SMEs.

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.

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, infectious diseases and psychiatric disorders, those affecting the elderly and neonates, and pregnancy-related conditions.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Scientific advice/protocol assistance pre-submission meetings	137	89	180
Scientific-advice and protocol-assistance requests, of which:	551	510	546
Parallel scientific advice with international regulators requests	2	3	6
Joint scientific advice with HTA bodies requests	11	30	33
Post-authorisation scientific advice	122	89	115
PRIME procedures involving SAWP			25
Protocol assistance	113	137	141
Novel technologies qualification advice/opinions	22	20	25
PRIME applications			120
Scientific advice finalised	432	386	393
Protocol assistance finalised	101	139	178
Orphan medicines applications, of which:	329	240	330
Parallel orphan applications with international regulators	109	86	100
Submitted applications on the amendment of an existing orphan designation	0	1	5
Oral explanations for orphan designation			90
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	485	515	500
Finalised procedures for compliance check on PIPs	85	67	85
Annual reports on paediatric deferred measures processed	157	172	170
EMA paediatric decisions processed	344	350	350
Requests for classification of ATMPs	28	61	25
Innovation Task Force briefing meetings requests	28	34	42
Innovation Task Force Art 57 CHMP opinion requests	5	0	4

Performance indicators

	Results		Targets
	2014	2015	2016
Scientific advice/protocol assistance procedures completed within regulatory timeframes	99%	100%	100%
Orphan designation opinions delivered within the legal timeframe		100%	100%
PDCO opinions sent to applicants within legal timelines	99.7%	99.7%	100%
Increase in scientific-advice requests	17%	-8%	10%
SME requests for SA (% of total SA requests)		32%	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:

Objective	Activity
Provide high quality, efficient and consistent support to medicines development	Develop and implement best practices for significant benefit in protocol assistance letters
	Organise workshop for the Network and EMA on the definition of orphan condition
	Revise collaboration between SAWP and SWP to focus it on the most relevant issues for expert input
Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product lifecycle	Draft recommendation documents/white papers and provide regulatory input to the methodology and outcomes of the selected four IMI Get Real Consortium case studies
	Implement a collaboration framework with HTAs with regards to the maintenance of orphan status at the time of marketing authorisation application
Facilitate research and development of new medicines	Identify areas in need of further research and communicate it to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects
	Develop a triage process to increase effectiveness of selection and coordination of EMA involvement in various research activities, including IMI
	Develop business forecasting and analysis tools to enhance availability of information on prospective developments of medicines
	Identify recurring questions in areas of highest potential benefit from science and innovation and develop the relevant Q&A or regulatory guidance documents
	Develop and implement an scheme to provide reinforced regulatory and scientific advice to priority medicines from early stages of the development
	Organise workshop on development of orphan medicinal products for academic researchers
	Support scientific committee discussions on PrEP (pre-exposure prophylaxis) to combat HIV infection
	Strengthen the collaboration and integration across the Network and with academia to facilitate the translation of innovation into medicinal products, including through the work undertaken by the Innovation Network
	Organise workshops with key opinion leaders and innovators, and involving NCAs, to address specific areas for innovation
Support development and availability of medicines for specific target groups	Implement EMA geriatric medicines strategy
	Finalise 10-year report to the Commission on the implementation of the Paediatric Regulation. Identify activities to increase compliance and results
	Provide recommendations to the Commission on priority areas for research in paediatrics, in line with the objectives outlined in the Horizon 2020 strategy
	Develop with the FDA regulatory science approaches for paediatric diseases (including rare diseases), including finalise joint guidance document for Gaucher disease and formally implement TIGRE
	Establish Early interaction on paediatric development
	Conduct open regulatory sessions on Alzheimer's disease in academic settings, including a follow-up session at the ECNP congress
	Promote data-sharing from applicants with failed Alzheimer trials, in order to explore pitfalls and opportunities
	Develop a regulatory framework for extrapolation across age groups, supporting informed and efficient drug development
Optimise use of existing regulatory framework for early access to	Coordinate review of guideline on conditional marketing authorisation and update of existing guidance documents (Q&As) on conditional marketing

Objective	Activity
medicinal products	authorisation
	Review experience gained with compassionate use procedure at the EU level and identify aspects to optimise use of this procedure through review of existing guidance
	Provide technical support to the EC in relation to optimisation of existing regulatory framework, including development and/or implementation of new or amended laws and regulations
	Develop implementation strategy on companion diagnostics legislation and related guidance documents for the industry
	Conduct joint-reviews and participate in other support activities with WHO and regulators from LMICs on regulatory aspects related to vaccines and treatments for neglected diseases
Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	Hold early flexible brainstorming discussions with applicants and other stakeholders to explore adaptive ways to optimise development pathways and accelerated patients' access to medicines
	Reinforce early dialogue with HTAs through existing procedures and finalize guidance for parallel SA with HTAs
	Implement regulatory advice to promising medicines benefiting from PRIME scheme from early stages of the development
	Lead and coordinate EMA's input into and engagement with HTA Joint Action 3
	Provide scientific leadership to the ADAPT-SMART project

Resources

	2016
Financial resources (cost, thousand Euro)	41,627
Human resources (FTEs)	93

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 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; and scientific guidelines are developed to guide applicants with regard to the requirements for demonstrating quality, safety and efficacy of a medicine.

This scientific review is documented in an assessment report, which is made publicly available as a European public assessment report (EPAR).

Drivers

The complexity of the regulatory system, where marketing authorisation is just one of the steps on the medicine's path to patients, requires a coordinated path towards robust and sound outcomes. The need to consider the involvement and requirements of other stakeholders leads to increased cooperation with other stakeholders and decision-making bodies, such as 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 arising public-health threats, highlight the importance of ensuring 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, will be reviewed.

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
Number of MAA pre-submission meetings			50
Initial evaluation applications, of which:	100	111	110
New non-orphan medicinal products	38	36	46
New orphan medicinal products	21	25	24
Similar biological products	3	12	8
Generic, hybrid and abridged products	37	37	31
Scientific opinions for non-EU markets (Art 58)	1	1	1
Paediatric-use marketing authorisations	0	1	1
Number of clarification meetings during MAA evaluations			35
Number of granted requests for accelerated assessment			18
Number of consultations of SAGs / Ad-hoc expert groups in the			15

	Results		Forecasts
	2014	2015	2016
context of MAAs			
Reviews on the maintenance of the orphan designation criteria at MAA stage			35

Performance indicators

	Results		Targets
	2014	2015	2016
Applications evaluated within legal timeframes	100%	100%	100%
Average assessment time for new active substances and biosimilars		200.7	205
Average clock-stop for new active substances and biosimilars		138.4	180
Labelling review of the English product information Annexes for new MAAs and line extensions by Day 10 and Day 140 of the evaluation process			90%
% of requests granted for accelerated assessment			70%
% of MAAs initiated under accelerated assessment that have been completed as accelerated assessment			70%
% of initial marketing authorisation applications (orphan/non-orphan/biosimilar) that had received centralised scientific advice		82%	75%

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:

Objective	Activity
Provide high quality, robust, scientifically sound and consistent scientific assessments of marketing authorisation applications	Consolidate use of patients' preferences in benefit-risk assessment for initial marketing authorisation application
	Discuss with HTA bodies the use of and experience with the effects tables, identifying improvement opportunities
	Organise workshops to identify areas for improvement in the assessment reports and develop tool-kit for improvement of quality, consistency and robustness of benefit-risk assessments
	Develop and implement a specific benefit/risk guidance to support evaluation of biosimilar medicines
	Implement and monitor provision of early background summaries
	Improve the tools (guidance, templates, databases) available to assessors and EMA staff supporting scientific evaluation activities of the committees
	Review and optimise conduct of pre-submission meetings to improve support for the later evaluation process
	Develop guidance to ensure early availability of core (overview) document to deliver high quality assessment report in the area of quality of medicines
	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
	Strengthen the support in clinical pharmacology aspects to the centrally

Objective	Activity
	authorized products along their life-cycle with special focus on innovative medicines including GMOs
	Coordinate and develop the capability of the network in the area of new methodological approaches to clinical trials
Ensure and run highly effective and efficient processes to deliver initial evaluation activities	Implement process performance management system with strong customer focus on quality, simplification and regulatory procedural excellence
	Develop and improve guidance and provide internal training to ensure regulatory procedural consistency
	Establish internal system of knowledge sharing with the aim of providing consistent regulatory advice to the NCAs and MAHs
	Identify improvement opportunities and optimise regulatory procedures supporting initial evaluation
	Develop and implement complexity-based approach to handling generic product applications
	Develop regular interactions with industry focusing on centralised procedure and engage with industry in optimising operations of the evaluation activities
Provide high quality, robust, scientifically sound and consistent product information	Develop and maintain guidance and other tools (training material, checklist, metrics or labelling review guide) supporting SmPC review
	Develop tools for improved oversight of labelling development during the lifecycle, supporting consistent and evidence-based reviews
	Monitor implementation of the new labelling review process to ensure scientific committees' labelling review is based on evidence from the scientific review
	Update internal reflection paper describing elements to consider when assessing the “therapeutic indication”
	Analyse external requests regarding the contents of approved SmPC and provide consistent response
	Review the use of patient reported outcomes in approved SmPCs and develop guidance, based on the outcomes of the review
	Provide technical and scientific support of review safety concern of excipients and their appropriate labelling
Reduce time-to-patient of medicines through use of existing and new assessment approaches within existing legal frameworks, including through collaboration with international partners	Analyse application of accelerated assessment, including acceptance outcomes and reasons for changing from accelerated to standard review
	Develop and implement a framework to provide CHMP assessment reports to HTA bodies
	Support activities stemming from Joint Action 3, to facilitate provision of relevant information from regulatory assessment to HTA bodies for relative effectiveness assessments
Improve knowledge on the risks of medicinal products' use for the environment	Revise Safety working party guideline on environmental risk assessment for human medicinal products

Resources

	2016
Financial resources (cost, thousand Euro)	34,312
Human resources (FTEs)	79

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.

