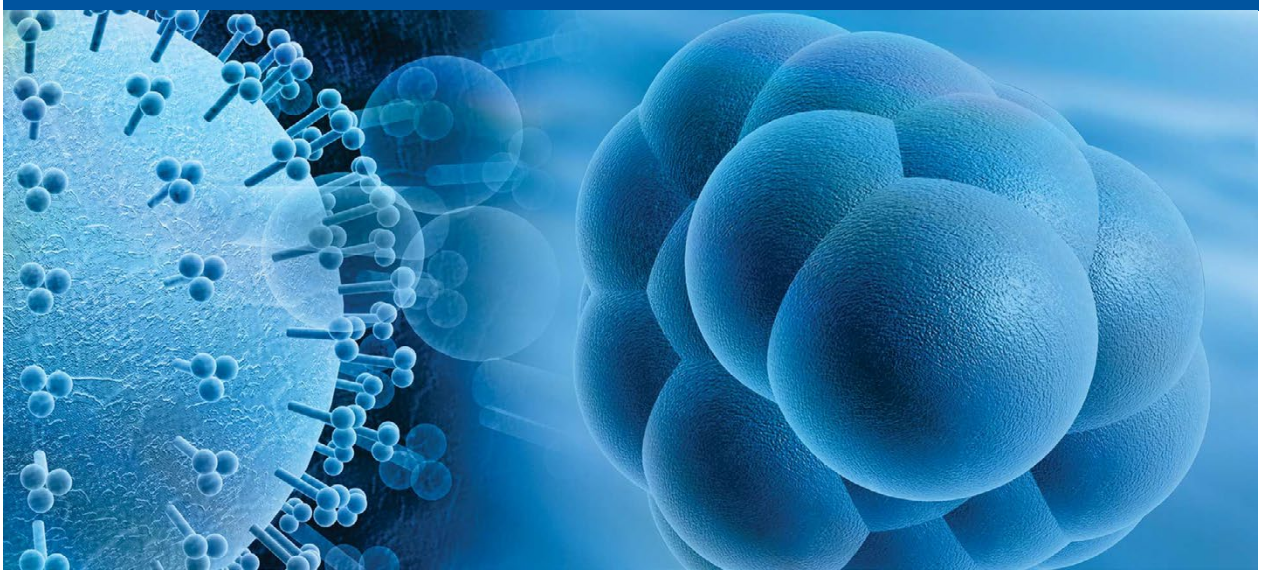
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2012
EMA/MB/945561/2011
Executive Director

Work programme
2013

Adopted by the Management Board on 13 December 2012



7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

© European Medicines Agency, 2013. Reproduction is authorised provided the source is acknowledged.

Note on figures

All figures for 2013 provided in the charts in this document are estimates.

Table of contents

Introduction by the Executive Director

Guido Rasi

The business environment and priorities for 2013

In its 'Road map to 2015'[1] strategy document, the European Medicines Agency (the Agency) identified a number of business drivers that impact on our choice of priorities and objectives, including advances in science, globalisation, demand for better communication and greater openness.

We have analysed the business environment in 2012 and concluded that the factors identified in the strategy remain valid. Some of them, such as advances in science, have a longer-term effect, while others have an immediate impact, including stakeholders' expectations for greater communication, openness and transparency, the impact of new legislation and the impact of the economic climate on resources.

Taking into account the strategy of the Agency and the analysis of its current business environment, we will focus on the following priority areas in 2013:

- Continuing to ensure that assessment activities are conducted to the highest levels of quality and of regulatory and scientific consistency.
- Continuing to prepare for the implementation of the pharmacovigilance legislation, depending on resources.
- Continuing to prepare for the implementation of the falsified-medicines legislation.
- Preparing for the outcome of the European Commission's impact assessment on revision of the veterinary-medicines legislation.
- Further developing the communication and transparency activities of the Agency.

To support these priorities, we will also focus on contributing towards successful collaboration within the European medicines regulatory network, and will run a number of projects and initiatives aimed at increasing the effectiveness and efficiency of our operations.

Annually, we also conduct a strategic risk-management review. Following this year's exercise, we concluded that the key risks to achieving the mission of the Agency lie within areas that may impact on the quality of the scientific-assessment and pharmacovigilance activities, the availability of scientific expertise and the quality of data received by the Agency. Further risks relate to the fact that manufacturing and clinical trials are carried out outside of the European Union (EU). The projects mentioned in the priority areas below aim at mitigating those risks, as do a number of activities in the work programme.

Scientific-assessment activities

Continuing to ensure that assessment activities are conducted to the highest scientific levels is the main focus of the Agency. A number of underlying initiatives are taking place that aim to increase the support to the scientific committees and to further assure the quality and consistency of the Agency's scientific outputs. These include the continuing implementation of the conflicts-of-interests policies and their monitoring, reviewing how the underlying assessment processes are functioning, and reviewing

[1] 'Road map to 2015: The European Medicines Agency's contribution to science, medicines and health'.

how related data necessary for the effective operation of assessments are processed. Improvements that would further contribute to the quality of the work carried out will be made.

The establishment of the Pharmacovigilance Risk Assessment Committee and the possibility of divergent opinions among the Agency committees further put in the spotlight the complex interactions among committees that the Agency needs to manage. We will continue our review of how committee activities are coordinated, making certain that this results in effective interactions and a smooth, timely and complete flow of information.

The pharmacovigilance legislation

The legislation aims to promote and protect public health by strengthening the Europe-wide system for monitoring the safety and benefit-risk balance of medicines. It builds on existing processes and structures for pharmacovigilance, such as the EudraVigilance system for monitoring suspected side effects.

A number of provisions are yet to be implemented, in cooperation with national authorities, and depend on whether resources can be made available. Our priorities for the implementation remain as follows: activities contributing to public health are the highest priority, followed by activities that increase transparency and improve communication, followed by activities that simplify processes.

The falsified-medicines legislation

The legislation enters into force in January 2013. The Agency has a number of milestones to reach in relation to this legislation. Implementation work will continue in 2013. The Agency and national competent authorities will work on topics such as the development of the Union database, assisting the European Commission in developing further implementing acts, and preparing guidance on behalf of the European Commission. Numerous detailed aspects will be discussed and agreed with national authorities to facilitate a harmonised implementation.

Revision of the veterinary-medicines legislation

Subject to the outcome of the impact assessment, the European Commission plans to submit a legal proposal in the first half of 2013 that will represent a major revision of the legal framework for the authorisation of veterinary medicines. The intention is ambitious, with the major drivers being to reduce the administrative burden for marketing-authorisation holders, to promote a genuine single market in veterinary medicines across the EU, thereby increasing availability, and to provide a more robust set of tools for managing risks associated with the use of veterinary antimicrobials. For the veterinary sector of the Agency, 2013 will therefore be a busy year, planning for change and providing assistance to the European Commission in its fields of expertise.

Communication and transparency

We will continue to foster our approach to communication and transparency, to strengthen public confidence in the Agency and in the EU system for the evaluation and supervision of medicines. It is our objective to explain better how decisions are made with respect to all our opinions, and to provide more quantitative data in documents accompanying our opinions, where this helps to promote understanding. To this end, we will further integrate new benefit-risk methodologies in our assessment work in the area of human medicines, and will use the data to communicate with the public about the benefits and risks of medicines, and about the rationale for the opinions we adopt. This sharing of information and knowledge will benefit the scientific community and various bodies working in the field of medicines (e.g. health-technology-assessment bodies).

Similarly, we will advance our goal of opening the Agency's rich repository of data, information and knowledge and providing these resources to broader audiences, to benefit drug development and improve patient care.

Following our successful workshop in November 2012, we will continue our planned procedure for consultation with stakeholders, to be in a position to publish the Agency's policy on the release of data from clinical trials in the latter part of the year.

We will continue to implement the Agency's online strategy, as part of our overall communications strategy. We will further refine our understanding of what stakeholders expect from our websites, which will help us to fine-tune the next stages of our project to bring together our separate websites into one corporate website, and to progress the development of the European medicines web portal.

Increasing the efficiency of operations

These tasks are not without challenges in the difficult economic climate that both the Agency and the national authorities find themselves. The budget for 2013 does show an increase compared to 2012, but this is mainly due to fees being increased in line with inflation. At the same time, the Agency needs to find compensation for services that do not generate revenue (of which there have been an increasing number in recent years) and to finance new legislative tasks.

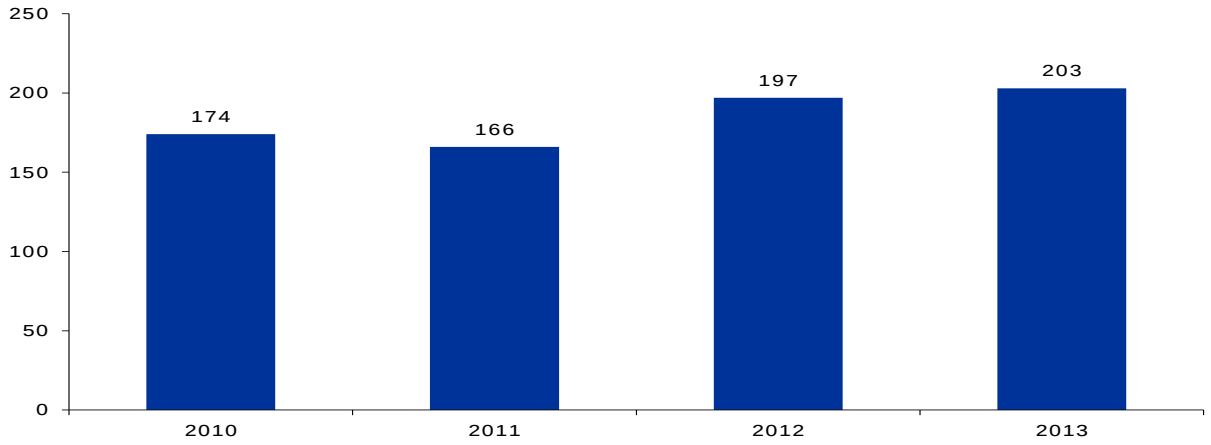
In light of these economic trends, we are running numerous initiatives aimed at optimising the use of resources, which will increase the effectiveness of our work in the related domains. These are brought together within the Operational Excellence programme. As a parallel and related activity, we will implement a new ICT strategy, the key elements of which include reviewing the data architecture, streamlining the ICT-application portfolio, and assuring the best use of ICT to support the optimised processes of the Agency.

