



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 December 2011
EMA/MB/554514/2011
Executive Director

Work programme 2012

Adopted by the Management Board on 15 December 2011



7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409

E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union



Note on figures

All figures for 2012 provided in the charts in this document are estimates.

Table of contents

| | |
|---|-----------|
| Introduction by the Executive Director..... | 5 |
| 1. The European Medicines Agency in Europe and the world | 8 |
| 1.1. European medicines network | 8 |
| 1.2. European cooperation | 9 |
| 1.3. International cooperation | 10 |
| 1.4. Communication, provision of information and transparency | 11 |
| 1.5. Support for innovation and availability of medicines..... | 13 |
| 1.6. Regulatory science | 15 |
| 1.7. Governance | 16 |
| 2. Medicines for human use | 18 |
| 2.1. Orphan medicinal product designation..... | 18 |
| 2.2. Scientific advice and protocol assistance | 19 |
| 2.3. Initial evaluation | 21 |
| 2.4. Post-authorisation and maintenance activities..... | 22 |
| 2.5. Pharmacovigilance activities | 24 |
| 2.6. Arbitration, Community referrals and opinions on scientific matters | 26 |
| 2.7. Medicines for paediatric use..... | 27 |
| 2.8. Herbal medicinal products | 28 |
| 2.9. Advanced therapy medicinal products | 29 |
| 2.10. Emerging therapies and new technologies | 31 |
| 2.11. Scientific committees, working parties and scientific advisory groups | 32 |
| 2.12. Coordination group | 32 |
| 3. Veterinary medicines..... | 33 |
| 3.1. Scientific advice | 33 |
| 3.2. Initial evaluation | 34 |
| 3.3. Evaluation of applications for maximum residue limits..... | 36 |
| 3.4. Post-authorisation and maintenance activities..... | 37 |
| 3.5. Pharmacovigilance and maintenance activities | 38 |
| 3.6. Arbitration, Community referrals and opinions on scientific matters | 40 |
| 3.7. Scientific committees and working parties | 41 |
| 3.8. Coordination group | 42 |
| 4. Compliance and inspections | 43 |
| 4.1. Manufacturing and quality compliance..... | 44 |
| 4.2. Clinical and non-clinical compliance | 45 |
| 4.3. Clinical-trials support | 46 |
| 4.4. Parallel distribution..... | 47 |
| 4.5. Certificates..... | 48 |
| 5. Information and communications technology..... | 49 |
| 5.1. Implementation and operation of ICT in support of internal activities | 49 |
| 5.2. EU telematics..... | 50 |
| 5.3. Maintenance and support of ICT | 52 |

Annex 1 Establishment plan 2010-2012 53
Annex 2 Revenue and expenditure overview 2010-2012 54
Annex 3 Working-party guidelines..... 55

Introduction by the Executive Director

Guido Rasi

The work programme of the European Medicines Agency for 2012 is influenced by a number of factors, among which are:

- the new pharmacovigilance legislation;
- the new legislation on falsified medicines;
- the climate of austerity, both for the Agency and the national competent authorities (NCAs).

The work programme takes into account the above factors, the broader context of the Agency's legislative, economic, social and technological environment, and relevant measures outlined in the implementation plan for the Agency's 'Road map to 2015'.

Highest quality standards

Conducting ongoing scientific responsibilities to the highest quality standards remains the Agency's main priority. The volume of core activities will remain at a similar level to last year, with a marginal increase in certain areas.

In addition to assessing applications to set quality standards and timelines, the Agency will implement measures to strengthen the quality, scientific and regulatory consistency of assessments and of the regulatory science underpinning the Agency's work, in line with the road map implementation plan.

Pharmacovigilance legislation

The implementation of the pharmacovigilance legislation is a main area of focus for the Agency and for the European medicines network as a whole, due to the significance of this legislation for public health, the amount of work that will have to be undertaken over the coming years by both the Agency and the network, and the significant amount of resources that will have to be found through internal reallocation and efficiency gains to finance this work.

The Agency and its partners have set priorities for the stepwise implementation of the legislation in line with available resources. Activities contributing to public health are given the highest priority, followed by those that will increase transparency and improve communication, then by simplification measures.

It is important to stress that the scope of the new pharmacovigilance legislation goes far beyond the traditional scope of pharmacovigilance for human medicines. While the new legislation significantly amends or adds to classic pharmacovigilance tasks, it also directly impacts many parts of the regulatory process related to patient safety that were not historically considered as pharmacovigilance.

The majority of the pharmacovigilance work currently undertaken by the Agency relates to approximately 600 centrally authorised products for human use. The most important change in the new legislation is the direct involvement of the Agency in pharmacovigilance of the nationally authorised products.

Anti-falsification legislation

The majority of requirements of the new legislation that will help to prevent entry into the legal supply chain of falsified medicinal products will come into force in January 2013, but preparatory work has to be undertaken in 2012. The scope of the legislation covers centrally and nationally authorised products. The new legislation in particular places requirements on the Agency to develop and manage

certain databases, to cooperate in the coordination of inspections in third countries, to cooperate in assessment and verification of third countries' regulatory framework for active pharmaceutical ingredients (APIs) and a number of other new measures. The resources needed to implement the legislation on falsified medicines and on pharmacovigilance will need to be reconciled.

Transparency

Work is ongoing within the network to define what information is considered commercially confidential and how to best comply with protection of personal data. Agreement on these issues will pave the way for further measures that will allow the Agency to move from reactive to proactive publication of various documents. The Agency and its network partners believe that the latter would save resources in the long term. In the meantime, the most notable deliverables in the area of transparency in 2012 will be granting access to EudraVigilance data for human and veterinary medicines, providing more information on clinical trials and starting the publication of scientific committee agendas and minutes. The Agency will also finalise its transparency policy, following the outcome of the public consultation.

Access to documents will remain an area that consumes significant resources. The Agency will further develop processes and systems to make information of interest to the public available quicker and in a more efficient manner. The Agency's website will be adapted to include a single point of entry for all requests for documents or information.

Communication and engagement with stakeholders

To make further progress in the area of communication and provision of information, the Agency will prepare a communications strategy. One of the pillars of the implementation will be the strengthening of the Agency's collaboration with the national competent authorities in the area of communication and provision of information.

By virtue of its unique position in the life sciences and healthcare environments, the Agency is a rich repository of data, information and knowledge. Opening up these resources to broader audiences could benefit drug development and improve patient care. The Agency will step up its efforts to share primary data and information, provide secondary analyses of data and experiences, and proactively communicate its knowledge and grounds for regulatory opinions to the scientific community.

The Agency will continue to strengthen and widen the scope of interactions with civil society by revising the framework for interaction with patients' organisations, and by gradually implementing the framework for interaction with healthcare professionals. Discussions on how to ensure patients' values are taken into account in benefit-risk assessments will start.

Public-health needs and availability of medicines

In the area of availability of medicines, the Agency will implement a number of initiatives outlined in the road map implementation plan. Planned activities include identifying areas where additional medicines are needed, reflecting on the difficulties faced by SMEs in addressing unmet medical needs, and considering the merits and mechanics of an optional approach to the early authorisation of medicines in a restricted population. The Agency will reinforce its contribution to the treatment of elderly patients and pregnant women. Similarly, the Agency will continue its contribution to, and cooperation with, health technology assessment bodies. The project to improve the European public assessment reports will come to fruition, and the pilot provision of joint scientific advice with health technology assessment bodies and payers will continue.

Veterinary medicines

The theme for 2012 in the veterinary field will be one of continuing to manage core activities against a backdrop of resource constraints.

With respect to veterinary medicines, the European Commission is expected to finalise the legislative proposals arising from its consultation on better regulation in the veterinary sector and the impact assessment of the veterinary legislation that took place during 2010. The Agency will support the work of the Commission by providing technical advice, particularly with respect to how the proposals will impact on the availability of veterinary medicinal products in general and centrally authorised products in particular.

An increase in scientific-advice and marketing-authorisation applications for novel veterinary therapies is expected and encouraged. The Agency will work with stakeholders and the regulatory network to ensure adequate and appropriate guidance is in place to facilitate the access to market of new technologies either in advance of, or as part of, the revision of veterinary legislation.

As reflected in the road map and its implementation plan, the Agency and its Committee for Medicinal Products for Veterinary Use will continue to contribute on a wide range of topics related to veterinary medicines at European Union and international level, such as antimicrobial resistance, maximum residue limits, risk assessment, benefit-risk analysis methodology and harmonisation of standards and requirements. The extent and timetable for the contribution from the veterinary sector will be determined by the resources available, bearing in mind the priority that must be placed on maintaining core scientific responsibilities. Emphasis will continue to be given to working within the 'one health' agenda, whereby promoting health in animals promotes health in man.

Governance of the Agency

Throughout 2012, focus will be placed on achieving efficiency gains and on reviewing and redesigning processes. The challenge for the Agency is that it is increasingly difficult to match the growing workload and new tasks with adequate resources. This requires that the Agency step up the implementation of its rationalisation programme, to generate internal resources for the conduct of new and existing responsibilities to the highest quality standards. To this end, the Agency will accelerate the rollout of the Operational Excellence (OpEx@EMA) programme, which, among other objectives, will progressively review core business processes and ensure they are underpinned by efficient and effective IT systems.

Following the implementation of the revised policies on handling of conflicts of interests in 2011, the Agency will focus on ensuring the full implementation and effective functioning of its updated policies on managing potential conflicts of interests with respect to the Management Board, experts and staff.

Another important issue for the Agency is assuring the continuity of its operations during the 2012 London Olympic Games. This will create an opportunity to test arrangements in case of logistical disruptions and to increase the use of virtual meetings for core activities. Main committee meetings during the critical July 2012 period will be hosted by national competent authorities and the European Commission.

1. The European Medicines Agency in Europe and the world

1.1. European medicines network

Trends and new issues

The Agency and the European medicines network enter the second year of the 'Road map to 2015'¹ and of the European Heads of Medicines Agencies (HMA) strategy paper². The implementation of the road map as outlined in the implementation plan will continue.

The implementation of the pharmacovigilance legislation will remain a major challenge for the network in 2012. The implementation of the falsified medicines legislation as of 2013 is another area that demands the effort and attention of the Agency and its partners.

