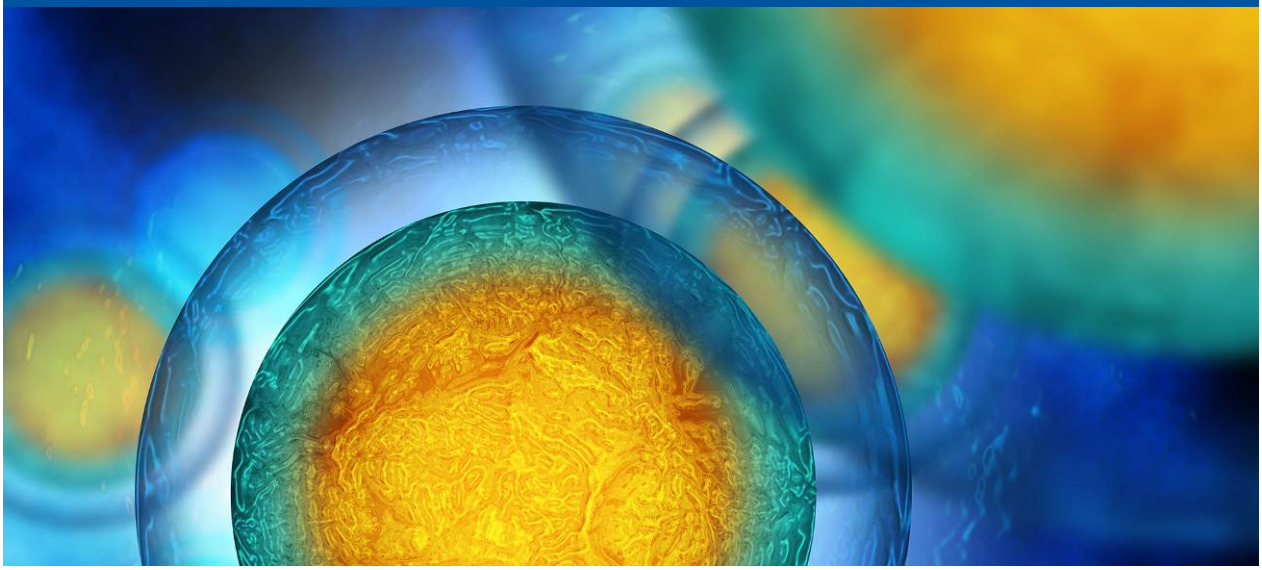
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2013
EMA/695772/2013
Management Board

Work programme
2014

Adopted by the Management Board on 12 December 2013



7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 02074188416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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.

Table of contents

Structure of the work programme 2014

This work programme reflects the European Medicines Agency's (EMA) objectives and activities for 2014 that are aimed at reaching longer-term strategic goals. The document consists of four main sections:

1. **Human medicines evaluation activities.** This section covers all Agency activity areas specifically related to human medicines. These are split into pre-authorisation, initial evaluation, post-authorisation, pharmacovigilance, and referrals and arbitrations sections. Any other activities within the human medicines area are covered in the last part of this section.
2. **Veterinary medicines evaluation activities.** This section covers all Agency activities relating to veterinary medicines evaluation and monitoring, and is structured similarly to the human medicines section.
3. **Horizontal activities.** These are business activities that span both human and veterinary areas, and enable and support the evaluation activities. They cover committee coordination, business IT support, inspections, and partner and stakeholder relationship management.
4. **Corporate governance and support activities.** These are non-business-specific corporate-support functions and activities, such as finance, HR, quality management, etc., that exist in all organisations and are performed to ensure continuous operations of the Agency.

Each section is structured to reflect:

- **Description of activity areas.** This is a short explanation of the types of activities undertaken – what they entail and what the Agency does in each of those areas.
- **Objectives 2014.** These are the objectives set for 2014 that facilitate reaching the Agency's longer-term strategic goals. The objectives are in line with the overall strategy and reflect the strategic priorities of the Agency.
- **Activities 2014.** These are specific steps and activities that will be performed in 2014 to reach the above objectives.
- **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 the targets, progress and achievement of the above objectives and activities.
- **Resources.** This is an overview of human and financial resources by activity area. Human resource data include temporary agents, contract agents, interims and national experts. The data provided are subject to change, based on the results of the ongoing reorganisation and process-redesign work, and the streamlining of the time-management system.

Information on the main **projects** planned for 2014 is added at the end of each business section.

Information on the 2014 **budget**, **cash flow**, **human resource needs** and **operational procurement decisions** of the Agency is provided in the **annexes**.

Priorities and key influences

Key influences

The legislative, scientific and global environment in which the European Medicines Agency operates is constantly evolving. Legislative developments remain one of the prevailing business environment factors. The pharmacovigilance legislation that came into effect in July 2012 is one of the most important pieces of the legislation, implementation of which remains a significant area of activity in 2014. At the same time, the Agency closely monitors and contributes to the debate on the legislative proposals on veterinary medicinal products and the conduct of clinical trials.

The Agency observes that the development model for medicines and the opportunities offered by new and emerging technologies pose new challenges to bringing new medicines to patients. Therefore, the Agency considers the provision of support during the early stages of medicines development as an important element in increasing the likelihood of new medicines reaching patients.

Globalisation, which sees manufacturing and clinical trials increasingly being carried out outside the European Union (EU), is another important development. This poses new challenges, and changes the way the Agency must operate to ensure that medicines tested and manufactured outside the EU meet the stringent EU requirements.

We also see two important societal developments relevant to our area of operation: first, the growing demand for transparency and openness in how medicines are regulated; and second, the increasing expectation of patients to be involved in and to contribute to the benefit-risk evaluation of medicines. Both areas are addressed in our work programme for this year.

These increasing expectations and demands on the performance of the Agency are taking place within a challenging economic environment that is affecting the whole of the European medicines regulatory network. This exerts pressures on the resources of the Agency and of our partners in the network, and warrants a set of initiatives to address the rising challenges.

Priorities and major initiatives

In light of the above influences and other business environment factors, the Agency has set the following priorities for 2014:

- Deliver core business activities to a high level of quality and consistency.
- Facilitate the early stages of medicines development.
- Implement the pharmacovigilance and clinical trials legislation, continue to implement the falsified medicines legislation, and support the development of the veterinary medicines legislation.
- Increase international cooperation, with emphasis on inspections capability.
- Enhance cooperation within the European medicines network and with other European and international partners.
- Address the issue of antimicrobial resistance and availability of anti-infective treatment options, both in the human and veterinary areas.
- Further increase transparency and implement strategic communication activities.
- Improve the quality, integration and accessibility of the data we hold.
- Continue to improve the operational effectiveness and efficiency of the Agency.

- Assure a successful relocation of the Agency to its new premises.

In 2014, the main priority for the Agency will remain the effective conduct of **core business** activities, and ensuring both scientific and regulatory quality and consistency of its output, and delivery within legislative timelines. A number of initiatives aimed at improving the support provided to scientific committees and assuring high-quality outputs are included in the work programme.

As outlined earlier, the Agency will maintain its emphasis on the **pre-authorisation phases** of medicines development, where it provides a variety of support measures to sponsors and applicants. These include: technical and administrative support to small and medium-sized enterprises; designation of orphan medicinal products, which, once they reach the market, can benefit from a number of market protection mechanisms; access to the Agency's Innovation Task Force, which provides a platform for confidential discussions on cutting-edge technologies that may result in potential applications for marketing authorisation; scientific advice on any aspect of medicines development, and the Agency's ability to provide such advice together with health technology assessment (HTA) bodies, thus reducing the requirements on companies and facilitating the availability of medicines for patients and healthcare professionals.

Continued implementation and operation of the **pharmacovigilance legislation** remains the next important area of priority for the Agency. Implementation of this legislation will continue to affect a number of activities performed by the Agency and the network. The implementation activities will include further development of methods for collecting best evidence, and their application in the pharmacovigilance activities. The Agency will also continue enhancing the functionality of the EudraVigilance system, which is used to collect and analyse information about adverse drug reactions. As required by the legislation, the Agency will develop the repository for periodic safety update reports and implement the system for monitoring scientific literature, so as to identify safety issues relevant to the benefit-risk assessment of medicines.

The Agency will also continue supporting development of the **legislation on veterinary medicinal products** and the **legislation on clinical trials**. The European Commission plans to publish a proposal on the revision of the legislation governing veterinary medicines in early 2014. A major priority for the Agency will therefore be to contribute to the discussion of that proposal. The availability of veterinary medicines is one of the main objectives of the new legislation, and the Agency will contribute to the reflection on this issue.

The **European medicines network** is the cornerstone of the work and success of the Agency. The Agency has supported and developed the collaboration within the network throughout the years, and in 2014 will further consolidate its cooperation with the national competent authorities (NCAs). To do this, the Agency will support launching a revised training and competence-development programme, in cooperation with the NCAs, will expand the national experts programme, and will prioritise projects in its IT-development programme that support the work, effectiveness and efficiency of the NCAs.

The Agency has a wide-ranging international cooperation. The continuing trend of clinical trials and manufacturing moving to non-EU countries is one that maintains the attention of the Agency and its international partners. For this reason, the Agency will continue to work with other authorities to develop capacity and information exchanges in the area of **inspections** of manufacturing and clinical trials, to ensure that clinical trials conducted outside the EU and medicines destined for EU citizens are of the required high quality.

Antimicrobial resistance (AMR) is a growing problem in humans and in animals. This is exacerbated by the fact that few new antimicrobials have been authorised over the past few years. The Agency 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 to contribute 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 to implement 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.

Transparency and communication have been key to the Agency's efforts to maintain and improve trust in its work, to strengthen its relations with stakeholders, and to support initiatives among academia, researchers and healthcare professionals that contribute to protecting and promoting public health. The Agency will launch its policy on publication of clinical-trial data in 2014, taking into consideration the outcomes of the court case and legislative proposals on clinical trials. This will supplement the many transparency initiatives already in place, such as access to medicines' safety data, access to documents, and publication of declarations of interests and curricula vitae of experts, committee members and managers. With regard to communication, the Agency will complete the establishment of its Stakeholders and Communication Division, implement stakeholder-oriented policies, and continue the development of IT tools to improve the availability and accessibility of information.