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
Variations applications, of which:	6,006	5,999	5,555
Type-IA variations	2,969	2,864	2,665
Type-IB variations	1,886	1,980	1,913
Type-II variations	1,151	1,155	977
Line-extensions of marketing authorisations	16	14	20
PASS scientific advice through SAWP			30
Number of consultations of SAGs / Ad-hoc expert groups in the context of post-authorisation activities			5

	Results		Forecasts
	2014	2015	2016
Renewal applications			85
Annual reassessment applications			26
Transfer of marketing authorisation applications			25
Article 61(3) applications			190
Post Authorisation Measure data submissions			900
Plasma Master File Annual update and variation applications			20

Performance indicators

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

Additional objectives and activities

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

Objective	Activity
Provide high quality, robust, scientifically sound and consistent scientific assessments of post-authorisation changes to marketing authorisations	Explore opportunities for peer review in later phases of the MAA review process and in case of substantial changes to the marketing authorisation
	Streamline and coordinate the clinical pharmacology support to centrally authorised products along their life-cycle
	Develop and improve guidance and provide internal training to ensure regulatory procedural consistency
	Develop a process for monitoring the fulfilment of specific obligations for conditional marketing authorisations to ensure timely switch to full marketing authorisation
	Establish internal system of knowledge sharing with the aim of providing consistent regulatory advice to the NCAs and MAHs
Further promote use of scientific advice throughout the lifecycle of the product, including further development of authorised medicines (e.g. extensions of indications, post-authorisation safety and efficacy studies)	Analyse the impact of scientific advice on the likelihood of obtaining a positive opinion for extensions of indications
	Implement procedure for non-imposed PASS through the SAWP and finalise guideline on PAES
Ensure and run highly effective and efficient processes to deliver post-authorisation activities	Implement framework to monitor implementation of imposed PAES
	Implement process performance management system with strong customer focus on quality, simplification and regulatory procedural excellence
	Conduct surveys and meetings with NCAs to capture satisfaction level and improvement opportunities in handling procedures for CAPs and NAPs

Resources

	2016
Financial resources (cost, thousand Euro)	91,541
Human resources (FTEs)	88

1.4. Referrals

Activity area

Referrals are initiated regarding 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. However, there are at present no varying events to justify an increase, so numbers are expected to 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 seen as value added, and will continue to be sought where applicable to best inform these decisions.

Workload indicators

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

Performance indicators

	Results		Targets
	2014	2015	2016
Referral procedures managed within the legal timelines	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:

Objective	Activity
Provide high quality, robust, scientifically sound and consistent scientific assessments of referrals	Develop and improve guidance and provide internal training to ensure regulatory procedural consistency
Ensure and run highly effective and efficient processes to deliver assessment of referrals	Implement process performance management system with strong customer focus on quality, simplification and regulatory procedural excellence
	Conduct surveys and meetings with NCAs to capture satisfaction level and improvement opportunities in handling procedures for CAPs and NAPs

Resources

	2016
Financial resources (cost, thousand Euro)*	3,322
Human resources (FTEs)*	13

* Excludes resources related to pharmacovigilance referrals.

1.5. Pharmacovigilance 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

The final elements of the pharmacovigilance legislation will be implemented through 2016 and 2017. As a result of full implementation of the legislation, the coordinating role of the Agency in the monitoring of all EU medicines, irrespective of their route of authorisation, will increase, and with it, the scope of EMA responsibilities in the pharmacovigilance field. This means the volume of data and information, as well as number of safety issues to be managed and procedures run, will increase significantly over the next few years. For example, PSUR procedures are forecast to increase up to 776 in 2016, which constitutes a significant workload for the network and EMA committees, as well as procedure management. In addition, the introduction of the single assessment for nationally authorised medicines in 2015 has shifted the focus of these procedures, highlighting the complexity of assessing such safety information.

Availability of new IT tools and functionalities, in combination with implementation of the results of regulatory science projects (notably EU PROTECT and ADVANCE), will allow improvements to be made in the efficiency and effectiveness of pharmacovigilance.

The ever-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 for generation of additional scientific evidence to supplement the contribution of the pharmaceutical industry and to support decision-making of the EMA scientific committees. At the same time, this also demands that surveillance methods evolve to accommodate these developments. Thus, the need to strengthen the science and evidence base for pharmacovigilance through the product lifecycle is recognised as a focus area through 2016.

Linked to the demand for transparency and information, society wants to see the outcomes of pharmacovigilance, from publication of reported suspected adverse reactions, through to labelling changes and demonstration, in selected cases, of the impact on prescribing and health outcomes.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Number of signals peer-reviewed by EMA	2,030	2,372	1,800
Number of signals validated by EMA	34	61	35
PSURs (standalone CAPs only) started	520	512	566
PSUSAs started		268	210
Number of imposed PASS protocol procedures started	32	31	40
Number of imposed PASS result procedures started		2	20
Number of emerging safety issues received		34	35
Number of notifications of withdrawn products received		160	165
Cumulative number of products on the list of products to be subject to additional monitoring		261	321
Number of Incident Management Plans triggered			4
Number of non-urgent information (NUI) or Rapid Alert (RA) notifications submitted through EPITT			64
Number of external requests for EV analyses			60
Number of MLM ICSRs created			5,800

Performance indicators

	Results		Targets
	2014	2015	2016
Periodic Safety Update Reports (PSURs standalone CAPs only) assessed within the legal timeframe		100%	100%
Periodic Safety Assessment Reports (PSUSAs result procedures) assessed within the legal timeframe		98.5%	95%
Protocols and reports for non-interventional imposed post-authorisation safety studies assessed within the legal timeframe	100%	98.4%	100%
Reaction-monitoring reports supplied to the lead Member State monthly	100%	100%	100%
PRAC recommendations on signals and translation of labelling changes in EU languages published			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:

Objective	Activity
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes and services	Coordinate collection and analysis of data to measure pharmacovigilance impact
	Finalise update of the GVP module V on Risk management systems and the revision of the marketing authorisation holders' template for Risk management plan

Objective	Activity
	Draft and implement GVP on pregnancy, to enhance drug safety in pregnancy consideration across a product's lifecycle
	Conduct public consultation on GVP module on biological medicines and on updates for ADR reporting and signal management
	Finalise draft proposals on governance and code of conduct for vaccine benefit risk studies from the ADVANCE project
	Develop and integrate a sustainable process to collect information on clinical use, based on the experience gained and on collaboration with NCAs and academics
	Organise follow-up workshop on medication errors. Revise as necessary the guidance and Q&As on medication errors
	Conduct a dry run and implement public hearings in PRAC
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	Finalise and publish revised guidance for signal detection methods
	Organise 2nd workshop with stakeholders to review interim WebRADR project deliverables and obtain feedback on recommendations of the draft policy on the use of social media and other tools in ADR reporting
	Finalise operational aspects for the registries strategy, to support decision making
	Finalise a proposal for an integrated system for management of notifications and alerts
	Develop a new process for reception, prioritisation, assessment and action of signals detected by MAHs
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	Publish annual report on EudraVigilance
Provide high quality, robust, scientifically sound and consistent post-authorisation scientific assessments	Implement improved scientific support to imposed and non-imposed PASS protocol review
	Develop guidance on PASS and complete reflection on the use of registries for regulatory purposes

Resources

	2016
Financial resources (cost, thousand Euro)*	40,979
Human resources (FTEs)*	114

* 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 in exploring opportunities for new and effective anti-infective treatment options to overcome the problem of antimicrobial resistance. Work in this field is done in regard to both human and veterinary medicines.
- **Influenza-pandemic preparedness**. The 2009 influenza pandemic led to a review of the cross-European strategy for pandemic preparedness. The Agency continues to implement actions to improve pandemic preparedness, in collaboration with NCAs and the EC.