Work on reviewing the Agency's pandemic-influenza plan will continue, on the basis of lessons learned and in line with the established programme that involves the network and the European Commission.

As in previous years, the workload within the network has again grown significantly, as reiterated in the evaluation of the Agency and the network in 2009. Work to assure continuous availability of expertise in various existing and emerging scientific fields will remain an important area of activity in the interests of the long-term sustainability of the Agency. In this context, the Agency will continue to support the HMA strategy with regard to the operation of the Joint HMA/EMA Office of Training Steering Group.

Reflection on the future fee system is expected to continue. This is an important area to assure sustainability of the Agency and the network.

The EU financial perspective beyond 2013 will be marked by austerity measures. This will be reflected in the level of the EU subsidy to the Agency, the availability of staff to tackle the increasing workload, and the Agency's and the network's initiatives to increase the effectiveness and efficiency of operations.

Preparations for future enlargement

Enlargement preparation activities will continue, within the framework of the Instrument for Pre-accession Assistance (IPA) programme, to support the participation of Albania, Bosnia-Herzegovina, the former Yugoslav Republic of Macedonia, Kosovo under UNSC Resolution 1244/99, Montenegro, Serbia and Turkey in the Agency's activities. Preparations for the follow-up IPA programme will take place.

Pre-accession activities will include participation of representatives of the beneficiary NCAs in selected meetings and training courses, as observers, to familiarise those authorities with the work performed by the Agency. Conferences, workshops and seminars will be organised for training purposes, as required.

As an acceding country, Croatia will be invited to send representatives as active observers in Agency meetings.

¹ 'Road map to 2015: The European Medicines Agency's contribution to science, medicines and health' (EMA/299895/2009), available on the Agency's website [here](#).

² 'A Strategy for the Heads of Medicines Agencies, 2011-15', available on the HMA website [here](#).

Meetings at the Agency

Trends and new issues

The Agency expects the numbers of meetings and reimbursed delegates in 2012 to be around 550 and 8,600 respectively, maintaining the same levels as in 2011.

During the period of the London Olympic Games, a number of Agency meetings will be hosted by NCAs and the European Commission, in view of the expected travel and accommodation disruptions in London.

Alternatives to conventional meetings will continue to be employed to achieve greater efficiency of the network. This is dependent on the availability of adequate IT equipment at the NCAs. The number of virtual meetings is expected to increase to 410 in 2012, compared to 350 forecast in 2011.

Overall, the Agency will make every effort to reduce the number of sub-groups and streamline participation to levels necessary for efficient operations.

1.2. European cooperation

The Agency will be involved in the following topics as part of its cooperation with EU institutions, agencies and other bodies:

- Implementation of the new pharmacovigilance legislation.
- Preparation for implementation of the new legislation on falsified medicines.
- Health technology assessment and relative effectiveness.

The Agency will continue to contribute to activities in this field in collaboration with the European Commission and EUnetHTA, and will further cooperate with health technology assessment (HTA) bodies in the area of scientific advice.

- Emerging science.

The Agency will maintain cooperation with the European Commission in the areas of medicines development and emerging science such as personalised medicines, medicine-medical device combined products, borderline products and nanomedicines.

- Psychoactive substances.

The Agency will maintain cooperation with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in the area of misuse, risk-assessment and risk-management of new psychoactive substances.

- Vaccine effectiveness.

The Agency will collaborate with the European Centre for Disease Prevention and Control (ECDC) on epidemiology and surveillance studies related to vaccine effectiveness, on strengthening the monitoring of safety of vaccines and on paediatric vaccines development and schedules.

- Antimicrobial resistance.

The minimisation of risks arising from the use of antimicrobials in human and veterinary medicine is increasingly a point of focus at European and international level. Following the publication in November 2011 of the European Commission strategy on antimicrobials, the Agency will be one of the key EU institutions in delivering the necessary actions. To this end, the Agency will ensure both

the continued availability of the antimicrobials necessary for treating infections in man and animals, and that antibiotics are authorised appropriately to minimise the risks of resistance.

- 3R principles.

The Agency will strengthen its engagement with the pharmaceutical industry, the European Commission, the European Directorate for the Quality of Medicines and HealthCare (EDQM) and the European Centre for the Validation of Alternative Methods (ECVAM) to promote the 3R principles (replacement, reduction, refinement). (Road map initiative.)

- Veterinary medicines.

Following a public consultation initiated by the European Commission in 2010 and the expected drafting of a revised legislation for veterinary medicines in 2011 addressing the particular needs of the veterinary medicines sector, the Agency is expected to play an active part in assisting the Commission in the discussion of the draft in the Council.

The Agency will continue its contribution to the Community Animal Health Strategy, in the areas of antimicrobial resistance, epizootic disease and the availability of veterinary medicines.

1.3. International cooperation

The Agency will consolidate its international activities during 2012. Building on the work carried out during 2011, interactions with key international regulatory authorities will be further developed and the activities commenced in 2010 and 2011 will continue. Particular attention will be paid to the international aspects associated with implementation of the new legislation on pharmacovigilance and falsified medicines.

Following the publication of a revised reflection paper on the handling of clinical-trial data from countries outside the EU, the Agency will step up its activities to promote networks and international collaboration in the area of good clinical practice (GCP).

The pilot projects on cooperation with the US Food and Drug Administration (FDA) on GCP and good-manufacturing-practice (GMP) inspections completed in 2011 will continue to enable better use of resources, greater inspection coverage and reduction of duplicate inspections. Similarly, cooperation on inspections of API manufacturers will continue, and will take into account the requirements of the legislation on falsified medicines.

The pilot project embarked upon with the FDA aiming to ensure consistency of approaches to applications incorporating principles of quality by design is expected to have moved to the evaluation phase and consideration will be given to formalising transatlantic interactions in this area.

The final report of the initial phase of work by the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) was adopted by the EU and the US in September 2011. During 2012, an implementation plan for the recommendations in the report will be drawn up. Actions will be initiated with a view to gaining added value from transatlantic cooperation in the field of minimising the risks arising due to antimicrobial resistance in human and veterinary medicine.

Cooperation with the International Organisation for Animal Health (OIE) will focus on providing assistance to the OIE directly and through the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) on enhancing the systems for regulation of medicines in regions that trade with the EU. This will require close cooperation with the European medicines network as the source of the expertise required by OIE.

1.4. Communication, provision of information and transparency

Trends and new issues

Transparency and communication is one of the main pillars of the new pharmacovigilance legislation. The Agency will implement it gradually, focusing on the provision of information through access to EudraVigilance data, the coordination of safety announcements for nationally authorised products within the network, and preparations for public hearings. This will also include the strengthening of core activities, focusing on improving product information to minimise the risk of medication errors.

Objectives

| Objective | |
|---|--------|
| Strengthen the interactions described above involving patients' and healthcare professionals' organisations to build up a network of excellence at EU level. | |
| Performance indicators for the objective | Target |
| Communication strategy published | Q4 |
| Coordinate the publication of safety-related issues (to be further defined according to the implementation of the pharmacovigilance legislation) | Q3 |
| Objective | |
| Adapt the structure and content of the European public assessment report and use the new website tools to improve communication of the decisions on the benefit-risk of authorised medicines to stakeholders, including patients, the scientific community and health technology assessment bodies, putting more emphasis on the quantitative aspects of the benefit-risk assessment. | |
| Performance indicators for the objective | Target |
| Workshop organised | Q4 |
| Objective | |
| Initiate discussion involving patient groups and health technology assessment bodies aimed at exploring how to ensure patient values are taken into account in benefit-risk assessments (Road Map initiative). | |
| Performance indicators for the objective | Target |
| Report and recommendations | Q4 |
| Objective | |
| Increase the involvement of patients, academia and healthcare professionals in the scientific work of the Agency to ensure that these stakeholder views are taken into account in benefit-risk decision making (Road map initiative). | |
| Performance indicators for the objective | Target |
| Framework for interaction with patients and consumers revised | Q4 |
| Framework for interaction with healthcare professionals implemented | Q4 |
| Modalities of participation of stakeholders in the Agency's public hearings on major safety issues defined | Q3 |
| Objective | |
| Strengthen core activities focusing on the improvement of product information to address new challenges deriving from the new legislation on pharmacovigilance, including the prevention of medication errors. | |

| Performance indicators for the objective | Target |
|---|--------|
| Public access to the EudraSmPC webpage provided | Q4 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|--|-------------|
| Percentage of summaries of opinions published at the time of the CHMP press release | 100% of summaries of opinion | 100% |
| Percentage of initial EPARs published within 4 weeks of the Commission decision | 80% of marketing authorisations granted ³ | 67% |
| Percentage of EPAR summaries published together with the EPAR | 100% 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 | 94% |
| 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 | n/a |

Transparency

Trends and new issues

The Agency may face an increased number of challenges relating to access to documents. The recent decision to grant access to data from clinical trials submitted by applicants is likely to increase such requests. The Agency expects around 200 requests for access to documents (180 were forecast for 2011) and 4,500 requests for information (4,000 were forecast for 2011). These figures do not include the expected number of requests for information on EudraVigilance data, nor the expected number of requests for access to the EudraVigilance data.

The transparency policy and its implementation, expected to be introduced in 2012, will have an impact on the committees' and working parties' practices and procedures.