The vast amount of **data and information** managed by the Agency is one of its fundamental assets. In 2013, the Agency set itself the objective of improving the way it manages its data. Ongoing work in this area — which is being conducted in collaboration with the Agency's network partners, and with input from its stakeholders — will enhance the quality of the data and improve the speed with which they can be processed, analysed and used by the Agency, its committees, the network and other stakeholders. In 2014, the aim is to establish data-managed services for substances and referential data, which, in the next phases, will be supplemented by revised ways of managing product and organisational data. In parallel, the IT systems containing these data will be adapted, to bring all this information into one repository from which all IT systems will draw necessary information.

In 2013, the Agency started and significantly progressed work to reorganise and improve the **efficiency and effectiveness** of its operations to support the work of its scientific committees. This work will continue in 2014, and the focus on achieving efficiencies will remain at its core. Among other initiatives, the Agency will complete the redesign and implementation of updated processes, the centralisation of management of access to documents, and the rationalisation of scientific committees' secretariats. The Agency plans to complete the majority of the remaining organisational aspects prior to its move to new premises in the second half of 2014.

Risk management

The Agency regularly reviews the **risks** to achieving its mission through a strategic risk-management process. Risks are assessed at a residual level, i.e. taking into account controls and mitigations that are already in place.

The key risks identified in core activities relate to the quality of scientific assessments (including the availability of resources to perform the assessments), the availability of scientific expertise, and efficient interaction among the Agency's scientific committees. On the support side, the main risks concern the Agency's ability to efficiently meet the growing demands for access-to-document requests, project implementation, as well as stakeholder and reputation management.

A number of activities and projects mentioned throughout the work programme aim to mitigate these risks.

1. Evaluation activities for human medicines

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

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

1.1. Pre-authorisation activities

Activity areas

Pre-authorisation support aims to facilitate and improve the availability of safe and effective medicinal products 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 HTA bodies and international partners. The main activity areas in this domain include those below.

- **Scientific advice and protocol assistance**. To facilitate the product-development process, the Agency provides scientific advice (initial and follow-up) to sponsors on all products and issues related to the development of medicines. In the case of orphan medicinal products, the Agency provides advice in the form of protocol assistance, which can include advice on the significant benefit of a product. The Agency also provides advice on and 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. 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 that, for economic reasons, would otherwise not be developed.
- **Paediatric procedures**. To improve the availability of medicinal products 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. An agreed PIP may lead to information on the paediatric use of medicines being included in a centralised or national marketing authorisation for new or already authorised medicinal products, and in a paediatric-use marketing authorisation 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). The ITF serves as a discussion platform for early dialogue with applicants, identifying scientific, legal and regulatory issues of emerging therapies and technologies, providing advice on product eligibility for the EMA's scientific services and procedures, as well as scanning the horizon and exchanging information and establishing networks, to develop and maintain expertise in the field. The ITF works closely with the European medicines regulatory network and academia specialists, and the EU network of Innovation and Technology Forum Offices. The ITF also collaborates with the European institutions and international partners on its procedures.
- Support the development of **medicines for specific target groups**. This includes increasing focus on **geriatric** medicines and medicines for **pregnant and lactating mothers**. Changes in the world's demographic composition draw increasing attention to the health needs of an older, frailer population. The Agency encourages research and development of medicines, with a particular emphasis on areas of unmet need such as frailty, formulations and packaging adapted to an 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.

Key objectives

- Increase the success rate for marketing-authorisation applications through promotion and more active use of scientific advice and other pre-application support.
- Provide and further promote the support to the development of new medicines, especially in areas of unmet need.
- Facilitate use and development of emerging technologies and approaches in developing new medicinal products.
- Improve international cooperation in pre-authorisation support, especially in the scientific-advice area.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Reinforce availability of pre-application advice from the EMA to support access to the EU market. Offer joint support in the areas of scientific advice, interaction with HTA bodies, orphan medicines, paediatric medicines, advanced therapies, regulatory assistance, including to SMEs, and post-authorisation follow-up as applicable.
- Promote use of scientific advice regarding innovative methodologies, e.g. biomarker qualification.
- Continue development of a framework that satisfies the needs of the EMA, regulators and HTA bodies, through common clinical and methodological guidelines, trial design and modelling approaches that comply with the principles and requirements of the legal framework; with a view to reducing time-to-patient of medicinal products and their development costs.

- Actively engage with HTA bodies in the medicinal product lifecycle, especially through providing joint scientific-advice processes. Develop and implement a procedure for parallel HTA scientific advice.
- Support development of new approaches and medicines, such as stem-cell technology, personalised medicines, etc., through review of the current scientific and regulatory guidelines in line with the legal framework, to consider specific aspects of the emerging technologies and approaches, as well as conducting stakeholders' workshops to prepare for new relevant guidelines.
- Reinforce European and international collaboration on nanotechnologies in medicines development and use.
- Ensure important public-health needs are addressed with corresponding research. To do this, the Agency will submit research questions to include in the public-private partnership research agenda.
- Develop scientific guidance for development of medicines for specific target segments (e.g. geriatrics and use of medicines in pregnancy) and integrate the particular aspects in the evaluation of these medicines.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Scientific-advice and protocol-assistance requests, of which:	357	357	331
Parallel scientific advice with international regulators	4	6	4
Joint scientific advice with HTA bodies	10	7	7
Designation of orphan-medicine applications, of which:	213	201	197
Parallel orphan designations with international regulators (applications)	120	82	99
Paediatric-procedure applications (PIPs, waivers, PIP modifications, compliance checks)	485	477	417
Requests for classification of ATMPs	15	20	17
Innovation Task Force briefing-meeting requests	30	28	32
Innovation Task Force Art 57 CHMP opinion requests	10	10	8

Performance indicators

- **100%** of scientific procedures completed within regulatory timeframes. This includes scientific advice and protocol assistance, orphan designation and paediatric procedures, as well as recommendations on ATMP classification.
- **9%** increase in scientific-advice requests.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
33,735	87

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

1.2. Initial-evaluation activities

Activity areas

Initial evaluation refers to the process of **scientific assessment of the medicines submitted for centralised marketing authorisation**.

The Agency coordinates and performs (through committees) the scientific evaluation of the applications and risk-management plans, and issues an opinion to the European Commission. The Commission grants the marketing authorisation, and the process is concluded by publishing a European public assessment report (EPAR). Applications for certification of plasma master files (PMFs) and vaccine antigen master files (VAMFs) are processed in a similar manner but without the production of an EPAR.

Key objectives

- Provide high-quality and consistent scientific opinions to the European Commission.
- Reduce time-to-patient of medicines through use of new assessment approaches within the existing legal frameworks.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Support assessor training to ensure active and consistent use of the updated benefit-risk assessment methodology, in order to enhance transparency of decision-making criteria.
- Improve standards and provide a good regulatory and scientific reference framework to support the robustness and consistency of scientific assessment.
- Introduce reviewed biostatistics guidelines into the scientific-assessment process.
- Enhance involvement of patients and healthcare professionals during the benefit-risk evaluation of medicines.
- Implement the revised EMA policy on conflicts of interests to ensure the availability of the best scientific expertise, while maintaining the independence of the scientific committees' work.
- Review the guidance for application of existing legislative tools for medicines in a restricted population.
- Continue improving data scrutiny, including a dry-run for the project on assuring quality of data and information submitted in MA applications.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Initial evaluation applications, of which:	88	78	95
New non-orphan medicinal products	47	48	45
New orphan medicinal products	23	16	19
Similar biological products	4	1	8
Generic products	6	5	16
Hybrid and abridged applications	6	6	5

	2014 forecast	2013 actual	2012 actual
Scientific opinions for non-EU markets (Art 58)	1	1	2
Paediatric-use marketing authorisations	1	1	0

Performance indicators

- **100%** of applications evaluated within legal timeframes. This includes marketing-authorisation and plasma-master-file applications.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
27,724	66

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

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, strength, pharmaceutical form or route of administration of the product.

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

Key objectives

- Provide high-quality, consistent post-authorisation support, including scientific assessment of changes to marketing authorisations.
- Continuously monitor the benefit-risk balance of authorised medicines through collection of data on real-life use of medicines.
- Integrate post-authorisation medicines development into the Agency's scientific-advice framework.
- Improve the understanding of the impact of medicines' use on the environment.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Promote use of scientific advice for post-authorisation development of medicines.
- Develop and implement guidelines and procedures for data requirements and collection in the post-authorisation phase that meet the needs of both regulators and HTA bodies.
- Further develop and implement effective tools and methods to collect comprehensive data and monitor the benefit-risk balance of authorised medicines. Explore the use of electronic health records and in-house and other data sources on drug utilisation, to collect relevant information.
- Increase the involvement of patients, healthcare professionals and academia in collecting information on the use of medicines in real life, including off-label use. Establish procedures for data collection and complete the pilot study.
- Implement the extended peer-review process for primary assessments of major changes to the marketing authorisation.
- Conduct peer review of environmental risk assessments. Evaluate the impact of the Commission's recommendations for minimising environmental impact.
- Assess the applicability of approach to environmental impact used for veterinary medicines.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Extensions and variations applications, of which:	5,592	4,837	5,385
Type-IA variations	2,880	2,922	2,889
Type-IB variations	1,498	1,958	1,468
Type-II variations	1,196	961	1,012
Line-extensions of marketing authorisations	18	16	16
Post-authorisation scientific-advice requests	125	116	89

Performance indicators

- **100%** of post-authorisation applications evaluated within the legal timeframes.
- **100%** of risk-management plans peer reviewed within the assessment process of variations and line-extensions.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
83,727	92

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

1.4. Arbitrations and referrals

Activity area

The Agency conducts referral and arbitration procedures, as described below.

- **Arbitration** procedures are initiated for nationally authorised products when Member States cannot reach agreement (e.g. in granting a variation or a marketing authorisation), or when theyhave adopted different decisions over the years for some medicines, resulting in discrepancies in indication, posology, contraindications or other sections of the product information that need to be harmonised.
- **Referrals** are initiated for either centrally or nationally authorised products in cases where there is a safety-related issue with the product, a 'Community interest', or a need to harmonise within the EU 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.

Key objectives

- Provide high-quality and consistent scientific opinions to the European Commission and Member States.

Activities in 2014

Previous trends are expected to continue in 2014, with no major activities or events outside the regular activities expected regarding referrals and arbitration of human medicines. Thus, the Agency expects to carry on 'business as usual' in this area.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Arbitrations and Community referral procedures initiated	55	43	40

Performance indicators

- **100%** of arbitration and referral procedures managed within the legal timelines.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
5,878**	24

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.
** Pharmacovigilance-related payments only expected to start towards the end of 2014.