Drivers

Increasing globalisation of the conduct of clinical trials drives the need to ensure these are carried out to a certain standard. 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. During 2016 and 2017 the Agency will finalise development of the EU portal and database and other functionalities that will allow the Regulation to become applicable.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Herbal monographs, new	11	14	10
Herbal monographs, revised	5	3	15
List entries	1	0	1

Performance indicators

	Results		Targets
	2014	2015	2016
n/a			

Additional objectives and activities

Objective	Activity
Implement the new Clinical Trials Regulation (EU) No 536/2014	Review existing and prepare new procedures and guidance documents supporting full implementation of the Clinical Trial Regulation
Support high level of coordinated cross-European preparedness to act upon public health threats	Interact with ECDC and VE to develop new platform for influenza vaccines effectiveness
	Continue discussion with ECDC and EC on development of sustainable framework for vaccines benefit risk monitoring in the EU
	Deliver pandemic plan revision, transforming the previous pandemic influenza preparedness plan into a wider-ranging preparedness for emerging health threats
	Develop a revised policy for dealing with emerging health threats and issue specific working procedures, according to the new structure and plan
Facilitate development of new antibiotics for treatment of multi-resistant bacteria, including through enhanced international cooperation	Organise workshops or discussions with interested parties (e.g. CPTR and IMI PREDICT-TB) to obtain latest scientific input for revision of the guideline for developing medicines for tuberculosis
	Provide scientific support to writing a new guideline on paediatric aspects of new antibiotics and to revision of SmPCs for already approved antibiotics
Facilitate availability of herbal medicines in the European Union	Compile an overview for herbal substances/-preparations from non-European traditions, related to pharmacopoeia, as tools to identify candidates for future EU Herbal monographs
Contribute to minimising the need for animal testing of human medicinal products	Improve the guidance on regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches
	Engage with scientific advances in experimental models to refine or replace in vivo animal studies
Effectively manage risks to the environment arising from the use of human and veterinary medicines	Provide technical support to the European Commission as part of the development of a Commission strategy for managing risks to the environment related to the use of medicines (both human and veterinary)
Promote application of harmonised international standards	Provide technical and scientific contribution to the development of an addendum to the ICH statistical principles guideline E9 and of an addendum to the ICH Paediatrics guideline E11, relating to the design and analysis of clinical trials
	Provide technical and scientific contribution to the development of ICH safety guidelines (Carcinogenicity assessment document evaluation for ICH S9)

Resources

	2016
Financial resources (cost, thousand Euro)	13,273
Human resources (FTEs)	32

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 2016. The main projects in 2016 will be related to:

- **Pharmacovigilance**. The main focus here 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**. During 2016-2017 the Agency will finalise development of the EU portal and database and other functionalities that will allow the Clinical Trials Regulation to become applicable.
- **eCollaboration.** The focus in 2016 will be on finalising the PSUR Repository and relevant updates to the eSubmission Gateway, and implementing the single entry point for electronic submissions for the network through integration of the EMA's gateway and the CESP.

Programme / Project	Start date	End date	Deliverables 2016
Pharmacovigilance programme			
Pharmacovigilance fees	Q4 2013	Q1 2016	• Invoicing automation and technical functionalities completed
EudraVigilance auditable requirements	Q4 2013	2017	• Start of stakeholder training • EudraVigilance system audit conducted • New EudraVigilance system available for pilot use
EudraVigilance critical requirements	Q4 2013	2018	Project on hold in 2016
EudraVigilance Fixes	2016	2017	• Analysis and design completed
Clinical trials programme			
EU portal and clinical trials database	Q3 2014	2018	• Delivery of the functional system for auditing • Initiation of the audit • Start implementation of the communication plan
Safety reporting	Q4 2014	2017	• Analysis and design completed
EudraCT and EU Portal	Q3 2016	2018	• Discussions on transition approach
eCollaboration programme			
eSubmission Gateway v3	Q4 2013	Q2 2016	• Delivery of functionality to provide and process metadata delivery files required to process all submissions via the eSubmission Gateway
PSUR repository	Q4 2013	Q2 2016	• Delivery of functionality required for mandatory use of the PSUR Repository
eCTD 4 pre-project activities	Q3 2015	2016	• Finalisation of the eCTD v4.0 standard • Development of the validation rules for eCTD v4.0 • Analysis to understand the impact of eCTD4 on the IT architecture and business processes • Environmental analysis of the eCTD v4.0 tools available on the market
Single submission portal	2016	2017	• Requirements gathering for implementation of the initial application forms (H&V) to the Single Submission Portal
Standalone projects			
AddValue: raising the standard of scientific output	Q3 2015	2017	• Standards of quality for relevant scientific outputs defined and agreed • Pilot benefit/risk methodology in post-authorisation • Guidance on integration of patients' input in benefit/risk assessment developed
Building EU Network capacity to gather and analyse information on clinical use	Q4 2015	Q4 2016	• Improved coordination of internal activities whilst collaborating with Member States and academia to develop pragmatic solutions to evidence generations • Strategy developed for how to leverage and better coordinate existing resources to achieve aims • Pilots with Member States finalised

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. 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.

Drivers

In 2016 and 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 start of operation of the ADVENT group in 2015, the work on delivering guidance according to its work plan will continue in 2016.

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 will be a major driver during 2016 and beyond.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Innovation Task Force briefing requests	2	2	4
Scientific advice requests received	31	27	30
Requests for classification as MUMS/limited market	29	27	25

Performance indicators

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

Objective	Activity
Provide support and incentives to development of new medicines for MUMS/limited markets	Publish annual report on MUMS/limited market activities
	Finalise review of the MUMS/limited market guidelines
Promote innovation and use of new approaches in development of veterinary medicines	Promote access the Agency's Innovation Task Force through presentations to industry and as part of existing pre-authorisation procedures
	Evaluate the impact of measures recently put in place to support innovation (ADVENT, ITF) and plan improvements in measures to support innovation
	Develop regulatory guidance in priority areas for technologies that are new to veterinary medicine (including cell based therapies, monoclonal antibodies for veterinary use)
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners	Analyse the outcomes of the survey on recipients' views regarding the usefulness and quality of the scientific advice received and decide on the potential for improvement
	Explore ways to promote the uptake of parallel scientific advice with the FDA, as part of pre-submission advice
Support development and availability of veterinary medicines	Identify and 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

Resources

	2016
Financial resources (cost, thousand Euro)	1,290
Human resources (FTEs)	1

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 the current level, indicating continuous interest in the industry in developing new veterinary medicines for food-producing animals.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Initial evaluation applications	12	10	18
New MRL applications	4	4	2
MRL extension and modification applications	2	3	2
MRL extrapolations	2	1	1
Art 10, Biocides	0	0	2
Review of draft Codex MRLs	5	0	5

Performance indicators

	Results		Targets
	2014	2015	2016
Procedures completed within legal timeframes	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:

Objective	Activity
Provide high quality and consistent scientific outputs of the EMA	Finalise development and promote uptake of revised guideline, procedures and templates for CVMP assessment reports
Ensure the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health	Provide technical support to the European Commission in drafting implementing acts specified in Regulation 470/2009
	Review the approach on genotoxic substances in the establishment of MRLs and authorisation of veterinary medicinal products
	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)

Resources

	2016
Financial resources (cost, thousand Euro)	5,126
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 be reviewed, taking into account the best practice developed in the human medicines divisions.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Variations applications, of which:	340	373	350
Type I A variations	175	196	180
Type I B variations	118	116	125
Type II variations	47	61	45
Line extensions of marketing authorisations	6	3	5

Performance indicators

	Results		Targets
	2014	2015	2016
Post-authorisation applications evaluated within the legal timeframes	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:

Objective	Activity
Ensure efficient delivery of post-authorisation procedures	Start of review the procedures for post-authorisation procedures other than variations and introduce necessary improvements

Resources

	2016
Financial resources (cost, thousand Euro)	5,206
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, high workload of referrals that has been experienced in recent years to continue.

Referrals concerning individual antibiotics or classes of antibiotics that are particularly important for use in human medicine will remain a priority area in 2016-2017. A number of these referrals are expected to be triggered by the Commission as part their Action plan against the rising threats from Antimicrobial Resistance, 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
Arbitrations and Community referral procedures initiated	7	7	10

Performance indicators

	Results		Targets
	2014	2015	2016
Referral procedures managed within the legal timelines	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.

Objective	Activity
Facilitate prudent and responsible use of antimicrobials and other classes of products	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

Resources

	2016
Financial resources (cost, thousand Euro)	1,059
Human resources (FTEs)	3

2.5. Pharmacovigilance activities

Activity area

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

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

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

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

Drivers

Veterinary pharmacovigilance represents an area with considerable scope for simplification and reduction of duplication through improved cooperation within the EU regulatory network. In addition to providing technical support to the European Commission with respect to future changes that are envisaged in the 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.

As an important step in 2015, the Agency established the Common European Database of veterinary medicinal products, based on EudraPharm, and effort will now be directed to working with Member States to populate this database with high-quality data on nationally authorised products.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Periodic safety-update reports (PSURs)	158	159	150
Total AERs, of which:	28,404	31,467	29,400
Adverse-event reports (AERs) for CAPs	11,878	14,387	13,000

Performance indicators

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

Additional objectives and activities

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

Objective	Activity
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes	Develop an approach to systematically ensure quality control and data verification of product data in the common European database of veterinary medicinal products and link these data to adverse event information related to CAPs and non-CAPs in the Eudravigilance Veterinary data warehouse to allow signal detection in preparation for the new veterinary legislation
	Revise the reflection paper on promoting pharmacovigilance reporting to address adverse events in food-producing species
	Revise the surveillance strategy for centrally authorised products to link signal detection and PSURs and ensure better use of pharmacovigilance resources
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	Publish the veterinary pharmacovigilance annual bulletin

Resources

	2016
Financial resources (cost, thousand Euro)	1,493
Human resources (FTEs)	7

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 in 2017. 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 2016.