Objectives

| Objective | |
|--|--------|
| Make information relating to clinical trials accessible to the public (results-related information). | |
| Performance indicators for the objective | Target |
| Summary results and protocol-related information loaded into EudraCT by the national competent authorities and made available to the public for eligible new trials (when EudraCT version 9 becomes available) | 100% |
| Timetable for providing access to clinical-trial data submitted as part of marketing-authorisation applications made public | Q3 |

³ The target was reduced due to the request by the Management Board considering a consistently low score of this KPI.

| Objective | |
|--|---|
| Further increase transparency in the daily operation of the EudraVigilance System (transparency policy/PhV legislation). | |
| Performance indicators for the objective | Target |
| Aggregated data output from the EudraVigilance database as part of the EV Access Policy published | Q1-Q4 |
| Publication of the EudraVigilance Medicinal Product Dictionary (EVMPD) validated entries | Q4 |
| Objective | |
| Full implementation of the EudraVigilance Veterinary access policy. | |
| Performance indicators for the objective | Target |
| Implementation of Category II and III of the EVVet Access Policy | Full access for general public and marketing-authorisation holders to EudraVigilance veterinary, in line with access policy |
| Objective | |
| Further increase transparency in the daily operation of the Agency's activities. | |
| Performance indicators for the objective | Target |
| Gradual publication of agendas and minutes of the scientific committees | First CHMP and CVMP agenda and minutes published by Q4 First COMP and PDCO agenda and minutes published by Q2 |
| Measures to provide more information within the EPAR implemented | Q4 |
| Objective | |
| Support completion of GMP ⁴ certificates in EudraGMP and publication of information on these. | |
| Performance indicators for the objective | Target |
| Eligible certificates loaded into EudraGMP by Member State inspectorates and made public | 100% |

1.5. Support for innovation and availability of medicines

Trends and new issues

Supporting availability in the area of unmet medical needs and facilitating new approaches to medicines development are among the areas within which the Agency will focus its core business activities in the coming years.

Trends in this area are influenced by various initiatives at EU level. The European Commission is undertaking initiatives to harmonise relative effectiveness assessment and increasing EU cooperation on healthcare.

The new EU research and innovation strategy is in place. Among other initiatives, emphasis will be placed on public-sector support to innovation at national, European and international level. The number of small and medium-sized enterprises (SMEs) registered with the Agency is expected to continue to increase in 2012-2013 due to this initiative.

⁴ GMP = good manufacturing practice.

For veterinary medicines, the policy started in 2009 on providing support for medicines for minor species and minor uses/limited markets will continue. This provides regulatory and financial assistance to products, increasing the availability of safe and effective medicines to improve animal welfare and public health. Early dialogue with applicants for potentially innovative products has been initiated for products in early stages of development and appropriate guidance/assistance provided, including scientific advice, referral to the Innovation Task Force, etc.

Objectives

Please also see the objectives in the 'Scientific advice', 'Emerging therapies' and 'Advanced therapy medicinal products' sections.

| | |
|---|--------------------|
| Objective | |
| Explore how the process of learning from failed development can be used to influence future regulatory decisions (road map initiative). | |
| Performance indicators linked to objective | Target |
| Report and recommendations | Q4 |
| Objective | |
| Conduct a mapping exercise to identify disease areas where additional medicinal products are needed (road map initiative). | |
| Performance indicators linked to objective | Target |
| Report on exercise published | Q4 |
| Objective | |
| Create a platform for dialogue with DG Research to raise awareness of the use of information from failed development studies and facilitate inclusion on the research agenda (road map initiative). | |
| Objective | |
| Consider specific difficulties faced by SMEs in addressing unmet medical needs (road map initiative). | |
| Performance indicators for the objective | Target |
| Annual analysis published by the SME Office | Q4 |
| Objective | |
| Continue activities relating to the use of medicinal products in pregnancy. | |
| Performance indicators linked to objective | Target |
| Expert group established | Q2 |
| Objective | |
| Consider the need to involve older patients in clinical trials, impacts of polypharmacy, sources of adverse reactions (road map initiative). | |
| Performance indicators for the objective | Target |
| Report on the analysis of applications regarding the assessment of clinical data on geriatric population | Q4 |
| Consideration for geriatric requirements in CHMP safety and efficacy guidelines under consultation | 100% of guidelines |

1.6. Regulatory science

Trends and new issues

The Agency has identified analysing the impact of regulatory decisions on public health as an important activity in its road map. Efforts in this field started a number of years ago and will continue, with a number of milestones to be achieved in 2012. The Agency's programme in this area aims not only to evaluate outcomes and the impact of regulatory actions but to provide methodologies for a more detailed justification of benefit-risk assessments done by the relevant Agency committees. The benefit-risk project finalised in 2011 will enter its implementation phase with training of assessors.

Objectives

| | |
|---|----------------|
| Objective | |
| Utilise the ENCePP ⁵ network to enhance outcome assessment related to medicines regulation. | |
| Performance indicators for the objective | Target |
| Four studies on outcome assessment making use of the ENCePP network conducted | Q1-Q4 |
| Objective | |
| Establish strategy on measuring the effectiveness of risk-minimisation activities. | |
| Performance indicators for the objective | Target |
| Strategy and process in place | Q4 |
| Objective | |
| Continue implementing the project on adaptive clinical-trial designs. | |
| Performance indicators for the objective | Target |
| Training session on case studies | One session Q4 |
| Objective | |
| Consider merits and mechanics of optional approach to early authorisation of medicines in a restricted population, e.g. based on early information from good responders. Explore broader applicability of 'staggered' approvals and prepare guidance on the applicability of such approaches (road map initiative). | |
| Performance indicators linked to objective | Target |
| Report and recommendations | Q2 |
| Revised guidance | Q4 |
| Objective | |
| Implement pilot projects under the concept of staggered approval/progressive authorisation by Q4. | |
| Objective | |
| Facilitate linkage of vaccination to health outcomes. | |
| Performance indicators linked to objective | Target |
| Business case submitted to senior management on vaccine health outcome data link | Q2 |
| Objective | |
| Explore 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 | |

⁵ ENCePP = European Network of Centres for Pharmacoepidemiology and Pharmacovigilance.

| (road map activity). | |
|---|--------|
| Performance indicator for the objective | Target |
| Information exchange on, and mutual contribution to, clinical and methodological guidelines takes place | Q4 |

1.7. Governance

Trends and new issues

The Agency has seen growth in its activities over a number of years. At the same time, the Agency is experiencing resource limitations in various areas of its activities. These external factors accelerate the Agency's efforts for increased efficiency of its activities. A number of process-improvement projects are under way and in the pipeline to improve efficiency and quality.

Implementation of the new draft rules on handling staff declared interests will continue in 2012. The rules are expected to be finalised, subject to a positive outcome of the ongoing consultation of the European Commission.

The Agency is preparing for disruptions that may arise during 2012 due to the London Olympic Games in July and August.

The Operational Excellence initiative is now a reality. It is intended to meet demands for:

- saving resources without compromising on quality;
- reengineering processes and reallocating resources to deliver on core activities;
- improving efficiency to better handle workload;
- demonstrating European best practice.

Strengthened data-quality governance and control systems are needed to ensure that data is reliable and can therefore support the Agency's scientific role and fact-based decision-making. In 2011, a number of business processes were streamlined; 2012 will see these activities extended further.

Objectives

| Objective | |
|--|--------|
| Implement Operational Excellence (OpEx@EMA) in the following streams: <ul style="list-style-type: none"> • business-process improvement; • operational strategy and management systems; • staff-skills improvement; • information-management strategy and governance; • business and ICT alignment. | |
| Performance indicators for the objective | Target |
| Detailed implementation plan with prioritised activities up to 2015, in line with the Agency's road map | Q2 |
| Ongoing efficiency-improvement activities completed in line with provided plans (validation-process improvement, 'Ask EMA', change-management, planning and reporting and information-asset management) | Q4 |

| | |
|---|--|
| Delivery of improvement benefits in each of the streams | In line with implementation-plan timelines |
| Objective | |
| Put in place arrangements to ensure continuity of operations during the 2012 Olympic Games. | |
| Performance indicators for the objective | Target |
| The Agency's ongoing scientific responsibilities delivered | In line with the work programme |

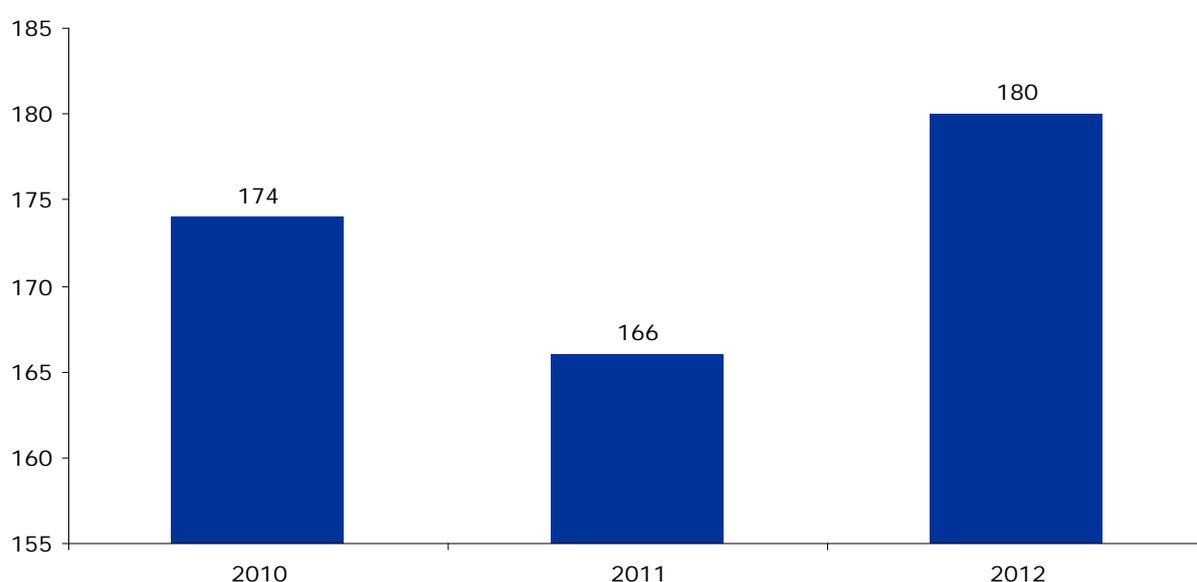
2. Medicines for human use

2.1. Orphan medicinal product designation

Trends and new issues

- Orphan medicinal product designations expected to increase steadily in number and complexity as a consequence of the incentives for development and marketing of advanced therapies and innovative products for disease subsets.
- Continued collaboration with the FDA on joint designation assessment.