1. Strategic area: Addressing public-health needs

1.1. Evaluation activities related to the strategic area

1.1.1. Orphan-medicinal-product designation

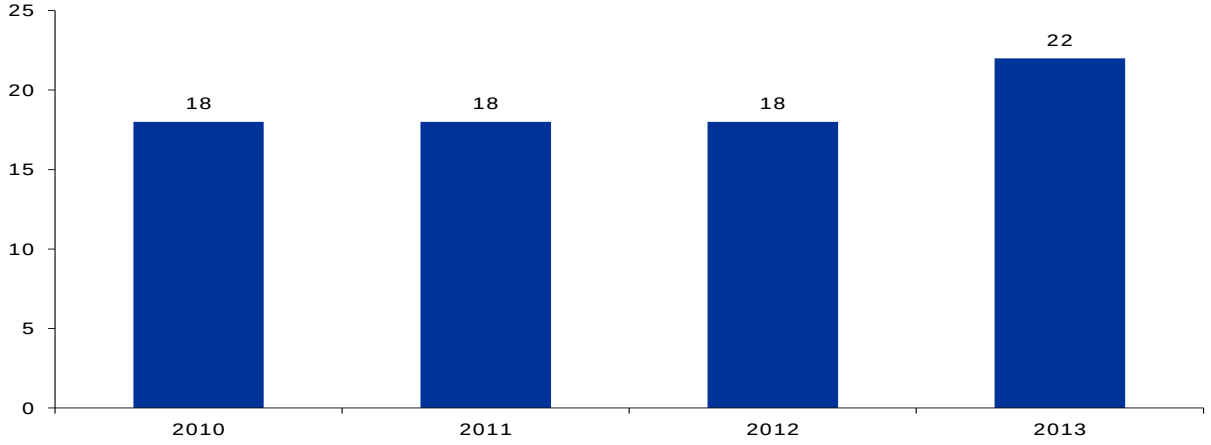
Figure 1. Number of applications for designation as an orphan medicinal product



Performance indicator	Target 2013	Actual 2011
Percentage of designation applications evaluated within the 90-day timeline	100%	100%
Percentage of summaries of opinion published within 4 months of the opinion on designation from the Committee for Orphan Medicinal Products (COMP)	95%	100%
Percentage of public assessment reports on review criteria published within 1 month of the European public assessment report for the initial marketing authorisation	90%	100%

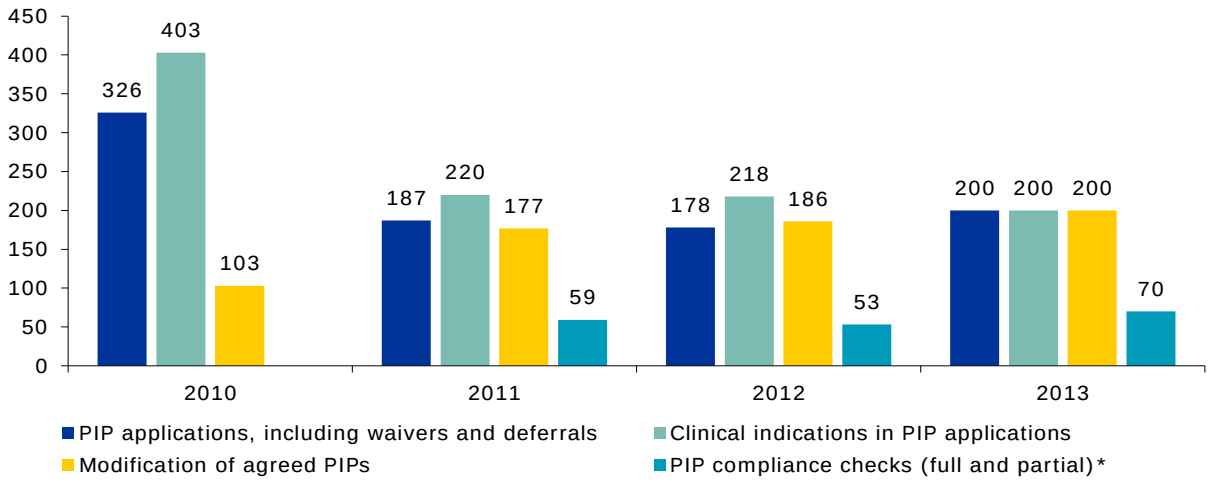
1.1.2. Minor use, minor species (MUMS) / limited markets

Figure 2. Number of applications for MUMS/limited-markets designation



1.1.3. Medicines for paediatric use

Figure 3. Applications relating to paediatric investigation plans (PIPs)



* Figure not available for 2010.

Performance indicator	Target 2013	Actual 2011
Number of PIP or waiver opinions and decisions within legal timelines	100% of opinions/decisions	99.6%
Percentage of Agency decisions on paediatric PIPs/waivers published within 6 weeks of the decision	95%	93%

1.2. Strategic and specific objectives

Strategic objective 1.1: Bridging gaps in medicines development and supply

Specific objective 1.1.1: Exploring options for new and effective antibiotic treatments

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Working with the European Commission and the Committee for Veterinary Medicinal Products (CVMP) to be in a position to provide guidance to stakeholders on the development of new veterinary antimicrobials that takes into account both the interests of animal health and the need to preserve the efficacy of certain critically important antimicrobials for human use.	Q4 2013	The format and timing for this guidance has yet to be decided with the European Commission and the CVMP.
Reviewing existing options to promote development of new antibiotics to treat multi-resistant bacteria, including	Q4 2013	Additional guidance documents to be finalised.

adaptation of clinical-guidance documents, consideration of the balance between the amount of prior data needed and enhancing post-marketing surveillance, use of orphan legislation, etc.		

Specific objective 1.1.2: Promoting the availability of veterinary medicines

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Review criteria for designation and provide more objective criteria on which to classify products as indicated for MUMS/limited markets; produce guidance on minor use/prevalence of disease thresholds for different target species. Annually review products designated as intended for MUMS/limited markets and the link with authorisations issued for these products, to objectively demonstrate increased availability.	Q4 2013	Review designation guidance in light of experience. Publish annual report.
Providing assistance with the development of novel tools for disease control and ensure best use of existing tools, such as revised regulation on maximum residue limits (MRLs), to promote authorisation of new medicines and retain existing medicines on the market.	Q4 2014	Assist with access to regulatory and scientific guidance for tools developed as part of the DISCONTOOLS and ETPGAH projects. Liaise with the Commission on optimal use of existing legal tools (MRLs, biocides, borderline products, etc.).

Specific objective 1.1.3: Addressing unmet medical needs

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Analysing the reasons why specific types of medicines, e.g. orphans and advanced-therapy medicinal products (ATMPs), fail to progress to applications for marketing authorisation, to propose possible remedial measures.	Q1 2013	Report and recommendations on the analysis of ATMPs that made it through to a marketing-authorisation procedure having previously received orphan designation or scientific advice/protocol assistance.
Increasing international cooperation in the field of neglected diseases, to promote development of new medicinal products through existing bilateral and multilateral arrangements, in cooperation with the World Health Organization (WHO).	Q4 2013	Publish updated guideline on Article 58 procedure, taking into account Agency-WHO alignment-procedure discussions and experience gained. Report to the Committee for Human Medicinal Products (CHMP) and the WHO on the number of centralised marketing-authorisation applications (MAAs) used as

		the basis for WHO pre-qualifications, on the impact on the Agency-WHO collaboration and on the need for further developments.

Strategic objective 1.2: New and emerging science

Specific objective 1.2.1: Meeting the challenge of new technologies

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Enhancing collaboration on borderline discussions with the Commission's Borderline and Classification Medical Devices Expert Group and its related subgroups.	Q4 2013	Report to the CHMP on the provision of Art. 57(p) of Regulation (EC) No 726/2004 scientific opinions with proposals to enhance participation in Commission-related meetings/expert committees.

Specific objective 1.2.2: Facilitating biomarker development and other new approaches

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Providing regulatory and scientific support to the Innovative Medicines Initiative (IMI), to facilitate calls for research in areas such as lifecycle genomics biomarkers.	Q4 2013	Submit proposals for call topics for IMI.
Reinforcing European and international collaboration on nanotechnologies in life sciences, to encourage greater understanding and synergies across disciplines, taking into account the conclusions of the specific international workshop organised by the Agency in September 2010.	Q3 2013	Publication of article on nanotechnologies.

Specific objective 1.2.3: Adapting the regulatory framework for veterinary medicines

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Adapting existing scientific and regulatory guidelines to ensure that criteria for the regulation of established veterinary medicines do not create a barrier to the development of new approaches, and create new guidelines as appropriate.	Q4 2015	Adaptation or creation of guidelines with impact on new technologies.

Strategic objective 1.3: Public-health threats

Specific objective 1.3.2[2]: Joint activities between human and veterinary sectors

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Developing the European Surveillance of Veterinary Antimicrobials Consumption (ESVAC) project from a pilot into an operational system to collate, analyse and report on sales and use of veterinary antimicrobials, to assist with risk-assessment and risk-management of antimicrobial resistance at EU level.	Q4 2014	Routine collection and analysis of sales data for antimicrobial agents. Annual publication of a report.
Ensuring the safety and continuity of supply of medicines, and particularly raw materials, arising as a result of threats to the supply chain.	Q4 2013	Joint approach to minimising risks to supply chain and assuring continuity of availability: • Initiate work on the implementation plan developed in 2012 in relation to supply problems arising from good-manufacturing-practice and quality failures. Promote better and proactive risk-management by marketing-authorisation holders (MAHs), to anticipate and avoid shortages by addressing risks and building in failsafe approaches to manufacturing for centrally authorised products (CAPs). This could include aspects such as the submission by all MAHs for CAPs of a risk-analysis of their manufacturing process, identifying any weaknesses and, depending on the severity, providing a contingency plan and proposals to strengthen the identified weaknesses. Subsequently, rapporteurs will assess and discuss at CHMP level.
Improving the linkages between the protection and improvement of animal health and the protection and improvement of human health, particularly in the area of zoonotic and emerging diseases, antimicrobial resistance, and ensuring the safety of substances of animal origin used in the production of human and veterinary medicines.	Q4 2015	Application of the 'one world, one health' concept as shown by an increasing number of joint human/veterinary scientific activities. Participation in the Transatlantic Task Force on Antimicrobial Resistance (TATFAR), in cooperation with the US. Cooperation between human and veterinary sectors on request(s) for opinions received from the Commission on the risks posed by the use of medicines. Release of final version of addendum to guidance on development of new antibacterial products focusing on specific indications and development for multidrug-resistant pathogens.

[2] Please note that the numbering of specific objectives follows that used in the Agency's multiannual plan.

