EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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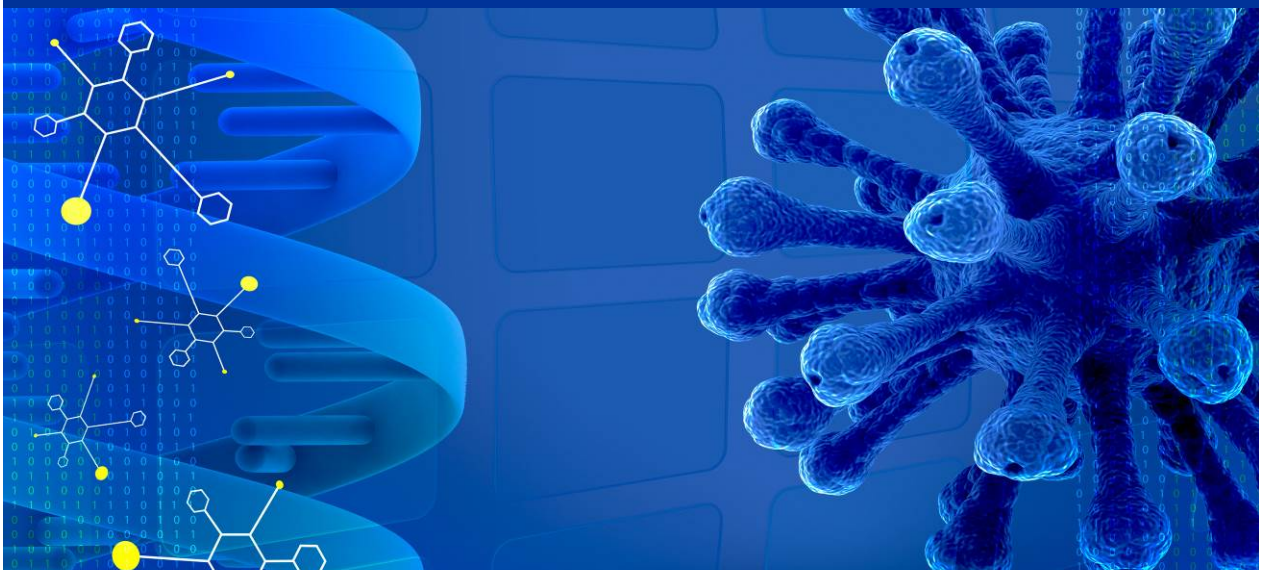
Management Board

Work programme
2015

Adopted by the Management Board on 18 December 2014



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An agency of the European Union

Mission

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

Legal role

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

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

Principal activities

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

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

Guiding principles

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

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

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Structure of the work programme 2015

'Work programme 2015' is a reflection of the European Medicines Agency's (EMA) priorities and main focus areas for 2015, and describes the objectives and activities that are aimed at reaching longer-term strategic goals. The document consists of four parts:

1. **Human medicines evaluation activities**. This chapter covers all Agency activities specifically related to 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 is structured similar 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, HR, quality management, and others — that 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 2015.
- **Key objectives and activities.** These are the objectives set for 2015, and the main activities carried out to achieve these objectives, reach the EMA longer-term strategic goals and mitigate risks that may affect fulfilling its mission.
- **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.
- **Resources.** This is an overview of human and financial resources involved in the activity areas. Human resource data reflects the utilisation of the 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 2015 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 priorities and key influences

The European medicines regulatory system 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 countries and the European Medicines Agency. 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 of objectives and activities described in this work programme will impact the national authorities and their work as well.

Key influences

The environment in which the Agency operates is constantly changing and evolving. Factors such as advances in and growing complexity of medicines development, globalisation, the increasing role of social media as an information source, growing expectation for transparency, key legislation changes and continuous striving for increased efficiency, all impact the Agency's work.

This year, 2015, will be the 20th anniversary of the inauguration of the EMA, and the beginning of not only centralised approval of medicines, but of the whole European medicines network. It will be an opportunity to look back at how much has been achieved in promoting public and animal health over 20 years and to plan for the future.

Scientific advancement and managing complexity to facilitate patient access to medicines

The move towards developing more targeted and individualised medicines, continuous development and use of state-of-the-art knowledge and technologies in drug development, and integration of development and use of medicines and medical devices all contribute to the increasing complexity of the scientific advice and other Agency's activities. Following closely these developments and ensuring availability of the required expertise 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. 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 the SMEs.

The ever-increasing expectations of patients and healthcare professionals to have medicines available to treat various conditions, in combination with the continuous need for flexible and fast reaction to arising public health threats, highlights the importance of ensuring faster patient access to medicines on the market, while maintaining the quality of scientific assessment.

To address the above scientific and societal trends, the Agency is reinforcing its development support to various stakeholder groups, and has undertaken a number of initiatives to ensure early dialogue to foster drug development and improve regulatory pathways for early patient access to medicines. This includes integrated support to early stages of medicines development, covering legally established scientific advice, orphan designation, paediatric procedures and support to SMEs. In addition, the Agency is reviewing the available regulatory tools and their use, to allow patient access to medicines

for conditions with unmet medical need, and exploring concepts such as adaptive pathways and specific mechanisms to support innovative medicines with high public-health potential.

Along with SMEs, academia and public-private partnerships are also becoming an increasingly important source of innovation in medicines. The growing need for industry and academia to approach the regulators early in their endeavours increases the role of the Agency in facilitating such contact and ensuring early knowledge sharing. To account for this, the Agency will reinforce its support to these stakeholder groups as well.

Improving the quality and efficiency of our work

Efficiency is key to the successful delivery of the Agency's activities and to coping with the growing number of responsibilities and increasing complexity of the regulatory procedures. Growing interdependencies between committees and scientific disciplines in the decision-making further emphasise the need to continuously simplify and align processes, improve quality assurance and quality control, increase robustness of the processes and reach higher efficiency of the evaluation procedures. In 2015, the Agency will be capitalising on its recent programme to increase the effectiveness and efficiency of activities. The revised and improved processes, and the improved ways of working, will be embedded across the organisation as part of the transition into the continuous improvement phase.

The process for evaluating medicines is constantly evolving. The coming years will see an increasing need to consider aspects such as patients' values and preferences, the needs of other stakeholders (e.g. health-technology assessment bodies, or HTAs) when planning clinical research programmes and post-authorisation measures, the impact of 'real life' evidence data, and others. This will affect the way the scientific committees evaluate medicines, and consequently the workload of the Agency, both in its endeavour to support the scientific assessment of the committees and in its role as a key provider of training, technical and methodological guidance for the scientific work. Robust internal processes and expansion of the overall capabilities of the Network will be required.

In a continuous effort to meet the demands for increased efficiency of operations, while increasing the level of service the Agency provides, data management has become a key activity in creating an integrated, shared environment that provides a single, accurate, consistent source of data for the Agency, its partners and stakeholders. The implementation of the data-integration programme is the key activity for the Agency in this area.

European medicines regulatory network

The European medicines regulatory network (Network) is the cornerstone of the work and success of the European system. In the coming years, the Agency expects a significant increase in its activities, both in terms of volumes (e.g. scientific advice and pharmacovigilance) and in terms of complexity of products, scientific issues and procedures, due to the scientific development. The increasing workload will call for higher involvement of the NCAs. At the same time, the ability to manage the increasing workload is on occasion limited by the current capacity of the Network, and finding sustainable solutions for maintaining and increasing the Network's capacity will be an important focus area.

To address these developments, the Agency continues to consolidate and enhance its collaboration with and support to the NCAs through a number of initiatives, including a revised training and competence development programme in cooperation with national authorities, promoting the national experts programme, and prioritising its information technology development programme with projects that support the work, effectiveness and efficiency of the NCAs.

The NCAs and the Agency will also need to prepare for the upcoming revision of the fee legislation, to ensure adequate financing and sustainability of the Network.

Globalisation

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 that medicines tested and manufactured outside the EU meet the EU requirements will drive efforts to develop and strengthen collaboration with international partners regarding collaborative inspections, information exchange, capacity building and greater mutual reliance. The increasing complexity and globalisation of medicines supply chains will also require improved information exchange and closer, more streamlined cooperation among authorities, to ensure product and data integrity, and continuity of the medicines supply chain.

At the same time, there is increasing awareness of the need to avoid duplication of work done by regulators across the world and use global resources more effectively. Hence, the Agency will additionally support efforts to increase international worksharing in all areas, as well as support convergence of international practices and work within international coalitions to encourage better and more effective use of global regulatory resources.

Pharmacovigilance and clinical trials legislation

The final elements of the EU's pharmacovigilance legislation will be implemented during 2015 and 2016. 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 the Agency's responsibilities in the pharmacovigilance field. As part of this change, the volume of data and information to be managed and the number of procedures to be run will increase significantly over the next years. To manage this, and to improve pharmacovigilance activities and the safety of European patients, the Agency will be developing further data sources.

The Clinical Trials Regulation was published in May 2014, assigning the Agency the responsibility for developing the systems necessary to implement the Regulation. As a result, development of the EU Clinical Trial Portal and Database, and other associated systems, will be one of the key focus areas of the Agency in the coming years.

Veterinary medicines legislation

The revision of the EU's veterinary medicines legislation, with the aim of significantly simplifying the regulatory requirements, while maintaining a high level of protection of human and animal health, is expected to impact the Agency's activities once the legislation is adopted. The discussions are expected to continue over the next years, with the adoption of the legislation expected in 2016. Therefore, the Agency will continue providing technical support to the European Commission (‘Commission’, or EC) with respect to discussion in the European Parliament and the 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, which will arise as a result of the implementation of the revised legislation, will start in 2015.

Antimicrobial resistance and other public health threats

Antimicrobial resistance (AMR) is a growing problem for both humans and animals. This is exacerbated by the low number of new antimicrobials having been authorised over the past few years. 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 pandemics of an infectious disease.

As the Agency regulates both human and veterinary medicines, it is well placed to implement the 'One Health' approach and follow its application in tackling the AMR, both in its own work and through collaboration with its European and international partners. Therefore, the EMA will continue its collaboration with its EU and international partners on a number of initiatives aimed at limiting the development of AMR. As part of this work, the Agency will continue contributing to the work of the Transatlantic Task Force on Antimicrobial Resistance (TATFAR), which aims to increase levels of communication, coordination and cooperation between the EU and the United States on human and veterinary antimicrobials. The Agency will also continue implementing the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, which collects information on how antimicrobial medicines are used in animals across the EU, and thus allows for a better understanding of the risk factors that lead to the development and spread of antimicrobial resistance.

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

Transparency

As the EMA enhances its efforts to share knowledge and information with the NCAs, patients, healthcare professionals, the media and other stakeholders, the demand for data is expected to increase, and the central coordination role of the Agency, combined with improvements in data integration, becomes more important. In addition, the requests from stakeholders will increasingly relate not only to accessing data, but also to interpretation and analyses of those data. This translates into an increasing need for managing and sharing reliable data, in particular to support evidence-based regulatory decision-making grounded on science, improve the use of medicines and satisfy the demands for greater transparency and openness.