1.5. Pharmacovigilance activities

Activity area

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

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

The area covers:

- The management of ADR reports, periodic safety-update reports, risk-management plans and oversight of post-authorisation safety studies (PASS) and post-authorisation efficacy studies (PAES).
- The management of safety signals for centrally authorised products (CAPs) and for nationally authorised products (NAPs), and management 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 practice (GVP) and standards for the system.

Key objectives

- Support conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes.
- Support pharmacovigilance decision-making through use of high-quality data, and maximise the benefits to public-health promotion and protection by ensuring the critical assessments of risk and benefit-risk are underpinned by the best-available evidence.
- Enhance international cooperation in the follow-up of emerging safety issues.
- Provide consistent, high-quality information on pharmacovigilance topics to stakeholders and partners.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Develop guidance and methodological standards for the design, conduct and analysis of post-authorisation safety and efficacy studies, including guidance for joint studies.

- Develop a programme for studying public-health impact, including monitoring the effectiveness of targeted risk-minimisation measures. Design methodologies for drug-utilisation studies, to estimate the potential public-health impact of adverse drug reactions.
- Develop evidence-based tools for the visualisation of the benefit-risk of medicinal products, to support assessment and transparency of decision-making.
- Review the risk-management process and update relevant guidance based on experience.
- Review the signal-detection process and guidance based on evidence-based recommendations on the choice and application of methods for signal detection from spontaneous reports (including patient reports) and signal confirmation, including strengthening the threshold of evidence needed for confirming a signal.
- Improve the quality of data in the EudraVigilance system, including timely updating of the database with new information.
- Support ENCePP in the conduct of multinational post-authorisation studies.
- Finalise business requirements for enhanced EudraVigilance system functionalities with the European regulatory network for medicines.
- Finalise business requirements for a PSUR repository with the network. Continue single-assessment procedures where at least one CAP contains the relevant active substance. Start single assessments for substances contained only in NAPs, if resources are available to support the assessment.
- Finalise the guidance on literature monitoring for case reports to be entered in EudraVigilance. Develop options for the scope of products monitored. Conduct a tender for a service provider.
- Conduct pharmacovigilance audits (as required by Article 28f of Regulation (EC) No 726/2004, as amended) and prepare a report on the results for the Management Board.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Reviewed signals	2,500	2,449	2,213
Validated signals	55	43	52
PSURs received	490	518	535
PASS/PAES	35	2*	0

***** Includes only the number of imposed reports.

Performance indicators

- **100%** of reaction-monitoring reports supplied to the lead Member State monthly.
- **100%** of protocols and reports for non-interventional post-authorisation safety studies assessed within the legal timeframe.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
24,566	87

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

1.6. Other specialised areas and activities

Activity area

This area covers Agency activities in the human-medicines field, other than evaluation and monitoring of these medicines. It includes work in the areas described below.

- **Herbal medicinal products.** The Agency provides scientific opinions on questions relating to herbal medicines, establishes Community herbal monographs for traditional and well-established-use herbal medicines, and drafts the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. The monographs prepared by the Agency facilitate the granting of traditional-use registrations and well-established-use marketing authorisations for herbal medicines, allowing them to be placed onto the EU market.
- **Antimicrobial resistance** and availability of anti-infective treatment options. The Agency cooperates with European and international partners in exploring opportunities for new and effective anti-infective treatment options to overcome the problem of antimicrobial resistance. Work in the field of antimicrobial resistance is done in regard to both human and veterinary medicines.
- **Pandemic-influenza preparedness.** The 2009 influenza pandemic led to a review of cross-European strategy for pandemic preparedness. The Agency continues to implement actions to improve pandemic preparedness, in collaboration with the network and the EC.
- **Clinical trials.** The growing trend to conduct clinical trials outside the EU/EEA raises the importance of ensuring the trials meet certain clinical, ethical and quality standards, and provide comprehensive, reliable data for assessment and decision-making requirements. Cooperating with international partners, the Agency contributes to improving the design, management, oversight and analysis of the clinical trials, as well as working to provide capacity-building and develop information exchanges and shared planning of GCP inspections.

Key objectives

- Facilitate the development of new antibiotics for treatment of multi-resistant bacteria.
- Assure the 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 the EU/EEA.
- Improve the safety and continuity of supply chains for medicines. Prevent circulation of falsified medicines.
- Support a high level of coordinated cross-European preparedness to act on public-health threats.
- Enhance international cooperation in the fields of antimicrobial resistance, clinical trials, supply-chain continuity and preparedness for public-health threats.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Develop clinical guidance to support development of new treatments for multi-resistant bacteria. Develop a proposal for streamlined pre-authorisation data requirements and post-marketing surveillance enhancements.
- Provide input into the work of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) to minimise the risk of antimicrobial resistance arising from use of human or veterinary medicines.
- Contribute to the development of regulatory frameworks on the conduct, monitoring and analysis of clinical trials. This includes input into the clinical-trials legislation, and developing guidance on risk-based approaches to quality management in clinical trials.
- Adjust EPARs to include a standardised set of information on clinical trials conducted in third countries.
- Implement frameworks for ethics experts to advise the Agency.
- Contribute to the development of a coordinated European strategy for ensuring rapid response and decision-making in event of a public-health threat.
- Provide training to the network on the revised pandemic-influenza plan.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Herbal monographs, new*	15	9	15
Herbal monographs, revised	5	7	2
List entries	2	0	0

* Where assessment does not lead to the establishment of a monograph, a public statement will be prepared.

Performance indicators

- **At least 1** workshop/training session on clinical-trial supervision held with international partners.
- **At least 1** workshop held in the area of GMP inspections and quality defects.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
7,378	18

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

1.7. Projects

The main projects that the Agency has planned for 2014 in order to support and improve performance of its core activities are listed below. These projects and their deliverables might be reviewed and clarified according to the Agency's project-prioritisation process; the Agency may also undertake other projects, as deemed necessary.

Programme / Project	Project completion target	Deliverables 2014
Data integration Stage 2	Q4 2014	· Analysis and design of EU ISO Identification of Medicinal Products (IDMP) compliant product-management service and system
Data integration Stage 3	Q3 2015	· First iteration of the organisations-management system · Organisations data cleaned · Managed service for organisations · Integration across EMA systems
Data integration Stage 4	Q1 2016	· Agreement across the Telematics network on the extent of the ISO IDMP substance standards implementation · Analysis and design of an EU substance-management service and system
Pharmacovigilance EudraVigilance Human v7	Q2 2014	· Database that facilitates electronic submission and maintenance of core information on medicinal products by MAHs · Reliable product data available to support calculation and collection of PhV fees · Agency receiving formal notifications of 'withdrawn products' by MAHs
Pharmacovigilance Medical-literature monitoring	Q4 2014	· Procurement for service provider to provide services for medical-literature screening and entry of individual cases in EudraVigilance · Partitioned EV literature repository accessible to the EMA · Forwarding of ICSRs entered in EV to NCAs
Pharmacovigilance Tactical remediation of medicines web portal (for fees)	Q4 2014	· Changes to the existing medicines web portal to allow pharmaceutical companies access to pharmacovigilance fee and invoice information. This is a tactical change to an existing system ahead of the strategic solution to be implemented as part of the Agency's online roadmap
Pharmacovigilance PhV fees implementation	Q2 2015	· Required functionality to: - charge fees for PhV activities and pay NCAs - automate processes (where possible) and minimise the administrative burden of the legislation - provide the performance data requested in the legislation to the EC
EudraCT EudraCT 10	Q2 2014	· Functions to: - publish and manage CT result data - provide visibility for NCAs about the submitted and published results - enable EMA administrators to view and edit result

Programme / Project	Project completion target	Deliverables 2014
		datasets and user rights - allow EMA administrators to 'soft delete' CTAs - include Article 45/46 trials in EudraCT · Enhancements to existing CTA and soon-to-be-released results module · Enhancements of the EU Clinical Trials Register
BI Migration to OBIEE EVDAS DAP (data access policy)	Q3 2014	· EVDAS Microstrategy Data Access Policy dashboards (interactive PDFs) migrated to OBIEE

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 the development and availability of medicines, and to protect public and animal health.

Work in the veterinary-medicines area concerns not only animal health but also public health, through the use of authorised veterinary medicines in food-producing animals, and control of diseases transmissible to man. Hence, the development and evaluation of veterinary medicines must consider the 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 the 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 the 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, which encourage the development of products that would otherwise not be developed in the current market conditions. Product eligibility is reviewed on a five-yearly basis.
- Support the 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.

Key objectives

- Provide support and incentives to the development of new medicines, especially with regard to medicines for smaller market segments.
- Promote innovation and use of new approaches in the development of veterinary medicines.
- Foster bilateral cooperation with the FDA, especially in the areas of parallel scientific advice and provision of assistance to companies bringing innovative products to the market.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Review the criteria and guidance for MUMS/limited-markets classification, to ensure objective and efficient support for the development of new medicines. Adopt the revised MUMS policy by Q4 2014.
- Review the status of products designated as MUMS/limited market, according to the review cycle.
- Provide access to the Agency's Innovation Task Force, to enable advice to be provided in the early stages of development; benefit from experience gained in the human-medicines field.
- Identify reasons why veterinary medicines — especially those for which scientific advice was given — fail to progress to the application stage, and explore improvements to increase the number of applications submitted.
- Continue to promote the use of scientific advice in the veterinary sector to applicants. Continue to improve the content and procedure of scientific advice to increase its availability and effectiveness.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Innovation Task Force briefing requests	2	0	0
Scientific-advice requests	32	40	28
MUMS applications	18	23	21

Performance indicators

- **100%** of scientific-advice procedures completed within set timeframes.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
1,496	1

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

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 European Commission. The Commission grants the marketing authorisation, following which the Agency publishes a European public assessment report (EPAR).
- **Establishment of MRLs.** The use of veterinary medicinal products in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. Before a veterinary

medicinal product can be authorised, the safety of its residues must be evaluated. The Agency establishes maximum residue limits (MRLs) for pharmacologically active substances used in veterinary 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.