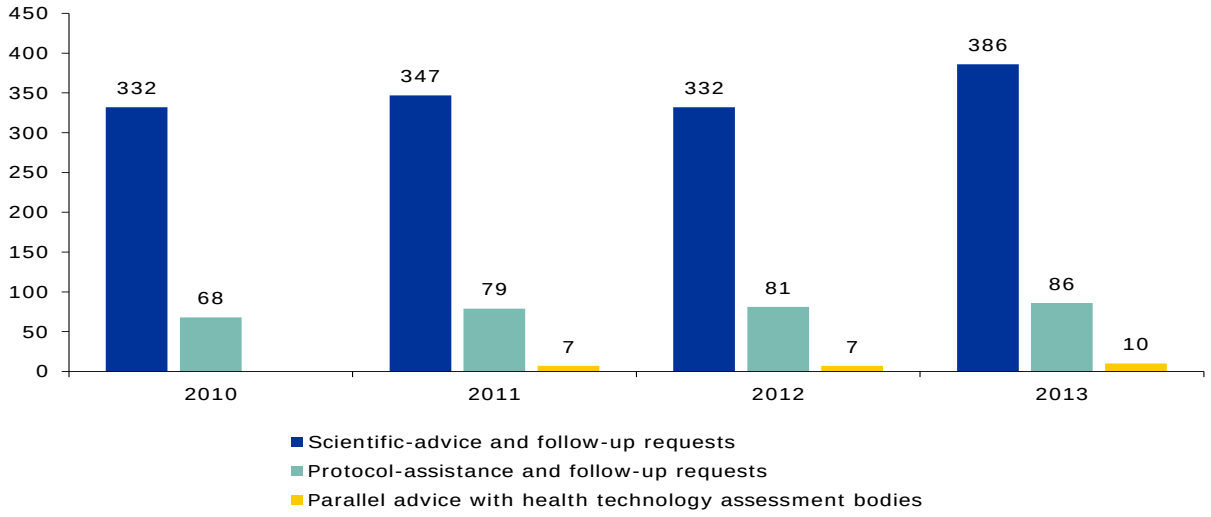
2. Strategic area: Facilitating access to medicines

2.1. Evaluation activities related to the strategic area

2.1.1. Scientific advice

Human medicines

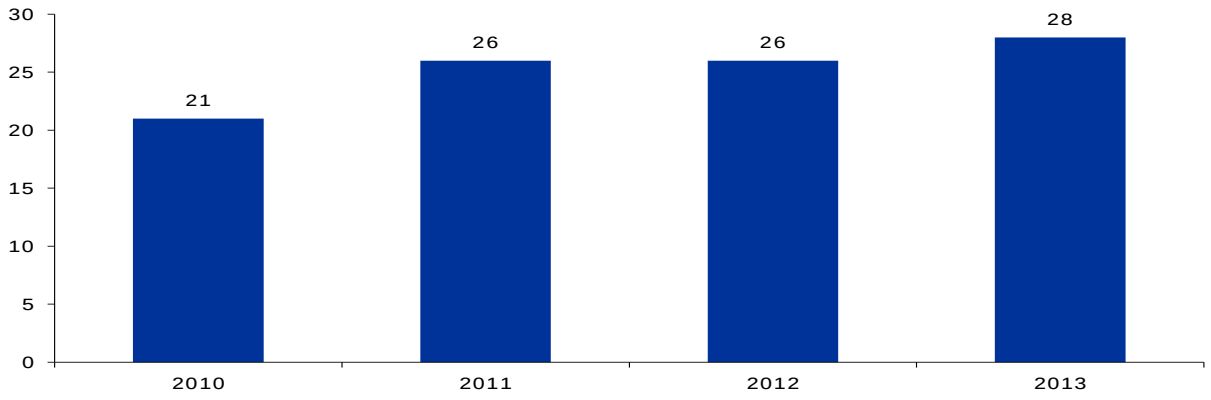
Figure 4. Scientific-advice and protocol-assistance requests



Performance indicator	Target 2013	Actual 2011
Scientific-advice (SA) and protocol-assistance (PA) requests evaluated within the procedural timelines	100% of requests	99%
External experts involved in procedures	30% of SA and PA requests	15%
Percentage of marketing-authorisation applications for new technology products having received SA/PA	50% of applications	57%

Veterinary medicines

Figure 5. Scientific-advice and follow-up requests

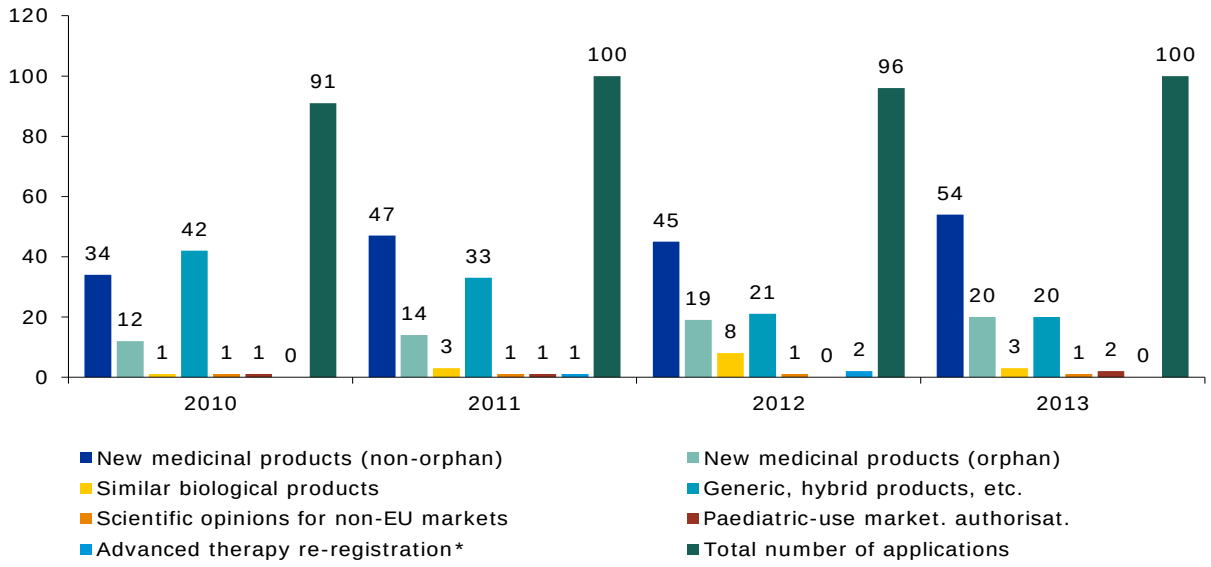


Performance indicator	Target 2013	Actual 2011
Scientific-advice requests evaluated within the procedural timelines	95% of applications	100% of applications

2.1.2. Initial evaluation

Human medicines

Figure 6. Applications for initial evaluation



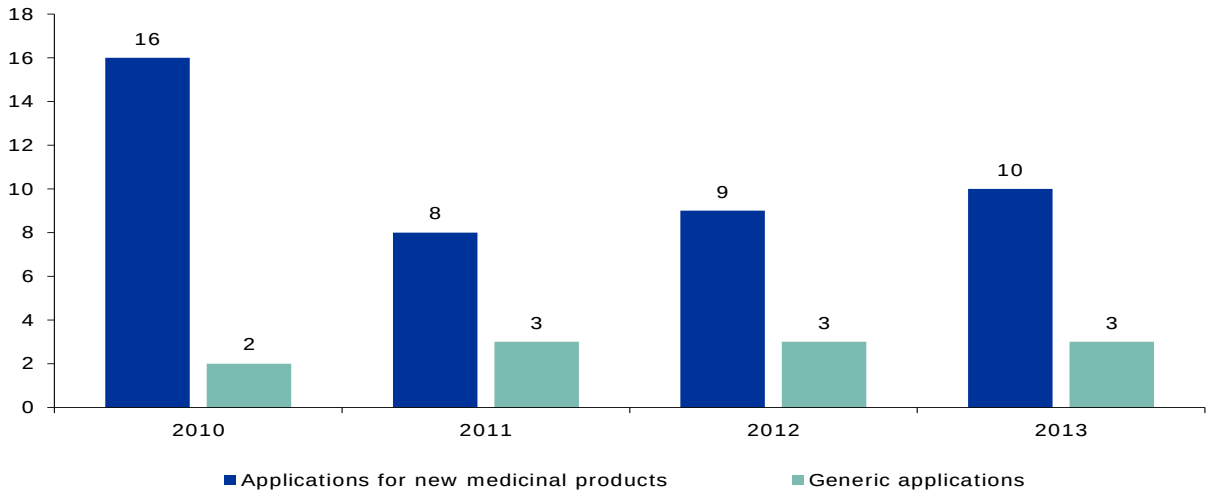
* Provisions for re-registration of advanced-therapy medicinal products ceased to apply after 30 December 2012.

Performance indicator	Target 2013	Actual 2011
Percentage of applications evaluated within the regulatory timeline: • Marketing-authorisation (MA) applications (210 days) • Accelerated-assessment applications (150 days) • Plasma-master-file applications	 • 100% • 100% • 100%	 • 99% • 100% • 100%
Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days	100%	100%
Percentage of summaries of opinions (SmPCs) published at the time of the CHMP press release	90% of SmPCs	100%
Percentage of initial European public assessment reports (EPARs) published within 4 weeks of the Commission decision	80% of MAs granted	73%
Percentage of EPAR summaries published together with the EPAR	90% of EPARs	100%
Percentage of withdrawal Q&A documents published at the time of the next appropriate CHMP monthly report	90% of Q&A documents	90%

Performance indicator	Target 2013	Actual 2011
Percentage of refusal Q&A documents published at the time of the CHMP opinion	90% of Q&A documents	100%
Percentage of safety Q&A documents following a CHMP opinion published at the time of the CHMP press release	90% of Q&A documents	100%

Veterinary medicines

Figure 7. Applications for initial evaluation

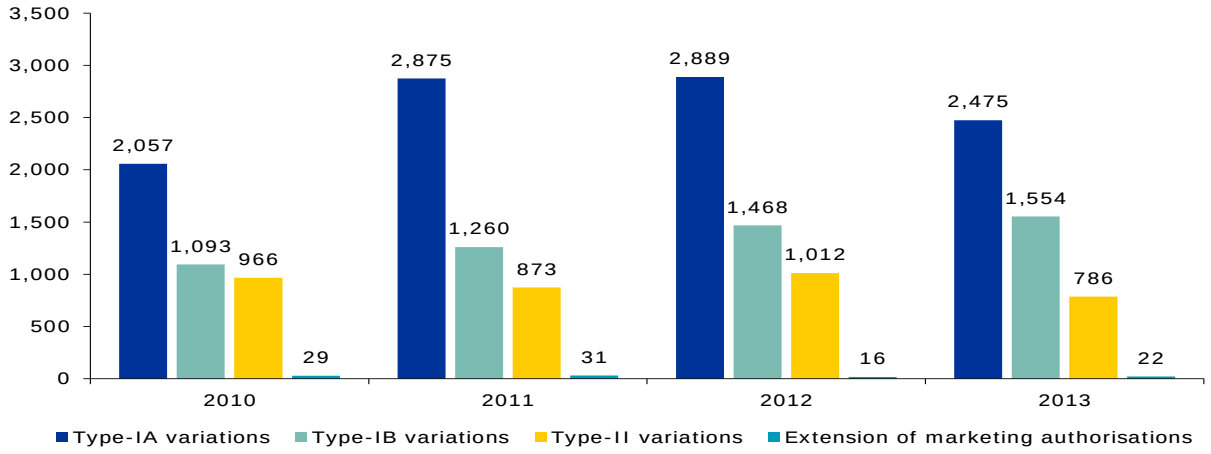


Performance indicator	Target 2013	Actual 2011
Percentage of products evaluated within the regulatory timeline of 210 days	100% of applications	100% of applications