Figure 1. Number of applications for designation of orphan medicinal products



Objectives

| Objective | |
|--|--------|
| Develop a pilot project on orphan medicines to explore how to better communicate and justify significant-benefit decisions reached by the Committee for Orphan Medicinal Products (road map initiative). | |
| Performance indicators for the objective | Target |
| Public document on the review of designation at the time of marketing authorisation | Q4 |
| Inter-committee meeting on methods to assess significant benefit | Q4 |
| Objective | |
| Review orphan medicines development to identify bottlenecks in development and provide feedback for the EU research policy on rare diseases. | |
| Performance indicators for the objective | Target |
| Recommendations on fostering orphan-drug development | Q3 |

| Objective | |
|---|-----------------------|
| Identify advanced therapy medicinal products (ATMPs) designated as orphan medicinal products and their specific regulatory needs. | |
| Performance indicators for the objective | Target |
| Inventory of ATMPs designated as orphan products 2000-2011 | Inventory prepared Q4 |
| Report on regulatory needs of orphan-designated ATMPs | Report finalised Q4 |

Core business performance indicators for the area

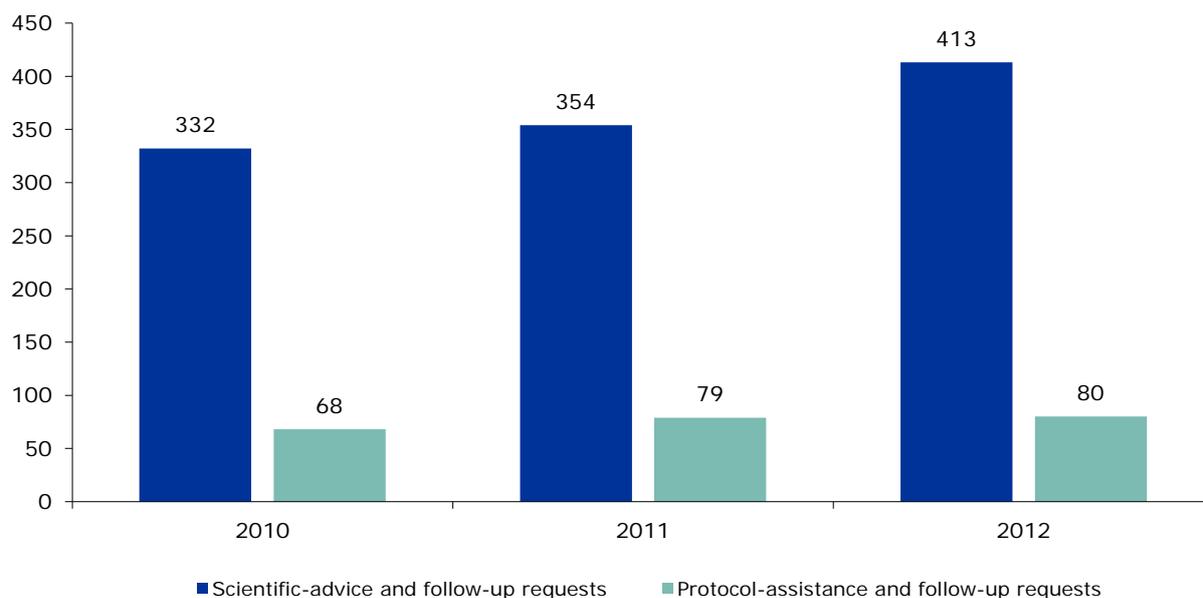
| Performance indicator | Target 2012 | Actual 2010 |
|--|--------------------|--------------------|
| Percentage of designation applications evaluated within 90-day timeline | 100% | 93% |
| Percentage of summaries of opinion published within 1 month of the Commission decision on designation | 95% | 97% |
| Percentage of public assessment reports (on review criteria) published within 1 month of the European Commission's decision on marketing authorisation | 90% | 100% |

2.2. Scientific advice and protocol assistance

Trends and new issues

- 10% increase in the number of scientific-advice applications.
- The most significant topics will remain innovative clinical-trial designs and use of biomarkers as endpoints in clinical trials.
- More requests for qualification of novel methodologies are expected in 2012-2013.
- Interaction with HTA bodies and consortia (for example IMI and C-Path) expected to be important activities in 2012-2013.

Figure 2. Scientific-advice and protocol-assistance requests



Objectives

| Objective | |
|--|-------------|
| Increase engagement with health technology assessment bodies from early medicine development throughout the medicinal product's lifecycle, including participation in scientific-advice discussions (road map initiative). | |
| Performance indicators for the objective | Target |
| Multi-stakeholder scientific-advice procedures | 5 completed |
| Objective | |
| Continue to implement action plan for reinforcement of biomarker-qualification procedure, based on outcome of assessment of impact of procedure on qualification of novel methodologies. | |

Core business performance indicators for the area

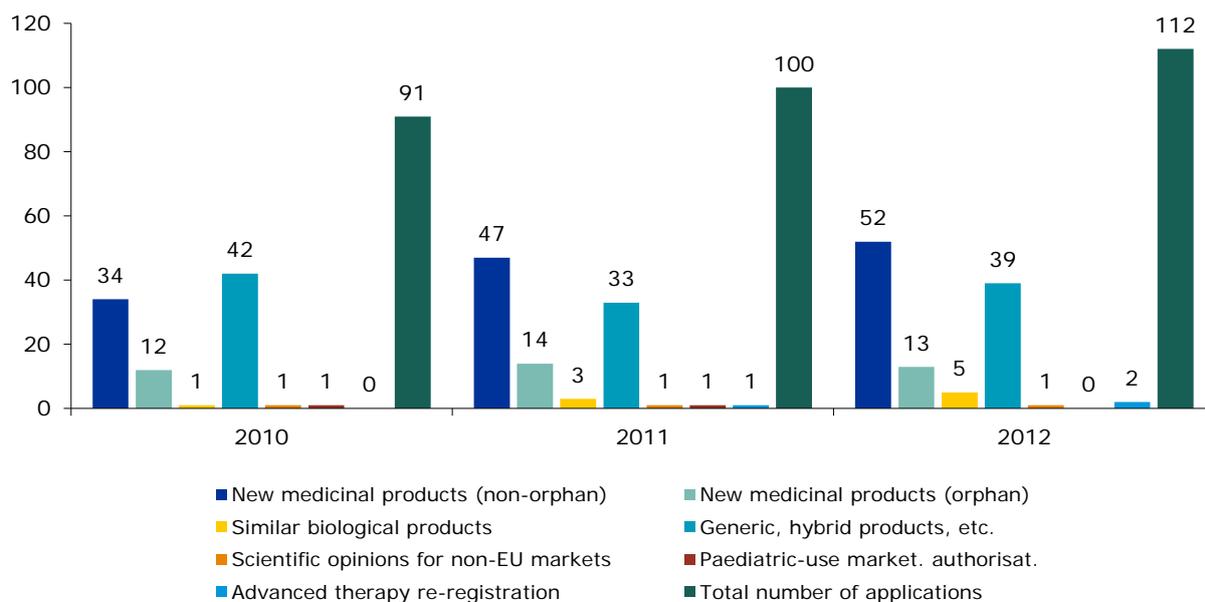
| Performance indicator | Target 2012 | Actual 2010 |
|--|---------------------|-------------|
| Scientific-advice and protocol-assistance requests evaluated within the procedural timelines | 100% of requests | 99.5% |
| Percentage of marketing-authorisation applications for new technology products having received scientific advice/protocol assistance | 50% of applications | n/a |

2.3. Initial evaluation

Trends and new issues

- Recommendation stemming from the evaluation of the Agency expressing stakeholder expectations, in particular the need to strengthen monitoring, quality assurance and consistency of Agency outputs.

Figure 3. Applications for initial evaluation



Objectives

| Objective | |
|--|--------|
| Review procedure for centralised initial applications to include early dialogue with rapporteur and Agency and to define roles and responsibilities in the early phase, exploring the possibility of earlier appointment/continuous rapporteurship on a voluntary basis (road map initiative). | |
| Performance indicators for the objective | Target |
| Initiate review procedure | Q4 |
| Objective | |
| Continue work on development of more quantitative tools aimed at improving the consistency of the benefit-risk assessment process (road map initiative). | |
| Performance indicators for the objective | Target |
| Implementation of findings | Q4 |
| Objective | |
| Ensure adequate standards of quality, consistency, simplification and harmonisation of CHMP assessment reports, opinions and related templates and guidelines (this objective is also relevant for post-authorisation activities). | |
| Performance indicators for the objective | Target |
| Implementation of action plan | 100% |

| Objective | |
|--|----------------------------------|
| Strengthen monitoring, quality assurance and consistency of CHMP initial evaluation (day 120 list of questions). | |
| Performance indicators for the objective | Target |
| Peer-review of initial marketing-authorisation-assessment reports (day 80 assessment reports and peer-review teleconference) | 100% of non-generic applications |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|--|--------------------|--------------------|
| Percentage of applications evaluated within the regulatory timeline: | | |
| • marketing-authorisation applications (210 days); | 100% | 96% |
| • accelerated assessment applications (150 days); | 100% | 100% |
| • plasma-master-file applications. | 100% | 100% |
| Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days | 100% | 100% |

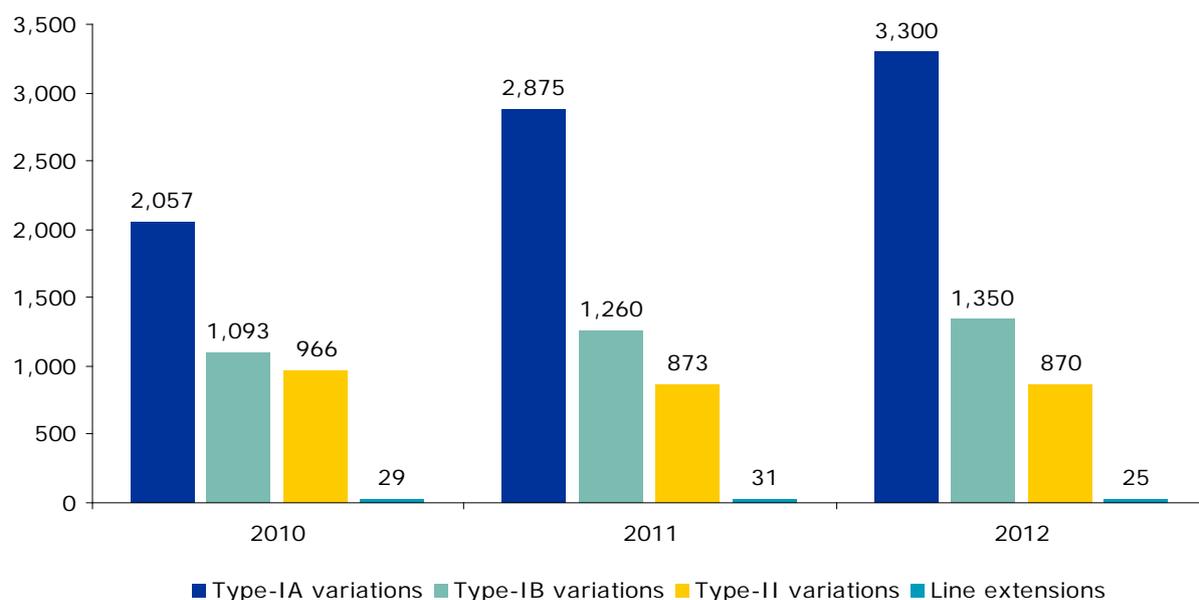
2.4. Post-authorisation and maintenance activities

Trends and new issues

- The implementation of new legislation on post-authorisation efficacy and safety and pharmacovigilance in mid-2012 will have high impact in later years.
- Extension of scope of Variations Directive to national (non-MRP/DCP⁶) products likely to impact on worksharing procedures handled by the Agency.