Key objectives

- Provide high-quality and consistent scientific opinions to the Commission.
- Ensure the establishment of MRLs supports safe use of veterinary medicines with regard to their impact on human health.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Embed the benefit-risk methodology in the veterinary medicines assessment process. Provide assessor training, to ensure consistent use of assessment methodology.
- Implement the revised EMA conflicts-of-interests policy, to ensure the availability of the best scientific expertise, while maintaining independence of the scientific committees' work.
- Increase the quality and consistency of scientific opinions through regular reviews of the quality-assurance of scientific opinions produced.
- Continue the work to resolve the challenge represented by veterinary medicines that persist at sites of injection, in terms of establishing MRLs.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Initial evaluation applications	20	23	12
New MRL applications	3	7	1
MRL extension and modification applications	5	6	5
MRL extrapolations	1	0	0
Art. 9, Biocides	2	0	0
Review of draft Codex MRLs	3	0	5

Performance indicators

- **100%** of procedures completed within legal timeframes. This includes product-application and MRL-application evaluations.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
4,757	13

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

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 of 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 the 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.

Key objectives

- Provide high-quality, consistent post-authorisation support, including scientific assessment of changes to marketing authorisations.

Activities in 2014

No major activities or events outside the regular activities of the Agency are expected regarding post-authorisation of veterinary medicines in 2014.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Extensions and variations applications, of which:	245	320	260
Type-I variations	200	283	200
Type-II variations	40	32	52
Line extensions	5	5	8

Performance indicators

- **100%** of post-authorisation applications evaluated within legal timelines.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
4,649	15

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

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 issue. 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.

The referral of individual antibiotics, or classes of antibiotics that are particularly important for use in human medicine, is expected to remain a priority area in 2014. 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.

Key objectives

- Provide high-quality and consistent scientific opinions to the European Commission.

Activities in 2014

Previous trends are expected to continue in 2014, with no major activities or events outside the regular activities of the Agency expected regarding referrals and arbitration of veterinary medicines.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Arbitrations and Community referral procedures initiated	12*	10	12

*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 valid for referrals relating to antibiotics.

Performance indicators

- **100%** of arbitration and referral procedures managed within the legal timelines.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
1,043	5

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

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 throughout the EU network, 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 reports (AERs)**;
- Management and assessment of **periodic safety-update reports (PSURs)**.

Key objectives

- Support conduct of pharmacovigilance by providing the necessary guidance and systems, and delivering high-quality processes.
- Continue with international cooperation to promote the efficiency and effectiveness of pharmacovigilance for regulators and industry.
- Provide consistent, high-quality information on pharmacovigilance topics to stakeholders and partners.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Work with partners in the European medicines regulatory network to complete and start to implement an agreed strategy for IT support to veterinary medicines, with a particular focus on tools for pharmacovigilance.
- Migrate IT tools used for pharmacovigilance surveillance to a new system, with additional work required for validation and training.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Periodic safety-update reports (PSURs)	150	149	139
Total AERs, of which:	22,500	22,326	22,983
Adverse-event reports (AERs) for CAPs	7,200	8,166	7,783

Performance indicators

- **90%** of PSURs evaluated within the established timeline.
- **95%** of AERs for CAPs monitored within the established timelines.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
1,137	6

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

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

Key objectives

- Support increased availability of veterinary medicines through providing necessary input to the review of veterinary legislation.
- Contribute to minimising the risk to man and animals from the use of antibiotics.
- Foster cooperation between EU and international agencies in the area of antimicrobial resistance.
- Support further development of the VICH Outreach programme.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Provide advice to the European Commission regarding minimising the risk to man and animals from the use of antibiotics in veterinary medicines.
- Provide advice to the European Commission on the requirements for the development of new veterinary antimicrobials that address animal-health issues, while preserving the efficacy of antimicrobials crucial for human use.
- Develop a methodology and initiate a pilot project to measure antimicrobial use per species as part of the ESVAC project. Monitor the use of veterinary antimicrobials through collection and analysis of sales and usage data within the ESVAC project.
- Implement IT systems to facilitate the supply of data to the ESVAC database.
- Provide input to the work of TATFAR to minimise the risk of antimicrobial resistance arising from the use of antibiotics in human and veterinary medicine.

- Continue the development of internationally harmonised guidelines within VICH, to avoid duplication of testing and allow the successful implementation of the '3Rs' goals (reduction, refinement and replacement) with respect to minimising the need for testing of medicinal products in animals.

Workload indicators

Not applicable.

Performance indicators

None identified.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
1,598	4

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

2.7. Projects

The main projects that the Agency has planned for 2014 in order to support and improve the performance of its core activities are listed below. These projects and their deliverables might be reviewed and clarified according to the project-prioritisation process; the Agency may also undertake other projects, as deemed necessary.

Programme / Project	Project completion target	Deliverables 2014
BI migration to OBIEE / EVDAS Vet migration	Q3 2014	· Reports in the EV Vet Microstrategy web application migrated to OBIEE.
ESVAC web-based collection of data	Q4 2014	· A web-based system to collect data from NCAs on sales of antimicrobials and on management of data on animal population. · Interactive database with predefined reports.
Veterinary, new initiatives	TBC	· Implementation of recommendations of the IT strategy and implementation plan for veterinary medicines.

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 the committees' work, maintaining necessary IT systems, coordinating inspections, and managing relationships with stakeholders and partners.

3.1. Committees and working parties

Activity area

The scientific-opinion making of the Agency is done primarily through committees and working parties. The Agency has seven scientific committees, each focusing on a specific area of work. Six committees provide scientific opinions regarding human medicines (CHMP, COMP, PDCO, HMPC, CAT and PRAC), and one focuses on veterinary medicines (CVMP). The Agency's committees typically meet on a monthly basis, and the Agency provides all the support in organising 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 scientific advice working parties, as well as members of the Agency's senior management. It ensures there is sufficient coordination between the committees, so as to increase the robustness and predictability of the outcome of the benefit-risk assessment, by having consistent standards set for the development of medicines across the whole product lifecycle.
- **Committees Secretariat.** The Committees Secretariat provides organisational, secretarial and budget management for the operation of the Agency's scientific committees, as well as necessary regulatory support to the committees. It includes coordinating adequate scientific support and leadership across the Agency's divisions, as well as ensuring coordination and communication across scientific committees, working parties and scientific advisory groups, and facilitating interactions between these groups. In addition, the Committee Secretariat coordinates work-programme proposals and prioritisation, according to the impact of work on the committees and the 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).
- **Guideline development.** To facilitate the development of medicinal products, the Agency, through its working parties, prepares and reviews guidelines on a variety of scientific topics. The guidelines are consulted upon with stakeholders, and are made available on the Agency's website.
- **Meeting management.** The Meeting and Conference Management Department organises EMA meetings, conferences, workshops and training sessions, including those under the EU enlargement programme. The Department also makes travel and accommodation arrangements for delegates, and provides assistance with logistical and administrative issues.

Key objectives

- Increase the efficiency and effectiveness of the support and coordination of scientific committees and working parties.
- Improve the use and availability of scientific resources across the committees.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Complete the project on centralisation of committee secretariats, including streamlining of scientific support and implementation of harmonised administrative processes for coordination of committee meetings.
- Establish a coordinated secretariat for the working parties.
- Establish a cross-committee oncology scientific advisory group, and deliver analysis of results of this initiative. Explore expanding this pilot initiative to other established scientific advisoy groups.

Workload indicators

The workload of the scientific committees is largely driven by the activities described in the chapters above on evaluation activities for human and veterinary medicines. Thus, the relevant workload drivers are found in the corresponding sections fo this document.

	2014 forecast	2013 actual	2012 actual
Number of meetings	426	354	400
Number of teleconference meetings*	2,850	2,737	2,135
Number of delegates	8,500	6,869	7,341

* Total audio, video and web-conference meetings.

Performance indicators

- **80%** delegate satisfaction with the service level provided by the secretariat.
- **100%** up-to-date electronic declarations of interests submitted by committee members and experts prior to participating in a committee, SAG or other meeting.
- **100%** of first-stage evaluations of conflicts of interests for committee members and experts completed prior to their participation in the first meeting after the submission of a new or updated declaration of interests.
- **80%** of ex-ante verifications of declarations of interests for new experts completed within 2 weeks after upload of the DoI in the experts database.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
5,345	24**

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.
** Resources include Meeting and Conference Management support and CMD activities. Resources related to guideline development and committee coordination are allocated to the relevant human medicines and veterinary medicines activities.

3.2. Inspections and compliance

Activity area

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

- **Inspections.** The Agency coordinates inspections to verify compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP), good laboratory practice (GLP) and good pharmacovigilance practice (GVP), and with certain other aspects of the supervision of authorised medicinal products in use in the EU. Inspections are initiated following the request of the CHMP or CVMP in connection with the assessment of marketing-authorisation applications or the on-going supervision of authorised products. Similarly, the Agency coordinates inspections of blood establishments within the plasma master file (PMF) certification framework.
- **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 for 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 EU, especially in developing countries. Certificates are issued by the Agency, on behalf of the European Commission, to confirm the marketing-authorisation status and GMP compliance of the manufacturing sites of products authorised by the Commission through the centralised procedure, or of products for which a marketing-authorisation application has been submitted to the Agency.
- **Parallel distribution.** Parallel distribution is the distribution of a centrally authorised medicinal product from one Member State to another by a pharmaceutical company independent of the marketing-authorisation holder. The Agency checks the compliance of products distributed in parallel with the conditions laid down in EU legislation and in the marketing authorisation for the products.
- **Supply chain**. Recent years have seen cases of global supply shortages of medicines, caused by manufacturing-process issues. This has led to the development of recommendations to minimise the risks of such shortages occurring in the future, as well as to mitigate the impact of shortages that do occur. The Agency continues to promote proactive risk-management by manufacturers and marketing-authorisation holders, and, within its scope, instilling controls to ensure supply-chain quality and continuity.

Key objectives

- Improve the efficiency, consistency and quality of inspections, through enhanced international cooperation.
- Expand total international inspection coverage through the exchange of information with international partners. Minimise the duplication of inspections performed by regulatory authorities.
- Strengthen collaboration with the NCAs, the WHO and MAHs in relation to certificates and parallel-distribution activities.
- Assure the protection of clinical-trial participants and the quality of data generated in clinical trials destined for submission in marketing-authorisation applications, especially for trials conducted outside the EU/EEA.
- Improve the mitigation of the causes and impact of shortages of human medicines caused by GMP non-compliance and quality defects.
- Promote a global approach to the quality of APIs, finished products and the integrity of the supply chain. Promote adherence to ICH and VICH principles.
- Strengthen and further develop the quality-defects network, procedure and tools for the systematic collection, analysis and follow-up of data.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Coordinate the conduct of inspections with international partners.
- Provide training to support the development of capacity, harmonisation and exchange of best practice on inspections.
- Deliver training and capacity-building for inspectors, assessors and ethics committees. Organise a workshop on GCP inspections.
- Strengthen international collaboration in the area of clinical-trial inspections. Develop tools for information exchange in the GCP network.
- Improve public information on GCP inspections and their impact on the assessment outcome.
- Develop the concept of and initiate a pilot joint-pharmacovigilance-inspection programme.
- Implement procedures for inspections of wholesale distributors and EU-based manufacturers, importers and distributors of active substances.
- Continue the implementation of the action plan on medicine shortages due to manufacturing deficiencies, including the development of recommendations for better and proactive risk management by MAHs, to avoid supply shortages of medicines and raw materials.
- Improve the EU process for handling GMP non-compliance situations, including related supply shortages, and its interaction with global regulatory partners.
- Develop contacts with main countries where the manufacture of APIs or finished products takes place. Provide and host training sessions involving non-ICH regulators.
- Support the expansion of the MRA with Japan to sterile and biological medicinal products, as well as active pharmaceutical ingredients.