Transparency of the decision-making process throughout the lifecycle of medicines remains a key driver. Patients, consumers and healthcare professionals demand more and better information to support their decision-making, together with high levels of transparency from industry and regulators. 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 thus becoming subject to more intense scrutiny by the stakeholders and the community as a whole, with impact on public trust in the Agency's work.

The implementation of the policy on access to clinical data will also be a significant aspect of the Agency's transparency initiatives.

Information technology and social media

The growing trend for patients and healthcare professionals to use the internet, mobile communications and social media when searching for medicines-related information raises the importance of using these communication channels more widely, to ensure easy, consistent and timely access to authoritative, reliable and understandable information on medicines.

The ever-increasing role of information technology in health-related matters, including use of e-health records and databases, mobile communications and social media by consumers and healthcare professionals, also demands that surveillance methods evolve to consider these developments.

Priorities

In light of the above influences and other business environment factors, the Agency has set out the following priorities for 2015:

- Deliver business activities to a high level of quality, efficiency and consistency in both the human and veterinary areas.
- Facilitate early stages of medicines development in both the human and veterinary areas.
- Enhance cooperation within the Network, as well as with European and international partners.
- Implement pharmacovigilance legislation and the clinical trials legislation.
- Provide technical support to the European Commission during the co-decision process for the proposal on revision of the veterinary medicines legislation in the Council and the European Parliament.
- Ensure efficient crisis management and responsiveness to public health threats, including addressing antimicrobial resistance and the availability of anti-infective treatments.
- Further increase transparency and implement stakeholder and communication strategies.
- Improve quality, integration and accessibility of data held by the Agency.

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 EC on their marketing authorisation, as well as monitors the safety, quality and benefit-risk balance of the authorised medicines. It develops scientific guidelines to facilitate 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 EC. The Agency is not involved in assessment of nationally authorised medicines, except regarding pharmacovigilance activities under the new legislation or to solve a disagreement between two or more Member States.

1.1. Pre-authorisation activities

Activity areas

Pre-authorisation support aims to facilitate and improve availability of safe and effective medicinal products to 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 the 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:

- **scientific advice** and **protocol assistance**. To facilitate product development process, the Agency provides scientific advice (initial and follow up) to sponsors on all products and issues related to 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 on 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 development of products which, for economic reasons, would otherwise not be pursued.
- **paediatric procedures**. 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, and consequently assesses and verifies compliance with 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 (SMEs). 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). 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 to EMA scientific services and procedures, as well as scan the horizon and exchange information and establish networks, to develop and maintain expertise in the field. ITF works closely with our partners within the Network, Academia specialists and EU network of Innovation and Technology Forum Offices. ITF also collaborates with the European Institutions and international partners on the Innovation Task Force procedures.
- support development of **medicines for specific target populations**. 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, formulations and packaging adapted to the ageing population, and the challenges posed by co-morbidities and multiple medications.

  Building on the activities in the area of paediatric medicines, the Agency is increasing its focus on the safer use of medicines in pregnancy and by lactating mothers.

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 complexity of the scientific advice and other Agency activities. Following closely these developments and ensuring 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 the SMEs. To do this, the Agency has undertaken a number of initiatives to ensure early dialogue to foster drug development and to improve regulatory pathways for early patient access to medicines.

The expected growing need for industry and academia to approach the 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, elderly and psychiatric disorders, neonates and pregnancy-related conditions.

Key objectives and activities

Objective	Activities
Promote more active use of scientific advice and other pre-application support, including early and iterative dialogue with pharmaceutical sponsors	Launch a scheme to facilitate interaction and early dialogue with sponsors throughout the medicines lifecycle
	Organize a workshop on significant benefit
Improve cooperation with partners (e.g. HTA bodies, European networks, international partners) throughout the product life-cycle	Finalize guidance to applicants to facilitate access to parallel SA HTA procedure
	Review existing guidance on parallel scientific advice with the FDA
	Develop guidance for the qualification of novel methodologies, in collaboration with IMI, EFPIA and FDA
Facilitate research and development of new medicinal products	Complete the adaptive pathways pilot project and review outcomes of the pilot
	Provide scientific and regulatory input to the European Commission on specific borderline products
	Identify areas in need of further research and communicate it to funding bodies (e.g. IMI, Horizon 2020) to stimulate targeted research projects
Support development and availability of medicines for specific target groups	Develop and implement EMA Gender strategy
	Implement EMA Geriatric medicines strategy

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Scientific advice/protocol assistance pre-submission meetings	116	153	165
Scientific advice and protocol assistance requests**, of which:	357	448	493
Parallel scientific advice with international regulators requests	6	8	6
Joint scientific advice with HTA bodies requests	7	11	12
Protocol assistance requests	108	106	116
Novel technologies qualification advice/opinions	15	21	23
Scientific advice finalised	365	422	464
Protocol assistance finalised	111	93	102
Orphan medicines application pre-submission meetings	125	200	190
Orphan medicines applications, of which:	201	290	260
Parallel orphan applications with international regulators	82	100	120
Paediatric procedures applications (PIP, waivers, PIP modifications, compliance checks)	477	470	480
Finalised procedures for compliance check on PIPs	58	65	72
Requests for classification of ATMPs	20	21	25
Innovation Task Force briefing meetings requests	28	30	35

	Results		Forecasts
	2013	2014*	2015
Innovation Task Force Art 57 CHMP opinion requests	10	10	8

* expected results
** excluding SA requests after receiving marketing authorisation

Performance indicators

	Results		Targets
	2013	2014*	2015
Scientific procedures completed within regulatory timeframes**	99.5%	100%	100%
Increase in scientific advice requests	12.6%	25%	10%
SME requests for SA (% of total SA requests)	24%	20%	20%
% of initial evaluation applications (for new active substances and biosimilars) that have received SA	72%	74%	76%
% of applications designated as orphan medicines	69%	73%	75%
Number of confirmation of applicability of paediatric class waivers	78	63	45

* expected results
** these include scientific advice and protocol assistance, orphan designation and paediatric procedures

Resources

Financial resources (cost, thousand Euro)	35,755
Human resources (FTEs)	89

1.2. Initial evaluation activities

Activity areas

Initial evaluation refers to the process of **scientific assessment of the medicines submitted for centralized marketing authorisation**. It also covers the provision of scientific opinions, in co-operation 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 the applications for marketing authorisation, including the risk management plans, and issues opinions which form the basis for the EC decision to grant the 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 in regard to requirements for demonstrating quality, safety and efficacy of a medicine.

This scientific review is documented in the assessment report, which is made publically available as European public assessment report (EPAR).

Drivers

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

The product information on the safe and effective use of the medicine is a key source of information for various stakeholders. 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.

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 involvement and requirements of other stakeholders leads to increased cooperation with other stakeholders and decision-making bodies, such as HTA, in relation to exchange of information around the time of licensing and introducing a more comprehensive approach to the planning of and data generation for post-authorisation measures.

In efforts 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 to involve patients in benefit/risk assessment process.

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 assessment. In order to improve utilisation of various mechanisms to bring medicines to market, the available regulatory tools to allow patient access to medicines for conditions with unmet medical need, including accelerated assessment and conditional marketing authorisation, will be reviewed. In addition, the usefulness of these mechanisms in the context of innovative licensing approaches, such as adaptive pathway, will be explored.

Key objectives and activities

Objective	Activities
Provide high quality, robust, scientifically sound and consistent scientific opinions to the EC	Embed the use of Effects table in all assessment reports
	Implement guidance to support a consistent approach for imposed PASS/PAES
Provide high quality, evidence-based and consistent product information that meets stakeholders' needs	Implement an improved process for the review of the product information
	Initiate discussions with HTA bodies on labelling usability
	Strengthen existing guidance on labelling and promote the use of the guidance and advisory groups to support labelling discussions during product evaluation
Increase patient involvement in benefit/risk evaluation of medicines	Prepare 1-year analysis report on patient involvement in benefit/risk evaluation in CHMP
	Develop recommendations on the feasibility of convening focus groups in specific disease areas to obtain real-life data
	Analyse the applicability of methods, including visualisation and patient values, for benefit risk assessment (2015) and publish an interim report (2016)

Objective	Activities
Reduce time-to-patient of medicines through use of existing and new assessment approaches within the existing legal frameworks, including through collaboration with international partners	Deliver analysis of the use of conditional marketing authorisation concept and review changes needed regarding tools or training
	Deliver analysis of accelerated approval concept and review changes needed regarding tools and training
	Provide guidance on optimal use of the full range of available regulatory tools to address emerging public health threats
	Explore with HTA bodies the opportunity for information exchange on assessments around time of licensing to support rapid relative effectiveness assessments
Enrich the tools available to the European regulatory network to support a robust benefit-risk evaluation of human medicines throughout their lifecycle	Explore approaches and scenarios for use of individual patient data (IPD) to enhance committees' scientific assessment

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Initial evaluation applications, of which:	78	118	114
New non-orphan medicinal products	48	48	48
New orphan medicinal products	16	23	24
Similar biological products	1	5	8
Generic products	5	30	24
Hybrid and abridged applications	6	10	8
Scientific opinions for non-EU markets (Art 58)	1	1	1
Paediatric use marketing authorisations	1	1	1

Performance indicators

	Results		Targets
	2013	2014*	2015
Applications evaluated within legal timeframes**	99%	100%	100%
Average assessment time for new active substances and biosimilars	207	205	205
Average clock-stop for new active substances and biosimilars	218	169	180

* expected results
** these include marketing authorisation and plasma master file applications

Resources

Financial resources (cost, thousand Euro)	28,821
Human resources (FTEs)	66

1.3. Post-authorisation activities

Activity area

Post-authorisation activities include all the activities performed by the Agency in order 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:

- **extensions of** and **variations to marketing authorisations** (MAs). Variations to marketing authorisations 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.

  Line extension applications 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**. Maintenance activities include follow up of certain obligations and measures that marketing authorisation holders need to fulfil following the grant of marketing authorisations. These include re-assessment and renewal of MAs, post-authorisation measures, transfers of MAs, Article 61(3) notifications.

Drivers

The workload of post-authorisation activities is expected to continue increasing, due to the organic increase in the number of centrally authorised products.

Product profiles change and evolve as new data on medicines is gathered and introduced after obtaining marketing authorisation. This raises the importance of maintaining 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.

Key objectives and activities

Objective	Activities
Provide high quality, efficient and consistent scientific assessment of post-authorisation changes to marketing authorisations	Develop agreed high quality standards to support review PASS protocols
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)	Implement a pilot process for review of non-imposed PASS protocols through scientific advice procedures
Improve the knowledge of the impact of medicines' use on environment	Update review of environmental risk assessment in submitted dossiers

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Variation applications, of which:	5,841	5,074	5,605
Type I A variations	2,922	2,498	2,665
Type I B variations	1,958	1,610	1,960
Type II variations	961	966	980
Line extensions of marketing authorisations	16	18	18
Post authorisation scientific advice requests	116	95	105

* expected results

Performance indicators

	Results		Targets
	2013	2014*	2015
Post-authorisation applications evaluated within legal timeframes	99%	100%	100%
Risk management plans peer reviewed within the assessment process of extensions of indications and line extensions	100%	100%	100%

* expected results

Resources

Financial resources (cost, thousand Euro)	88,830
Human resources (FTEs)	93

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 European Commission, any Member State or by the company that markets the medicine.