Efforts to combat risks arising from antimicrobial resistance will remain a high priority in the coming years. 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 be involved during 2016 in measures initiated by the Commission, such as additional advice, referrals and the production of guidance documents.

Work on the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) will expand further over the period covered in this plan. In addition to continued annual monitoring and reporting on the consumption of veterinary antimicrobials across the EU, in 2016 the focus will be on developing methodologies to monitor consumption by species and by category (e.g. weaners, growers, sows, etc.), as well as on refining and publishing the work done to date in developing standardised units of consumption (e.g. Daily Defined Doses (Animals)).

In 2015, veterinary involvement in the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) increased and now includes identification of knowledge gaps in the train of transmission of AMR from animals to man. The objective for 2016 will be to identify those activities from which maximum value can be gained through transatlantic cooperation in bridging the identified knowledge gaps.

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 with less developed regulatory systems.

Workload indicators

	Results		Forecasts
	2014	2015	2016
n/a			

Performance indicators

	Results		Targets
	2014	2015	2016
n/a			

Additional objectives and activities

Objective	Activity
Support increased availability of veterinary medicines	Provide necessary input to the European Commission during the co-decision process for new veterinary legislation
Promote uptake of harmonised standards at international level	Participate in training events that raise awareness and enhance uptake of VICH standards by non-VICH countries
	Consider international scientific approaches for the establishment of MRLs for harmonisation purposes
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	Refine and continue data collection on the consumption of antimicrobials in veterinary medicine and publish the outcome in ESVAC annual report
	Prepare and deliver a joint EMA-EFSA opinion on how to reduce the need for antimicrobials in food-producing species
	Draft and validate methodology to measure the use of antimicrobials in poultry
Effectively manage risks to the environment arising from the use of veterinary medicines	Continue scientific reflections on the management of risks related to the use of veterinary medicines where concerns have been raised regarding the potential for harmful effects on the environment
Contribute to minimising the need for testing of veterinary medicinal products in animals	Contribute to development of internationally harmonised guidance by VICH on applying the 3Rs approach to batch testing of veterinary vaccines and other relevant areas
	Improve the guidance available on regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches

Resources

	2016
Financial resources (cost, thousand Euro)	2,798
Human resources (FTEs)	10

2.7. Projects

To support the Agency's work and achievement of the 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 2016. The main projects in 2016 will relate to the veterinary IT programme and implementation of veterinary legislation.

Programme / Project	Start date	End date	Deliverables 2016
Veterinary IT programme			
EudraVigilance veterinary v3.0	2016	2018	• Analysis and design completed • An updated access policy in line with Human EudraVigilance • Analysis for integration with the data warehouse
Union database	Q1 2016	2017	• Impact analysis of ISO IDMP • Analysis of master data compliance and integration plan • Analysis and plan for data warehouse integration • Analysis and design completed
Veterinary change programme			
Implementation of veterinary legislation	Q2 2016	2019	• Operating model for veterinary division developed, based on the revised legislation • Analysis and design completed for start of implementation of processes not affected by the new legislation • Implementation of first processes

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.

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 the 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 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 will drive a review of the current implementation of the policy for publication of agendas and minutes of the committees, in order to increase transparency of the committees' discussions and decision-making processes throughout the lifecycle of medicines.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Number of meetings	397	437	484
Number of teleconference meetings (audio, video and web)	3,215	4,273	5,000
Number of delegates	7,488	8,105	9,000

Performance indicators

	Results		Targets
	2014	2015	2016
Delegate satisfaction with service level provided by the secretariat	87%	93%	90%
Up-to-date electronic declarations of interests submitted by	100%	99%	100%

	Results		Targets
	2014	2015	2016
committee members prior to participating in a scientific committee meeting			
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%
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%	90%

Additional objectives and activities

Objective	Activity
Improve collaboration and communication between committees, working groups and SAGs to increase quality, efficiency and consistency of outputs	Analyse involvement of scientific advisory groups in evaluation activities to identify gaps and improve guidance
	Develop and embed in the Agency the concept of therapeutic area-specific communities (starting with the Oncology community) to facilitate knowledge exchange and create knowledge development on therapeutic area aspects within the Agency
Provide up-to-date, timely state-of-art guidance documents on relevant topics of medicines' development	Explore opportunities for collaboration with HTA organisations of the development and revisions of methodological and disease-specific guidelines
	Develop scientific guidance for the development of medicines in the elderly
	Support the finalisation of the revised Dementia guideline by the Central Nervous System Working Party
	Provide administrative and scientific support to the drafting/revision of BSWP guidelines on adjustment for baseline covariates, multiplicity and the investigation of subgroups in clinical trials
	Draft a paper to summarise progress and to suggest new areas of guidance / training on the use of Modelling and simulation methodology
	Draft a paper to summarise progress and to suggest new areas of guidance / training on the use of Extrapolation methodology

Resources

	2016
Financial resources (cost, thousand Euro)	5,342
Human resources (FTEs)	26

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 EDQM (European Directorate for the Quality of Medicines and Healthcare). 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.

Overall, the workload indicators will remain stable, mainly due to EU network capacity. While the initial notifications for parallel-distribution notices remain stable, there is a marked increase in annual update procedures as a result of the increasing numbers of new notices issued over the years. 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 does 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
GMP inspections	420	567	450
GLP inspections	0	1	1
GCP inspections	66	86	70
Pharmacovigilance inspections	20	14	16
Notifications of suspected quality defects	147	164	180
Notifications of GMP non-compliances*			20
Medicinal products included in the sampling and testing programme	46	48	50
Standard certificate requests	3,338	3,221	3,100
Urgent certificate requests	535	785	750
Parallel distribution initial notifications received	2,492	2,838	2,600
Parallel distribution notifications of change received	1,295	2,096	1,600
Parallel distribution notifications of bulk changes received	n/a	13	12
Parallel distribution annual updates received	2,339	4,550**	3,600

* Previously: "Other GMP inspections related notifications"
** includes 560 parallel distribution annual update notifications that were received in 2014 but processed in 2015

Performance indicators

	Results		Targets
	2014	2015	2016
Inspections conducted within established regulatory timeframes	100%	100%	100%
Standard certificates issued within established timelines (10 working days)	30.4%	91%	90%
Average days to issue standard certificate	13.7	7	10
Urgent certificates issued within established timelines (2 working days)	100%	100%	100%
Parallel-distribution notifications checked for compliance within the established timeline	97%	99%	90%
Number of training activities organised in the area of inspections (minimum number)	7	10	4
Additional GCP inspections addressed through information exchange on inspections carried out by international partners	29%	46%	35%
Additional routine GMP re-inspections of manufacturing sites addressed through exchange of information with international partners	8%	14%	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%

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:

Objective	Activity
Increase efficiency, consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities	Continue practical implementation of the risk-based inspections programme for 3rd country manufacturing plants of centrally authorised products, focusing EU inspectional resources on sites of highest risk
	Identify and develop 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)
	Deliver training and capacity-building for inspectors and assessors on inspection related activities
	Develop the plan to further extend cooperation with Member States in co-ordinating 3rd country inspections
	Continue work to establish a mutual reliance framework with FDA to increase the scope of EU international inspections activities
Improve mitigation of shortages of human medicines caused by GMP non-compliance and quality defects	Implement process improvements on the handling of quality defects and non-compliance issues
	Continue researching the root causes of quality defects

Resources

	2016
Financial resources (cost, thousand Euro)	14,514
Human resources (FTEs)	36

3.3. Partners, stakeholders 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.
- **Information and transparency**. The Agency places high importance on the transparency, openness and efficiency of its interactions with partners and stakeholders. The Agency ensures consistent, planned and targeted communication with its stakeholders, partners and the general public to provide up-to-date information on its work and outputs, including plain-language summaries on medicines and regulatory outcomes. This information is also shared within the European regulatory network before its publication by the Agency, 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.

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 the 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.

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. 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.

In line with demands for increased transparency, the Agency will start proactive publication of clinical reports submitted as part of marketing-authorisation applications and applications for line extensions/extension of indications as a result of the 2014 EMA policy on publication of clinical data for medicines for human use, as of mid-2016.

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.