- Review the current process for quality defects in collaboration with international partners, and identify areas for improving international cooperation and coordination in managing quality defects.
- Organise meetings with NCAs and companies regarding parallel distribution and certificates, and further develop the available tools to allow simplification and improved transparency with companies submitting requests.
- Organise pharmacovigilance IWG and QWP assessor training sessions. Organise a GCP IWG international workshop, a quality-by-design workshop with stakeholders, and a Qdefect workshop.

Workload indicators

	2014 forecast	2013 actual	2012 actual
GMP inspections	360	397	368
GLP inspections	2	0	0
GCP inspections	71	70	72
Pharmacovigilance inspections	11	13	10
Quality-defect reports	180	178	148
Number of medicinal products sampled	45	45	41
Certificate requests	3,500	3,434	3,041
Urgent certificate requests	350	297	n/a
Parallel-distribution initial notifications	3,000	2,532	2,388
Parallel-distribution notifications of change	1,600	2,563	3,264
Parallel-distribution annual updates*	1,300	1,279	n/a

* Parallel-distribution annual updates have only been introduced since May 2013.

Performance indicators

- **100%** of inspections conducted within established regulatory timeframes.
- **90%** of standard certificates and 100% of urgent certificates issued within the respective legal timelines (10 working days and 2 working days, respectively).
- **90%** of parallel-distribution notifications checked for compliance within the standard timeline.
- **At least 4** training/workshop activities organised in the area of inspections.
- **Additional 10%** of GCP inspections addressed through information exchange on inspections carried out by international partners.
- **Additional 10%** of routine re-inspections of manufacturing sites addressed through exchange of information with international partners.
- **100%** of outcome reports of the sampling-and-testing programme for centrally authorised products followed up with the MAH within one month of receipt.

Resources

Financial resources (cost, thousand euro)*	Human resources (FTEs)
12,457	39

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

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, the European Commission, other EU institutions and EU agencies, non-EU competent authorities and regulators (U.S. 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) and health-technology-assessment bodies (HTAs). These interactions range from exchanges of information, collaboration on guideline development and capacity building to providing scientific expertise in the evaluation processes, cooperation on inspections, various international initiatives and other activities. In addition, the Agency has a specific legislative responsibility to support the evaluation of medicines intended for use in developing countries through its 'Article 58' provision.
- **Stakeholder interactions** with patients, healthcare professionals, industry organisations and academia. As part of these interactions, the Agency works together with patients and healthcare professionals and involves them in its activities, in particular in the scientific work of the Agency, and in preparing and reviewing information on human medicines for the public.
- **Support for small and medium-sized enterprises (SMEs).** The Agency has an office specifically dedicated to supporting smaller companies — the SME Office. It provides eligible SMEs with access to various incentives and regulatory assistance, including fee reductions, deferrals and conditional exemptions, and administrative and procedural support, as well as assistance with translations of the product-information documents submitted in applications for marketing authorisation. Around 1,000 SMEs are registered with the Agency.
- **Information and transparency.** The Agency places high importance on the transparency, openness and efficiency of its interactions with partners and stakeholders. The Agency maintains and manages specific communication and information-exchange platforms, and provides information on its work and outputs, as well as other relevant information. Public access to documents and information is provided in accordance with Regulation (EC) No 1049/2001.

Key objectives

- Enhance cooperation within the European medicines regulatory network.
- Enhance international cooperation activities towards the development of greater work-sharing.
- Implement the Agency's transparency and open-data commitments.
- Provide stakeholders and partners with consistent, high-quality, targeted and accessible information on the Agency's work, outputs and medicinal products.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- In collaboration with national authorities, set up and run a training and competency-development centre for the network, covering scientific, regulatory and procedural topics.
- Expand the national visiting experts programme.

- Develop a programme to gather data to inform the future revision of the general fee legislation. Develop the new public-hearings concept for human medicines.
- Implement a framework for interacting with pharmaceutical-industry organisations and launch a corporate-stakeholder function to coordinate contacts with industry stakeholders.
- Launch the policy on proactive publication of clinical trials, considering the outcomes of the court case and legislative proposals on clinical trials.
- Review the process of handing requests for access to documents.
- Promote the EU regulatory system for veterinary medicines at an international level in the FAO, OIE, WHO and VICH Outreach.
- Cooperate with the FAO, OIE and WHO to promote harmonisation of the requirements for authorisation of veterinary medicines at international level, and participate in VICH Outreach and other training activities.
- Deliver training activities related to veterinary medicines to the network as part of the package of measures delivered by the Agency.
- Contribute to the reform and reorientation of ICH governance and scientific-harmonisation activities, and contribute to the development of the IPRF and other emerging international coalitions.
- Support the EC on scientific and technical aspects of trade negotiations with third countries, including the FTA with Japan, the CETA with Canada and the TTIP with the US.
- Further develop and streamline Article 58 activities in close cooperation with the WHO. Evaluate the possibility of using this activity for capacity-building for non-EU regulators.
- Develop and launch a new extranet to facilitate cooperation and collaboration with delegates and other national-competent-authority groups.
- Establish a web managers' network with Member State authorities, to promote cooperation on digital issues relating to the online provision of information on science, medicines and health.
- Review the coordination of medicines information, particularly safety information, within the network and with international partners.

Workload indicators

	2014 forecast	2013 actual	2012 actual
Requests for SME qualification	500	401	684
SME status renewal requests	1,000	808	602
Requests for access to documents	350	307	281
Pages released following requests for access to documents	400,000-700,000	308,931	685,489
Requests for information	6,500	5,840	5,065
Number of EMA activities involving patients and consumers, of which:	575	550	525
Information to the public reviewed by patients	300	200	162

Performance indicators

- **100%** of declarations of interests updated prior to set deadlines.

Resources

Area of activity	Financial resources (cost, thousand euro)*	Human resources (FTEs)
Partners and stakeholders	5,904	23
Transparency and access to documents	2,050	14
Information	4,766	25

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.

3.4. 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 is an ongoing, centralised support function that comprises 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.

Key objectives

- Engage the Agency's stakeholders in the governance of data, and promote a wider and deeper understanding of the value of data assets.
- Continually improve the quality of data and information, including through creating an effective master-data management service.

Activities 2014

Agency activities to achieve the objectives set for this area:

- Implement a 'data governance' structure at the Agency, aligning people, processes and technology, and involving partners and stakeholders, to enable the Agency to leverage data as an enterprise asset.
- Create a master-data management service (initially for substances and referentials), available for the Agency and its stakeholders to ensure and check quality, accuracy and completeness of data, and provide faster, better resolution of problems. This service will be the foundation for managing other types of master data.
- Coordinate data-management projects across the Agency in order to meet new legislative requirements or other strategic goals with a higher success rate and more value.

- Identify opportunities to use centralised services for the collection and maintenance of data related to veterinary medicines.

Performance indicators

- Effective master-data management service:
  - **90%** of substance and referentials data registered in 24 hours. **99%** of these data registered in 48 hours.
  - **No more than 3%** of calls reopened due to incorrect handling.
- **Over 80%** of stakeholders satisfied with the responsiveness, cooperation and communication of data-management services.

3.5. Process improvements

Activity area

This area covers all those activities that the Agency is currently undertaking to improve the processes that support the evaluation, maintenance and safety monitoring of medicines.

Key objectives

- Enable evaluation, maintenance and safety-monitoring of medicines by simplified and efficient processes, designed to deliver scientific opinions in accordance with legal and regulatory requirements.
- Optimise expert and committee input by mobilising the appropriate expertise at the right time and providing support through appropriate systems and competent staff.

Activities in 2014

Agency activities to achieve the objectives set for this area:

- Review the current processes ('as is' state) and identify improvement areas.
- Redesign processes with a quantifiable improvement that can produce outcomes of intended quality.
- Review and define procedures related to the authorisation of veterinary medicines, benefiting from the use of Agency-level centralised services.
- Define quality metrics to monitor process performance.
- Consult internal and external stakeholders to estimate the impact of process-improvement change and ensure that their expectations are met.
- Implement the revised processes and build in a culture of continuous improvement.

Workload indicators

Not applicable.

Performance indicators

- **80 %** of existing regulatory procedures reviewed and improvement areas identified by the end of 2014.

Resources

Process-improvement activities cover a wide range of Agency activities with the relevant resources being involved, as required. Hence, these are covered in relevant sections of this document.

3.6. Projects

The main projects that the Agency has planned for 2014 in order to support and improve the performance of its core activities are listed below. These projects and their deliverables might be reviewed and clarified according to the project-prioritisation process; the Agency may also undertake other projects, as deemed necessary.