2.1.3. Post-authorisation and maintenance activities

Human medicines

Figure 8. Post-authorisation applications received



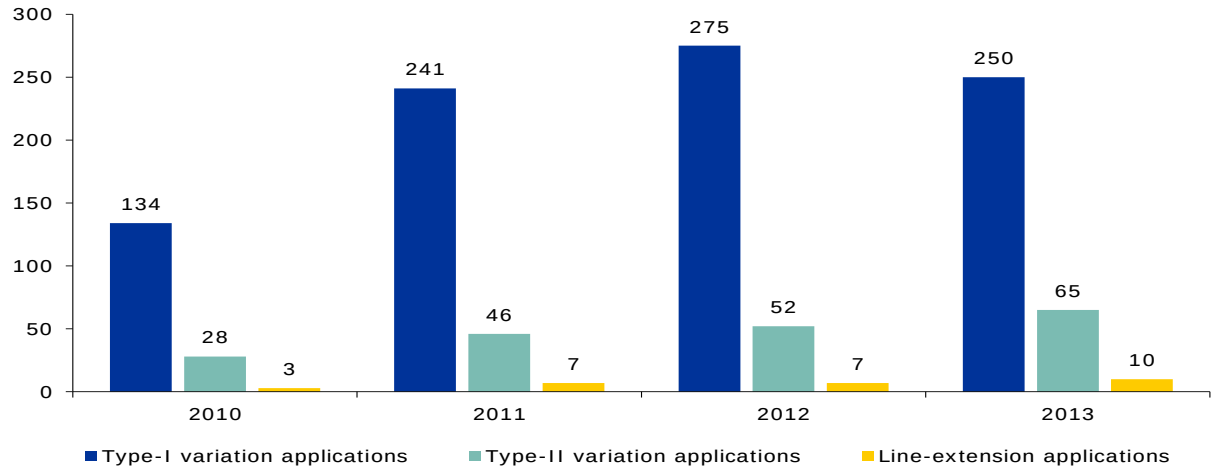
Impact of Pharmacovigilance Regulation in 2013

- Switch from detailed description of pharmacovigilance system (DDPS) to pharmacovigilance system master file (PSMF), resulting in fewer type-IA variations.
- Reduction in type-II variations, as they will no longer be submitted separately after assessment of periodic safety-update reports (PSURs).
- An estimated 41 former type-IB and 104 former type-II variations will be integrated in PSUR assessments.

Performance indicator	Target 2013	Actual 2011
Percentage of applications for post-authorisation procedures evaluated within the regulatory and procedural timelines	100% of applications	97% (on average)
Percentage of Agency recommendations on classification of variations delivered within the regulatory timelines	100% compliance	None in 2011
Percentage of grouping and worksharing procedures completed in the procedural timelines	100% compliance	100%
Submission of outcome reports for post-authorisation commitments (PACs) to applicants/MAHs within 2 weeks of the CHMP meeting	90% of reports	85%
Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications	79%

Veterinary medicines

Figure 9. Post-authorisation applications



Performance indicator	Target 2013	Actual 2011
All post-authorisation procedures processed in accordance with legal requirements	100% of applications	100% of applications

2.1.4. Herbal medicinal products

Performance indicator	Target 2013	Actual 2011
Community herbal monographs*		
• Final • Released for public consultation	• 15 • 15	• 20 • 21
Revision of Community herbal monographs		
• Final • Released for public consultation	• 5 • 5	• N/A • N/A
Community-list entries		
• Transmitted to the European Commission • Released for public consultation	• 2 • 2	• 0 • 0

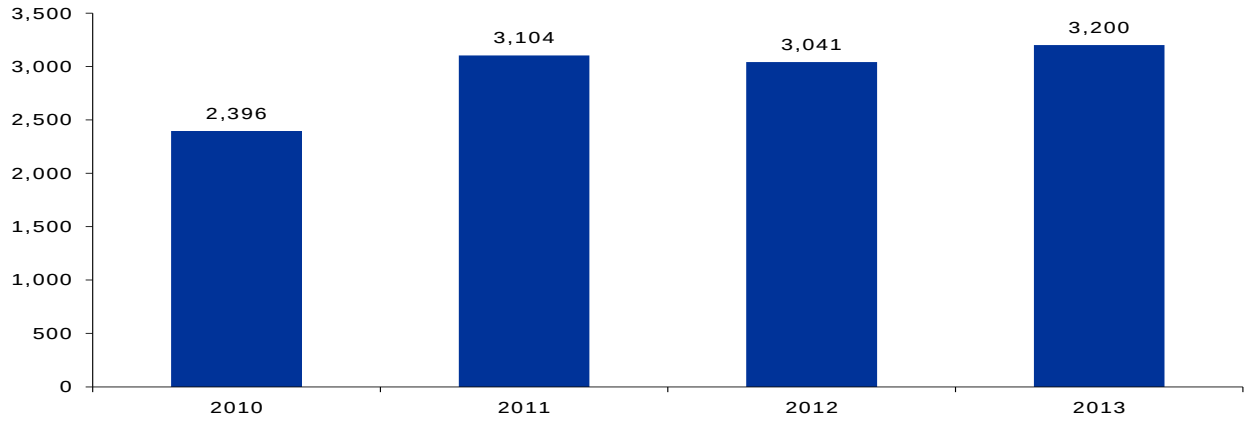
* Where assessment work does not lead to the establishment of a monograph, a public statement will be prepared.

2.1.5. Advanced-therapy medicinal products

Performance indicator	Target 2013	Actual 2011
Applications handled by the Committee for Advanced Therapies (CAT) within the procedural timelines (allowing adoption of the opinion by the CHMP within the legal timeline of 210 days)	100% of applications	100%
Scientific recommendations on advanced-therapy classification provided within the legal timeline	100% of requests	100%
Certification of quality and non-clinical data issued within the procedural timelines	100% of requests	N/A for 2011, as no applications for certification were received

2.1.6. Certificates

Figure 10. Certificate requests



Performance indicator	Target 2013	Actual 2011
Percentage of certificates of medicinal products issued to requesting parties within the standard timeline (i.e. 10 working days)	90%	47% (average 10.4 days)
Percentage of certificates of medicinal products issued to requesting parties within the urgent timeline (i.e. 2 working days)	90%	The procedure will start in 2012

2.2. Projects related to the strategic area

Project	Project delivery	Milestone or deliverable to be achieved by end of 2013
SIAMED v.4.2	Q1 2013	This project is to deliver a fully comprehensive business solution completing interfaces and reporting functionality.
SIAMED v.5	Q3 2013	Release 5.1: Support for implementation of the variations legislation. Release 5.2: Extend support for the Pharmacovigilance Risk Assessment Committee (PRAC), other committees & multi-committees; provide support for multi-phase procedure post-authorisation measures.
eSubmissions programme	Q2 2014	**Central repository** 1. Establish a central repository that can be used by: • centralised procedures; • all agencies; • human applications. 2. Implement an interface that can be integrated by other associated systems to provide controlled and secure access to submissions stored in the central repository. 3. Enable national competent authorities to communicate directly to the Agency's central repository holding electronic submissions, thus reducing the duplication of dossiers across the European regulatory network. **eSignature** The objectives of the system are to allow users (including committee/WP chairs) to sign documents while not physically present at the Agency, to insert an electronic signature into documents produced electronically at the Agency, and to receive electronically submitted documents that require a signature.
Regulation (EC) 1049/2001 — 'Ask EMA'	Q2 2013	Improve the processing, monitoring and tracking of requests for access to information and documents held by and produced by the Agency, to increase efficiency and reduce costs.

2.3. Strategic objectives

Strategic objective 2.1: Address the high attrition rate during the medicines-development process

Specific objective 2.1.2: Utilising information from failed development studies

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Exploring incentives to make information from failed studies available. Investigate ongoing initiatives, e.g. applicability of 'patent pooling' initiatives.	Q4 2013	Organisation of a workshop with industry and the European Commission.

Specific objective 2.1.3: Addressing the impact of globalisation

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Promoting a global approach to quality of active pharmaceutical ingredients (APIs), finished products and the integrity of the supply chain, by developing contacts with the main countries where manufacture takes place, promoting ICH and VICH principles, and assisting with training, capacity-building and networking.	Q4 2013	Greater information and worksharing with non-EU countries on API quality and supply, through implementation of processes for cooperation on planning of third-country inspections, and in relation to implementation of Commission processes for listing of third countries from which APIs are imported.
Preventing the circulation of falsified medicines, through measures designed to protect the legitimate supply chain as described in the falsified-medicines legislation.	Q4 2015	Carry out risk-analysis of third countries' API manufacturers for centrally authorised products and (via Member States) for nationally authorised products; based on this analysis, plan the inspections of greatest priority.
Promoting EU scientific approaches and ICH and VICH principles to regulators outside the regions involved in these activities.	Q4 2015	Participation at and hosting of training sessions involving non-ICH regulators. Support for the VICH outreach initiative.
Addressing the growing numbers of patients recruited to clinical trials in countries outside the EU, through the activities described in the Agency's draft reflection paper, with particular focus on ethical approaches, transparency of review and international collaboration. International collaboration aspects include the need to support training and capacity-building.	Q4 2013	Implementation of actions identified in the final reflection paper: • Develop a format for a standardised set of information on third-country trials to be included in each EPAR. • Refine the processes for identifying clinical trials or MAAs for additional focused review or inspection. • Progress international cooperation on training and capacity-building for inspectors, assessors and ethics committees. • Organise an international workshop on good-clinical-practice inspections.

Specific objective 2.1.4: Strengthening advice and incentive frameworks for veterinary medicinal products

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
As part of a pilot, provide draft scientific-advice reports to applicants, particularly for novel/new technologies, and invite them to comment either in writing or in person prior to adoption of the final report.	Q4 2013	Review procedure and feedback from pilot project.
Maintaining the current, increased level of uptake of the scientific-advice procedure in the veterinary sector, through promotion of the concept and potential benefits at pre-submission meetings with applicants and at external conferences.	Q4 2015	Maintenance or further quantifiable increase in uptake of scientific advice by veterinary sponsors.
Promoting early dialogue with sponsors to facilitate understanding of regulatory and scientific challenges.	Q4 2015	Integration of novel veterinary products in the Innovation Task Force (ITF) procedure.
Making better use of specialised expertise during the assessment phase.	Q4 2015	Revision of mandate for the Scientific Advisory Group on Antimicrobials, and ensuring veterinary input into the work of the Scientific Coordination Board.