⁶ MRP = mutual-recognition procedure; DCP = decentralised procedure.

Figure 4. Post-authorisation applications (2010 to 2012, based on revised classification)



Objectives

| Objective | |
|---|--------|
| Strengthen consistency of scientific assessment related to changes to the marketing authorisation with particular relevance for the benefit-risk assessment throughout the product lifecycle (road map initiative). | |
| Performance indicators for the objective | Target |
| Extended peer-review process for primary assessments of major changes to the marketing authorisation (e.g. variations and extensions) | Q4 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|----------------------|------------------|
| Percentage of applications for post-authorisation procedures evaluated within the regulatory and procedural timelines | 100% of applications | 93% (on average) |
| Percentage of the Agency's recommendations on classification of variations delivered within the regulatory timelines | 100% compliance | 82% |
| Percentage of grouping and worksharing procedures completed within 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 | 86% |
| Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check | 100% of applications | 70% |

2.5. Pharmacovigilance activities

Trends and new issues

A key goal for the Agency is to prepare for the implementation of the new pharmacovigilance legislation as of mid-2012. Major processes will need to be newly established or amended, or preparation will be needed for full introduction in 2013 and beyond.

In the past, the majority of the pharmacovigilance work undertaken by the Agency related to the 568 centrally authorised products for human use. While the number and complexity of procedures for centrally authorised products will increase, the most important change of the new legislation is the increased direct involvement of the Agency in the pharmacovigilance of nationally authorised products. New work includes involvement in the following fields: adverse drug reaction (ADR) reporting and data provision (estimated 80,000 ADR reports per year), data analysis for centrally authorised products to detect new or changing safety issues ('signal detection' - estimated 3,000 analyses in 2012), approval of post-authorisation safety-study protocols and results (624 new assessments per annum), and establishment and maintenance of a listing of product information for all EU medicines.

For other new pharmacovigilance tasks, the Agency has, in collaboration with the Member States, judged which tasks and processes are essential for July 2012 (the date of application of the legislation) and which can be the subject of full implementation in 2013 and beyond.

There will be a need to support vigilance and traceability of substances of human origin, particularly for those substances used in the manufacture of advanced therapy medicinal products.

New ISO standards for the electronic submission of individual case safety reports (ICSRs) and for the identification of medicinal products (IDMP) should be finalised in 2012; see also Section 6.2 – EU telematics.

There will be greater demand for use of epidemiological studies and the ENCePP network.

First results on new pharmacovigilance scientific methods will become available from the IMI Protect project.

There will be a drive to better integrate benefit and risk monitoring in the post-authorisation phase, and this will be achieved through the risk-management plan and inclusion of benefit-risk in the periodic safety update reports (PSURs).

Objectives

| Objective | |
|---|-------------|
| Implement the new pharmacovigilance legislation. | |
| Performance indicators for the objective | Target |
| Revised risk-management process | Established |
| Process for post-authorisation safety studies (PASS) | Enabled |
| New Pharmacovigilance Risk Assessment Committee (PRAC) | Established |
| Procedure on interaction between PRAC, CHMP and CMDh ⁷ | Established |
| Objective | |
| Progress the European signal-management initiative towards an integrated EU system. | |

⁷ CMDh = Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human.

| Objective | |
|--|---------------|
| Undertake the necessary activities in the field of traceability and vigilance of substances of human origin (SoHO). | |
| Objective | |
| Support ENCePP as a functional network of centres for the monitoring of authorised medicines. | |
| Performance indicators for the objective | Target |
| Based on the report prepared in 2011, enhance the functionalities of the existing e-register of studies to meet demands stemming from the new pharmacovigilance legislation | Q4 |
| Guidance on best practice for pharmacoepidemiology studies in light of data privacy legislation finalised and published | Q3 |
| Best-practice guide on interaction with regulators in case researchers have findings of public-health relevance (e.g. submission of study results in relation to timing of publication, scrutiny of analytical data set, etc.) published | Q2 |
| Objective | |
| Coordinate the PROTECT project under the Innovative Medicines Initiative. | |
| Performance indicators for the objective | Target |
| A strategy for the further integration and utilisation of epidemiology in medicine regulation finalised | Q4 |
| Objective | |
| Support DG Research of the European Commission on priorities for drug-safety and regulatory-sciences research needing public funding. | |
| Performance indicators for the objective | Target |
| An annual list of justified and prioritised drug-safety and regulatory-science research questions adopted at Agency level | Q4 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|--------------------|---|
| Percentage of risk-management plans (RMPs) that are peer-reviewed as part of the assessment of initial marketing-authorisation applications | 100% | 100% |
| Percentage of RMPs that are peer-reviewed by the Agency as part of the assessment of variations and line extensions which result in a significant change to a marketing authorisation | 100% | 100% of variations to extend the indication 100% of line extensions (where RMP has been submitted) |
| Percentage of centrally authorised products monitored at least monthly by the signal-detection group | 100% | n/a |

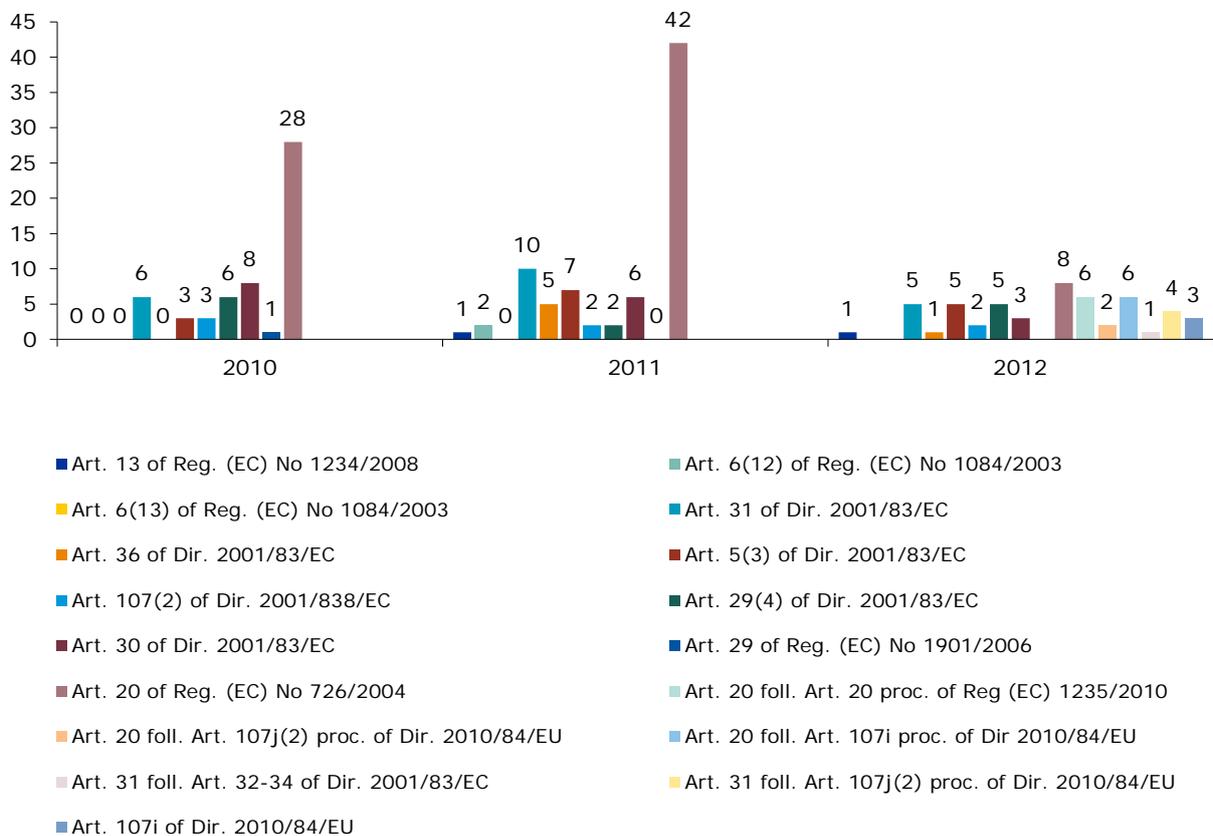
2.6. Arbitration, Community referrals and opinions on scientific matters

Trends and new issues

Changes to referral procedures stemming from the new pharmacovigilance legislation will come into force in the third quarter of 2012. Safety-related referral opinions will be discussed by both the new PRAC and the CHMP or CMDh, depending on the authorisation procedure of the concerned medicinal product(s).

The complexity of the management of safety-related referral procedures is expected to increase following the implementation of the new pharmacovigilance legislation, mainly due to involvement of various scientific committees, the possibility for the Agency to enlarge the scope of referrals to include medicinal products belonging to the same therapeutic class, the possibility for healthcare professionals and the public to submit relevant information, and the possibility of organising public hearings.