Programme / Project	Project completion target	Deliverables 2014
eSubmissions Gateway v3	Q3 2014	· Processing all mandatory submissions from 1 March 2014 · Processing other procedure types (e.g. paediatrics, veterinary medicines and referrals) · Maximum size of incoming submissions increased to 25Gb · Changes to the Gateway Filehandler to simplify file naming and allow use for any type of procedure · Further automation of registration of submissions
eSubmissions Gateway – CESP integration study	Q2 2014	· Options identified for integrating CESP with the eSubmission gateway and the Common Repository · Initial release of the eSubmissions gateway integrated with CESP
eSubmissions eAF – change requests	Q4 2014	· Relevant change requests incorporated into eAF functionality that will allow the network to mandate their use
eSubmissions eAF – SIAMED integration study	Q4 2014	· Options identified for automated upload of data from eAFs to SIAMED
eSubmissions Common repository v2	Q3 2014	· A PSUR repository (with minimum functionalities)
eSubmissions ECTD – definition of ECTD v4 standards	Q3 2014	· An eCTD standard suitable for the EMA
eSubmissions ECTD – Prep roadmap for compliance with network systems	Q4 2014	· Roadmap on how the EMA will comply with the new eCTD4 standard
eSignature eSignature	Q3 2014	· A solution for authorised EMA signatories (incl. all committee/WP chairs) to digitally sign all documents

Programme / Project	Project completion target	Deliverables 2014
		requiring a legally binding signature · A solution to receive electronically submitted documents that require a signature, and to verify their veracity · Other change requests as appropriate and affordable within the assigned budget · Integration with DREAM
Online roadmap Technologies proof of concept	Q2 2014	· Developed reference architecture, showing how the products will work together in the technology stack and how they integrate with other systems in the Agency
Online roadmap Social collaboration pilot	Q1 2014	· Prove feasibility of options for discussion forums, groups, document collaboration, etc. to staff members of the Agency and external teams (NCAs, HMAs)
Online roadmap Intranet/extranet	Q2 2015	· Platform for improved collaboration among the staff in the Agency and NCAs, to deliver business-critical tasks in an efficient, effective and controlled manner · Platform to allow deployment of the intranet/extranet solution
Online roadmap Interface design for intranet/extranet	Q2 2014	· Detailed requirements for, and design of the new look & feel of, the Agency's intranet/extranet
2014 programme Data-centre upgrade	Q4 2014	· Upgrades to existing infrastructure in the new premises' data centre
Review and reconnect	Q4 2014	· Process and data-management improvement initiatives outlined in different parts of the work programme

4. Support and governance activities

Activity areas

This area covers all the general functions and activities performed that are necessary to ensure the 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. They include support to the Management Board and senior management of the Agency, the 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 and communications technology.** IT services include the development of necessary IT systems, provision and maintenance of ongoing operations, and IT data management.
- **Legal services.** Legal activities within the 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 deals with all staff-related matters, including developing and maintaining HR strategy and policy, conducting recruitment and procurement, managing personnel administration and payments, running the trainee programme, managing staff declarations of interests, providing staff support and training, and dealing 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. Conducting self-assessment as part of the EU agencies benchmarking programme, annual reviews of sensitive functions, and 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 the Agency's premises and office accommodation, security, reception and switchboard, mail management, reprographics and catering.
- **Communication (corporate).** These are corporate communication activities, such as corporate-website management, press office and information centre.
- **Programme Design Board.** The Programme Design Board ensures that the Agency's business projects are aligned with the Agency's strategy and meet customer expectations.

- **Policy issues.** Chief Policy Adviser Division is responsible for defining and implementing the Agency policies. This division also takes part in implementation and monitoring of legislation changes, and liaises with and coordinates EMA interactions with the EU institutions.

Key objectives

- Ensure and further improve the efficiency and effectiveness of the Agency's corporate activities.
- Promote and maintain a positive reputation among stakeholders and partners as an authoritative and open source of information on medicines in the European Union.
- Ensure communication activities are in line with and support the Agency's strategy.

Activities in 2014

Corporate governance and support activities will continue as 'business as usual', ensuring continuity and efficiency of the Agency's work. Specific activities in 2014:

- Complete the project to relocate the Agency to new premises in August 2014.
- Continue implementing corporate-efficiency initiatives identified in the Review & Reconnect programme.
- Complete the staff-engagement survey.
- Perform self-assessment of the Agency's operations as part of best-practice benchmarking within the European medicines regulatory network.
- Perform audit and consultancy activities in line with the annual audit plan.
- Develop and launch a new EMA intranet to support staff and management communications.
- Improve the regulatory content on the EMA corporate website in order to provide more support to business users on achieving their goals with the Agency.
- Streamline and rationalise the Agency's web-publishing processes to ensure cost-effectiveness and efficiency.
- Develop a social-media strategy and reinforce the Agency's social-media presence, including an appropriate search-engine marketing strategy.
- Reinforce the Agency's media relations, with a focus on increasing the Agency's outreach to new audiences across EU Member States.

Performance indicators

- **97%** of posts on the Agency establishment plan filled.
- **99%** of revenue appropriations and 99% of expenditure appropriations implemented.
- **97%** of appropriations carried over from year N-1.
- The maximum rate of carryover to year N+1, of total commitments within the title:
  - Title 1: **2%**
  - Title 2: **20%**
  - Title 3: **28%**

- **97 %** of payments made within 30 days' time.
- Telematics and corporate IT systems available **98 %** of the time.
- IT service desk: meeting SLAs / issue resolution per system / priority level:
  - Critical (resolution time 4 hours): **80 %**
  - Severe (resolution time 1 business day): **80 %**
  - Important (resolution time 10 business days): **80 %**
  - Minor (resolution time 120 business days): **80 %**
- **100 %** of IT projects delivered on time.
- **100 %** of IT projects delivered within budget.
- **100 %** of IT projects delivered to original specification.

Resources

Area of activity	Financial resources (cost, thousand euro)*	Human resources (FTEs)
Governance, quality-management and internal audit	6,920	33
Finance	4,392	28
ICT	11,548	63**
Legal services	1,883	12
Human resources	4,906	35
Infrastructure services	2,530	19
Communication	2,570	15

* Includes cost of human resources, payment to rapporteurs, meetings and delegate reimbursements, other operational expenditure and overheads.
** Includes resources allocated to IT projects.

Annexes

Annex 1: Revenue and expenditure 2014 — key figures

Figure 1. Revenue evolution 2009–2014

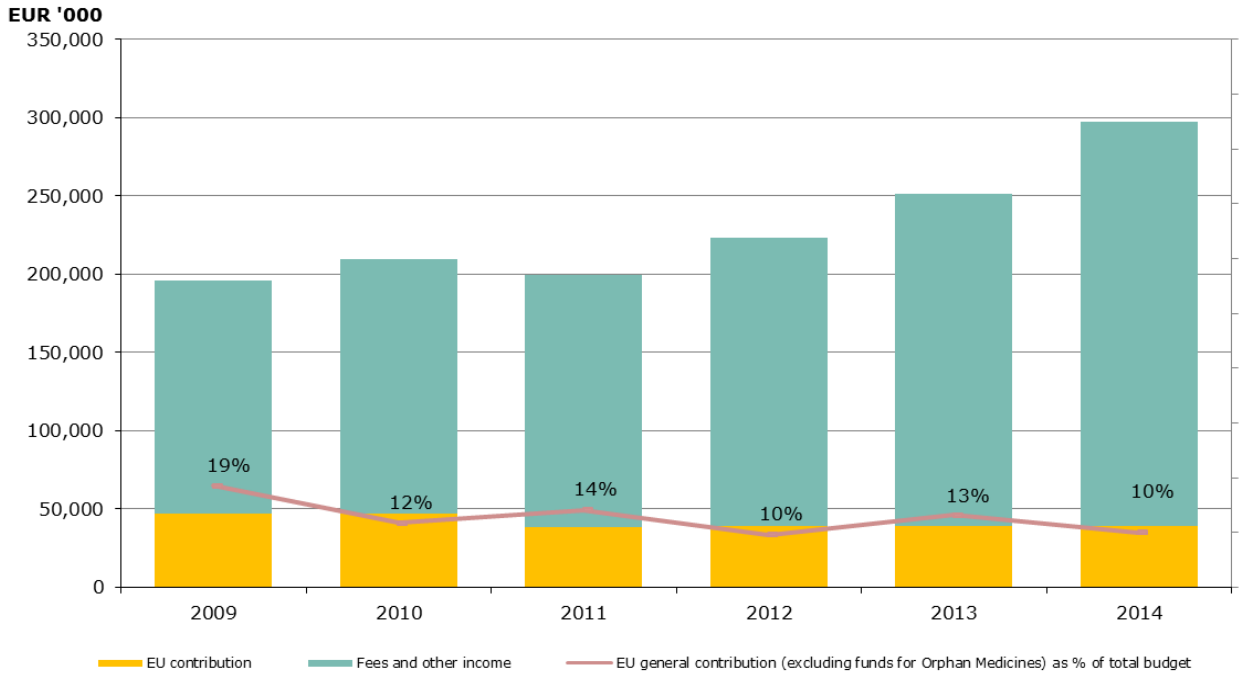
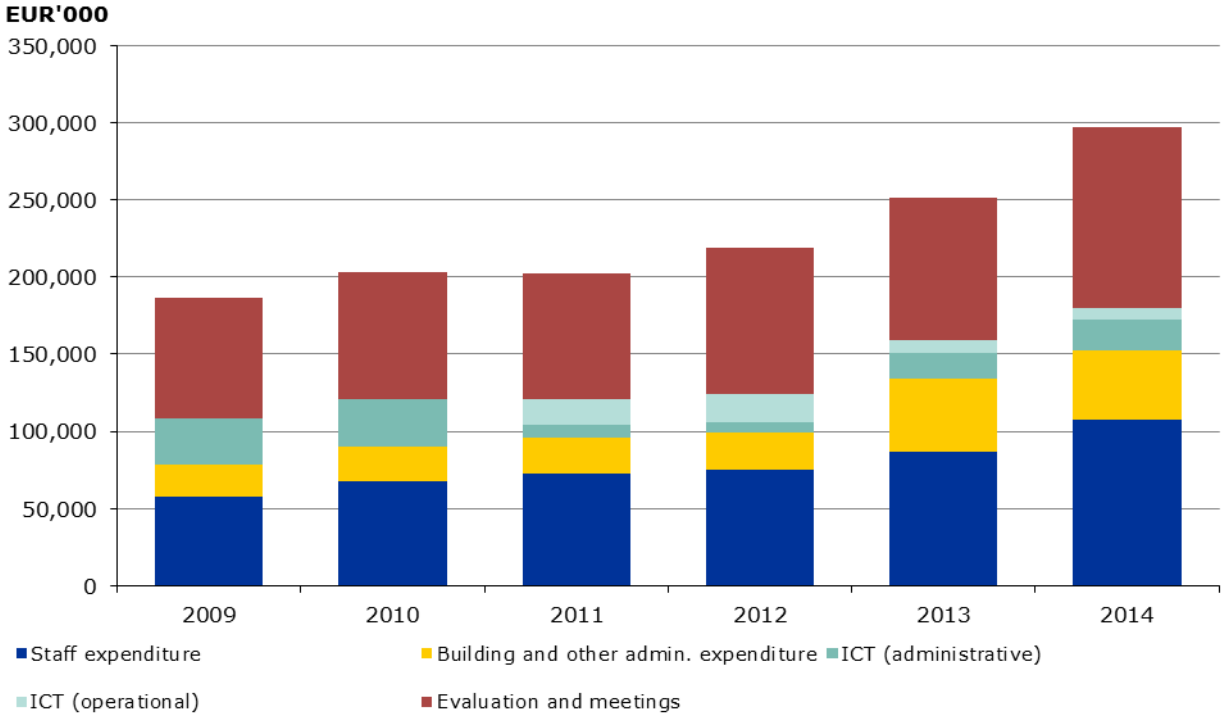