Strategic objective 2.2: Reinforce the benefit-risk assessment model

Specific objective 2.2.2: Embedding benefit-risk methodology in the assessment procedure for veterinary medicines

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
More clearly embedding benefit-risk methodology in the assessment procedure, communicating it better to the Agency's stakeholders, and providing training within the EU regulatory network.	Q4 2015	Revise the procedure for assessment reports by the CVMP.

Specific objective 2.2.4: Explore the balance between early approval with limited data and later approval with a more extensive data package

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Considering the merits and mechanics of an optional approach to early authorisation of medicines in a restricted population, e.g. based on early information from good responders. Exploring the broader applicability of	Q4 2014	Report and recommendations. Pilot cases.

'staggered' approvals, and preparing guidance on the applicability of such approaches.		

Specific objective 2.2.5: Improve communication on benefit-risk review to stakeholders

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Reviewing and implementing the recommendations of the recently published report reviewing case studies on stakeholders' expectations regarding benefit-risk communication.	Q4 2015	Revised structure for EPAR summaries, focusing on the benefit/risk balance of medicines in lay language. • GVP module XV (safety communication). • GVP module X (public participation in pharmacovigilance).
Initiating discussion with patient groups and health-technology-assessment (HTA) bodies, aimed at exploring how to ensure patient values are taken into account in benefit-risk assessments.	Q4 2014	Report and recommendations.

Specific objective 2.2.6: Improving and adapting existing legal tools

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Improving the formulation (wording), implementation and monitoring of post-authorisation commitments for marketing authorisations.	Q1 2013	Report to the CHMP on the experience gained and principles established on the classification of post-authorisation measures.

Specific objective 2.2.7: Increasing transparency and international collaboration

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Contributing to international activities involving both HTA bodies and international pharmaceutical regulators.	Q3 2013	Deliver NEWDIGS project.

Strategic objective 2.3: Facilitation of the relative-effectiveness assessment of medicines for human use by Member States

Specific objective 2.3.1: Bridging the gaps between scientific and cost-assessment processes

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Increasing engagement with HTA bodies from early medicine development throughout the product's lifecycle, including participation in scientific-advice discussions.	Q4 2014	Depending on EC strategy: • Continued collaboration with HTA bodies in areas of scientific advice and added therapeutic value. • Publication of guidance to applicants to facilitate access to parallel scientific advice/HTA procedure.
Considering the needs of both regulators and HTA bodies in determining which data should be collected during the post-authorisation phase, including the need for additional effectiveness data to be collected. Encouraging use of the scientific-advice procedure to achieve this.	Q4 2013	Exploring common approach for post-authorisation data generation.
Increasing mutual understanding of the respective roles of HTAs and pharmaceutical regulators, and of the impacts of decisions such as choice of clinical endpoints, efficacy versus effectiveness, and relative-efficacy versus placebo-controlled studies.	Q4 2013	Joint review with EUnetHTA of experience gained in increasing mutual understanding through exchange on clinical and methodological guidelines, as well as parallel scientific advice.
Exploring possibilities for collaboration on clinical and methodological guidelines, with a view to facilitating study designs that can generate data relevant for both regulatory and health-technology assessments.	Q4 2013	Establishment of a standardised process by which mutual input is sought on clinical and methodological guidelines.

3. Strategic area: Optimising the safe and rational use of medicines

3.1. Evaluation activities related to the strategic area

3.1.1. Pharmacovigilance and maintenance activities

Human medicines

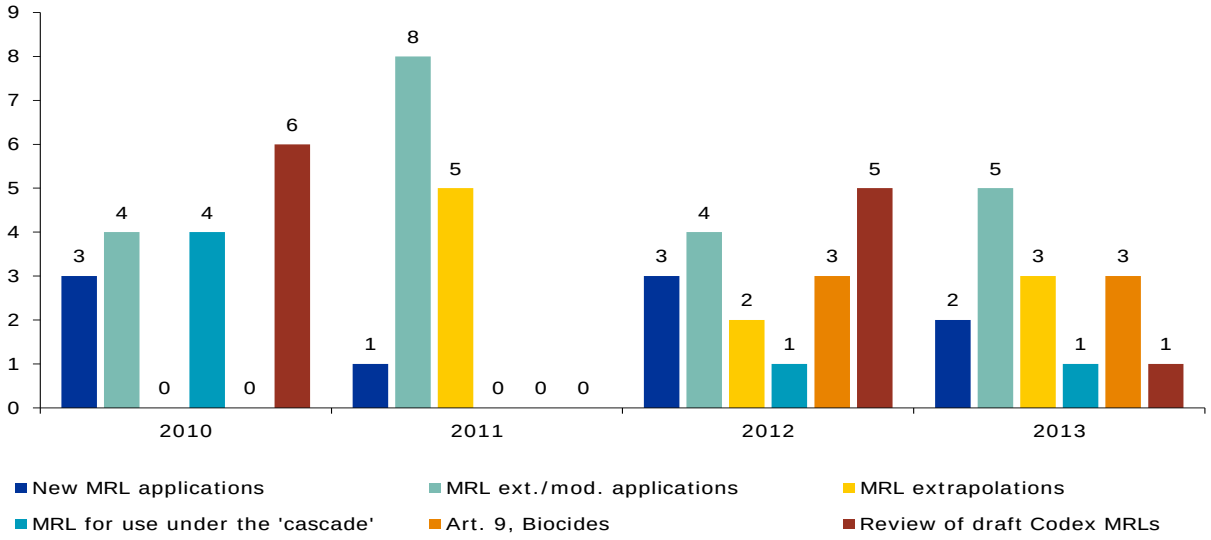
Performance indicator	Target 2013	Actual 2011
Percentage of risk-management plans (RMPs) peer reviewed as part of the assessment of initial marketing-authorisation applications	100%	100%
Percentage of RMPs peer reviewed by the Agency as part of the assessment of variations and line extensions that result in a significant change to a marketing authorisation	100%	100%
Percentage of CAPs monitored at least monthly by the signal-detection group	100%	100%
Percentage of PSURs for centrally authorised products assessed within the legal timeframe	100%	Not applicable
Percentage of reaction-monitoring reports supplied to the lead Member State monthly	100%	Not applicable
Percentage of protocols for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	Not applicable
Percentage of reports for non-interventional post-authorisation safety studies assessed within the legal timeframe	100%	Not applicable

Veterinary medicines

Performance indicator	Target 2013	Actual 2011
Percentage of PSURs evaluated within the established timelines	85%	88%
Percentage of adverse-event reports for CAPs monitored within the established timelines	100%	100%

3.1.2. Evaluation of applications for maximum residue limits

Figure 11. Applications for the establishment of maximum residue limits (MRLs)

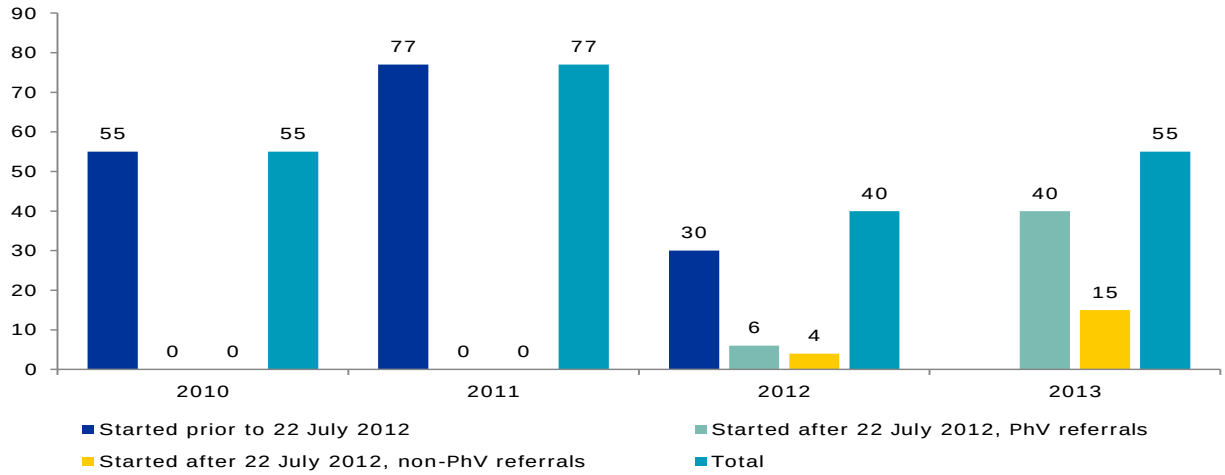


Performance indicator	Target 2013	Actual 2011
Percentage of MRL applications evaluated within the legal timeline	100% of applications	100% of applications
Assess biocide applications within agreed timelines	100% of applications 90% for old biocidal products	None received

3.1.3. Arbitrations, Community referrals and opinions on scientific matters

Human medicines

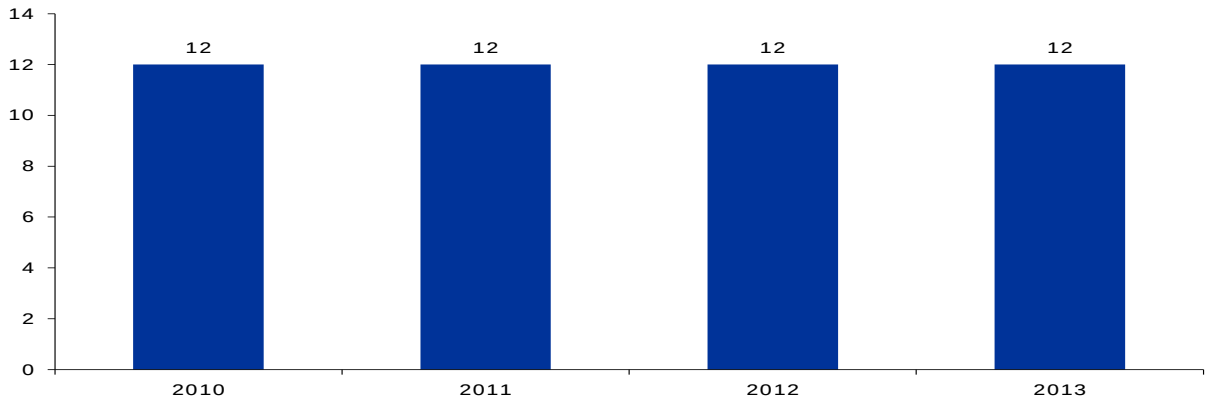
Figure 12. Arbitrations and Community referrals (including Article 20 procedures)