Drivers

The number of referrals is expected to remain the same as for 2014. Everyday medical practice will frequently provide data and information for pharmacovigilance referrals, which will need to be harnessed and incorporated into the assessments to increase the quality and relevance of referral conclusions.

Key objectives and activities

In regards to referrals, the Agency expects to continue its regular activities in order to deliver high quality and consistent scientific opinions to the EC and Member States.

Workload indicators

	Results		Forecasts
	2013	2014*^	2015
Pharmacovigilance referrals started	18	12	15
Non-pharmacovigilance referrals started	25	13	13

* expected results
^ starting 2014 lower number of referrals due to change in legislation and the grouping of products in the procedures

Performance indicators

	Results		Targets
	2013	2014*	2015
Referral procedures managed within the legal timelines	100%	100%	100%

* expected results

Resources

Financial resources (cost, thousand Euro)	4,814
Human resources (FTEs)	25

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 interconnecting 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 CAPs), post-authorisation referrals, inspection and data management and therefore related items are found also in those sections of this document.

The area covers:

- The management of Adverse Drug Reaction reports, Periodic Safety Update Reports, Risk Management Plans and oversight of Post-Authorisation Studies.
- Cooperation with the NCAs in the management of safety signals for Centrally Authorised Products and for 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 during 2015 and 2016. 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, a 46% increase in total number of PSURs is expected in 2015, due to the PSURs containing only NAPs being assessed through the PRAC.

Availability of new IT tools and functionalities in combination with the study on experience gained so far and results of regulatory science projects (notably EU PROTECT) will allow reaping improvements in 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, offer unprecedented opportunities for gathering and generation of additional scientific evidence to supplement the contribution of the pharmaceutical industry and 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 2015.

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.

Key objectives and activities

Objective	Activities
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes and services	Publish the report on the impact of the EU PROTECT project on medicines development, regulation and pharmacovigilance
	Launch literature monitoring service
	Publish Good practice guide on coding & reporting and on risk minimisation & prevention of medication errors
	Develop, test and validate a Standardised MedDRA Query (SMQ) on medication errors to facilitate ICSR data retrieval as a first step in investigating drug safety issues
	Prepare (2015) and publish (2016) a report on methods and approach for measuring pharmacovigilance impact
	Finalise remaining GVP modules
	Publish draft code of conduct (2015) and governance proposals (2016) for vaccine benefit risk studies from the ADVANCE project
	Conduct pilot studies, based on common protocols, with a small number of Member States in the context of PRAC safety assessments (2015). Develop recommendations for a sustainable process, based on the experience gained (2016)
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	Deliver a PCWP/HCPWP workshop on risk minimisation tools
	Define the scope and process of best evidence generation in the context of PRAC
	Establish a new framework procedure for the external procurement of effectiveness and pharmacoepidemiology studies on medicines
	Amend eRMR to include products that are subject to additional monitoring
	Initiate a pilot on EU collaborative framework for Patient registries
	Analyse in collaboration with the Member States the need to update relevant guidance for the industry to reflect the use of social media and other tools in ADR reporting, considering output from the WebRADR project
	Investigate compatibility of Applications for patient reporting developed at national level (WebRADR project) with subsequent reporting from Member States to EudraVigilance
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	Publish report on EMA pharmacovigilance activities
	Publish final report on the IMI PROTECT study of consumer reporting during pregnancy, including recommendations for action
	Deliver analysis from the pilot-phase conducted in 2014 on publication of Risk Management Plan summaries for newly centrally-authorised products

*in 2015, if reporting aligned with MS reporting. If not, report will be published in 2016

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Total adverse drug reaction reports, of which:	1,063,456	1,125,386	1,215,893
Adverse drug reaction (ADR) reports for CAPs	679,413	703,240	763,534
Number of signals peer-reviewed by EMA	2,449	2,100	2,000
Number of signals validated by EMA	43	35	40
PSURs received	518	530	566

	Results		Forecasts
	2013	2014*	2015
PSUSAs received**	n/a	n/a	210
Number of imposed PASS /PAES	2	41	51
Number of emerging safety issues received	24	18	20
Number of notifications of withdrawn products received	18***	128	150

* expected results
** PSUSA to start in 2015
*** notifications only received from November 2013

Performance indicators

	Results		Targets
	2013	2014*	2015
Reaction Monitoring Reports supplied to the lead Member State monthly	100%	100%	100%
Protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	100%	100%
Cumulative number of products on the list of products subject to additional monitoring	152	203	270

* expected results

Resources

Financial resources (cost, thousand Euro)	35,010
Human resources (FTEs)	90

1.6. Other specialized areas and activities

Activity area

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

- **clinical trials.** Growing trend to conduct clinical trials outside 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 works to provide capacity building and develop information exchange 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 granting 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.** 2009 influenza pandemic led to review of cross-European strategy for pandemic preparedness. The Agency continues implementing 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 exchange 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. This includes development of the EU Portal and Database in the coming years.

Key objectives and activities

Objective	Activities
Implement the new Clinical Trials Regulation (EU) No 536/2014	Deliver Clinical Trials programme
Assure quality of data and appropriate protection of participants of clinical trials through risk proportionate approaches to the design and management of clinical trials, especially those conducted outside EU/EEA	Implement a standardised set of information on clinical trials to be included in applications, CHMP assessment reports and EPARs
	Implement framework for ethics experts to advise CHMP
Facilitate development of new antibiotics for treatment of multi-resistant bacteria, including through enhanced international cooperation	Deliver workshops on pharmacokinetics / pharmacodynamics of antibacterial agents and bacteriophages
	Review the guideline for development of new tuberculosis medicines
Support high level of coordinated cross-European preparedness to act upon public health threats	Finalise guideline on clinical/non-clinical development of influenza vaccines
	Finalise procedural/regulatory guidance for pandemic vaccines
Facilitate availability of herbal medicines in the European Union	Identify remaining herbal substances requiring EU harmonisation and develop strategies/guidance to maintain up-to-date consistent standards (monograph/ guideline revisions)
	Assess combination products and herbal substances originating from non-European traditional systems

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Herbal monographs, new**	9	11	15
Herbal monographs, revised	7	5	10
List entries	0	1	1

* expected results
** where assessment does not lead to the establishment of a monograph, a public statement is prepared

Performance indicators

None identified.

Resources

Financial resources (cost, thousand Euro)	8,620
Human resources (FTEs)	21

1.7. Projects

In order 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 2015. The main projects in 2015 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 2016 and completing the projects on Article 57 and pharmacovigilance fee implementation.
- **Clinical trials**. Following the finalisation of the clinical trials legislation, preparations for the implementation of the regulation will take place in 2015. This includes developing the necessary IT solutions, such as EU portal, database and other functionality.
- **eCollaboration**. The focus in 2015 will be the implementation of a single entry point for electronic submissions for the Network through integration of the EMA's gateway and the CESP and the delivery of the PSUR repository.

Programme / Project	Start date	Delivery target	Deliverables 2015
Pharmacovigilance programme			
Art 57 - Initial Validation	2013	Q2 2015	• Functional Art 57 • Article 57 data validated to support PhV fee calculation (initial submission)
Medical Literature Monitoring	Q2 2014	Q3 2015	• MLM service in full production
Pharmacovigilance	Q1 2014	Q3 2015	• System and processes for invoicing, collection and

Programme / Project	Start date	Delivery target	Deliverables 2015
Fees			payment of Procedural and annual Fees
EV Auditable Requirements	Q2 2014	2016	• Functionality to: – receive, process and forward ICSR R3 messages to MS of occurrence – manage and analyse ICSR R3 information • Updated training capability to the industry and NCAs of the service with ICSR R3 information handling
EV and signal management Critical Requirements	2014	2016	• Published sustainable business process for industry notification of signals
Clinical Trials programme			
EU Portal and database	Q3 2014	2016	• Detailed business case • Functional specifications • Design and development of EU Portal and database and related workspace
Safety reporting	Q3 2014	2016	• Business case • Functional Specifications
eCollaboration programme			
eSubmission Gateway v.3	2013	Q1 2015	• Functionality to enable submissions to PSUR repository
Electronic application form (eAF)	Q4 2013	Q1 2015	• eAF ready for mandatory use for Centralised, National, MRP and DCP procedures
PSUR Repository	Q4 2013	Q2 2015	• Functional PSUR repository (basic functionality)
eCTD 4 review tool	Q3 2015	2017	• eCTD 4 standard • Impact analysis of the eCTD 4 standard on the EMA eSubmission systems
Single Submission Portal	Q1 2015	2017	• First version of the Single Submission Portal: Link the eSubmission Gateway to CESP • Analysis of requirements and possible solutions for the final version of the Single Submission Portal
Repository	Q1 2015	2017	• Improved version of PSUR repository with enhanced functionality • Analysis of requirements and possible solutions for repository with single interface for all types of applications and related documents submitted
Standalone projects			
ENCePP - EU PAS register upgrade	Q2 2015	2016	• Detailed business case

2. Evaluation activities for veterinary medicines

The European Medicines Agency supports and facilitates the development of medicines for veterinary use, evaluates 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 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:

- **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 which 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.

Drivers

In 2015 the focus in terms of pre-authorisation activities will remain on promoting the access to market of veterinary products, particularly those based on novel technology and those indicated for MUMS/limited markets.

Following the Management Board endorsement of the creation of the AD hoc expert group on VEterinary Novel Therapies (ADVENT), the work on establishing these groups and their operations will commence in 2015.

The revised policy on MUMS is expected to come into force in 2015, and is expected to make the procedure simpler, and more transparent and predictable. In 2015 the MUMS status of the products classified five years ago, at the start of the formal MUMS classification procedure, will expire and it is expected that a number of these applicants will request a review of their entitlements.

Key objectives and activities

Objective	Activities
Provide support and incentives to development of new medicines for MUMS/limited markets	Inform companies of expiry of MUMS status of their products and possibilities for requesting extension, and review products currently classified as MUMS/limited markets whose status expires in 2015
	Publish annual report on MUMS/limited market activities
Provide and further promote continuous and consistent pre-application support to applicants, including through collaboration with international partners	Review the procedures for scientific advice to identify areas for improvement, considering the views of recipients regarding the usefulness and quality of the advice received
	Inform applicants of the possibility to apply for parallel scientific advice with the FDA, as part of pre-submission advice
Promote innovation and use of new approaches in development of veterinary medicines	Establish and start operation of the ADVENT group
	Inform industry through presentations and as part of existing pre-authorisation procedures of the possibility to access the Agency's Innovation Task Force

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Innovation Task Force briefing requests	0	2	4
Scientific advice requests received	40	28	30
Requests for classification as MUMS/limited market	23	25	25

* expected results

Performance indicators

	Results		Targets
	2013	2014*	2015
Scientific advice procedures completed within set timeframes	100%	96%	100%

* expected results

Resources

Financial resources (cost, thousand Euro)	1,494

Human resources (FTEs)	2

2.2. Initial evaluation

Activity area

Initial evaluation refers to the process of scientific assessment of applications for veterinary medicines submitted for marketing authorisation through the centralised procedure. Activities within this domain are:

- **initial evaluation.** The initial evaluation phase includes pre-submission discussions with future applicants, scientific evaluation of the applications and issuing an opinion to the EC. The European 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 medicinal products as well as for 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 to 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 by industry in developing new veterinary medicinal products for food producing animals. The completion of guidance regarding MRLs for biocides, prepared jointly by EMA and ECHA, in 2015 will remove a hurdle for MRL applications relating to biocides used in veterinary husbandry. This type of application will require new ways of working for the CVMP, involving increased collaboration with other European bodies such as ECHA and EFSA. However, at this point it is still difficult to predict the impact in terms of actual applications to establish MRLs for substances used as biocides.