Figure 2. Expenditure evolution 2009–2014



Annex 2: Revenue and expenditure overview 2012–2014

		2012 (outturn)[1]		2013 (budget)[2]		2014 (budget)[3]	
		€ '000	*% of total*	€ '000	*% of total*	€ '000	*% of total*
	Revenue						
100	Fees and charges	182,912	*81.8%*	210,587	*83.7%*	236,156	*79.5%*
200	General EU contribution	21,466	*9.6%*	33,230	*13.2%*	29,777	*10.0%*
200	Surplus of previous year	9,875	*4.4%*	0	*0.0%*	3,453	*1.2%*
201	Special EU contribution for orphan medicinal products	7,491	*3.4%*	6,000	*2.4%*	6,000	*2.0%*
300	Contribution from EEA	753	*0.3%*	1,098	*0.4%*	1,084	*0.4%*
600	External assigned revenue	128	*0.1%*	520	*0.2%*	20,524	*6.9%*
5+9	Other	902	*0.4%*	125	*0.0%*	175	*0.1%*
	TOTAL REVENUE	**223,527**	*100.0%*	**251,560**	*100.0%*	**297,169**	*100.0%*
	Expenditure						
	Staff						
11	Staff in active employment	69,457	*31.7%*	80,841	*32.1%*	99,945	*33.6%*
13	Mission expenses	575	*0.3%*	465	*0.2%*	605	*0.2%*
14	Socio-medical infrastructure	557	*0.3%*	641	*0.3%*	758	*0.3%*
15	Exchange of civil servants and experts	2,293	*1.0%*	2,428	*1.0%*	3,724	*1.3%*
16	Social welfare	236	*0.1%*	306	*0.1%*	320	*0.1%*
17	Representation expenses	15	*0.0%*	28	*0.0%*	38	*0.0%*
18	Staff insurances	2,118	*1.0%*	2,255	*0.9%*	2,395	*0.8%*
	Total Title 1	**75,251**	*34.4%*	**86,964**	*34.6%*	**107,785**	*36.3%*
	Building / equipment						
20	Investment in immovable property, renting of building and associated costs	21,066	*9.6%*	40,997	*16.3%*	39,530	*13.3%*
21	Expenditure on corporate data processing	7,108	*3.2%*	17,141	*6.8%*	19,776	*6.7%*
22	Movable property [..]	1,351	*0.6%*	3,986	*1.6%*	3,210	*1.1%*
23	Other administrative expenditure	785	*0.4%*	1,118	*0.4%*	1,591	*0.5%*
24	Postage	401	*0.2%*	514	*0.2%*	184	*0.1%*
25	Expenditure on other meetings	105	*0.0%*	125	*0.0%*	136	*0.0%*
	Total Title 2	**30,817**	*14.1%*	**63,881**	*25.4%*	**64,427**	*21.7%*
	Operational expenditure						
300	Meetings	6,759	*3.1%*	7,117	*2.8%*	8,035	*2.7%*
301	Evaluation of medicines	81,992	*37.5%*	77,247	*30.7%*	97,151	*32.7%*
302	Translations	3,958	*1.8%*	5,452	*2.2%*	5,532	*1.9%*
303	Studies and consultants	2,044	*0.9%*	2,300	*0.9%*	6,399	*2.2%*
304	Publications	76	*0.0%*	106	*0.0%*	116	*0.0%*
305	Community programmes	298	*0.1%*	400	*0.2%*	0	*0.0%*
31	Expenditure on business related ICT projects	17,662	*8.1%*	8,093	*3.2%*	7,724	*2.6%*
	Total Title 3	**112,790**	*51.5%*	**100,715**	*40.0%*	**124,957**	*42.0%*
	TOTAL EXPENDITURE	**218,858**	*100.0%*	**251,560**	*100.0%*	**297,169**	*100.0%*

[1] Financial Year 2012: as per final accounts, rounded to nearest thousand Euro

[2] Financial Year 2013: as per current budget (including transfers and amending budet as of 30.10.2013)

[3] Financial Year 2014: as proposed to Management Board 12 December 2013

Annex 3: Human-resource needs and establishment plan

Function Group & Grade	Authorised for 2012		Occupied as at 31.12.2012			Authorised for 2013		Requested 2014	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts
				Grade filled	Actual grade				
AD 16	-	1	-	1	0	-	0	-	0
AD 15	-	4	-	4	2	-	4	-	4
AD 14	-	6	-	6	2	-	6	-	6
AD 13	-	7	-	7	8	-	8	-	8
AD 12	-	38	-	38	32	-	38	-	42
AD 11	-	38	-	36	23	-	38	-	38
AD 10	-	34	-	33	23	-	36	-	36
AD 9	-	39	-	37	30	-	40	-	37
AD 8	-	47	-	44	40	-	47	-	49
AD 7	-	45	-	44	44	-	45	-	51
AD 6	-	37	-	37	73	-	42	-	39
AD 5	-	33	-	33	38	-	42	-	30
Subtotal AD	***0***	***329***	***0***	***320***	***315***	***0***	***346***	***0***	***340***
Total AD	***329***		***0***	***320***	***315***	***346***		***340***	
AST 11	-	2	-	2	1	-	2	-	2
AST 10	-	5	-	4	1	-	5	-	5
AST 9	-	7	-	7	2	-	7	-	7
AST 8	-	13	-	13	8	-	13	-	15
AST 7	-	20	-	20	13	-	20	-	19
AST 6	-	33	-	33	12	-	33	-	36
AST 5	-	35	-	35	27	-	35	-	37
AST 4	-	51	-	50	46	-	51	-	55
AST 3	-	37	-	35	46	-	39	-	39
AST 2	-	40	-	38	38	-	40	-	34
AST 1	-	18	-	18	66	-	20	-	10
Subtotal AST	***0***	***261***	***0***	***255***	***260***	***0***	***265***	***0***	***259***
Total AST	***261***		***0***	***575***	***575***	***265***		***259***	
Grand subtotal	***0***	***590***	***0***	***575***	***575***	***0***	***611***	***0***	***599***
Grand total	***590***		***0***	***575***	***575***	***611***		***599***	

Contract Agents	**2012**		**2013**	**2014**
	Actual FTE as at 31.12.2012	**Actual headcount as at 31.12.2012**	**Planned FTE**	**Planned FTE**
FG IV	42	40	51	46
FG III	11	10	13	12
FG II	63	56	61	72
FG I	0	0	0	0
Total	**116**	**106**	**125**	**130**

National Experts	**2012**		**2013**	**2014**
	Actual FTE as at 31.12.2012	**Actual headcount as at 31.12.2012**	**Planned FTE**	**Planned FTE**
Total	**15**	**16**	**15**	**25**

Annex 4: Operational-procurement decisions

Activity statement:	**Monitoring of medical literature**
Objective:	See WP2014, heading 1.5.
Budget:	€ 1.0 - €2.0 million per year over 4 years (total: € 7.0 million); € 800,000 in 2014
Financial year:	2014 - 2017/18
Description of action:	Implementation of Pharmacovigilance legislation
Type of contract:	Framework Contract - Operational consultancy; Specific contracts
Number of contracts:	5
Indicative timeframe for contract:	Commencing in 2014
Indicative timeframe for procurement:	1st quarter 2014
Indicative budget for procurement:	€ 4.0 million
Legal basis:	Article 27 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3030

Activity statement:	**EudraVigilance data management**
Objective:	See WP2014, heading 1.5.
Budget:	€ 1.6 million per year over 4 years (total: € 6.5 million)
Financial year:	2015-2018/19
Description of action:	Data management and cleaning to ensure individual case reports are accurate, retrievable and analysable for safety signal detection and evaluation
Type of contract:	Framework Contract - operational consultancy; specific contracts
Number of contracts:	5
Indicative timeframe for contract:	Commencing in 2015
Indicative timeframe for procurement:	2nd quarter 2014
Indicative budget for procurement:	€ 1.6 million per year over 4 years (total: € 6.5 million)
Legal basis:	Article 24 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3030

Activity statement:	**ENCePP studies**
Objective:	See WP2014, heading 1.5.
Budget:	€ 344,000
Financial year:	2014
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:	Call for Expression of Interest; Specific contract per study
Number of contracts:	3
Indicative timeframe for contract:	Three procurements of approximately 115,000 Euros each, one in each of the first three quarters of 2014
Indicative timeframe for procurement:	each of the first three quarters of 2014
Indicative budget for procurement:	€ 344,000
Legal basis:	Regulation 726/2004 and Directive 2001/83 notably articles 31 and 107i - k
Budget line:	B3030

Activity statement:	**Subscription to medical database**
Objective:	See WP2014, heading 1.5.; page 16
Budget:	€ 500,000 over 4 years
Financial year:	2015 - 2018
Description of action:	Access to and use of primary care data set (UK)
Type of contract:	Service contract
Number of contracts:	1
Indicative timeframe for contract:	March 2015 - March 2019
Indicative timeframe for procurement:	1st quarter 2014
Indicative budget for procurement:	€ 500,000 over 4 years
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3031

Activity statement:	**Information Centre**
Objective:	See WP2014, heading 4.
Budget:	€ 245,000 over 4 years
Financial year:	€ 2,014
Description of action:	Upgrade of Agency's current printing services, promotional material and exhibition systems.
Type of contract:	Separate restricted procedure for a) printing services; and negotiated procedures for b) promotional material; c) exhibition systems
Number of contracts:	3
Indicative timeframe for contract:	2nd quarter 2014
Indicative timeframe for procurement:	Commencing in 2015
Indicative budget for procurement:	€ 245,000 over 4 years
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3040

Activity statement:	**Business IT development for IT network and security**
Objective:	See WP2014, heading 4.
Budget:	€ 4.0 million over 4 years; of which € 3.5 million administrative and € 500,000 operational
Financial year:	2014 - 2017/18
Description of action:	IT network and security consultancy services.
Type of contract:	Framework Contract + Specific contracts
Number of contracts:	14 - 20
Indicative timeframe for contract:	Commencing in 2014
Indicative timeframe for procurement:	2nd quarter 2014
Indicative budget for procurement:	€ 4,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2114/2115/3105