Figure 5. Arbitrations and Community referrals (including Article 20 procedures)



Objectives

| Objective | |
|---|--------|
| Implement the new pharmacovigilance legislation with regard to referral procedures. | |
| Performance indicators for the objective | Target |
| Internal and external guidance, SOPs and templates relating to Art. 107(i) and Art. 31 referrals and procedures under Art. 20 updated | Q3 |

| Objective | |
|---|--------|
| Establish interaction with industry associations with regard to improving the handling of referral procedures. | |
| Performance indicators for the objective | Target |
| A working group and a draft work plan with industry representatives on improvement of handling of referral procedures established | Q4 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|-------------|-------------|
| Percentage of arbitration and referral procedures evaluated within the legal timeline | 100% | 100% |
| Publication of question-and-answer documents for all referral procedures at the time of the CHMP opinion | 100% | 100% |
| Publication of the CHMP opinion and assessment report for Art. 5(3) procedures no later than 2 weeks following the CHMP opinion | 100% | 100% |

2.7. Medicines for paediatric use

Trends and new issues

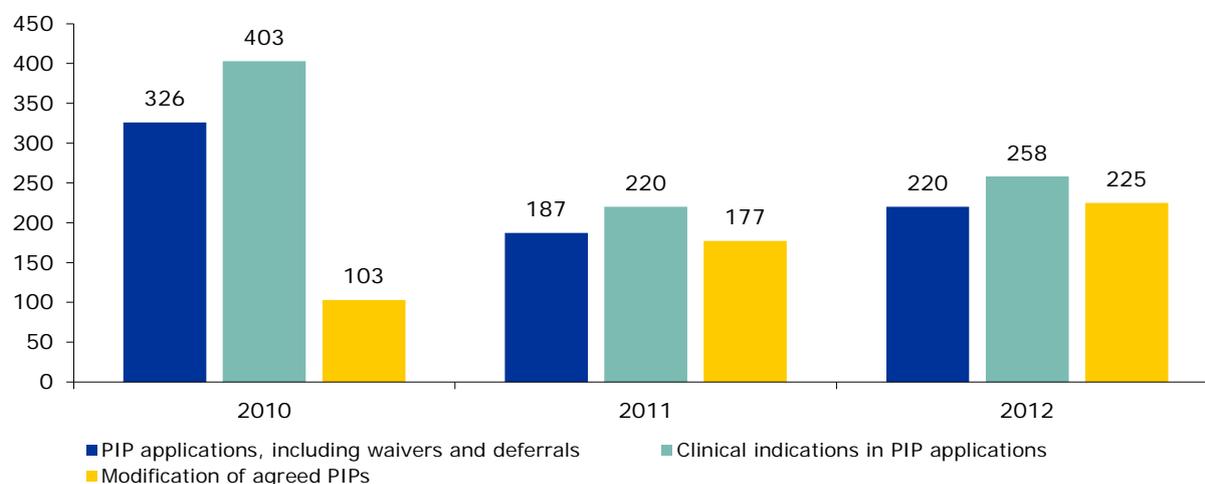
Pharmaceutical forms, non-clinical studies and the methodology of clinical trials will remain critical aspects of the evaluation of paediatric investigation plans (PIPs).

The feasibility of clinical trials and competition for available patients are key issues in conditions that are rare, or highly prevalent in adults but not in children.

Jointly with the Paediatric Committee, consideration will be given to measures to be taken as a result of stakeholder feedback in 2011 after four years of implementation of the Paediatric Regulation.

At the request of the European Commission, the Agency with its Paediatric Committee will in 2012 prepare a report in preparation for the 5-year review of the Paediatric Regulation required by the legislation.

Figure 6. Paediatric investigation plans and related applications



Objectives

| Objective | |
|--|-----------------------------------|
| Implement data quality check of submissions by applicants of third-country (outside EU) paediatric clinical trials in EudraCT. | |
| Performance indicators for the objective | Target |
| Random verification of clinical trials entered by applicants | At least 3% of trials |
| Objective | |
| Increase dialogue with applicants on activities relating to paediatric investigation plans | |
| Performance indicators for the objective | Target |
| Pre-submission meetings and teleconferences organised with applicants for PIPs/waivers | At least 80% of requests accepted |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|----------------------------|-------------|
| Number of PIP or waiver opinions and decisions within legal timelines | 100% of opinions/decisions | 100% |
| Percentage of Agency decisions on paediatric investigation plans/waivers published within 6 weeks of the decision | 95% | 86% |

2.8. Herbal medicinal products

Trends and new issues

Following the end of the transition period by which Member States had to apply the provisions of Directive 2004/24/EC to traditional herbal medicinal products already on the market on 30 April 2004, potentially more marketing-authorisation applications will be submitted via national procedures and the mutual-recognition or decentralised procedures.

The simplified registration procedure may potentially be opened to other traditional products of a long-standing tradition in the EU, including certain products of animal origin.

Objectives

| Objective | |
|---|--------|
| Respond to the possible extension of the scope of the simplified registration procedure. | |
| Performance indicators for the objective | Target |
| Contribute to the preparation of a possible extension of the scope by providing scientific and technical support to the European Commission | Q4 |

| Objective | |
|--|---------------------|
| Report on the uptake of the traditional-use registration scheme. | |
| Performance indicators for the objective | Target |
| Publish and update on a 6-monthly basis an overview of applications received, under evaluation and registrations granted per Member State | Publication Q2 & Q4 |
| Report on the impact of published Community herbal monographs on assessment of marketing authorisations and traditional-use registrations granted by the Member States | Publication Q4 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 | Actual 2011 |
|---|----------------|-------------|-------------|
| Community herbal monographs: | | | |
| • final; | 20 | 19 | 20 |
| • released for public consultation. | 20 | 20 | 21 |
| Community list entries: | | | |
| • transmitted to the European Commission; | 5 ⁸ | 3 | 0 |
| • released for public consultation. | 5 | 2 | 0 |

2.9. Advanced therapy medicinal products

Trends and new issues

It is recognised that advanced therapy medicinal products (ATMPs) are new, complex products with requirements that go beyond those from the traditional pharmaceutical field. Regulatory procedures and guidelines are necessary to provide a clear path for the development of safe and effective ATMPs. The Committee for Advanced Therapies (CAT) has already reviewed and will continue in 2012 to review scientific-advice and classification requests for ATMPs. The majority of these products under development, however, have not yet reached the marketing-authorisation stage. It is therefore envisaged that in 2012 the number of marketing-authorisation applications will not exceed 5.

In 2012, industry and Member States will also face the end of the transitional period, by which, according to the provisions of Article 29 of the Advanced Therapies Regulation⁹, all ATMPs have to be centrally authorised. However, not all companies are likely to apply for a centralised application, as some of their products will remain on the market via the 'hospital exemption' clause in the ATMP legislation. Two applications for tissue-engineered products are expected to enter the centralised procedure for re-registration in 2012.

⁸ Depending on the genotoxicity data situation.

⁹ Regulation No (EC) 1394/2007.

Objectives

| Objective | |
|--|--|
| Review the implementation of the Advanced Therapies Regulation and advanced therapy medicinal products processes on the basis of experience gained in the first 4 years of operations. | |
| Performance indicators for the objective | Target |
| Contribution to the report of the European Commission on the application of the Advanced Therapies Regulation as foreseen in Article 25 | Q4 |
| Report on the use and implementation status of the ATMP certification procedure published | Q4 |
| Objective | |
| Strengthen dialogue of the CAT with its stakeholders (industry, academia, hospitals, charities, regulators), with a view to facilitating development of ATMPs and access to the marketing-authorisation procedure. | |
| Performance indicators for the objective | Target |
| Provision of support to: <ul style="list-style-type: none"> external stakeholders to increase awareness and understanding of scientific guidelines, assessors and inspectors to facilitate the evaluation of ATMP marketing-authorisation applications and inspection of ATMP manufacturing facilities | by Q4 provide <ul style="list-style-type: none"> Scientific workshop Tutorial training |
| Action plans from the 2011 CAT Interested Parties Focus Group interactions implemented | Report on the actions by Q4 |
| Investigation of specific difficulties faced by academia, charities and hospitals addressing unmet medical needs (road map initiative) | Dedicated meeting with relevant stakeholders by Q4 |
| Objective | |
| Consolidate and streamline the consultation and interactions with notified bodies for medical devices for the evaluation of combined ATMPs. | |
| Performance indicators for the objective | Target |
| The implementation of the procedure for the consultation of notified bodies for medical devices for combined ATMPs reviewed and the consultation procedure revised if needed | Q4 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|----------------------|-------------|
| Applications handled by the Committee for Advanced Therapies 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 | 100% |

2.10. Emerging therapies and new technologies

Trends and new issues

The field of borderline and combined products is significantly expanding as a result of converging technologies, e.g. required for new products encompassing more functionalities (e.g. diagnostic and treatments in the case of certain emerging nanomedicines).

New enabling technologies emerge that impact on all stages of development and clinical use of such emerging therapies, for example genomics (including epigenetics) and nanotechnology applications of pharmaceuticals (including new liposomal formulations of different levels of complexity).

New technologies are prompting the development of innovative tools in non-clinical and clinical development, including identification and use of translational biomarkers, novel biomarkers suitable for enrichment and stratification in clinical trials, as well as personalised medicines in the clinical setting.

Objectives

| Objective | |
|--|-------------------|
| Review impact of genomics in personalised medicines evaluated in the Agency's procedures (road map initiative). | |
| Performance indicators for the objective | Target |
| Contribution to European Commission's report on personalised medicines | Q4 |
| Objective | |
| Promote Agency and European network competences development in the area of nanomedicines, genomics and emerging therapies. | |
| Performance indicators for the objective | Target |
| Training sessions for senior assessors during working party plenary meetings | 2 sessions |
| Content and outcome of the training published on the Agency's website | 1 paper published |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|--|------------------|-------------|
| Innovation Task Force (ITF) briefing meetings organised within 60 days from receipt of a request | 100% of meetings | 100% |
| Percentage of ITF reports on requests for CHMP scientific recommendation on eligibility as a medicinal product for Agency procedures and as a new, emerging or borderline medicinal product (excluding ATMPs) given within 60 days | 80% of requests | 100% |

2.11. Scientific committees, working parties and scientific advisory groups

Trends and new issues

In 2012, the new Pharmacovigilance Risk Assessment Committee (PRAC) will be inaugurated and will replace the CHMP Pharmacovigilance Working Party, in line with the new pharmacovigilance legislation. Interactions between the CHMP and the new PRAC need to be established and current interactions between the CHMP and the CMDh need to be reviewed.