Key objectives and activities

Objective	Activities
Provide high quality and consistent scientific opinions to EC	Put in place the arrangements necessary to facilitate multinational national assessment teams and update the register of expertise of CVMP members and experts
	Update assessment report templates to provide new guidance on the principles for preparing veterinary medicines' assessment reports and further embed benefit-risk methodology in the

Objective	Activities
	veterinary medicines assessment process
	Provide assessor training to ensure consistent use of the above-mentioned assessment methodology
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 the implementing acts specified in Regulation (EC) No 470/2009
	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)

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Initial evaluation applications	23	16	20
New MRL applications	6	5	5
MRL extension and modification applications	6	3	2
MRL extrapolations	1	2	1
Art 9, Biocides	0	0	2
Review of draft Codex MRLs	0	5	0

* expected results

Performance indicators

	Results		Targets
	2013	2014*	2015
Procedures completed within legal timeframes**	100%	100%	100%

* expected results
** includes initial product applications and MRL application evaluations

Resources

Financial resources (cost, thousand Euro)	5,228
Human resources (FTEs)	14

2.3. Post-authorisation activities

Activity area

Post-authorisation activities include all the activities performed by the Agency in order 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:

- **Variations and extensions**. Variations to marketing authorisations can be either minor (type IA or IB) or major (type II) changes to the product information and dossier with regard to quality, safety and efficacy for the authorised product.

  Extension applications 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**. Maintenance activities include follow-up on certain obligations that marketing authorisation holders need to fulfil following the granting of the marketing authorisation. These include re-assessment 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 in 2015. The internal procedures for variations for veterinary products will be reviewed, taking into account the best practice developed in the human medicines divisions.

Key objectives and activities

Objective	Activities
Ensure efficient delivery of post-authorisation procedures	Review the procedures for variations and introduce necessary improvements
	Develop revised templates and guidance for the assessment of Type II variations

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Extension and variation applications, of which:	320	282	310
Type I A variations	175	150	150
Type I B variations	108	100	110
Type II variations	32	45	45
Line extensions of marketing authorisations	5	7	5

* expected results

Performance indicators

	Results		Targets
	2013	2014*	2015
Post-authorisation applications evaluated within legal timeframes	100%	100%	100%

* expected results

Resources

Financial resources (cost, thousand Euro)	5,270
Human resources (FTEs)	15

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 either in order 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 other safety-related issues. 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.

Drivers

In 2015, the Agency expects the same, high workload of referrals that has been experienced in recent years to continue.

The referrals of individual antibiotics or classes of antibiotics that are particularly important for use in human medicine will remain a priority area in 2015. A number of these referrals are expected to be triggered by the European Commission as part their Action plan against the rising threats from Antimicrobial Resistance 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.

Key objectives and activities

In regards to referrals in veterinary area, the Agency expects to continue its regular activities in the coming years. This will also include processing referrals that arise as part of the European Commission's Action Plan against the Rising Threat of Antimicrobial Resistance.

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Arbitration and community referral procedures initiated	10	10**	12**

* expected results
** it is expected that a substantial proportion of referrals will each relate to a large number of products, sometimes even hundreds of products. This is especially characteristic of referrals relating to antibiotics

Performance indicators

	Results		Targets
	2013	2014*	2015
Referral procedures managed within the legal timelines	100%	100%	100%

* expected results

Resources

Financial resources (cost, thousand Euro)	1,298
Human resources (FTEs)	5

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.

Key objectives and activities

Objective	Activities
Support efficient and effective conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high quality processes	Publish reflection papers on integration of signal detection and PSUR assessments, and promotion of pharmacovigilance reporting
	Develop a scheme for categorising products in the product database to further facilitate cross-EU pharmacovigilance
	Revise the process for CAPs and develop a new one for NAPs for surveillance of EVVet data
	Implement parts of the veterinary EU Telematics strategy covering pharmacovigilance elements not dependent on the new legislative proposal, including product data, data warehouse and others
	Publish reflection paper on causality assessment
Provide consistent, high quality information on pharmacovigilance topics to stakeholders and partners	Publish the veterinary pharmacovigilance annual bulletin

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Periodic Safety Update Reports (PSURs)	149	150	150
Total AE reports, of which:	22,326	22,500	22,500
Adverse Event Reports (AERs) for CAPs	8,166	7,200	8,000

* expected results

Performance indicators

	Results		Targets
	2013	2014*	2015
PSURs evaluated within the established timeline	97%	90%	90%
Adverse events reports for CAPs monitored within the established timelines	100%	95%	95%

* expected results

Resources

Financial resources (cost, thousand Euro)	1,800
Human resources (FTEs)	6

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:

- 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 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 focussed in particular on ensuring the continued availability of antimicrobials for treatment of infectious disease in animals whilst 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. The discussions are expected to continue in the next years, with the legislation expected to be adopted in 2016. Therefore, the Agency will continue providing technical support to the EC with respect to discussion 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, which will arise as a result of the implementation of the revised legislation, will start in 2015.

Efforts to combat risks arising from antimicrobial resistance will remain a high priority. Following the anticipated 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 expects to be involved in follow-up 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 in 2015. In addition to continued annual monitoring and reporting on the consumption of

veterinary antimicrobials across the EU, in 2015 the focus will be on developing methodologies to monitor consumption by species and by category (e.g. weaners, growers, sows etc.) as well as developing standardised units of consumption (e.g. Daily Defined Doses (Animals).

Following the review and report carried out in 2014, veterinary involvement in the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) has increased and now includes identification of knowledge gaps in the train of transmission of AMR from animals to man. The objective will be to explore how transatlantic cooperation might help bridge identified knowledge gaps so that risk management measures can be optimally applied.

In 2015, an updated strategy for the next five years will be developed for the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The Agency will continue to contribute actively to both, the development of this strategy and its subsequent 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.

Key objectives and activities

Objective	Activities
Support increased availability of veterinary medicines	Provide necessary input to the European Commission during the co-decision process for new veterinary legislation
Contribute to minimising the risk to man and animals from the use of antibiotics in veterinary medicine	Clarify the regulatory requirement for the development of new veterinary antimicrobials by providing further guidance/advice to applicants
	Prepare with the Commission workshop for stakeholders on advice provided by the EMA on assessment and control of the risks to man that may arise from the use of antimicrobials in animals
	Complete a pilot survey of antimicrobial consumption in pigs
	Contribute to TATFAR recommendations related to veterinary medicines
	Produce first drafts of reflection papers on extended-spectrum penicillins and on benefit risk assessment in the case of veterinary antimicrobials
Promote uptake of harmonised standards at international level	Contribute to development of the VICH Strategy (phase IV)
	Participate in training events that raise awareness and enhance uptake of VICH standards by non-VICH countries
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

Workload indicators

Not applicable.

Performance indicators

None identified.

Resources

Financial resources (cost, thousand Euro)	2,419
Human resources (FTEs)	6

2.7. Projects

In order 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 2015.

In the veterinary area work on the **systems supporting regulation of veterinary medicinal products** will continue, based on the architectural principles laid out in the Veterinary IT Strategy adopted by the EU Telematics Management Board in 2014.

Programme / Project	Start date	Delivery target	Deliverables 2015
Veterinary IT programme			
Veterinary Product Management Service v1	Q1 2015	2018	• Detailed requirements and objectives for the data in the Common European Database of Veterinary Products • Development of tools for stakeholders' data cleansing process
Business and Solution Architecture for Veterinary Medicines	Q1 2015	2017	• Preliminary business case for solution architecture

3. Horizontal activities and other areas

Horizontal activities of the Agency cover those business-related activities that are not specific to only human or veterinary medicines, but span both areas and define, enable and support the medicines evaluation activities. These activities are directly linked to and necessary for delivering the core services of the Agency and include coordinating committees' work, maintaining necessary IT systems, 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 specific area of work. Six committees provide scientific opinions regarding human medicines (CHMP, COMP, PDCO, HMPC, CAT, PRAC), and one focuses on veterinary medicines (CVMP). The Agency's committees typically meet on a monthly basis, and the Agency provides all the support in organizing and conducting these meetings.

The activities within this domain include:

- **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 co-ordination between the committees, so as to increase robustness and predictability of the outcome of the benefit-risk assessment by having consistent standards set for development of medicines across the whole product lifecycle.
- **Committee secretariat.** Committee secretariat provides organisational, secretarial and budget management for the operation of the Agency's scientific committees, as well as necessary regulatory support to the committees. It includes coordinating adequate scientific support and leadership across the Agency's divisions, as well as ensuring co-ordination and communication across scientific committees, working parties and scientific advisory groups, and facilitating interactions between these groups. In addition, the committee secretariat coordinates work programme 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).
- **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 products assessment 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 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 trainings, including those under the Enlargement programme. Meeting Management organises travel and accommodation arrangements for delegates whilst also providing assistance with logistical and administrative issues.

Drivers

The evaluation process of the medicines increasingly needs to consider aspects such as incorporating patients' preferences in the benefit-risk assessment, considering the needs of stakeholders (e.g. HTA) 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 the medicines, and consequently — the workload of the Agency, both in its endeavour to support the scientific assessment of the committees, and in its role of key provider of training, technical and methodological guidance for the scientific work. An emphasis in the consistency of scientific and regulatory decision will require robust internal processes and expansion of the overall capabilities of the NCAs and EMA.

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 be increasing.

Key objectives and activities

Objective	Activities
Improve collaboration and communication between committees to increase quality, efficiency and consistency of opinions	Implement harmonised product evaluation and post-authorisation processes for human medicines Committees
Provide up-to-date, timely state-of-art guidance documents on relevant topics of medicines' development	Improve planning and delivery of working parties guidance documents

Workload indicators

The workload of scientific committees is largely driven by the activities described under Human and Veterinary medicines evaluation activities chapters of this document. Thus, the relevant workload drivers are found in the corresponding sections.