Performance indicator	Target 2013	Actual 2011
Percentage of arbitration and referral procedures evaluated within the legal timeline	100%	100%
Publication of Q&A documents for all referral procedures at the time of the CHMP opinion	100%	100%
Publication of the CHMP opinion and assessment report for Article 5(3) procedures no later than 2 weeks following the CHMP opinion	100%	0%

Veterinary medicines

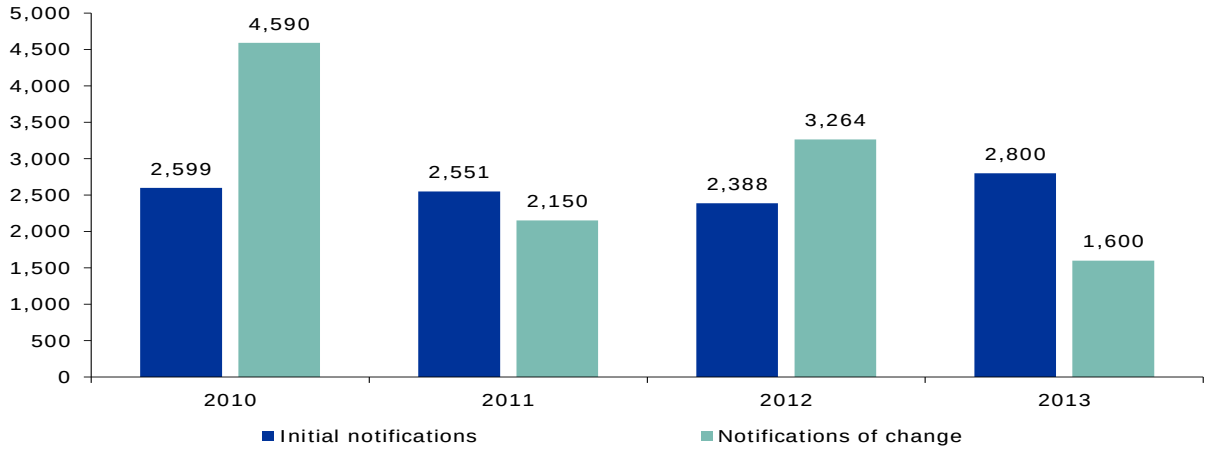
Figure 13. Arbitrations and Community referrals



Performance indicator	Target 2013	Actual 2011
Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100% of procedures

3.1.4. Parallel distribution

Figure 14. Parallel-distribution notifications

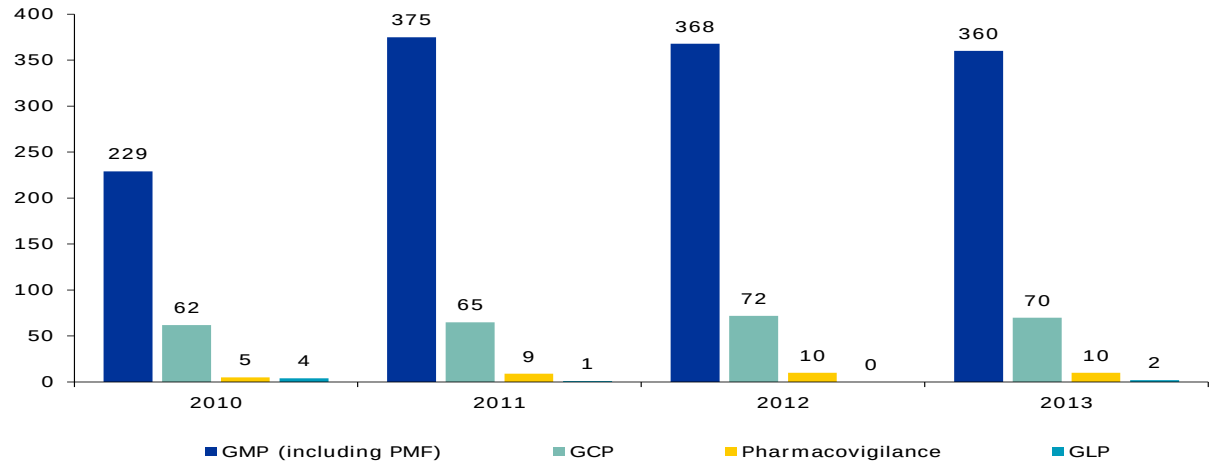


Performance indicator	Target 2013	Actual 2011
Percentage of initial notifications checked for compliance within the regulatory timeline: paper submission validation and regulatory check 35 days	90%	96.6%
Number of parallel-distributed products sampled on the EU market checked for compliance with the notices issued by the Agency	20 products	7 products
Promote the electronic submission system among all parallel distributors	90%	n/a*

* Electronic submission not available prior to 2011, so target set for first time in 2012.

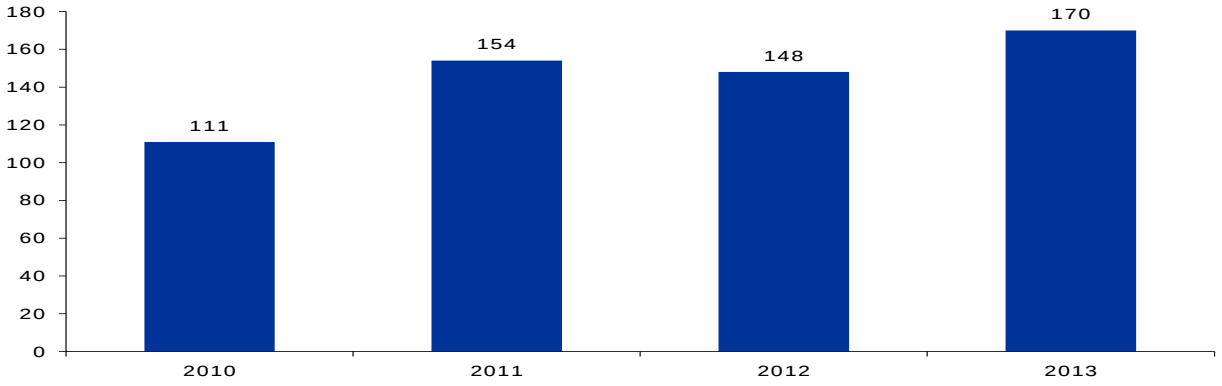
3.1.5. Inspections

Figure 15. Number of inspections



Performance indicator	Target 2013	Actual 2011
Management of inspections within the legal timelines	100% of inspections	100%

Figure 16. Number of quality defects reported



Performance indicator	Target 2013	Actual 2011
Sampling-and-testing programme	138 samples taken and tested (46 medicinal products)	129 samples taken and tested (56 medicinal products)
Complete sampling-and-testing programme	100% of samples taken and tested	100% of samples taken and tested

3.2. Projects related to the strategic area

Project	Project delivery	Milestone or deliverable to be achieved by end of 2013
EudraCT v9 development.	Q4 2013	Improved search and reporting functionality of the EU Clinical Trials Register, including the use of thesaurus-enabled searching. Improved user interface.
Online roadmap – phase 1: High-level requirements, design and plan.	Q2 2013	Deliver a roadmap on how to streamline and optimise the Agency's external and internal websites.

3.3. Strategic objectives

Strategic objective 3.1: Patient safety

Specific objective 3.1.1: Adopting more proactive approaches to pharmacovigilance

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Undertaking additional actions within the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), including: • review of ENCePP study concept, based on acquired experience; • guidance on methodological standards in pharmacoepidemiology; • facilitating conduct of multinational studies; • consistent interpretation of the definition of non-interventional study; • further development of ENCePP databases, considering interface with new pharmacovigilance legislation, HTA and the Enpr-EMA network.	Q4 2013	Update of ENCePP databases: • Strategy on role of ENCePP in bridging regulatory decision-making and HTA.

Implementing the new pharmacovigilance legislation.	Q4 2015	• Operate procedures for PSURs for active substances contained in both centrally and nationally authorised products. • Implement assessment of protocols and reports of non-interventional post-authorisation safety studies for nationally authorised products. • Deliver scientific guidance on methodological aspects of post-authorisation efficacy studies. • Redesign the urgent Union referral procedure, following the new 2012 legislation. • Publish a first list of substances subject to additional monitoring. • Develop and implement EU procedures on pharmacovigilance inspections that contain common provisions for the conduct of these inspections, to support harmonisation for the mutual recognition of inspection findings within the EU.
Identifying research topics for which funding is needed.	Q4 2013	Yearly list of drug-safety research priorities published and sent to the European Commission. Coordinate research questions linked to pandemic preparedness.

Specific objective 3.1.2: Strengthening the research supporting safety-monitoring and improving the capacity of the network

Activity	**Activity delivery**	**Milestone or deliverable to be achieved by end of 2013**
Strengthening research in the areas of signal detection, pharmacoepidemiology and supporting benefit-risk decision, and translating research funding into implementation of process.	Q4 2013	Methodological standards for the design, conduct and analysis of pharmacoepidemiology studies. Assess existing or develop new methods for signal detection from spontaneous reports, electronic health records and clinical trials. Develop graphical methods for use in benefit-risk assessment. Report on outcome of study exploring the usefulness, added value and transferability of data collection directly from consumers, using internet and telephony.

		Good-practice recommendations for signal detection, based on both existing and new methods, and exploring the use of electronic health records and clinical-trials data finalised. Guidelines and methodological standards for conceptualising pharmacoepidemio-logical studies adopted.
Working with the IMI Joint Undertaking to ensure the research agenda addresses important public-health needs as identified by the Agency.	Q4 2013	Exchange of information between the Agency, the U.S. Food and Drug Administration and the IMI on medicines development, evaluation and monitoring. Twice-yearly list of research questions sent to IMI Joint Undertaking.

Specific objective 3.1.3: Making best use of international resources in the safety area

Activity	**Activity delivery**	**Milestone or deliverable to be achieved by end of 2013**
Collaborating on international standardisation, including ICSRs, IDMPs, risk-management, electronic PSURS and formats for clinical trials.	Q4 2013	Published international standards agreed in the identified areas. Adoption of HL7 standards on RMPs and PSURs.
Developing international cooperation on pharmacovigilance inspections to improve supervision and inspection in a global context.	Q42013	Initiate a pilot joint-inspection programme.

Strategic objective 3.2: Post-authorisation follow-up

Specific objective 3.2.1: Integration of real-life experience into the benefit-risk assessment model

Activity	**Activity delivery**	**Milestone or deliverable to be achieved by end of 2013**
Increasing the collection of information from 'real-life' use of medicinal products, including off-label use, through work within the ENCePP framework, and the use of in-house data sources to better integrate the assessment of benefits and risks.	Q4 2013	Routine processes established for real-life use of medicinal products, including drugs utilisation defined.
Increasing contribution from patients and healthcare professionals on assessment of benefit-risk, particularly by obtaining information on real-life use of medicines.	Q4 2013	Develop methods for graphical expression of the benefits and risks of medicines for use by healthcare professionals.