Workload indicators

	Results		Forecasts
	2014	2015	2016
Requests for SME qualification	499	793	650
SME status renewal requests	813	994	1,400
Access to documents requests	416	701	500
Access to documents, documents released	1,771	2,972	2,300
Requests for information	4,625	4,573	4,500
Number of patients involved in EMA activities	633	741	650

Performance indicators

	Results		Targets
	2014	2015	2016
Satisfaction level of Patient and Consumers' Organisations	95%	n/a	80%
Satisfaction level of SMEs	80%	92%	80%

	Results		Targets
	2014	2015	2016
Response to ATD within set timelines		94%	90%
Response to RFI within set timelines		97%	97%
Satisfaction level from patients and healthcare professionals who received a response from the Agency to their RFI		81.7%	70%

Additional objectives and activities

Objective	Activity
Enhance cooperation within European medicines regulatory network	Develop training courses to be provided through the Network Training Centre
	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
	Complete the data gathering initiative for fee-generating activities (2016) and non-fee generating activities (2016-2017)
Further strengthen Agency's transparency and open data commitments	Implement necessary processes for clinical data publication, including processes for document receipt, redaction consultation and conclusion, public access process and others
	Initiate reflection on providing access to individual patient data
	Publish for public consultation the transparency policy
	Develop principles for public consultation of EMA core scientific and corporate documents and implement them in a guidance document
	Publish for public consultation the revised policy on access to documents
	Finalise and publish policy on handling falsified data/information on medicines
	Publish a report of coordination of safety announcements within the Network and revise EU guidance on safety communication
Provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information on Agency work, outputs and medicinal products	Develop a crisis communication strategy
	Develop a framework for communicating the scientific output of EMA scientific committees
	Publish 'product-related communication guidance' on 'what' and 'when' EMA publishes information on products
	Expand user-testing by patients for all product-related communications that include patients as target audience
Strengthen stakeholder relation focusing on patients and consumers, healthcare professionals, industry associations and academia	Adopt framework for collaboration with academia
	Implement framework for interacting with industry stakeholders
	Publish annual report on EMA's interaction with industry associations
	Publish annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations
	Conduct a joint PCWP/HCPWP workshop on the use of social media to further engage with patients, consumers and healthcare professionals
	Publish 10 year report of PCWP operations
	Explore processes to capture patients' input on the value of evidence during benefit risk evaluation, based on the outcome of the pilot phase of patients involvement in benefit risk assessment
	Develop recommendations to promote GPs interactions with EMA
	Implement revised framework of EMA interaction with patients
Further develop support to and strengthen stakeholder relations with	Develop action plan arising from 10 year report on the implementation of SME Regulation

Objective	Activity
SMEs	Enhance communication and outreach to SMEs to increase regulatory awareness and promote the use of new approaches and tools in development
	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
	Develop a plan for further development of the network of SME and innovation support structures of EU Agencies and organisations, including greater work sharing and exchange of best practices with bodies offering support to SMEs in the national, European and international context

Resources

Area of activity	Financial resources (cost, thousand Euro) 2016	Human resources (FTEs) 2016
Partners and stakeholders	10,134	31
Transparency and access to documents	6,112	23
Information	1,674	4

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 worksharing 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.

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 – will come fully into force in 2016, allowing for a broader global membership and strengthening ICH as the leading platform for global pharmaceutical regulatory harmonisation. The Agency plays an important role in supporting the European Commission by coordinating the EU expertise and contribution to the work of ICH.

Alongside enhanced cooperation in the field of inspections and supply-chain continuity, the Agency will additionally support efforts to increase international worksharing 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 epidemic 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.

Workload indicators

	Results		Forecasts
	2014	2015	2016
n/a			

Performance indicators

	Results		Targets
	2014	2015	2016
n/a			

Additional objectives and activities

Objective	Activity
Ensure best use of resources through promoting mutual reliance and work-sharing	Enhance cooperation between international regulators in all therapeutic areas, including paediatric medicines, biosimilars, orphan medicines, veterinary medicines, generics and medicinal products derived from blood
	Implement and review the IGDRP information sharing pilot to the centralized procedure
	Establish additional collaborations with FDA on patient engagement and pharmaceutical quality
	Optimise Article 58 scientific opinion activities, including enhance collaboration with WHO and concerned regulators and develop additional communication tools
	Update existing guidance on Article 58 scientific opinion procedure
	Explore mechanisms to enhance involvement of non-EU regulators in EMA scientific reviews, in order to facilitate work-sharing
	Provide input to activities aimed at greater mutual reliance such as the mutual reliance initiative with FDA, ICMRA GMP, and exploring mechanisms for confidential exchange of trade secret information
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
	Conduct gap analysis of existing regulatory frameworks in paediatrics and dementia and organise workshops to improve understanding of the frameworks and facilitate development of medicines in these areas
	Support relevant external activities in dementia – Alzheimer's disease with international partners agencies and intergovernmental initiatives
Assure product supply chain and data integrity	Enhance mechanisms to facilitate local observers' participation in inspections carried out in non-EU countries
	Develop training and communication materials on the importance of data integrity, in collaboration with other regulators, such as FDA
	Contribute to ICH activities on starting materials and lifecycle management
	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
Support training and capacity building and promote the EU regulatory model	Increase involvement of non-EU regulators (including candidate countries) in other training activities and the work of the EU Network Training Centre
	Identify training priorities and explore how to address these with key regulators outside EU
	Increase involvement of experts and observers from concerned regulators in Article 58 activities

Resources

	2016
Financial resources (cost, thousand Euro)	3,109
Human resources (FTEs)	13

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 20 EU Telematics services:

  - EU electronic application form (eAF), eSubmission portal, Common Repository for Centrally Authorised Products for electronic regulatory submissions;
  - 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 service for collection of adverse drug reactions;
  - the EudraVigilance and clinical trials data warehouses for analysis;
  - EudraGMP 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.

  2016 will see the addition of the PSUR repository, the Reference Management Service and the Organisations Management Service.

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 the 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.

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
Number of Telematics information services provided by EMA	16	20	23
Number of ongoing Telematics IT projects where EMA is the delivery organisation	19	18	17
Number of ongoing non-Telematics IT projects where EMA is the delivery organisation	15	11	6

Performance indicators

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

Additional objectives and activities

Objective	Activity
Deliver Information Technology solutions required by EU law	Deliver information systems according to EU Telematics roadmap
	Implement ISO IDMP roadmap with EU NCAs and industry
	Develop and implement common policies, procedures and standards to maximise the sharing and optimise investment in data
	Implement effective communication systems to support the Network's readiness in using and integrating Telematics systems
Share information on medicines	Implement Information Provision and Analytics information services to increase value of information through web access to information, business intelligence, and analytics
Establish and improve EMA information services	Establish a set of standard information services to support efficiency and effectiveness of scientific and other core activities
	Develop and start implementing improvements in the management of electronic documents and records
	Improve EMA's technology landscape by means of enterprise architecture
	Develop and implement information security management system to protect data assets and strengthen information security

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 2016. The main projects in 2016 will relate to the following:

- **Data integration.** This programme aims to deliver ISO-compliant systems for substance management, product management, organisations management and referentials management, to support core regulatory processes across Europe.
- **The 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, based on a competency matrix and accompanied by a training strategy, curriculum and methodology.
- **Clinical-data publication**. This is a project to implement the Agency's policy on publication and access to clinical data, as part of wider transparency initiatives.

Programme / Project	Start date	End date	Deliverables 2016
Data integration programme			
Referentials management service	Q1 2015	2016	• Master data management (MDM) infrastructure installed and hosting static lists and lists for ISO IDMP 11239 and 11240 • Additional lists to support ISO IDMP 11615 (products) and ISO IDMP 11238 (substances) • New web user interface for data management and system services for data access • EUTCT web user interface decommissioned
Organisations management services	Q1 2015	2016	• Dictionary of organisation data accessible by the EMA, EU network and industry users • New process managed by EMA for industry and NCAs to request the registration and update of organisations directly in MDM • New organisation management services (processes, technology, data and change management) • Technical implementation for capturing, mastering, exchanging, publishing and reporting on organisation data
Substances management service	2016	2017	• EU Implementation Guidance - Substances
Products management service	2016	2017	• EU ISO IDMP Implementation Roadmap • EU Implementation Guidance – Products iterations 1 and 2
Identity and access management	Q4 2014	Q2 2016	• Data cleaning and reconciliation across directories • Self-service capability for password management for applications included in first roll-out (Tier 1) • Deployment of user management capabilities to Tier 1 applications (e.g. self-service user registration) • Deployment of role and entitlement management • Access certification capability for business processes related to Tier 1 applications • Single sign on capabilities for Tier 1 applications
ISO IDMP	Q4 2013	Q2 2016	• Draft EU Implementation Guide for ISO IDMP – Products • Draft EU Implementation Guide for ISO IDMP – Substances • EU version of the HL7 Message specification - Products and Substances
Online programme			
Extranet	Q1 2014	2019	• Content strategy • Wireframes • Prototype
European medicines web portal	Q1 2014	2019	• User research and user requirements reports • Reflection paper • Content strategy • Visual design • Change management strategy
Corporate website	Q1 2014	2019	• Rewriting and reorganisation of content • Additional features to enable improved browsing of content
Standalone projects			
EU Network training centre	Q2 2014	Q4 2016	• Launch of learning management solution • Development of competency matrices • Development of curricula