	Results		Forecasts
	2013	2014*	2015
Number of meetings	354	390	477
Number of teleconference meetings**	2,737	3,050	3,600
Number of delegates	6,869	7,300	8,900

* expected results
** total audio, video and web-conference meetings

Performance indicators

	Results		Targets
	2013	2014*	2015
Delegate satisfaction with service level provided by secretariat	-	80%	80%
Up-to-date electronic declarations of interest submitted by committee members and experts prior to participating in a committee, SAG or other meeting	-	100%	100%
First stage evaluations of conflicts of interest for committee members and experts completed prior to their participation in the first meeting after the submission of new or updated declaration of interest	-	100%	100%
Ex-ante verifications of declarations of interest for new experts completed within 2 weeks after upload of the DoI in the experts database	-	80%	80%

* expected results

Resources

Financial resources (cost, thousand Euro)	4,599
Human resources (FTEs)	25

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:

- **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), 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 on-going supervision of authorised products. Similarly, the Agency coordinates inspections of blood establishments within the plasma master file (PMF) certification framework.
- **harmonisation of inspections standards and practices**. The Agency contributes to the harmonisation of inspections 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 European 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.
- **supply chain integrity.** 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 minimize the risks of such shortages occurring in the future, as well as mitigate the impact of shortages that do occur. The Agency continues promoting 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 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. 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. The trends for the certificates and parallel distribution are similar, with parallel distribution activities remaining on similar level and certificates increasing slightly, when compared to 2014.

Key objectives and activities

Objective	Activities
Increase efficiency, consistency, quality and coverage of inspections through enhanced international cooperation and reliance on inspections by trusted authorities	Launch implementation of the risk-based inspections programme for 3rd country manufacturing plants of centrally authorised products, focusing EU inspectional resources to 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 activities for inspectors and clinical assessors
	Identify, develop (2015) and implement (2016) tools for GCP related information exchange within international GCP network
	Prepare (2015) and set up (2016) a pilot phase with FDA on sharing information on pharmacovigilance inspections
	Develop (2015) and implement (2016) tools to support pre-clinical assessors in identification of triggers for GLP inspections
	Identify, develop (2015) and implement (2016) a plan for further co-operating with Member States in co-ordinating 3rd country inspections
	Establish a mutual reliance framework with US FDA based on the existing mutual recognition agreements to increase the scope of EU international inspections activities
	Establish a mutual reliance framework with international partners performing inspections of manufacturers of active pharmaceutical ingredients and human and veterinary medicinal products
Maintain quality and continuity of medicines' supply chain and prevent circulation of falsified medicines	Develop procedures to link parallel distribution process with GMP procedures and allow use of parallel distribution information in the detection of falsified medicines in the supply chain
	Conduct lessons learnt exercise from the 2014 stolen medicines problem to further reflect on how the Network can address similar future threats to the supply chain
Improve mitigation of shortages of human medicines caused by GMP non-compliance and quality defects	Identify (2015) and implement (2016) process improvements on the handling of quality defects and non-compliance issues
	Research the root causes of quality defects and GMP non-compliance leading to shortages of human medicinal products

Workload indicators

	Results		Forecasts
	2013	2014*	2015
GMP inspections	397	395	390
GLP inspections	0	1	1
GCP inspections	70	71	70
Pharmacovigilance inspections	13	14	15
Notifications of suspected quality defects	178**	140	140
Other GMP inspections related notifications	-**	20	20
Medicinal products included in the sampling and testing programme	45	48	45
Standard certificates requests	3,137	3,300	3,300
Urgent certificates requests	297	450	450

	Results		Forecasts
	2013	2014*	2015
Parallel distribution initial notifications received	2,532	2,500	2,550
Parallel distribution notifications of change received	2,563	1,300***	1,100
Parallel distribution notifications of bulk changes received	7	17	10
Parallel distribution annual updates received^	1,205	2,500	2,600

* expected results
** please note, in previous years notifications of suspected quality defects and GMP related issues were counted under the heading of Notifications of suspected quality defect
*** sharp fall due to the introduction of annual updates. Numbers for 2015 and 2016 mainly reflect notifications of safety updates and only a small amount of notifications of a change
^ parallel distribution annual updates introduced in May 2013

Performance indicators

	Results		Targets
	2013	2014*	2015
Inspections conducted within established regulatory timeframes	100%	100%	100%
Standard certificates issued within established timelines (10 days)	51%	90%	90%
Average days to issue standard certificate	11	15	10
Urgent certificates issued within established timelines (2 days)	100%	100%	100%
Parallel distribution notifications checked for compliance within established timeline	90%	90%	90%
Training activities organised in the area of inspections	-	At least 4	At least 4
Additional GCP inspections addressed through information exchange on inspections carried out by international partners	-	25%	25%
Additional routine GMP re-inspections of manufacturing sites addressed through exchange of information with international partners	-	10%	10%
Outcome reports of Sampling and Testing for centrally authorised products followed-up with MAH within one month of receipt	100%	100%	100%

* expected results

Resources

Financial resources (cost, thousand Euro)	14,365
Human resources (FTEs)	42

3.3. Partners and stakeholders

Activity area

Activities covered in this area include:

- **interactions with partners.** In order to deliver its mission the Agency collaborates with National Competent Authorities in Europe, European Commission, other EU institutions and EU agencies, and health technology assessment bodies. These interactions range from exchange of information, qualification of novel methodologies with HTA bodies, collaboration on guideline and standard development, to capacity building, to providing scientific expertise in the evaluation processes, to 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 collaboration with academia, with a particular focus on innovation in medicines, such as qualification of biomarkers and new methodologies.
- **small and medium size enterprises'** (SMEs) **office.** The Agency has an office specifically dedicated to supporting smaller companies, the SME Office. It provides SMEs with access to various incentives and regulatory assistance, including fee reductions, deferrals and conditional exemptions to eligible companies, administrative and procedural support as well as assistance with translations of the product information documents submitted in applications for marketing authorisation. Around 1,250 SMEs are registered with the Agency.
- **information and transparency.** The Agency places high importance on transparency, openness and efficiency of its interactions with partners and stakeholders. The Agency maintains and manages specific communication and information exchange platforms, and provides up-to-date information to the public on its work and outputs as well as important subject matters and developments. Public access to documents and information is provided in accordance with Regulation (EC) no 1049/2001.

Drivers

As the EMA enhances its efforts to share knowledge and information with the NCAs, patients, healthcare professionals, media and other stakeholders, the central coordination role of the Agency becomes more important. The increased demand for access to data and data integration will thus bring new challenges for the Agency.

The implementation of the policy on access to clinical data and the clinical trials legislation, adopted in 2014, will require the Agency to review and adopt its data management and publishing systems. In addition, the requests from stakeholders will increasingly relate not only to accessing data, but also to interpretation and analyses of this data.

The increasing involvement of key stakeholders including patients and healthcare professionals and the increased workload of EMA and NCAs will require more user-friendly communication platforms. The increasing use of internet and social media when searching for medicines-related information raises the importance of EMA using these communication channels more widely, to ensure easy, consistent and timely access to authoritative, reliable and understandable information on medicines.

Academia, SMEs and public private partnerships are an increasingly important source of innovation in medicines. To account for this, the Agency will reinforce its development support to these stakeholder groups, including through the roll-out of the SME instrument in Horizon 2020 which will enable SMEs to access EU funding directly to support clinical development in response to specific calls.

Key objectives and activities

Objective	Activities
Enhance cooperation within European medicines regulatory network	Develop common vision and strategy 2016-2020 for the EMA and Member States
	Publish report on experience so-far on coordination of safety announcements, including outcomes of the survey on the use of 'Early Notification System' by NCAs
	Establish an EU Network Training Centre
	Complete initiative to collect procedure-related time data
	Expand implementation of multinational teams' concept
Further strengthen Agency's transparency and open data commitments	Develop the EMA Transparency policy
	Develop (2015) and implement (2016) necessary processes for clinical data publication, including processes for document receipt, redaction consultation and decision, public access process and others
	Initiate stakeholder consultation (2015) and develop methodology (2016) for preventing identification of individuals in clinical reports
Provide stakeholders and partners with consistent, high quality, timely, targeted and accessible information on Agency work, outputs and medicinal products	Publish EMA guidance on product-related communication' indicating to partners and stakeholders 'when' and 'what information' the EMA publishes on medicines
	Review communication products to streamline Agency information outputs
	Develop and agree with HMA a strategy paper on European Web Portal
	Deliver analysis on information needs of different stakeholders regarding the Agency's scientific output (2015). Review Agency's communication tools as per the results of the analysis (2016)
Strengthen stakeholder relation focusing on patients and consumers, healthcare professionals, industry associations and academia	Implement the stakeholders' relations management framework
	Implement the revised EMA framework of interaction with patients and consumers' organisations
	Conduct satisfaction survey on healthcare professionals' involvement in EMA activities
	Survey the SME stakeholders and prepare 10 year report
	Develop (2015) and implement (2016) framework for collaboration with academia
	Implement (2015) framework for interacting with industry stakeholders and conduct survey to monitor the progress (2016)
	Publish annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Requests for SME qualification	401	500	550
SME status renewal requests	808	1,000	1,200

	Results		Forecasts
	2013	2014*	2015
Access to documents requests	293	350	400
Access to documents, documents released	n/a	750	1,000
Requests for information	5,840	5,000	6,000

* expected results

Performance indicators

	Results		Targets
	2013	2014*	2015
Satisfaction level of Patient and Consumers' Organisations	-	80%	-
Satisfaction level of SMEs	-	-	80%
Response to ATD within set timelines	n/a	98%	99%
Response to RFI within set timelines	n/a	95%	98%

* expected results

Resources

Area of activity	Financial resources (cost, thousand Euro)	Human resources (FTEs)
Partners and stakeholders	9,856	25
Transparency and access to documents	2,635	16
Information	5,231	27

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 and others), as well as international organisations (such as EDQM, WHO, ICH, VICH, OIE, ISO, HL7, IPRF and others). These interactions span most of the activities of the Agency, and activities covered in this area include:

- regular **exchange of information** on products, guidelines, policies and approaches takes 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 FDA, qualification of novel methodologies, joint collaborations on orphan, paediatric and advanced therapies and in the area of nanomedicines. The potential for further international worksharing has led to additional cooperative activities particularly in the inspections area, pharmacovigilance and signal detection as well as 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 WHO to provide 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, present additional oversight challenges, increasing risks of falsification and concerns about data integrity.

At the same time, similarity of the 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 emerging economies, 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) has been established, to which the Agency contributes through its active membership.

Along the 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 coalitions to encourage better and more effective use of global regulatory resources.

Ebola epidemic has exemplified the need to support the strengthening of regulatory systems to protect global public health, as it was articulated in the 2014 World Health Assembly resolution.

Key objectives and activities

Objective	Activities
Enhance international cooperation activities to increase efficiencies and synergies through greater work-sharing	Implement strategy to enhance cooperation between regulators in the field of paediatric medicines
	Implement pilot information sharing on generic medicines
	Increase involvement of non-EU regulators in assessment activities as observers to further develop Article 58 as a capacity building opportunity
	Finalise confidentiality arrangements with WHO and other international partners
Support the development of a strategic global vision and oversight of international activities	Map the progress of international initiatives to identify gaps and duplications

Workload indicators

None identified.

Performance indicators

Not applicable.

3.5. Data management support

Activity area

Data and information on medicinal products is one of the Agency's fundamental assets and it is a priority to share this data and information with our partners and stakeholders, who rely on it to do their work.

Data management consists of the planning and execution of policies, practices, and projects that acquire control, protect, deliver and enhance the value of data and information assets.