Specific objective 3.2.3: Risk-management of veterinary medicinal products

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Reviewing developments and the outcome of European Commission-funded research projects in the field of environmental risk-assessment of veterinary medicines.	Q4 2015	Revision of CVMP guidelines and input into VICH guidelines, as appropriate.
Efficient telematics systems that are fit for purpose; subject to availability of resources, further development of EudraVigilance Vet v3.0 is planned that will deliver modules of the system such as integration with the medicinal products dictionary, improved data input and changes to assure compliance with international guidelines and enhanced processes.	Q4 2014	Deliverable EVVET3 part release of reporting module.

Strategic objective 3.3: Authoritative source of information

Specific objective 3.3.3: Adapting information to the needs of patients and healthcare professionals (HCPs)

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Providing better information to HCPs on the use of medicinal products in real-life situations within and outside the approved indications.	Q4 2013	Revised tools for communication with HCPs. Report on the one-year operation of the coordination of safety announcements.

Specific objective 3.3.4: Communicating with the public and the scientific community

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Review of online presence as part of the objectives of the Agency's communication strategy.	Q2 2013	User and business requirements for the implementation of the online roadmap established, covering corporate websites, the European medicines web portal (legal requirement) and the intranet/extranet for staff and national competent authorities.
Proactive publication of clinical trials.	Q4 2013	New policy agreed with stakeholders and published together with a roadmap outlining the timeline and deliverables for proactive publication of data on clinical trials.
Transparency initiatives.	Q4 2013	Finalisation of the transparency policy.

		Publication of minutes and agendas of the CHMP, CVMP, CAT and Committee on Herbal Medicinal Products (HMPC). Publication of the Agency's product-related communication strategy.

4. Corporate activities: Optimising the effectiveness and efficiency of the Agency

4.1. Strategic objectives

Strategic objective 4.1: Optimising the effectiveness and efficiency of operations

Specific objective 4.1.1: Redesigning data-management and architecture, and streamlining the ICT application portfolio

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Roadmap for data architecture, tier one.	Q4 2013	Deliver: • a high-level design for the services, business processes, applications and data stores to be put in place for the management of the Agency's data; • a design of how these should integrate with processes across the Agency and the network, allowing for the sharing and exchange of data.
Streamline ICT application portfolio.	Q4 2013	After reviewing all software applications, eliminate those that are no longer needed.

Specific objective 4.1.2: Optimising scientific processes

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Reviewing committee coordination and scientific support.	Q3 2013	Cross-Agency Oncology Scientific Advisory Group established (Q2). Document addressing formation of virtual Agency therapeutic groups (committees, secretariat) (Q3).
Analysis of raw data.	Q4 2015	Project scope, timelines and deliverables defined. Analysis of impact on current centralised-procedure practices.
Validation-process improvement.	Q3 2013	Veterinary: integrate the veterinary validation process into the validation centre. Post-authorisation variations: analyse and develop the strategy; design, build and deploy solutions for adopting the validation-centre approach for post-authorisation variations.

Records management.	Q4 2013	Identify and manage records created/ received during core business activities. Agree, standardise and enforce retention periods for all records according to legal requirements and business rules. Gather requirements to ensure compliance of IT tools with records-management standards. Deliver plan for reduction in paper records necessary for moving to new building (Project 2014), and start implementation.
ECD contact-data quality improvement.	Q2 2013	Deliver improved business processes for managing Eudra Common Directory contact records, and initial cleaning of data.

Specific objective 4.1.3: Assuring long-term sustainability of the Agency

Activity	Activity delivery	Milestone or deliverable to be achieved by end of 2013
Implement 'Project 2014: An agency on the move' (project to relocate the Agency to new premises).	Q3 2014	Completion of landlord's base-build construction. Network-infrastructure installation, testing and commissioning completed.

4.2. Performance indicators for ICT maintenance and support

Performance indicator	Target 2013	Actual 2011
Telematics and corporate IT systems' availability measured against Agency working hours	98%	Over 99%
ICT Service Desk: meeting of service-level agreements (SLAs) per system/priority level	(See table below)	(See table below)

ICT Service Desk: Performance indicators for meeting of SLAs per system/priority level

Severity rating	Description	Resolution time	Target 2013	Actual 2011
1. Critical	Users are unable to use the system	4 hours	80%	None logged
2. Severe	The system is operational, but severely restricting use	1 business day	80%	100%
3. Important	The system is operational, but one or more functions are restricted	10 business days	80%	100%
4. Minor*	The system is operational and no functions are restricted	120 business days	80%	100%

* Although fixing a minor defect might take very little time, it might take up to 120 business days until the fix is released as part of the scheduled release management. This is done to keep costs down.

Annexes

Financial forecasts

Figure 17. Forecast of the fee income by type of application for human medicines for 2013

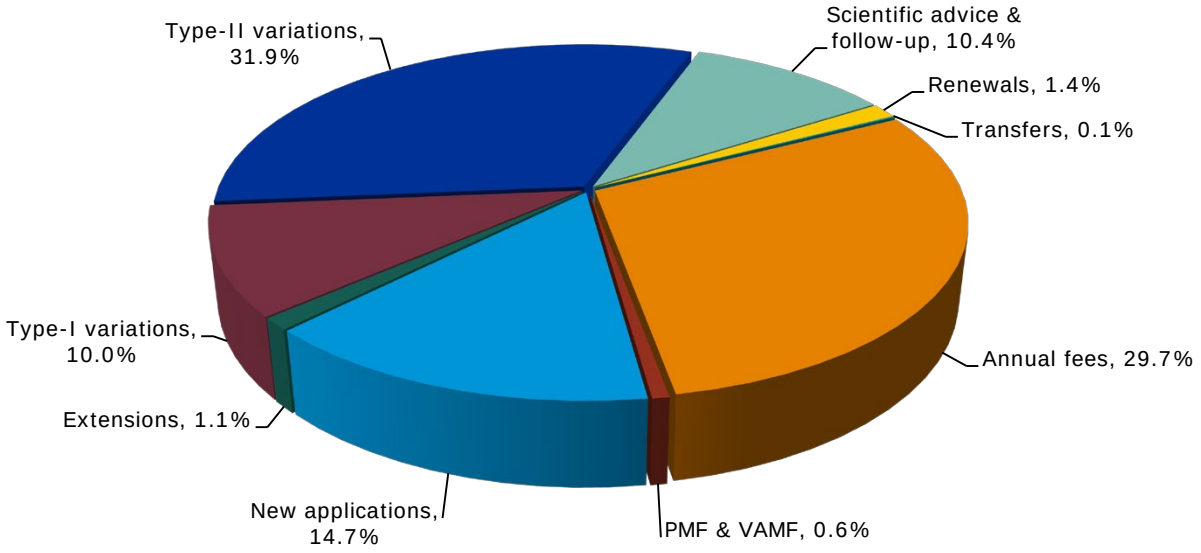


Figure 18. Forecast of the fee income by type of application for veterinary medicines for 2013

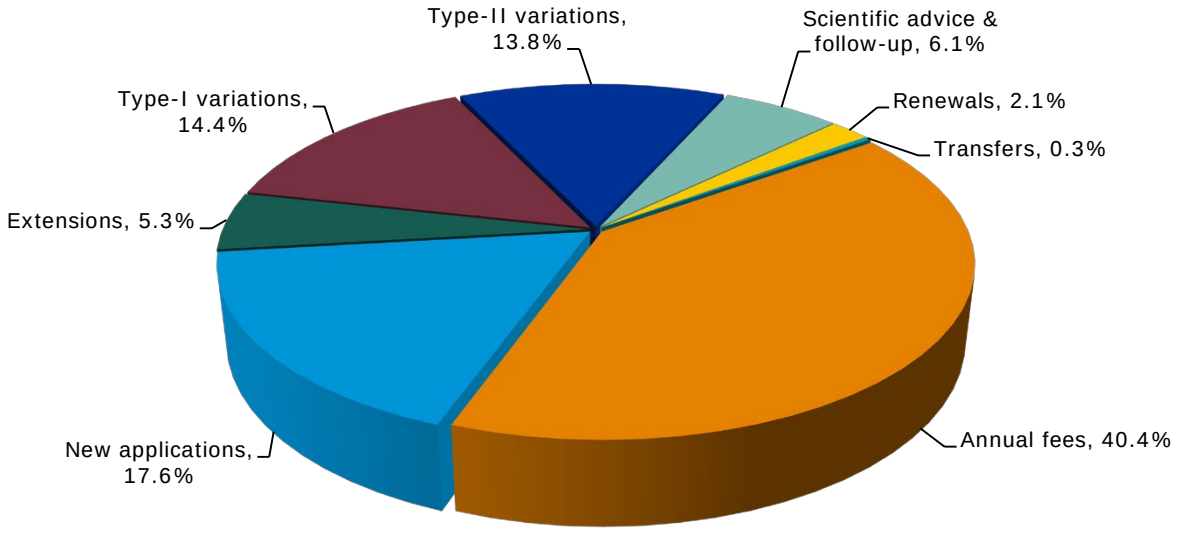


Figure 19. Resource consumption by activity; expenditure (forecast 2013)