Programme / Project	Start date	End date	Deliverables 2016
			• Launch of clinical trials training programme
SIAMED systems integration phase I	2016	2017	• SIAMED extended to support management of NAPs for PSURs, PASS, and referrals • Extended reporting capabilities for NAPs • Extend SIAMED to manage PSUR time-tables and scope definitions • Direct integration for pharmacovigilance fees data transfer
Publication and access to clinical data	Q2 2014	Q4 2016	• Finalised web site design • Start creation and frontend development for publication of clinical data • Tracking tool to manage and monitor end-to-end process workflow • Software service enabling automatic watermarking, digital rights management Self-registration and user management solution • Communication of the start-up of the Policy, including external guidance and training, awareness and expectation management
Rationalising working parties	Q1 2015	2017	• Description of types of groups, roles and composition • Description of the governance, monitoring and reporting process • Revised mandates and rules or procedure • Methodology for production of guidelines and other guidance documents • Best Practice Guide on meeting processes including a training plan • Communication plan • Implementation 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 activities 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, infrastructure services (including running the data centre), internal and external user support, and IT security and risk-management.
- **Communication (corporate)**. Corporate communication activities are aimed at supporting the Agency's mission of protecting public and animal health and the achievement of its strategic objectives and priorities. They cover management of the Agency's corporate website, external communications, press office and information centre. The Agency's main communication channel is its corporate website, *ema.europa.eu*. Its social-media activity includes a Twitter account and regular updates on LinkedIn and YouTube. Managing relationships with media through press materials, media interviews and press conferences, and responding to journalists' queries, also falls within this area.
- **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 Programme Design Board ensures that the Agency's business projects are aligned with strategy and meet customer expectations. The Project Management Office ensures the Agency's programmes and projects are managed according to agreed standards and project-management arrangements, and monitors, controls and reports on the progress of these projects and programmes.
- **Policy issues**. The Agency's Chief Policy Adviser Division is responsible for developing and revising EMA policies, as well as monitoring their implementation. It also coordinates preparation of the Agency for new and revised legislation, and liaises with and coordinates EMA interactions with the EU institutions.

Drivers

There is a need for the 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 that uses the right channels to provide meaningful content to these stakeholders is a prerequisite for any outreach activities by the Agency.

The communication perception survey conducted in 2015 revealed a need for further engagement from the Agency with different groups of users via social media, together with an enhanced online presence. This is driven by the predominance of electronic communication channels, with the use of mobile beginning to overtake use of desktop devices in many areas.

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 the EMA's reputation requires continuous monitoring of press and social media, as well as the ability to respond quickly and effectively to public concerns.

The 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
Requests for interviews and comments by media representatives		2,268	2,200
Number of press releases and news items published		190	200
Number of reports, brochures, leaflets laid out or printed	6	7	6
Number of documents published on EMA website	4,858	7,154	10,000
Number of pages published and updated on EMA website	2,201	2,911	5,000

Performance indicators

	Results		Targets
	2014	2015	2016
Posts on the Agency establishment plan filled	97%	98%	97%
Revenue appropriations implemented	96%	98.7%	97%
Expenditure appropriations implemented	94%	95.8%	97%
Payments against appropriations carried over from year N-1	97%	94%	97%
The maximum rate of carryover to year N+1, of total commitments within the title			
Title 1	1%	0.9%	1%
Title 2	23%	7.6%	15%
Title 3	28%	26.9%	25%
Payments made within 30 days' time	98%	99.7%	98%
Satisfaction level of partners/stakeholders with EMA communications	n/a	84%/87%	n/a
Key messages included in media articles generated by EMA press releases:			
At least 1 key message		100%	95%
At least 2 key messages		100%	70%
Quote included			60%
Average rating of pages on corporate website during the year			3
Availability of Telematics IT systems (% of time)		99.4%	> 98%
Availability of corporate IT systems (% of time)		100%	> 98%
Availability of corporate website (% of time)		99.7%	> 98%

Additional objectives and activities

Objective	Activity
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	Develop Agency's multi-annual programming, to implement the Network strategy 2016-2020
	Conduct self-assessment of the Agency's quality management system against the new ISO 9001:2015 standard
	Develop corporate communication strategy
	Develop social media strategy

Objective	Activity
Maintain high level of independence, integrity and transparency in all aspects of Agency's work	Implement the conflicts of interest policy for Management Board members and EMA employees
	Conduct annual review of the Agency's handling of independence
Align the agency with the highest European standards in environmental performance	Prepare and implement action plan to register the Agency for EMAS certification

Resources

Area of activity*	Financial resources (cost, thousand Euro) 2016	Human resources (FTEs) 2016
Governance, quality management and internal audit	8,117	34
Finance	5,500	27
ICT**	10,011	44
Human resources	7,218	41
Infrastructure services	2,627	16
Communication	6,075	25

* Legal services resources allocated to relevant activities throughout the work programme.
** Additional 18 FTEs in ICT services working on projects (mainly pharmacovigilance and clinical trials) 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 2016, along with their timelines and deliverables.

Programme / Project	Start date	End date	Deliverables 2016
EMA portfolio/ programme/ project methodology	Q3 2015	Q3 2016	• New methodology for portfolio/programme/project management and IT delivery lifecycle • Strategy and plan for evolution of the methodology and continual improvement
Desktop strategy and implementation	Q2 2015	Q4 2016	• Phased roll-out of new hardware to end users

Annex 1: Activity based budget 2016

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	**65,295**	**29,268**	**12,393**	**108,841**	**9,257**	**225,054**	**70%**
1.1 Pre-authorisation activities	14,130	4,331	4,386	18,680	100	41,627	13%
1.2 Initial evaluation activities	13,561	2,960	1,593	15,096	1,102	34,312	11%
1.3 Post-authorisation activities	13,363	10,685	1,684	63,250	2,559	91,541	28%
1.4 Referrals	1,904	477	548	-	392	3,322	1%
1.5 Pharmacovigilance activities	16,181	7,208	2,412	11,815	3,363	40,979	13%
1.6 Other specialized areas and activities	6,156	3,606	1,769	-	1,741	13,273	4%
2 Evaluation activities for veterinary medicines	**7,342**	**2,368**	**2,597**	**3,741**	**926**	**16,973**	**5%**
2.1 Pre-authorisation activities	328	79	601	267	15	1,290	0%
2.2 Initial evaluation activities	2,536	596	453	1,347	194	5,126	2%
2.3 Post-authorisation activities	1,434	990	228	2,126	429	5,206	2%
2.4 Arbitrations and referrals	538	116	203	-	202	1,059	0%
2.5 Pharmacovigilance activities	974	241	228	-	51	1,493	0%
2.6 Other specialized areas and activities	1,532	346	885	-	35	2,798	1%
3 Horizontal activities and other areas	**20,700**	**7,075**	**4,845**	**6,561**	**1,705**	**40,886**	**13%**
3.1 Committee coordination	3,460	902	981	-	-	5,342	2%
3.2 Inspection and compliance	4,309	2,486	1,078	6,561	80	14,514	5%
3.3a Partners and stakeholders	5,523	1,289	2,112	-	1,210	10,134	3%
3.3b Transparency and access to documents	3,883	1,784	344	-	100	6,112	2%
3.3c Information	869	160	329	-	315	1,674	1%
3.4 International activties	2,655	454	-	-	-	3,109	1%
4 Corporate governance and support activities	**28,667**	**7,779**	**604**	**-**	**2,498**	**39,548**	**12%**
4.1 Governance, quality management and internal audit	5,944	1,212	383	-	578	8,117	3%
4.2 Finance	3,821	1,673	-	-	6	5,500	2%
4.3 Information technology	7,961	1,576	-	-	474	10,011	3%
4.4 Human resources	5,349	1,869	-	-	-	7,218	2%
4.5 Infrastructure services	2,057	570	-	-	-	2,627	1%
4.6 Communication (corporate)	3,536	879	221	-	1,439	6,075	2%
Total	**122,004**	**46,491**	**20,438**	**119,142**	**14,386**	**322,461**	**100%**

* Excluding €2,250 exceptional investment cost for the refurbishment of the 10th floor