Activities covered in this area include: data governance, data quality, master data management, data architecture, data development, data security, data warehousing and business intelligence.

Drivers

Operational, legislative and financial factors are driving how the Agency manages data. There is an increasing need for managing and sharing reliable data with NCAs and industry in particular to support evidence-based regulatory decision-making, improve the use of medicines and satisfy the demands for greater transparency and openness.

Implementation of ISO IDMP standards is an opportunity to apply interoperability and consistency to the information that is shared across the regulatory authorities within the EU and internationally. The Regulation (EU) No 520/2012 requires the marketing authorisation holders, NCAs and the Agency to comply with ISO standards for the identification of medicinal products (ISO IDMP) by July 2016.

Also, in a continuous effort to meet the demands for increased efficiency of operations while increasing the level of service the Agency provides, data management has become a key activity in creating an integrated, shared environment that provides a single, accurate, consistent source of data for all our stakeholders.

Key objectives and activities

Objective	Activities
Engage the Agency's stakeholders in the governance of data and promote a wider and deeper understanding of the value of data assets	Consolidate the EU Network Data Board (EUNDB)
	Establish the IDMP Implementation Working Group with EMA and NCAs
	Develop and implement common policies, procedures and standards to maximise the sharing and optimise investment in data
	Develop and implement appropriate security and privacy policies to protect data assets
Increase consistency of information shared across the EU Network	Develop an end-to-end process map to integrate data flow across all systems (PhV, regulatory submissions, xEVMDP, etc.)
	Analyse (2015) and implement (2015-2016) ISO IDMP roadmap with EU NCAs and industry
Ensure effective decision making in the EU regulatory network by providing access to more analytical data	Develop and provide metrics and dashboards to EU NCAs on the state of the EU data management performance

Performance indicators

	Results		Targets
	2013	2014*	2015
Substance data registered in 4 working days	-	75%	75%
Substance data registered in 8 working days	-	90%	90%
Calls reopened due to incorrect handling	-	3%	<3%
Stakeholder satisfaction with service level of data management services	-	-	80%

* expected results

3.6. Projects

In order 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 2015. The main projects in 2015 will be related to:

- **Data integration**. This programme aims to deliver ISO compliant systems for substance management, product management, organisations management and referentials management in order 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.
- **Online roadmap.** This programme aims to deliver a platform for improved collaboration among the staff of the Agency and NCAs.

Programme / Project	Start date	Delivery target	Deliverables 2015
Data Integration programme			
SPOR (Art 57)	Q1 2015	2017	• MDM Solution implemented • Data Quality tool implemented • ISO IDMP Implementation guides & EU versions finalised • Access and Identity Management solution implemented • Referential Management System designed and referential data and processes migrated into MDMS
Tracking of applications	Q4 2014	Q3 2015	• Siamed enhancements to support NAPS - tracking of PSUSA, PASS and referrals • Siamed enhancements to include PSUR scheduling (incorporation of the EURD List)
Case Management	Q1 2015	2017	• Case Management Roadmap • Complete POC
Online programme			
Corporate website	2013	Q1 2017	• Revised information architecture • Process analysis/ reengineering

Programme / Project	Start date	Delivery target	Deliverables 2015
			• Reorganised and rewritten website content
Extranet	2013	Q1 2017	• User interface designs • New information architecture • Functional specifications • Prototype delivery • Business process analysis
Intranet	2013	Q1 2017	• User interface designs • Revised information architecture
Standalone projects			
EU Network Training Centre	Q2 2014	Q2 2016	• Training strategy • Training catalogue and materials • As-is Analysis, Proof of Concept Learning Management System
Publication and access to clinical data	Q4 2014	2016	• Business case • Analysis and risk impact assessment • IT solution for access to clinical trial data selected

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:

- **Management and planning.** These activities cover management of the Agency and corporate planning. These include support to the Management Board and senior management of the Agency, corporate planning cycle, including the planning processes (strategy, annual work programmes, link to the budget) and the following monitoring and reporting activities.
- **Finance.** Finance refers to budget processes (planning, monitoring and reporting), maintenance of the accounts, payment management and collection of revenue, as well as management of cash resources and ex ante verification of transactions.
- **Information technology.** These activities cover the development, provision and maintenance of IT systems required to support EMA corporate business processes, as well as those supporting the European medicines regulatory network (so called 'Telematics' systems). The delivery of IT solutions is described as part of projects falling under human medicines, veterinary medicines and horizontal activities.
- **Legal services.** Legal activities within corporate governance and support area refer to legal advice on internal matters, such as contracts and procurement, staff related matters, data protection and corporate governance matters. 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. Legal services deals regularly with legal officers of the Commission on the core activities and also provide advice and support on the implementation of the new legislation and legal scrutiny of the scientific opinions.
- **Human resources.** Human resources deal with all staff related matters — develop and maintain HR strategy and policy, conduct recruitment and procurement, manage personnel administration and payments, run trainee programme, manage staff declaration of interests, provide staff support and training, and deal with staff complaints and appeals.
- **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-assessment as part of EU Agencies benchmarking programme, annual review of sensitive functions, as well as ex post controls and register of exceptions also fall within this area.
- **Internal audit.** Internal audit reviews and evaluates risk management, governance and internal control processes of the Agency, in order 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 Agency premises and office accommodation, security, business continuity, health & safety, environment management, reception and switchboard, mail management, reprographics and offsite archives, as well as catering.

- **Communication (corporate).** These are corporate communication activities, such as corporate websites management, external communications and press office and information centre.
- **Project management.** Programme Design Board ensures that the Agency's business projects are aligned with the Agency strategy and meet customer expectations. Project Management Office ensures Agency's programmes and projects are managed according to agreed standards and project management arrangements and monitors, controls and reports on the progress of the projects and programmes.
- **Policy issues.** Chief Policy Adviser Division is responsible for defining and revising the Agency policies, as well as monitoring their implementation. It also coordinates preparation of the Agency for new and revised legislation, monitors implementation of such legislation, and liaises with and coordinates EMA interactions with the EU institutions.

Drivers

This year, 2015, will be the 20th anniversary of the inauguration of the EMA and the beginning of not only centralised approval of medicines, but of the whole European medicines network. It is an opportunity to promote our public and animal health contribution over 20 years and look to the future.

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

The 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 e-mail and electronic submissions instead of paper-based communication.

Key objectives and activities

Objective	Activities
Ensure and further improve efficiency and effectiveness of the Agency's corporate activities	Review IT operating model
	Develop a corporate communications strategy 2015-2020
	Select a new media monitoring and press office software management tool
	Develop (2015) and implement (2016) electronic documents / records' management strategy
Maintain high level of independence, integrity and transparency in all aspects of Agency's work	Implement the policy on handling of conflicts of interest of scientific committees' members and experts
	Implement antifraud strategy, including internal processes on reporting alleged fraud instances and anti-fraud office
	Develop and implement whistle-blower policy
	Revise (2015) and implement (2016) the conflicts of interest policy for Management Board members and EMA employees
	Develop (2015) and implement (2016) a policy on public consultations
Highlight the public and animal health contribution of the Agency and the whole European medicines network in recognition of 50th anniversary of pharmaceutical legislation in Europe and 20th anniversary of the Agency	Launch campaign on the 20th anniversary of the inauguration of the Agency

Workload indicators

	Results		Forecasts
	2013	2014*	2015
Requests for interviews and comments by media representatives	2,011	2,320	3,000
Number of press releases and news items published	271	220	240
Number of reports, brochures, leaflets produced	3	3	5-6

* expected results

Performance indicators

	Results		Targets
	2013	2014*	2015
Posts on the Agency establishment plan filled	95.4%	97%	97%
Revenue appropriations implemented	95.6%	97%	97%
Expenditure appropriations implemented	96.8%	97%	97%
Payments against appropriations carried over from year N-1	96%	97%	97%
The maximum rate of carry-over to year N+1, of total commitments within the title			
Title 1	0.6%	2%	1%
Title 2	11.6%	20%	15%
Title 3	24.6%	28%	25%
Payments made within 30 days' time	98.2%	97%	97%
EMA Perception Survey for Communications	n/a	80%	n/a
Key messages covered in media reports:			
At least one key message	n/a	n/a	95%
At least two key messages	n/a	n/a	70%
Quote included	n/a	n/a	60%
Availability of Telematics and corporate IT systems (of time)		98%	98%
IT service desk: meeting SLAs / issue resolution per system / priority level:			
Critical (resolution time 4 hours)	31.8%	80%	80%
Severe (resolution time 1 business day)	31.3%	80%	80%
Important (resolution time 10 business days)	89.1%	80%	80%
Minor (resolution time 120 business days)	99.4%	80%	80%

* expected results

Resources

Area of activity	Financial resources (cost, thousand Euro)	Human resources (FTEs)
Governance, quality management and internal audit	7,025	35
Finance	4,821	29
ICT	11,663	64
Legal services	2,240	13
Human resources	5,210	35
Infrastructure services	2,290	18
Communication	3,203	18