Another important activity will be the continuing coordination of the established Agency scientific committees, their working parties and satellite groups, to ensure the continued quality of scientific opinions delivered by the various committees. In view of the variety of incentives offered to applicants and marketing-authorisation holders in the fields of paediatrics, orphan medicines, variations, advanced therapies and data exclusivity, and their potential interdependence, the complexity of the procedures has increased, requiring increased oversight and management.

A particular challenge in 2012 will be to address the demand for greater transparency of the activities performed by the various Agency scientific fora, in particular with regard to the conduct of meetings and the publication of agendas and minutes.

2.12. Coordination group

Trends and new issues

Provisions of the new pharmacovigilance legislation that will come into force in 2012 will change the scope and strengthen the role of the CMDh, resulting in new tasks for the CMDh and its secretariat:

- Procedural management of referrals discussed at the level of the CMDh and recording of the position taken by the CMDh on Art. 107 and Art. 31 procedures for non-centrally authorised products.
- Appointment of rapporteurs in the framework of worksharing procedures for the assessment of PSURs.
- Coordination of the procedure for consultation of the PRAC following requests received from marketing-authorisation holders regarding the date and frequency of the PSURs.
- Coordination of questions regarding pharmacovigilance for non-centrally authorised products.
- Preparation for the publication of agendas and minutes.

Objectives

| Objective | |
|---|---------------|
| Implement the new pharmacovigilance legislation with regard to activities pertaining to the CMDh secretariat. | |
| Performance indicators for the objective | Target |
| Actions performed in line with the implementation plan for the CMDh secretariat | Q1-Q4 |

3. Veterinary medicines

3.1. Scientific advice

Trends and new issues

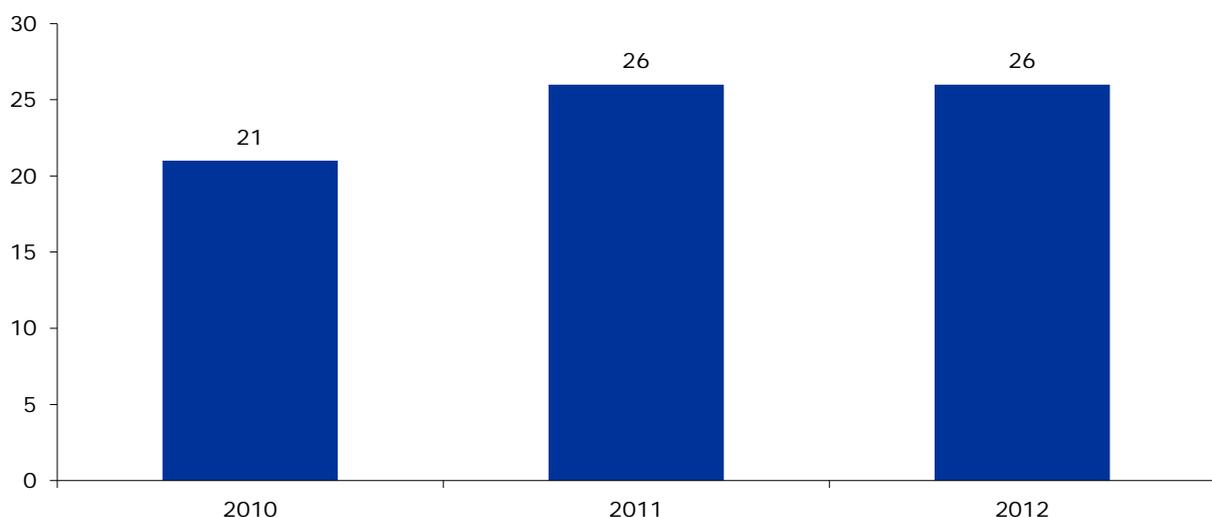
The Agency is keen to promote early applications for scientific advice in relation to the development of veterinary medicines. Uptake has been strong among SME companies (about 60% of total figures in 2009 and 30% in 2010 and 46 % in the first 6 months of 2011) taking advantage of the incentives offered, and this trend is expected to continue in 2012. About one third of applications are received for products not intended to be authorised via the centralised procedure, reflecting the understanding of industry that the procedure is also applicable to other routes of authorisation.

Following a doubling in the total number of applications for scientific advice between 2008 and 2009, and a further increase of 20% between 2010 and 2011, the level of applications is now expected to stabilise in 2012, with 26 applications forecast. Continuing collaboration with the FDA under the confidentiality agreement strongly supports applications for parallel scientific advice. It is hoped that 2012 will show an increased uptake of this type of activity.

MUMS/limited markets

The policy on minor uses, minor species (MUMS) and limited markets came into effect on 1 September 2009, offering the possibility of requesting classification of a product as a MUMS/limited market product by the Committee for Medicinal Products for Veterinary Use (CVMP). In 2010, 22 such requests for classification were received, with a further 16 requests received in the first 6 months of 2011. Many of these will result in requests for scientific advice at some stage in the development process. In 2010, 40% of scientific advice applications had been the subject of a MUMS classification request, as had 40% of those received in the first 6 months of 2011, thus contributing to the availability of products for MUMS and limited markets. A new category of scientific advice has also been introduced whereby applicants can request confirmation of the general data requirements for an application in line with the adopted MUMS data guidelines. An annual report on the MUMS/limited markets policy is published following endorsement by the Agency's Management Board.

Figure 7. Scientific-advice requests



Objectives

| Objective | |
|--|---------------------------------|
| Promote the Agency as the central point of contact for scientific advice in relation to the authorisation of innovative veterinary medicines within the European regulatory network, in the interest of promoting availability and innovation within the EU. | |
| Performance indicators for the objective | Target |
| Number of requests for scientific advice | Remains at 2011 level or higher |
| Objective | |
| Promote classification of products as MUMS/limited market under the policy announced in 2009 to encourage new product applications, and review the policy annually (road map activity). | |
| Performance indicators for the objective | Target |
| Review requests to the CVMP under the MUMS/limited markets policy and publish overview of products classified | Ongoing |
| Produce annual report on MUMS policy | End Q4 2012 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|--|---------------------|-------------|
| Scientific-advice requests evaluated within the procedural timelines | 95% of applications | 100% |

3.2. Initial evaluation

Trends and new issues

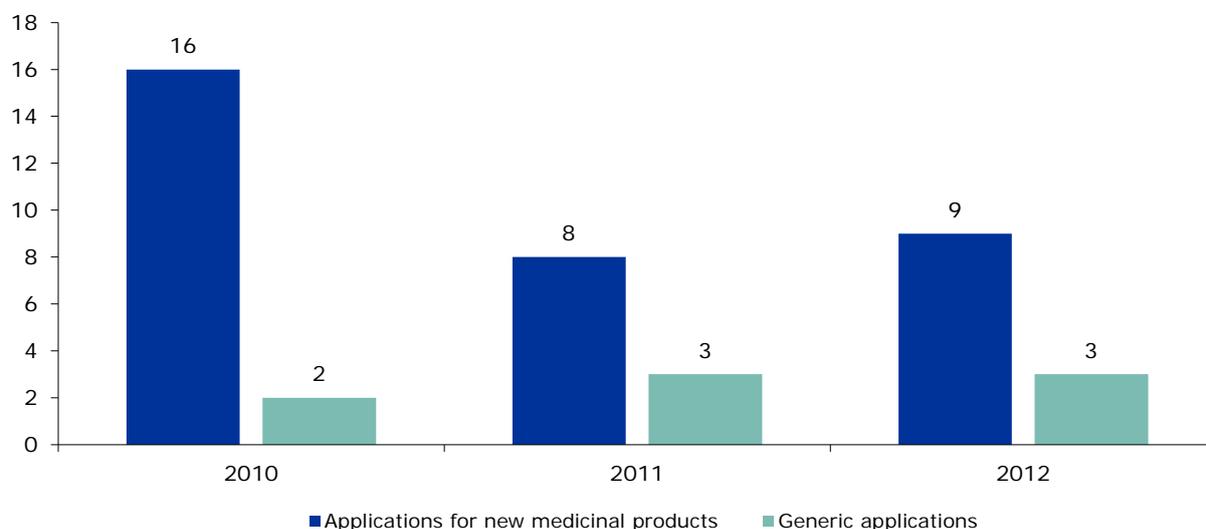
The number of applications in 2011 saw a decline compared to the previous two years, for the following reasons:

- In recent years, around 20% of new applications were requests for authorisation under exceptional circumstances for vaccines against epizootic diseases of livestock (avian influenza and bluetongue, in particular). With the availability of authorised products against avian influenza and bluetongue, and no new outbreak or known risk of an outbreak of an epizootic disease of livestock at present, only one further application for a vaccine against an epizootic disease was submitted in 2011.
- While the Agency's measures regarding the development of products for MUMS/limited markets have been very successful in terms of requests for classification and free scientific advice, together with incentives for development, the impact on applications for authorisation will take some time to feed through; 3 positive opinions for new products were adopted and 1 new application was received in 2011.
- Applications for generic versions of centrally authorised products continue to be limited due to the small number of molecules with the necessary commercial potential.
- The current economic situation has started to have an apparent impact on the decisions of companies to register new products.

There continues to be an increased demand for advice with respect to the submission of innovative products for veterinary medicines through the centralised procedure, including a number of medicines

containing active substances of biological origin, such as cytokines and novel vaccines. The CVMP hopes to receive at least 2 applications based on advanced therapies in the veterinary area in 2012.