Total budget for 2016:	**324,711**

Annex 2: Financial resources

		2014 (outturn)[1]		2015 (budget)[2]		2016 (budget)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
100	Fees and charges	217,670	*80.1%*	255,251	*82.8%*	276,961	*85.3%*
200	General EU contribution	20,504	*7.5%*	18,604	*6.0%*	11,690	*3.6%*
201	Special EU contribution for orphan medicinal products	9,432	*3.5%*	12,911	*4.2%*	12,785	*3.9%*
300	Contribution from EEA	675	*0.2%*	936	*0.3%*	676	*0.2%*
600	External assigned revenue	18,904	*7.0%*	17,767	*5.8%*	19,559	*6.0%*
700	Balance from previous year	3,453	*1.3%*	1,500	*0.5%*	1,950	*0.6%*
5+9	Other	1,147	*0.4%*	1,128	*0.4%*	1,090	*0.3%*
	TOTAL REVENUE	**271,786**	*100.0%*	**308,097**	*100.0%*	**324,711**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	84,352	*31.7%*	94,888	*30.8%*	102,365	*31.5%*
13	Duty travel	540	*0.2%*	666	*0.2%*	640	*0.2%*
14	Socio-medical infrastructure	805	*0.3%*	845	*0.3%*	870	*0.3%*
15	Exchange of civil servants and experts	3,016	*1.1%*	5,498	*1.8%*	6,962	*2.1%*
16	Social welfare	323	*0.1%*	545	*0.2%*	483	*0.1%*
17	Representation expenses	53	*0.0%*	149	*0.0%*	40	*0.0%*
18	Staff insurances	2,255	*0.8%*	2,386	*0.8%*	11,314	*3.5%*
	Total Title 1	**91,344**	*34.3%*	**104,977**	*34.1%*	**122,674**	*37.8%*
	Building / equipment						
20	Investment in immovable property, renting of building and associated costs	39,175	*14.7%*	34,156	*11.1%*	28,244	*8.7%*
21	Expenditure on corporate data processing	12,499	*4.7%*	19,534	*6.3%*	18,023	*5.6%*
22	Movable property [..]	1,927	*0.7%*	2,178	*0.7%*	1,785	*0.5%*
23	Other administrative expenditure	1,417	*0.5%*	1,619	*0.5%*	1,288	*0.4%*
24	Postage	130	*0.0%*	153	*0.0%*	183	*0.1%*
25	Expenditure on other meetings	102	*0.0%*	107	*0.0%*	54	*0.0%*
	Total Title 2	**55,251**	*20.7%*	**57,747**	*18.7%*	**49,577**	*15.3%*
	Operational expenditure						
300	Meetings	7,126	*2.7%*	8,904	*2.9%*	9,435	*2.9%*
301	Evaluation of medicines	96,145	*36.1%*	108,614	*35.3%*	119,142	*36.7%*
302	Translations	4,325	*1.6%*	4,321	*1.4%*	5,270	*1.6%*
303	Studies and consultants	4,730	*1.8%*	9,138	*3.0%*	7,862	*2.4%*
304	Publications	163	*0.1%*	173	*0.1%*	274	*0.1%*
305	Community programmes	0	*0.0%*	0	*0.0%*	0	*0.0%*
31	Expenditure on business related IT projects	7,336	*2.8%*	14,223	*4.6%*	10,477	*3.2%*
	Total Title 3	**119,825**	*45.0%*	**145,373**	*47.2%*	**152,460**	*47.0%*
	TOTAL EXPENDITURE	**266,420**	*100.0%*	**308,097**	*100.0%*	**324,711**	*100.0%*

[1] Financial Year 2014: as per final accounts, rounded to nearest thousand Euro
[2] Financial Year 2015: as per final budget (including transfers and amending budgets)
[3] Financial Year 2016: as adopted by the Management Board 17 December 2015

Annex 3: Human resource needs and establishment plan

Category and grade	Authorised for 2014		Occupied as of 31/12/2014			Authorised for 2015		Occupied as of 31/12/2015[1)]			Authorised for 2016	
	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	-	4	2	-	4	-	3	2	-	4
AD 14	-	6	-	6	1	-	6	-	5	1	-	6
AD 13	-	8	-	7	9	-	9	-	9	10	-	9
AD 12	-	42	-	39	29	-	42	-	41	24	-	42
AD 11	-	38	-	36	20	-	37	-	36	22	-	38
AD 10	-	36	-	35	34	-	40	-	39	33	-	44
AD 9	-	37	-	34	28	-	36	-	36	33	-	37
AD 8	-	49	-	47	52	-	52	-	51	51	-	54
AD 7	-	51	-	51	45	-	52	-	51	50	-	54
AD 6	-	39	-	39	71	-	36	-	36	77	-	37
AD 5	-	30	-	29	27	-	26	-	26	20	-	18
Subtotal AD	***0***	***340***	***0***	***327***	***318***	***0***	***340***	***0***	***333***	***323***	***0***	***343***
Total AD	**340**		**0**	**327**	**318**	**340**		**0**	**333**	**323**	**343**	
AST 11	-	2	-	2	0	-	2	-	2	0	-	2
AST 10	-	5	-	5	2	-	5	-	5	3	-	5
AST 9	-	7	-	7	2	-	7	-	6	2	-	7
AST 8	-	15	-	14	7	-	16	-	16	5	-	16
AST 7	-	19	-	19	14	-	19	-	18	14	-	19
AST 6	-	36	-	34	16	-	39	-	38	19	-	39
AST 5	-	37	-	36	33	-	42	-	42	33	-	43
AST 4	-	55	-	55	30	-	49	-	49	33	-	49
AST 3	-	39	-	38	65	-	43	-	41	65	-	47
AST 2	-	34	-	33	34	-	37	-	37	34	-	32
AST 1	-	10	-	10	59	-	0	-	0	56	-	0
Subtotal AST	***0***	***259***	***0***	***253***	***262***	***0***	***259***	***0***	***254***	***264***	***0***	***259***
Total AST	**259**		**0**	**253**	**262**	**259**		**0**	**254**	**264**	**259**	
AST/SC1	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC2	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC3	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC4	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC5	-	-	-	-	-	-	0	-	-	0	-	0
AST/SC6	-	-	-	-	-	-	0	-	-	0	-	0
Subtotal AST/SC	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***
Total AST/SC	**0**		**0**	**0**	**0**	**0**		**0**	**0**	**0**	**0**	
Grand subtotal	***0***	***599***	***0***	***580***	***580***	***0***	***599***	***0***	***587***	***587***	***0***	***602***
Grand total	**599**		**0**	**580**	**580**	**599**		**0**	**587**	**587**	**602**	

Contract agents	2014		2015		2016
	Actual FTE as of 31/12/2014	Actual headcount as of 31/12/2014	Actual FTE as of 31/12/2015[1)]	Actual headcount as of 31/12/2015	Planned FTE
FG IV	43	53	55	55	58
FG III	14	21	20	18	14
FG III	59	70	81	80	73
FG I	0	0	0	0	0
Total	**116**	**144**	**156**	**153**	**145**

National experts	2014		2015		2016
	Actual FTE as of 31/12/2014	Actual headcount as of 31/12/2014	Actual FTE as of 31/12/2015[1)]	Actual headcount as of 31/12/2015	Planned FTE
Total	**18**	**28**	**33**	**35**	**40**

1) Data as per draft provisional accounts of 20/01/2016

Annex 4: Risks

The European Medicines Agency operates in a risk environment of growing uncertainty. To assist the Agency in visualizing, 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 attainment of key organizational 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 assessments.
- 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 acknowledge the risks and validate 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 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 are outlined in the tables below.

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 using best available expertise In progress: • Joint EMA-HMA training strategy

Risk	Mitigating actions and controls
Product assessment – Conflict of interest / independence	
NCA experts participating in the assessment work at the level of national agencies influence the outcome due to a failure to disclose conflicts of interest	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 interest	In place: • Legal requirements for independence • Code of conduct and Guidance on handling declaration of interest in case of a committee or other scientific forum member's intention to become employee in pharmaceutical company • Framework for decision-making process at CxMP • Policy on handling declarations of interests of scientific committees' members and experts • Check of interests declared by members and experts participating in meetings • Publication of DoI and eCVs of committee members and experts on Agency website • Breach of trust procedures on conflicts of interest for scientific committee members and experts • Comparing eCVs and DoI to uncover discrepancies regarding conflict of interest • KPIs to monitor conflicts of interests declared Planned: • Improvements to the Experts database to incorporate DoI evaluation forms and overview of involvement of the experts
Product assessment – Applicant fraud	
Incorrect scientific opinion due to infringement of compliance involving data fraud by applicant or third party supplying data	In place: • Cross-Agency infringement action group In progress: • Active publication of clinical trials data post-authorisation • Policy and procedures for handling whistle-blowers/parties raising concerns Planned: • Policy and procedures on EMA activities relating to prevention, detection, investigation and action relating to infringement • Procedures for implementing Penalties Regulation • Standards for documentation of investigations and ensuing procedures to ensure integrity of any future infringement procedures
Inspections	
Inadequate quality of medicines due to framework for compliance with GxP from non-EU countries not meeting the EU standards at all times	In place: • EU Network / cooperation (Inspection Working Groups, inspections planning – EudraGMDP Planning Module, PhV inspection programme, CMDh subgroup on Bioequivalence trials) • International cooperation in GxP area: – The ICH process (GMP, GCP, PhV) – The OECD programme (GLP) – Mutual Recognition Agreements and Agreement on Conformity assessment (GMP) – International collaboration on GMP inspections of API manufacturers – EMA-FDA GCP initiative and EMA/EU MS/FDA initiative on inspections for generic applications – Exchange of inspections information and reports with non-EU Authorities with Confidentiality Agreements or other bilateral relations – Joint inspections with non-EU Authorities

Risk	Mitigating actions and controls
	– Training and capacity building activities • Legal and regulatory requirements • Risk based approach for GxP inspections allowing better use of available resources In progress: • Mutual reliance initiative between FDA and EU on GMP inspections
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 • Independency, 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
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 implemented and continuously reviewed • Security officer and dedicated ISS 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 interest 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) 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: • 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 Planned: • Policy on data security across EMA • 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