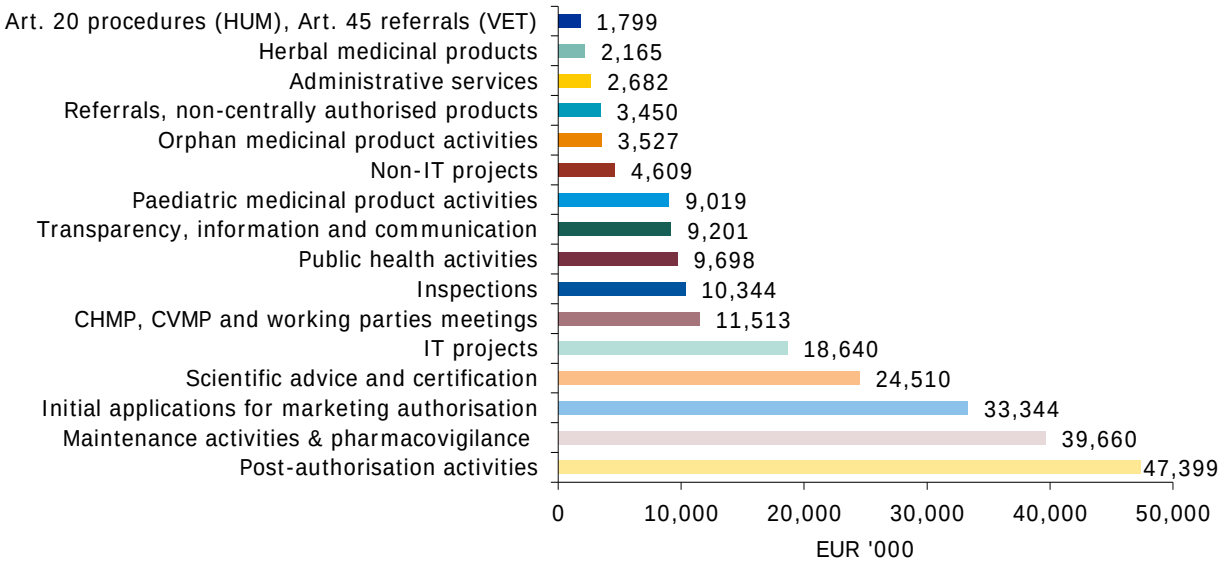
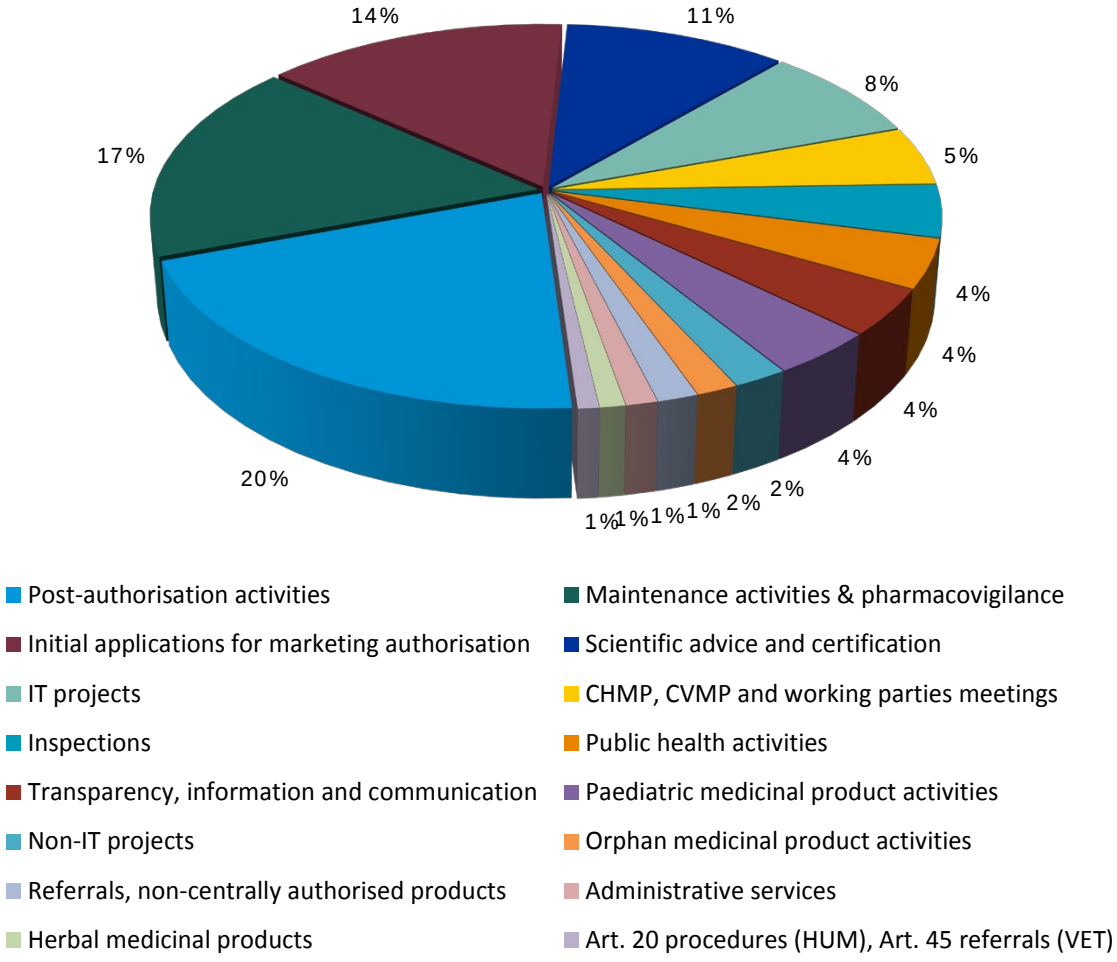


Figure 20. Resource consumption by activity; percentage (forecast 2013)



Establishment plan

Function group & grade	Authorised for 2011		Occupied as at 31.12.2011			Authorised for 2012		Authorised for 2013	
	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	-	1	-	0
AD 15	-	4	-	4	2	-	4	-	4
AD 14	-	5	-	5	3	-	6	-	6
AD 13	-	7	-	7	8	-	7	-	8
AD 12	-	37	-	36	27	-	38	-	38
AD 11	-	36	-	35	28	-	38	-	38
AD 10	-	32	-	30	19	-	34	-	36
AD 9	-	38	-	37	32	-	39	-	40
AD 8	-	43	-	43	36	-	47	-	47
AD 7	-	42	-	39	37	-	45	-	45
AD 6	-	37	-	35	64	-	38	-	42
AD 5	-	33	-	32	42	-	33	-	42
Subtotal AD	*0*	*315*	*0*	*304*	*298*	*0*	*330*	*0*	*346*
Total AD	**315**		**0**	**304**	**298**	**330**		**346**	
AST 11	-	2	-	2	1	-	2	-	2
AST 10	-	4	-	4	2	-	5	-	5
AST 9	-	8	-	8	1	-	7	-	7
AST 8	-	13	-	13	7	-	13	-	13
AST 7	-	19	-	19	14	-	20	-	20
AST 6	-	34	-	34	9	-	33	-	33
AST 5	-	35	-	35	26	-	35	-	35
AST 4	-	49	-	48	42	-	51	-	51
AST 3	-	32	-	32	43	-	36	-	39
AST 2	-	40	-	37	40	-	40	-	40
AST 1	-	16	-	16	69	-	18	-	20
Subtotal AST	*0*	*252*	*0*	*248*	*254*	*0*	*260*	*0*	*265*
Total AST	**252**		**0**	**248**	**254**	**260**		**265**	
Grand subtotal	*0*	*567*	*0*	*552*	*552*	*0*	*590*	*0*	*611*
Grand total	**567**		**0**	**552**	**552**	**590**		**611**	

Budget presented by title

		2011 (final)[3]		2012 (budget)[4]		2013 (budget)[5]	
		€ '000	%	€ '000	%	€ '000	%
	Revenue						
1+5	Fees and charges	159,634	80.1	181,905	81.8	190,587	82.3
200	General EU contribution	28,042	14.1	21,466	9.6	33,230	14.4
200	Surplus from previous year	5,477	2.7	9,875	4.4	0	0.0
201	Special EU contribution for orphan medicinal products	4,720	2.4	7,500	3.4	6,000	2.6
300	Contribution from EEA	784	0.4	753	0.3	1,098	0.5
600	Community programmes	389	0.2	640	0.3	520	0.2
5+9	Other	301	0.2	350	0.2	125	0.1
TOTAL REVENUE		**199,346**	**100.0**	**222,489**	**100.0**	**231,560**	**100.0**
	Expenditure						
Staff							
11	Staff in active employment	66,845	33.1	71,009	31.9	80,841	34.9
13	Mission expenses	502	0.2	745	0.3	465	0.2
14	Socio-medical infrastructure	572	0.3	597	0.3	641	0.3
15	Exchange of civil servants and experts	2,274	1.1	2,405	1.1	2,428	1.0
16	Social welfare	205	0.1	255	0.1	306	0.1
17	Entertainment and representation expenses	22	0.0	30	0.0	28	0.0
18	Staff insurances	2,120	1.0	2,253	1.0	2,255	1.0
	Total title 1	***72,539***	***35.9***	***77,294***	***34.7***	***86,964***	***37.6***
Building / equipment							
20	Investment in immovable property, renting of building and associated costs	20,069	9.9	21,491	9.7	20,997	9.1
21	Expenditure on admin. data processing	8,659	4.3	7,536	3.4	8,490	3.7
22	Movable property	1,474	0.7	1,480	0.7	4,215	1.8
23	Other admin. expenditure	826	0.4	858	0.4	1,119	0.5
24	Postage and communications	499	0.2	478	0.2	514	0.2
25	Expenditure on other meetings	87	0.0	122	0.1	125	0.1
	Total title 2	***31,613***	***15.6***	***31,965***	***14.4***	***35,460***	***15.3***
Operational expenditure							
300	Meetings	7,431	3.7	6,766	3.0	7,117	3.1
301	Evaluation of medicines	69,461	34.4	82,181	36.9	77,247	33.4
302	Translations	3,912	1.9	4,067	1.8	5,452	2.4
303	Studies and consultants	76	0.0	2,064	0.9	2,300	1.0
304	Publications	99	0.0	101	0.0	106	0.0
305	Community programmes	444	0.2	308	0.1	400	0.2
31	Expenditure on business-related ICT projects	16,491	8.2	17,743	8.0	16,514	7.1
	Total title 3	***97,912***	***48.5***	***113,230***	***50.9***	***109,136***	***47.1***
TOTAL EXPENDITURE		**202,063**	**100.0**	**222,489**	**100.0**	**231,560**	**100.0**

[3] Financial year 2011, as per final accounts, rounded to the nearest thousand.
[4] Financial year 2012, as per final budget.
[5] Financial year 2013, as adopted by the Management Board on 13 December 2012.

Financing decisions for procurement of operational expenditure in 2013

Activity statement:	**ENCePP studies**
Budget:	€319,000
Financial year:	2013
Description of action:	Ensuring best evidence is available to support Agency committees' assessments of the benefits and risks of authorised medicines (studies of risks and benefit risk)
Type of contract:	Call for expressions of interest; specific contract per study
Number of contracts:	3
Indicative timeframe for contracts:	Three procurements of approximately €106,000 each, one in each of the first three quarters of 2013
Indicative timeframe for procurement:	Each of the first three quarters of 2013
Indicative budget for procurement:	€319,000
Legal basis:	Regulation 726/2004 and Directive 2001/83, notably Articles 31 and 107i - k
Budget line:	B3030
Activity statement:	**EudraVigilance data management**
Budget:	€1.6 million per year, over 4 years (total: €6.5 million)
Financial year:	2014–2018
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 contracts:	Commencing in 2013
Indicative timeframe for procurement:	2nd quarter of 2013
Indicative budget for procurement:	€6,500,000
Legal basis:	Article 24 of Regulation 726/2004 as amended by Regulation (EU) No 1235/2010
Budget line:	B3030
Activity statement:	**Audit services**
Budget:	€120,000 + €40,000 per year, over 4 years (total: €640,000)
Financial year:	2013–2017/8
Description of action:	Provision of audit and consultancy services
Type of contract:	Framework contract: audit and consultancy services; specific contracts: audit advisory committee
Number of contracts:	8–10
Indicative timeframe for contract:	Commencing in 2013
Indicative timeframe for procurement:	2nd quarter of 2013
Indicative budget for procurement:	€640,000
Legal basis:	Agency's financial regulation, Article 71
Budget line:	B3030