Annexes

Annex 1: Revenue and expenditure 2010-2015: key figures

Figure 1 Revenue evolution 2010 - 2015

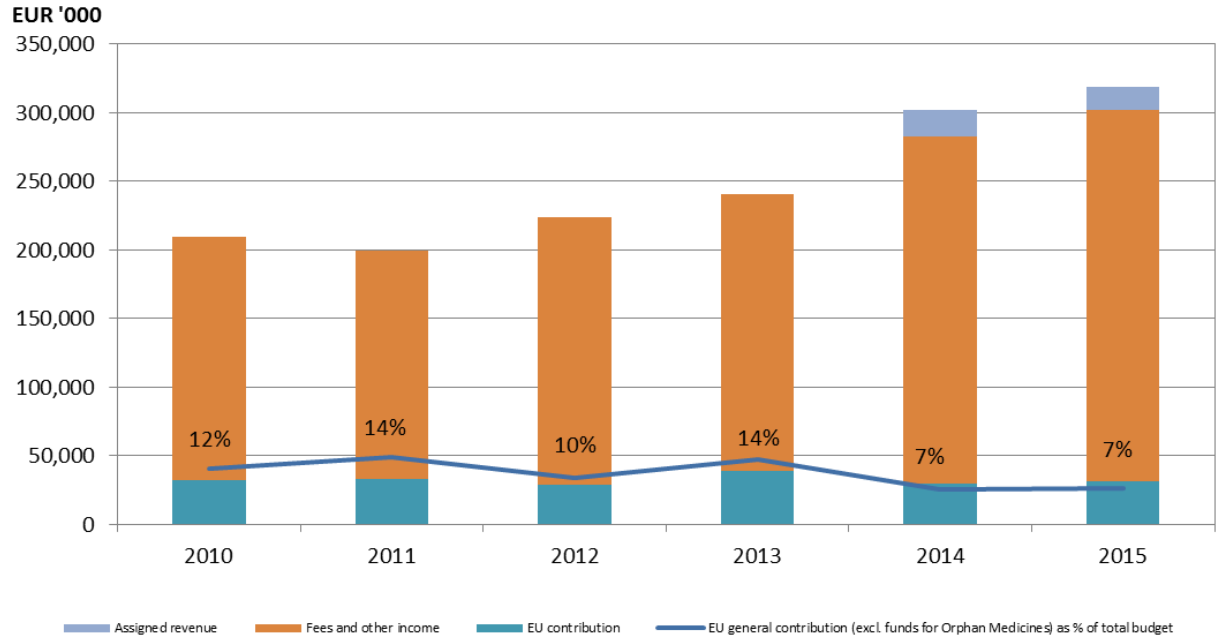
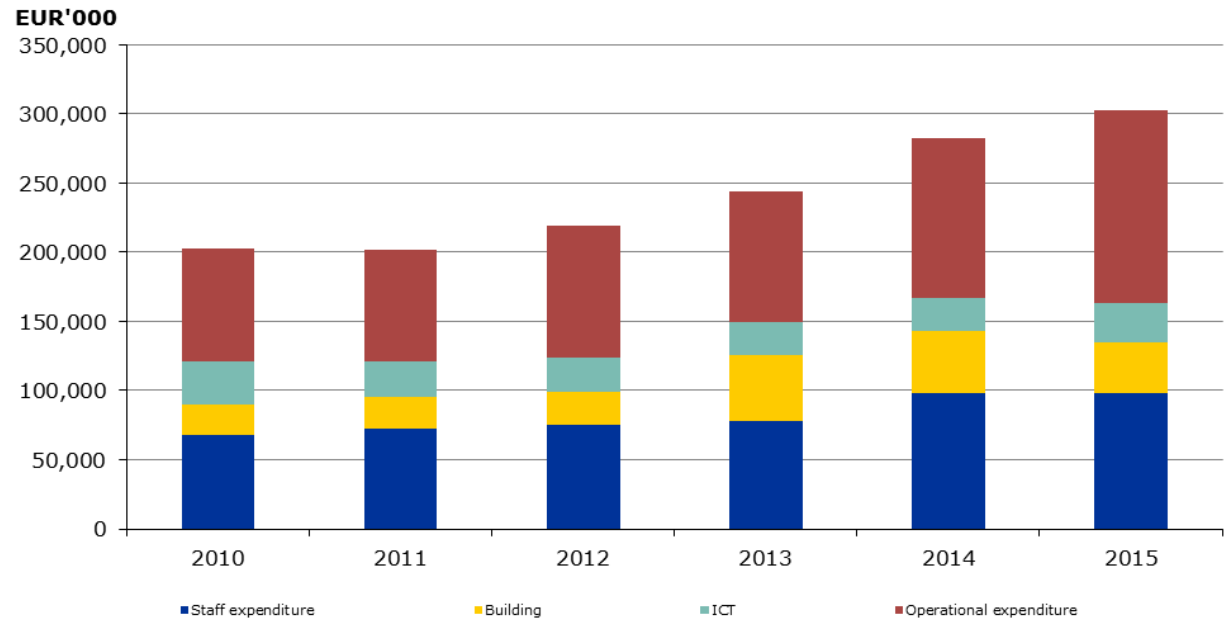


Figure 2 Expenditure evolution 2010 - 2015



Annex 2: Revenue and expenditure overview 2013-2015

		2013 (outturn)[1]		2014 (budget)[2]		2015 (budget)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
100	Fees and charges	198,865	*82.7%*	228,156	*80.8%*	250,801	*83.0%*
200	General EU contribution	32,630	*13.6%*	20,277	*7.2%*	22,516	*7.5%*
201	Special EU contribution for orphan medicinal products	6,509	*2.7%*	9,500	*3.4%*	9,000	*3.0%*
300	Contribution from EEA	1,098	*0.5%*	902	*0.3%*	936	*0.3%*
600	External assigned revenue	700	*0.3%*	19,283	*6.8%*	16,787	*5.6%*
700	Balance from previous year	0	*0.0%*	3,453	*1.2%*	1,499	*0.5%*
5+9	Other	585	*0.2%*	903	*0.3%*	578	*0.2%*
	TOTAL REVENUE	**240,387**	*100.0%*	**282,474**	*100.0%*	**302,117**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	71,497	*29.4%*	89,862	*31.8%*	86,415	*28.6%*
13	Duty travel	409	*0.2%*	605	*0.2%*	636	*0.2%*
14	Socio-medical infrastructure	521	*0.2%*	806	*0.3%*	765	*0.3%*
15	Exchange of civil servants and experts	2,672	*1.1%*	3,674	*1.3%*	7,494	*2.5%*
16	Social welfare	277	*0.1%*	335	*0.1%*	345	*0.1%*
17	Representation expenses	28	*0.0%*	54	*0.0%*	80	*0.0%*
18	Staff insurances	2,149	*0.9%*	2,395	*0.8%*	2,321	*0.8%*
	Total Title 1	**77,552**	*31.9%*	**97,731**	*34.6%*	**98,056**	*32.5%*
	Building / equipment						
20	Investment in immovable property, renting of building and associated costs	45,889	*18.9%*	40,916	*14.5%*	33,099	*11.0%*
21	Expenditure on corporate data processing	13,821	*5.7%*	15,748	*5.6%*	20,861	*6.9%*
22	Movable property [..]	1,009	*0.4%*	2,245	*0.8%*	2,178	*0.7%*
23	Other administrative expenditure	795	*0.3%*	2,171	*0.8%*	1,380	*0.5%*
24	Postage	444	*0.2%*	184	*0.1%*	153	*0.1%*
25	Expenditure on other meetings	98	*0.0%*	136	*0.0%*	107	*0.0%*
	Total Title 2	**62,056**	*25.5%*	**61,400**	*21.7%*	**57,778**	*19.1%*
	Operational expenditure						
300	Meetings	6,305	*2.6%*	7,623	*2.7%*	10,766	*3.6%*
301	Evaluation of medicines	80,018	*32.9%*	97,251	*34.4%*	113,705	*37.6%*
302	Translations	5,182	*2.1%*	5,032	*1.8%*	5,414	*1.8%*
303	Studies and consultants	2,031	*0.8%*	5,229	*1.9%*	9,138	*3.0%*
304	Publications	71	*0.0%*	166	*0.1%*	121	*0.0%*
305	Community programmes	340	*0.1%*	0	*0.0%*	0	*0.0%*
31	Expenditure on business related ICT projects	9,863	*4.1%*	8,042	*2.8%*	7,139	*2.4%*
	Total Title 3	**103,811**	*42.6%*	**123,343**	*43.7%*	**146,283**	*48.4%*
	TOTAL EXPENDITURE	**243,419**	*100.0%*	**282,474**	*100.0%*	**302,117**	*100.0%*

[1] Financial Year 2013: as per final accounts, rounded to nearest thousand Euro

[2] Financial Year 2014: as per final budget (including transfers and amending budgets as of 19.12.2014)

[3] Financial Year 2015: as adopted by the Management Board 18 December 2014

Annex 3: Human resource needs and establishment plan 2015

Function Group & Grade	Authorised for 2013		Occupied as at 31.12.2013			Authorised for 2014		Authorised for 2015	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts
				Grade filled	Actual grade				
AD 16	-	0	-	0	0	-	0	-	0
AD 15	-	4	-	4	2	-	4	-	4
AD 14	-	6	-	6	1	-	6	-	6
AD 13	-	8	-	7	7	-	8	-	9
AD 12	-	38	-	36	32	-	42	-	42
AD 11	-	38	-	36	20	-	38	-	37
AD 10	-	36	-	33	27	-	36	-	40
AD 9	-	40	-	36	28	-	37	-	36
AD 8	-	47	-	46	48	-	49	-	52
AD 7	-	45	-	44	44	-	51	-	52
AD 6	-	42	-	41	71	-	39	-	36
AD 5	-	42	-	33	37	-	30	-	26
Subtotal AD	***0***	***346***	***0***	***322***	***317***	***0***	***340***	***0***	***340***
Total AD	***346***		***0***	***322***	***317***	***340***		***340***	
AST 11	-	2	-	2	0	-	2	-	2
AST 10	-	5	-	5	1	-	5	-	5
AST 9	-	7	-	7	2	-	7	-	7
AST 8	-	13	-	13	8	-	15	-	16
AST 7	-	20	-	20	12	-	19	-	19
AST 6	-	33	-	31	12	-	36	-	39
AST 5	-	35	-	34	29	-	37	-	42
AST 4	-	51	-	50	36	-	55	-	49
AST 3	-	39	-	39	63	-	39	-	43
AST 2	-	40	-	40	37	-	34	-	37
AST 1	-	20	-	20	66	-	10	-	0
Subtotal AST	***0***	***265***	***0***	***261***	***266***	***0***	***259***	***0***	***259***
Total AST	***265***		***0***	***261***	***266***	***259***		***259***	
SC 6	-	-	-	-	-	-	0	-	0
SC 5	-	-	-	-	-	-	0	-	0
SC 4	-	-	-	-	-	-	0	-	0
SC 3	-	-	-	-	-	-	0	-	0
SC 2	-	-	-	-	-	-	0	-	0
SC 1	-	-	-	-	-	-	0	-	0
Subtotal SC	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***	***0***
Total SC	***0***		***0***	***0***	***0***	***0***		***0***	
Grand subtotal	***0***	***611***	***0***	***583***	***583***	***0***	***599***	***0***	***599***
Grand total	***611***		***0***	***583***	***583***	***599***		***599***	

Contract Agents	**2013**		**2014**	**2015**
	Actual FTE as at 31.12.2013	**Actual headcount as at 31.12.2013**	**Planned FTE**	**Planned FTE**
FG IV	37	37	46	48
FG III	10	9	12	13
FG II	52	46	72	69
FG I	0	0	0	0
Total	**99**	**92**	**130**	**130**

National Experts	**2013**		**2014**	**2015**
	Actual FTE as at 31.12.2013	**Actual headcount as at 31.12.2013**	**Planned FTE**	**Planned FTE**
Total	**16.5**	**15.5**	**25**	**50**

Annex 4: Operational procurement decisions

Activity statement:	**EU Network Training Centre: Virtual training from academia to support the scientific and regulatory training for the EU Network**
Objective:	See WP2015/16, heading 3.3
Budget:	~€400,000 per year over 4 years (total: € 1.6 million); € 200,000 in 2015
Financial year:	2015 - 2018/19
Description of action:	Enhance cooperation within European Medicines Regulatory Network
Type of contract:	Framework contracts - buy scientific and regulatory virtual training; Specific contracts
Number of contracts:	3
Indicative timeframe for contract:	Commencing in 2016
Indicative timeframe for procurement:	Q2 2015
Indicative budget for procurement:	€ 1.6 million
Legal basis:	Article 27 of Regulation 726/2004
Budget line:	B3003

Activity statement:	**Effectiveness & PhEpi studies**
Objective:	See WP2015/16, heading 1.5
Budget:	€ 350,000
Financial year:	2015
Description of action:	Ensuring best evidence is available to support the EMA committees assessments of the benefits and risks of authorised medicines (studies of risks and benefit risk)
Type of contract:	Framework contract; Specific contract per study
Number of contracts:	5 framework contracts; 4-6 specific contracts per year
Indicative timeframe for contract:	Framework contracts to be in place Q2 2015; first specific contract approx. Q4 2015
Indicative timeframe for procurement:	First reopening of competition: Q3 2015
Indicative budget for procurement:	€ 350,000
Legal basis:	Regulation 726/2004 and Directive 2001/83, notably articles 31 and 107i - k
Budget line:	B3030