Activity statement:	**Business IT development for internet & back-up data centre**
Objective:	See WP2014, heading 4.
Budget:	€ 5.0 million over 4 years; of which € 4.0 million administrative and € 1.0 million operational
Financial year:	2014 - 2017/18
Description of action:	Business continuity planning services, communication services (internet access and related web services) and off-site highly secure back-up data centre.
Type of contract:	Framework Contract + Specific contracts
Number of contracts:	10-Dec
Indicative timeframe for contract:	Commencing in 2014
Indicative timeframe for procurement:	1st quarter 2014
Indicative budget for procurement:	€ 5,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2114/2115/3105

Activity statement:	**Service provider for applications on on-line transactional processing**
Objective:	See WP2014, heading 4.
Budget:	€ 70.0 million over 4 years; of which € 25.0 million administrative and € 45.0 million operational
Financial year:	2014 - 2017/18
Description of action:	External service providers for software applications - Provision of resources for on-line transactional processing systems
Type of contract:	Framework Contract + Specific contracts
Number of contracts:	30 - 40
Indicative timeframe for contract:	Commencing in 2014/5
Indicative timeframe for procurement:	2nd quarter 2014
Indicative budget for procurement:	€ 70,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2114/2115/3105

Activity statement:	**Business IT development for software and related services (SACHA III).**
Objective:	See WP2014, heading 4.
Budget:	€ 15 million over 4 years; of which € 13.5 million administrative and € 1.5 million operational
Financial year:	2014 - 2017/18
Description of action:	Software channel for licences and licences support and related services (consultancy)
Type of contract:	European Commission tender procedure, Framework Contract + Specific Contracts
Number of contracts:	300 - 350
Indicative timeframe for contract:	Commencing in 2014
Indicative timeframe for procurement:	tbc by EC
Indicative budget for procurement:	€ 15,000,000
Legal basis:	Article 57 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B2110/3105

Annex 5: Activity-based budget

Chapter	Staff expenditure	Infrastructure, ICT 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 & Bud. Item 3105	Bud. Item 3000	Bud. Item 3010	Reminder Title 3		
1 Evaluation activities for human medicines	**46,651**	**23,538**	**14,334**	**87,949**	**10,537**	**183,008**	**70%**
1.1 Pre-authorisation activities	11,054	3,685	4,807	13,638	550	33,735	13%
1.2 Initial evaluation activities	9,020	2,783	2,011	12,485	1,426	27,724	11%
1.3 Post-authorisation activities	10,393	8,835	1,821	59,413	3,266	83,727	32%
1.4 Arbitrations and referrals	2,744	922	643	395	1,175	5,878	2%
1.5 Pharmacovigilance activities	10,910	5,689	1,975	2,018	3,973	24,566	9%
1.6 Other specialized areas and activities	2,529	1,624	3,077	-	148	7,378	3%
2 Evaluation activities for veterinary medicines	**5,736**	**2,125**	**2,726**	**3,859**	**234**	**14,680**	**6%**
2.1 Pre-authorisation activities	300	75	743	288	90	1,496	1%
2.2 Initial evaluation activities	1,981	499	466	1,702	110	4,757	2%
2.3 Post-authorisation activities	1,610	927	242	1,870	0	4,649	2%
2.4 Arbitrations and referrals	625	194	224	-	0	1,043	0%
2.5 Pharmacovigilance activities	592	205	340	-	0	1,137	0%
2.6 Other specialized areas and activities	628	224	711	-	34	1,598	1%
3 Horizontal activities and other areas	**15,126**	**5,431**	**3,329**	**5,344**	**1,290**	**30,521**	**12%**
3.1 Committee coordination	2,469	1,186	1,690	-	0	5,345	2%
3.2 Inspection and Compliance	3,775	1,992	1,346	5,344	0	12,457	5%
3.3 Partners and Stakeholders	4,035	849	282	-	738	5,904	2%
3.4 Transparency and access to documents	1,543	506	-	-	0	2,050	1%
3.5 Information	3,305	898	11	-	552	4,766	2%
4 Support and governance activities	**25,498**	**8,007**	**818**	**-**	**426**	**34,748**	**13%**
4.1 Governance, Quality Management and Internal Audit	4,949	1,218	595	-	158	6,920	3%
4.2 Finance	3,202	1,183	-	-	7	4,392	2%
4.3 Information and Technology	9,011	2,312	-	-	225	11,548	4%
4.4 Legal Services	1,432	450	-	-	0	1,883	1%
4.5 Human Resources	3,317	1,589	-	-	0	4,906	2%
4.6 Infrastructure	1,820	710	-	-	0	2,530	1%
4.7 Communication	1,767	545	223	-	35	2,570	1%
Total	**93,011**	**39,101**	**21,207**	**97,151**	**12,488**	**262,958**	**100%**

* Excluding exeptional costs

Annex 6: Draft cash-flow forecast

Note: this forecast excludes exchange-rate variances and VAT payments/receipts.

CASH FLOW FORECAST	Estimated	Estimated	Total	Dec (pre-pay)	Jan - Mar	Apr-Jun	Jul - Sep	Oct - Dec
YEAR 2014	Budget C1	RAL C8	Annual	estimated	estimated	estimated	estimated	estimated
	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000	€ '000
Fees and charges C1	236,156		236,156		32,964	61,749	66,216	75,226
Euopean Union contribution to the operating budget C1	29,777		29,777		0	0	20,481	9,296
Orphan contribution C1	6,000		6,000		0	2,056	721	3,223
Surplus from previous year C1	3,453		3,453		0	3,453	0	0
External assigned revenue R0	20,524		20,524		20,524	0	0	0
Other revenue C1	1,259		1,259		148	255	257	600
A - TOTAL RECEIPTS	**297,169**	**0**	**297,169**		**53,636**	**67,513**	**87,675**	**88,345**
Title I : staff								
Payments expected on C1 credits	106,186		105,336		28,814	16,842	26,081	33,598
Payments expected on R0 credits		350	350		96	56	87	112
Payments expected on C8+R8 credits (RAL)		850	850		561	99	189	1
Title II : administrative expenses								
Payments expected on C1 credits	44,427		34,427	2,800	7,389	6,235	9,775	8,228
Payments expected on R0 credits		20,000	20,000		10,000	10,000	0	0
Payments expected on C8+R8 credits (RAL)		10,000	10,000		3,816	3,814	1,548	822
Title III : operational expenditure								
Payments expected on C1 credits	124,757		99,757		13,471	29,579	23,667	33,041
Payments expected on R0 credits		200	200		27	59	47	66
Payments expected on C8+R8 credits (RAL)		25,000	25,000		15,560	5,788	2,049	1,603
B - TOTAL CASH OUT	**275,370**	**56,400**	**295,920**	**2,800**	**79,734**	**72,472**	**63,444**	**77,470**
Opening balance, cash and bank accounts			**57,000**		**57,000**	**30,901**	**25,943**	**50,174**
+ Total receipts (A)			297,169		53,636	67,513	87,675	88,345
- Total payments (B)			295,920	2,800	79,734	72,472	63,444	77,470
Closing balance, cash and bank accounts			**58,249**	**-2,800**	**30,901**	**25,943**	**50,174**	**61,049**
- Total anticipated carry-over - commitments not paid by year-end (C8 n+1)								56,400
Closing balance					**30,901**	**25,943**	**50,174**	**4,649**

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
AE	adverse event
AER	adverse-event report
Agency	European Medicines Agency
AMR	antimicrobial resistance
API	active pharmaceutical ingredient
ATMP	advanced therapy medicinal product
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
CMD	Co-ordination Group for Mutual Recognition and Decentralised Procedures
CMDh Coordination group	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
CMDv Coordination group	Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary
Commission	European Commission
committee(s)	scientific committee(s) of the Agency
Council	European Council
COMP	Committee for Orphan Medicinal Products
CT	clinical trial
CTA	clinical-trial application
CVMP	Committee for Medicinal Products for Veterinary Use
DREAM	document records electronic archive management system
eAF	electronic application form
eCTD	electronic common technical document
EDQM	European Directorate for the Quality of Medicines and HealthCare
EEA	European Economic Area
EC	European Commission
EMA	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EP	European Parliament
EPAR	European public assessment report
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EU	European Union
EudraCT	European Union Drug Regulating Authorities Clinical Trials
EudraVigilance	European Union Drug Regulating Authorities Pharmacovigilance
EV	EudraVigilance, European Union Drug Regulating Authorities Pharmacovigilance

Term / abbreviation	Definition
EVDAS	EudraVigilance data analysis system
FAO	Food and Agriculture Organization
FDA	United States Food and Drug Administration
GCP	good clinical practice
GLP	good laboratory practice
GMP	good manufacturing practice
GVP	good pharmacovigilance practice
HCP	healthcare professional
HL7	Health Level 7
HMA	Heads of Medicines Agencies
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
ICSR	individual case safety report
IDMP	identification of medicinal products
IPRF	International Pharmaceutical Regulators Forum
ISO	International Organization for Standardization
ISO IDMP	ISO Identification of Medicinal Products project
IT	information technology
ITF	Innovation Task Force
IWG	Inspectors Working Group
MA	marketing authorisation
MAH	marketing-authorisation holder
Member State	Member State of the European Union
MHLW	Ministry of Health, Labour and Welfare, Japan
MRA	mutual-recognition agreement
MRL	maximum residue limit
MUMS	minor use, minor species
NAP	nationally authorised products
NCA	national competent authority
Network	European Medicines Regulatory Network
OBIEE	Oracle Business Intelligence Enterprise Edition
OIE	World Organisation for Animal Health
OMCL	Official Medicines Control Laboratories
PA	protocol assistance
PAES	post-authorisation efficacy study
PASS	post-authorisation safety study
PDCO	Paediatric Committee
PhV	pharmacovigilance
PIP	paediatric investigation plan
PMDA	Pharmaceuticals and Medical Devices Agency, Japan
PMF	plasma master file
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	periodic safety-update report
Q (1, 2, 3, 4)	quarter (1, 2, 3, 4)

Term / abbreviation	Definition
QWP	Quality Working Party
R&R	'Review and Reconnect' programme
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)
SME	small and medium-sized enterprise
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
US	United States
TGA	Therapeutic Goods Administration, Australia
VAMF	vaccine antigen master file
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization
WP	working party