Risk	Mitigating actions and controls
	• 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 • CCTV • Access control • Printing control • Confidential waste stored in locked confidential bins Planned: • Guidance on 'clear desk policy'
Data protection issues due to non-compliance with the regulation	In place: • Legal requirements for identification and regular management review of systems to be notified • Appointment of Data protection officer within the Agency • Training programme for existing and new members of staff • Creation of data protection network within the Agency • Regular bilateral meetings between Executive Director and Data protection officer Planned: • Review of the system of EMA management responsibilities for processing personal data
Data management – data quality	
Data required for scientific and regulatory procedures and decision making is of poor quality, incomplete, inaccurate and/or lacks integrity	In place: • Validation of data entry in SIAMED and EudraVigilance • Data analytics tool and processes for monitoring data quality • Governance structure for data management 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 quality control level based on risk assessment of individual data assets
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 sets owner 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 Records 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

Risk	Mitigating actions and controls
	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
Finance - Revenue collection and Treasury management	
Loss of revenue due to inability/difficulty collecting pharmacovigilance fees from new customers	In place: • Proactive communication/engagement with stakeholders, including guidance/workshop with industry • New SAP technology for debt collection Planned: • Establishment of acceptable level of non-payment/to write-off debts (waiver of recovery)
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
Agency operation interrupted due to significant system failure	In place: • Monitoring, preventive maintenance and resilience • Trained teams to repair/fix systems, external support from companies In progress: • Tested disaster recovery systems and procedures
Clinical data publication	
Non-compliance of MAHs/pharmaceutical industry with the policy	In place: • Information sessions with industry prior to implementation • Consultation with stakeholders In progress: • Identification of non-compliance scenarios and remedial actions 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

Annex 5: Procurement plan

Activity statement:	**Effectiveness and pharmacoepidemiology studies**
Objective:	See Work programme 2016, heading 1.5
Budget:	€ 350,000
Financial year:	2016
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 3
Indicative timeframe for contract:	Three procurements of approximately € 115,000 each, in the first three quarters of 2016
Indicative timeframe for procurement:	Q1–Q3 2016
Indicative budget for procurement:	€ 350,000
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:	**Redaction review Clinical Data Policy 0070**
Objective:	See Work programme 2016, heading 1.6
Budget:	€ 1,000,000 over four years
Financial year:	2016–2019
Description of action:	Under supervision of EMA staff, undertake review of proposed redaction of commercial confidential information in a marketing authorisation application and review it against EMA redaction principles for acceptability, engage in correspondence thereon with the marketing authorisation holder using a justification table and via security communication system
Type of contract:	Framework contract implemented by Specific Contracts
Number of contracts:	1 framework contract
Indicative timeframe for contract:	Commencing in 2016
Indicative timeframe for procurement:	Q1-Q2 2016
Indicative budget for procurement:	€ 1,000,000 over four years
Legal basis:	Article 80 of Regulation 726/2004 and EMA Policy 0070 on the publication of clinical data for medical products for human use
Budget line:	B3030

Activity statement:	**Oracle software licences, maintenance and support, training and training materials and specialised high-level consultancy**
Objective:	See Work programme 2016, heading 4
Budget:	€ 6.75 million over four years of which €500,000 operational and €6.25 million administrative
Financial year:	2017-2020
Description of action:	Inter-institutional negotiated procedure to be run by European Commission (DIGIT) for Oracle software licences, maintenance and support, training and training materials and

	specialised high-level consultancy
Type of contract:	European Commission tender procedure, Framework Contract implemented by Specific Contracts & Purchase Orders
Number of contracts:	1 framework contract
Indicative timeframe for contract:	Commencing in 2017
Indicative timeframe for procurement:	Expected to be launched in 2016
Indicative budget for procurement:	€ 6,750,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2110/2114/2115/3105

Activity statement:	**Provision of information and communication technology advice, benchmarking and strategic consulting services: high level consultancy and studies**
Objective:	See Work programme 2016, heading 4
Budget:	€ 3,000,000 over 4 years of which € 2 million operational and € 1 million administrative
Financial year:	2014 - 2017/18
Description of action:	High-level consultancy and studies are seen as provision of customised and individual, non-standard information for high-level and strategic issues
Type of contract:	European Commission tender procedure, Framework Contract implemented by Specific Contracts
Number of contracts:	1 framework contract
Indicative timeframe for contract:	Commencing in 2017
Indicative timeframe for procurement:	Expected to be launched in 2016
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:	B2115/3105

Activity statement:	**Scientific e-learning for EMA staff and EU Network Training Centre**
Objective:	See Work programme 2016, heading 4
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 late 2016
Indicative timeframe for procurement:	Expected to be launched in 2016
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:	B1120/3003

Activity statement:	**Travel management company**
Objective:	See Work programme 2016, heading 4
Budget:	€ 12,000,000 over 4 years, of which € 2 million operational and € 10 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:	Q2 2016
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:	B1300/3000

Activity statement:	**Catering services**
Objective:	See Work programme 2016, heading 4
Budget:	£ 3,400,000 over 4 years of which £ 800,000 operational and £2.6 million administrative
Financial year:	2017-2021
Description of action:	Ensure continuous provision of catering and conference services for staff, delegates and visitors at the Agency's offices
Type of contract:	Service contract
Number of contracts:	1
Indicative timeframe for contract:	Commencing in 2017
Indicative timeframe for procurement:	Q4 2016
Indicative budget for procurement:	£ 3,400,000 over 4 years
Legal basis:	Articles 56 and 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B1400/1700/2359/3002

Annex 6: Terms and abbreviations

Term / abbreviation	Definition
3Rs	'3 R' principles in testing of medicines for regulatory purposes: replacement, reduction and refinement
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
ATD	access to documents
ATMP	advanced-therapy medicinal 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
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CoI	conflict of interest
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
Council	European Council
CPTR	Critical Path to TB Drug Regimens initiative
CT	clinical trial
CVMP	Committee for Medicinal Products for Veterinary Use
DoI	declaration of interests
eAF	electronic application form
eCV	electronic Curriculum Vitae
EC	European Commission
ECD	Eudra Common Directory
ECHA	European Chemicals Agency
ECNP	European College of Neuropsychopharmacology
eCTD	electronic common technical document
ECDC	European Centre for Disease Prevention and Control
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMAS	EU Eco-Management and Audit Scheme
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European public assessment report
EPITT	European Pharmacovigilance Issues Tracking Tool
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EudraGMP	European Union Drug Regulating Authorities good manufacturing practice
EudraLink	European Union Drug Regulating Authorities secure file sharing

Term / abbreviation	Definition
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
EUTCT	EU Controlled Terminology
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
FDA	United States Food and Drug Administration
FTE	full-time equivalent
GCP	good clinical practice
GLP	good laboratory practice
GMO	genetically modified organism
GMP	good manufacturing practice
GP	General practitioner
GVP	good pharmacovigilance practice
HCP	healthcare professional
HCPWP	Healthcare Professionals Working Party
HIV	human immunodeficiency virus
HL7	Health Level 7
HMA	Heads of Medicines Agencies
HR	Human Resources
HMPC	Committee on Herbal Medicinal Products
HTA	health technology assessment
ICH	International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICMRA	International coalition of medicines regulatory authorities
ICSR	individual case-safety report
ICT	information and communication technologies
IDMP	Identification of Medicinal Products
IGDRP	International Generic Drug Regulators Programme
IMI	Innovative Medicines Initiative
IPRF	International Pharmaceutical Regulators Forum
IRM	Institute of Risk Management
IT	information technology
ITF	Innovation Task Force
ISO	International Organisation for Standardisation
JEG 3Rs	Joint CVMP/CHMP Ad-hoc Expert Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products
KPI	key performance indicator
LMIC	low and middle-income countries
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
Member State (MS)	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MLM	medical literature monitoring
MRL	maximum residue limit
MSWG	Modelling and Simulation Working Group
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
NUI	non-urgent information
OECD	Organisation for Economic Cooperation and Development
OIE	World Organisation for Animal Health

Term / abbreviation	Definition
OMCL	Official Medicines Control Laboratories
PA	protocol assistance
PAES	post-authorisation efficacy study
Parliament	European Parliament
PAS	Post Authorisation Studies
PASS	post-authorisation safety study
PCWP	Patients' and Consumers' Working Party
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma master file
PRAC	Pharmacovigilance Risk Assessment Committee
PREDICT-TB	Model-based preclinical development of anti-tuberculosis drug combinations, IMI project
PRIME	PRIority MEdicine, a scheme to foster the development of medicines with high public health potential
PROTECT	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
PSUR	periodic safety-update report
PSUSA	PSUR single assessment
PUMA	paediatric-use marketing authorisation
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
Q&A	questions and answers
RA	rapid alert
RFI	request for information
SA	scientific advice
SAG	Scientific Advisory Group
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
SWP	Safety Working Party
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TIGRE	Team of International Global Rare Disease Experts initiative
TGA	Therapeutic Goods Administration, Australia
US	United States of America
VE	Vaccines Europe
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
(Web-)RADR	Recognising Adverse Drug Reactions
WHA	World Health Assembly
WHO	World Health Organization
WP	working party