Activity statement:	**Subscription to drug pipeline database**
Objective:	See WP2015/16, heading 1.1 and 1.5
Budget:	€ 468,000 over 4 years
Financial year:	2015 - 2018
Description of action:	Access to one or several databases containing lifecycle data about medicinal products and medical devices for human use worldwide from pre-clinical to clinical studies phase IV to marketing to discontinued projects including adverse reaction, scientific and industry related information
Type of contract:	Service contract
Number of contracts:	1
Indicative timeframe for contract:	Commencing in 2015
Indicative timeframe for procurement:	Q1 2015
Indicative budget for procurement:	€ 468,000 over 4 years
Legal basis:	Article 57 of Regulation 726/2004
Budget line:	B3031

Activity statement:	**Access to In-house database**
Objective:	See WP2015/16, heading 1.5
Budget:	€ 1,000,000 over 4 years
Financial year:	2016 - 2019
Description of action:	Access to In-house database in support of best evidence development (re-tender: ref. EMA/2011/47/PV)
Type of contract:	Service contract
Number of contracts:	1
Indicative timeframe for contract:	2016 - 2019
Indicative timeframe for procurement:	Q4 2015
Indicative budget for procurement:	€ 1,000,000 over 4 years
Legal basis:	Article 57 of Regulation 726/2004
Budget line:	B3031

Activity statement:	**Provision of software development, integration services, solutions and IT Security and Network consultancy**
Objective:	See WP2015/16, heading 4
Budget:	Approx. €80.0 million over 4 years; of which € 40.0 million administrative and € 40.0 million operational
Financial year:	2016 - 2020
Description of action:	Provision of software development, integration services, solutions and IT Security and Network consultancy
Type of contract:	Framework contract and Specific contracts
Number of contracts:	30 - 50
Indicative timeframe for contract:	Commencing in 2016
Indicative timeframe for procurement:	Q2/Q3 2015
Indicative budget for procurement:	€ 80,000,000
Legal basis:	Article 57 of Regulation 726/2004
Budget line:	B2114/2115/3105

Annex 5: Activity based budget

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, 3002 & 3003	Budget Item 3010 & 3013	Remainder of Title 3		
1 Evaluation activities for human medicines	**48,347**	**27,221**	**13,155**	**103,254**	**9,872**	**201,850**	**69%**
1.1 Pre-authorisation activities	11,185	4,114	4,256	16,010	191	35,755	12%
1.2 Initial evaluation activities	9,043	2,409	1,728	14,430	1,211	28,821	10%
1.3 Post-authorisation activities	10,813	11,326	1,894	60,967	3,830	88,830	30%
1.4 Referrals	2,658	889	566	-	701	4,814	2%
1.5 Pharmacovigilance activities	11,640	6,035	2,070	11,848	3,419	35,010	12%
1.6 Other specialized areas and activities	3,009	2,449	2,641	-	521	8,620	3%
2 Evaluation activities for veterinary medicines	**6,206**	**2,953**	**2,976**	**4,308**	**1,066**	**17,510**	**6%**
2.1 Pre-authorisation activities	334	105	698	347	9	1,494	1%
2.2 Initial evaluation activities	2,111	517	540	1,848	213	5,228	2%
2.3 Post-authorisation activities	1,554	1,052	268	2,113	284	5,270	2%
2.4 Arbitrations and referrals	638	171	246	-	243	1,298	0%
2.5 Pharmacovigilance activities	647	895	258	-	-	1,800	1%
2.6 Other specialized areas and activities	922	214	966	-	317	2,419	1%
3 Horizontal activities and other areas	**16,349**	**5,932**	**4,588**	**6,142**	**3,674**	**36,686**	**13%**
3.1 Committee coordination	2,801	855	944	-	-	4,599	2%
3.2 Inspection and compliance	4,288	2,491	1,289	6,142	155	14,365	5%
3.3 Partners and stakeholders	3,913	1,116	2,316	-	2,510	9,856	3%
3.4 Transparency and access to documents	1,743	547	-	-	345	2,635	1%
3.5 Information	3,605	923	40	-	663	5,231	2%
4 Corporate Governance and Support activities	**26,564**	**8,052**	**638**	**-**	**1,198**	**36,452**	**12%**
4.1 Governance, quality management and internal audit	5,043	1,196	447	-	338	7,025	2%
4.2 Finance	3,396	1,333	-	-	92	4,821	2%
4.3 Information technology	9,005	2,188	-	-	470	11,663	4%
4.4 Legal services	1,796	444	-	-	-	2,240	1%
4.5 Human resources	3,527	1,659	-	-	24	5,210	2%
4.6 Infrastructure services	1,675	615	-	-	-	2,290	1%
4.7 Communication (corporate)	2,124	615	190	-	273	3,203	1%
Total	**97,466**	**44,159**	**21,357**	**113,705**	**15,810**	**292,497**	**100%**

* Excluding exceptional investment cost for the refurbishment of the 10th floor

Total budget for 2015:	**302,117**

Annex 6: Draft cash-flow forecast 2015

CASH FLOW FORECAST YEAR 2015	Estimated Budget C1+R0	Estimated RAL C8	Total Annual	Dec (pre-pay) estimated	Jan - Mar estimated	Apr-Jun estimated	Jul - Sep estimated	Oct - Dec estimated
	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000
Fees and charges C1	250,801		250,801		35,009	65,578	70,323	79,891
Euopean Union contribution to the operating budget C1	22,516		22,516		0	0	15,487	7,029
Orphan contribution C1	9,000		9,000		0	3,084	1,082	4,834
Surplus from previous year C1	1,499		1,499		0	1,499	0	0
External assigned revenue R0	16,787		16,787		16,787	0	0	0
Other revenue C1	1,514		1,514		177	307	309	721
A - TOTAL RECEIPTS	**302,117**	**0**	**302,117**		**51,973**	**70,468**	**87,200**	**92,476**
Title I : staff								
Payments expected on C1 credits	97,725		97,025		26,541	15,513	24,023	30,947
Payments expected on R0 credits	331		331		91	53	82	106
Payments expected on C8+R8 credits (RAL)		700	700		462	81	156	1
Title II : administrative expenses								
Payments expected on C1 credits	41,423		34,223		7,996	6,747	10,577	8,904
Payments expected on R0 credits	16,355		16,355	4,089	4,089	4,089	4,089	0
Payments expected on C8+R8 credits (RAL)		7,200	7,200		2,748	2,746	1,115	591
Title III : operational expenditure								
Payments expected on C1 credits	146,268		120,268		16,241	35,661	28,533	39,834
Payments expected on R0 credits	15		15		2	4	3	5
Payments expected on C8+R8 credits (RAL)		26,000	26,000		16,183	6,019	2,131	1,667
B - TOTAL CASH OUT	**302,117**	**33,900**	**302,117**	**4,089**	**74,351**	**70,914**	**70,710**	**82,054**
Opening balance, cash and bank accounts			**32,000**		**32,000**	**9,622**	**9,177**	**25,667**
+ Total receipts (A)			302,117		51,973	70,468	87,200	92,476
- Total payments (B)			302,117	4,089	74,351	70,914	70,710	82,054
Closing balance, cash and bank accounts			**32,000**	**-4,089**	**9,622**	**9,177**	**25,667**	**36,089**
- Total anticipated carry-over - commitments not paid by year-end (C8 n+1)								33,900
Closing balance					**9,622**	**9,177**	**25,667**	**2,189**

Annex 7: 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
ADVENT	ad hoc expert group on veterinary novel therapies
AE	adverse event
AER	adverse event report
Agency	European Medicines Agency
AMR	antimicrobial resistance
AR	assessment report
Art	article
ATD	access to documents
ATMP	advanced-therapy medicinal product
BEMA	benchmarking of European medicines agencies
BI	business intelligence
CAP	centrally authorised product
CAT	Committee for Advanced Therapies
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
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
COMP	Committee for Orphan Medicinal Products
CT	clinical trial
CVMP	Committee for Medicinal Products for Veterinary Use
DCP	Direct procedure capture
DoI	declaration of interests
eAF	electronic application form
EC	European Commission
ECHA	European Chemicals Agency
eCTD	electronic common technical document
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European public assessment report
eRMR	Electronic reaction monitoring reports
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EURD	EU reference dates
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance
EVCTM	EudraVigilance Clinical Trials Module
EVVet	EudraVigilance veterinary
EVMDP	EudraVigilance Medicinal Product Dictionary
FDA	United States Food and Drug Administration
FTA	Full-time equivalent

Term / abbreviation	Definition
GCP	good clinical practice
GLP	good laboratory practice
GMP	good manufacturing practice
GVP	good pharmacovigilance practice
HCP	healthcare professional
HCPWP	Healthcare Professionals Working Party
HL7	Health Level 7
HMA	Heads of Medicines Agencies
HR	Human Resources
HMPC	Committee on Herbal Medicinal Products
HTA	health technology assessment
ICH	International Conference 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
IDPM	Information Day on the New Identification of Medicinal Products
IMI	Innovative Medicines Initiative
IPD	Individual patient data
IPRF	International Pharmaceutical Regulators Forum
IT	information technology
ITF	Innovation Task Force
ISO	International Organisation for Standardisation
MA	marketing authorisation
MAA	marketing authorisation application
MAH	marketing authorisation holder
MB	Management Board of the EMA
MDM	master data management
MDMS	Master Data Management Service
MRP	Mutual recognition procedure
Member State (MS)	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MRL	maximum residue limit
MUMS	minor use, minor species
NAP	nationally authorised product
NCA	national competent authority
Network	European medicines regulatory network
OIE	World Organisation for Animal Health
OMCL	Official Medicines Control Laboratories
PA	protocol assistance
PAES	post-authorisation efficacy study
PAS	Post Authorisation Studies
PASS	post-authorisation safety study
PCWP	Patients' and Consumers' Working Party
PCO	patients'/consumers' organisation
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency
PMF	Plasma master file
PMS	Product Data Management Service
PRAC	Pharmacovigilance Risk Assessment Committee
PROTECT	Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium
PSUR	periodic safety-update report
PSUSA	PSUR single assessment

Term / abbreviation	Definition
PUMA	Paediatric-use marketing authorisation
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)
R&R	'Review and Reconnect' programme
RFI	request for information
RMP	risk-management plan
SA	scientific advice
SAG	Scientific Advisory Group
SciCoBo	Scientific Coordination Board
SIAMED	Sistema de Información Automatizada sobre Medicamentos (Medicines Information System)
SLA	service level agreement
SME	small and medium-sized enterprise
SMS	substance management service
SPOR	Substances, Products, Organisations, Referentials
SMQ	Standardised MedDRA Query
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TGA	Therapeutic Goods Administration, Australia
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
(Web-)RADR	Recognising Adverse Drug Reactions
WHO	World Health Organization
WP	working party