Figure 8. New applications for veterinary medicines



Objectives

| Objective | |
|---|--------------------------------|
| Strengthen the quality-assurance system in respect of CVMP procedures, to ensure the quality and consistency of the scientific assessments conducted, with particular emphasis on embedding benefit-risk analysis as part of the methodology of assessment (road map activity). | |
| Performance indicators for the objective | Target |
| Submission of CVMP peer-review reports | 90% |
| Objective | |
| Promote authorisation through the centralised procedure of vaccines against epizootic diseases of livestock (road map activity). | |
| Performance indicators for the objective | Target |
| Assist the European Commission in developing proposals for legislation appropriate to the particular requirements of vaccines for controlling outbreaks of epizootic disease, incorporating the concept of benefit-risk assessment | Proposals developed by Q2 2012 |

Core performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|----------------------|---|
| Percentage of products evaluated within the regulatory timeline of 210 days | 100% of applications | 100% target fully met. Two bluetongue applications were on accelerated timetables and so were evaluated within 180 days. |

3.3. Evaluation of applications for maximum residue limits

Trends and new issues

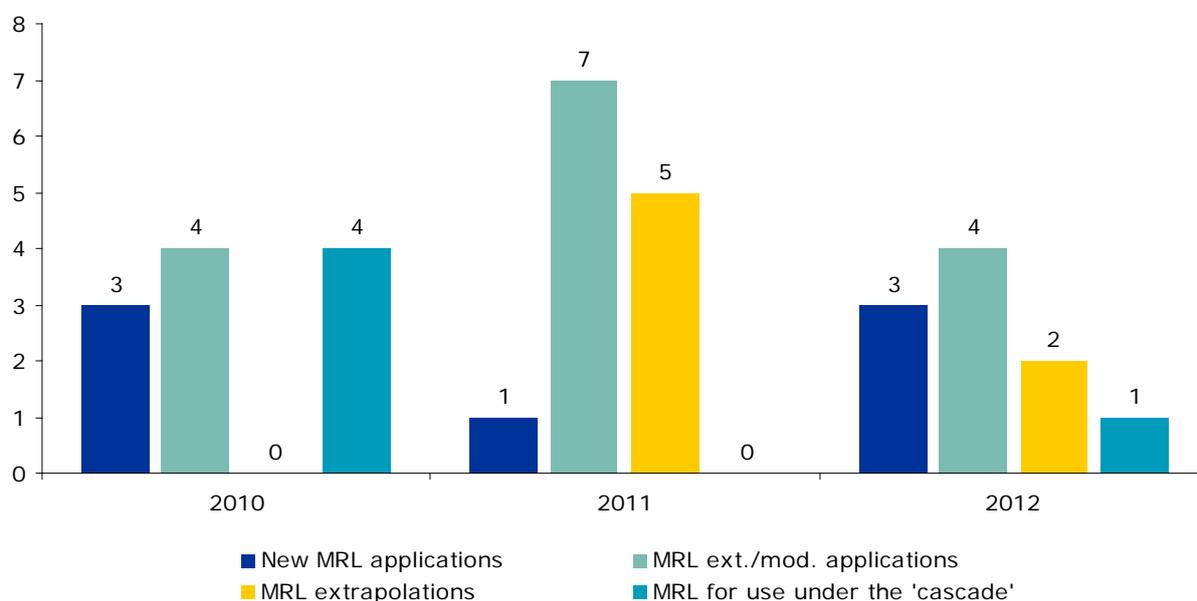
A low but constant number of new molecules for use in food-producing animals are being developed and this is expected to result in a steady state of maximum residue limit (MRL) applications. An increase in MRL applications for extension to new animal species and food commodities has been observed in recent years, but is expected to also reach a steady state in the coming years.

Further to the implementation of the MRL Regulation providing for Codex Alimentarius MRLs to be automatically adopted by the European Union if no objections are raised by the EU, the Agency/CVMP is expected to evaluate the MRLs proposed by the Codex in order to substantiate the EU position. In view of the Codex meeting schedule and the substances evaluated by the JECFA¹⁰, no requests have yet been submitted to the CVMP, but it can be estimated that some will need to be processed in 2012.

Although the new MRL Regulation gave the Agency responsibility for substances included in biocidal products used in animal husbandry, for which MRLs should be established in accordance with Directive 98/8/EC, no such requests have been received yet. The submission of such applications is expected to follow once the guidance on the evaluation of these substances for the purpose of establishing MRLs has been finalised, which is expected to be in the middle of next year. The evaluation of substances that are already on the market will be stretched over several years.

An increased need to consider the revision of previous opinions for the establishment of MRLs has resulted from implementation of the new legislation and from new developments on regulatory aspects or scientific knowledge. This is expected to result in an increased number of requests for revision of existing MRLs, which will increase the workload in this area.

Figure 9. New MRL applications



¹⁰ JECFA = Joint FAO/WHO Expert Committee on Food Additives.

Objectives

| Objective | |
|---|-------------------------------|
| Continue to further strengthen the quality-assurance system in MRL assessment, and foster systems for peer-review of the quality and consistency of scientific assessments. | |
| Performance indicators for the objective | Target |
| Submission of comments by CVMP peer-reviewers | 90% |
| Objective | |
| Finalise and implement the procedure for establishment of MRLs for biocides. | |
| Performance indicators for the objective | Target |
| Development of procedural guidance | Adoption of guidance |
| Objective | |
| Harmonisation of international standards for the establishment of MRLs. | |
| Performance indicators for the objective | Target |
| Collaboration with international bodies such as Codex Alimentarius on specific approaches and methodologies related to the establishment of MRLs | Harmonised guidelines adopted |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|--|---|-------------|
| Percentage of MRL applications evaluated within the legal timeline | 100% of applications | 100% |
| Assess biocide applications within agreed deadlines | 100% for new applications, 90% for old biocidal products | n/a |

3.4. Post-authorisation and maintenance activities

Trends and new issues

The increased workload for the Agency and the EU regulatory network with regard to the Variations Regulation¹¹ is anticipated to continue in 2012.

The numbers of type-IA and -IB variations are expected to continue to increase gradually with the increased number of centralised marketing authorisations. In addition, the number of type-IB applications has proven to be higher than originally predicted due to the new Variations Regulation, under which many variations were downgraded to type IB, and the change of the default classification from type II to type IB. These factors are considered in the forecast for 2012.

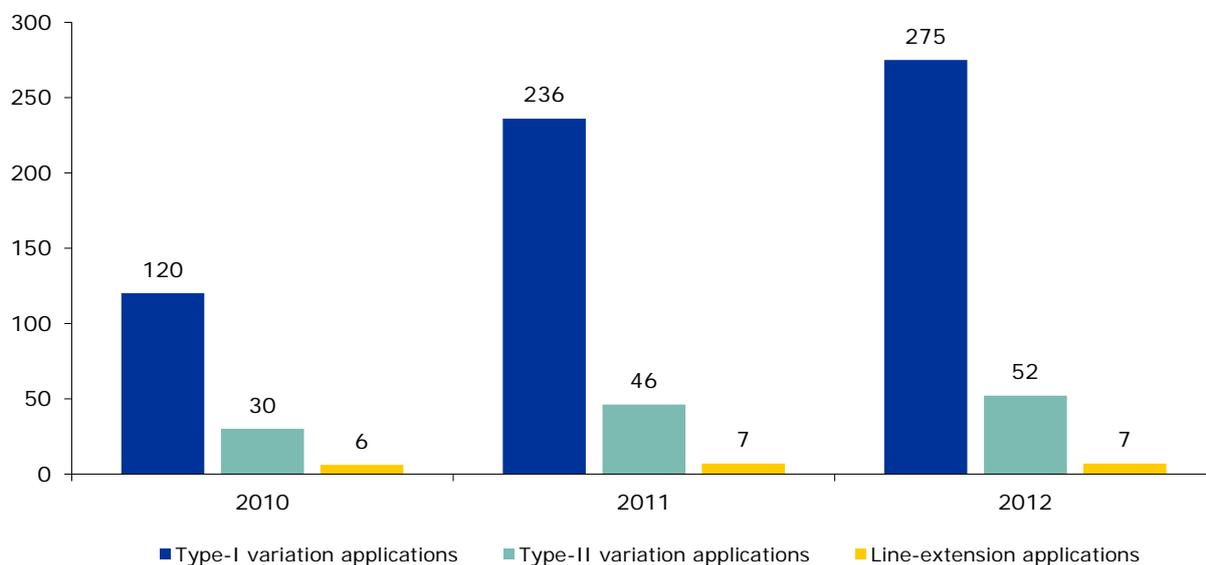
For the same reasons, the number of type-II variations is cautiously predicted to be at approximately the same level as in 2011.

The number of line extensions remains low, mainly due to the main types of marketing authorisations for veterinary medicines in the last years.

¹¹ Regulation (EC) No 1234/2008.

The Commission is expected to propose some amendments to the text of the Variations Regulation and the classification and procedural guidance documents. These will need to be taken into account in the Agency's post-authorisation guidance.

Figure 10. Post-authorisation applications



Objectives

| Objective | |
|---|---|
| Revision of procedures following revision of the Variations Regulation and Commission classification guidance document. | |
| Performance indicators for the objective | Target |
| Revised guidance in place | In time for application of new requirements |

Core performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|--|---------------------|-------------|
| All post-authorisation procedures processed in accordance with legal requirements. | 95% of applications | 100% |

3.5. Pharmacovigilance and maintenance activities

Trends and new issues

Now that electronic reporting of adverse event reports has been firmly established by all stakeholders in the EU, the focus has shifted to the analysis and surveillances of the data in EudraVigilance Veterinary (EVVet).

With the Agency having a key coordinating role in the surveillance of all EU pharmacovigilance information, there will be considerable resource devoted to the publication of safety-profile information for veterinarians, as well as the general public, to increase visibility and awareness, with the ultimate goal of increased protection of animal and public health.

There will be continued need for manual quality control and recoding of the available product data until the time of full availability of a fully functional central EU veterinary medicinal product database linked to the revised EVVet, which is under development.

Cautious estimates for 2012 predict the number of expedited adverse-event reports for centrally authorised products to be around 4,500 (estimate for 2011: 4,500; actual for 2010: 4,474).

The number of PSURs submitted in 2012 for centrally authorised products is expected to remain stable, at 125 (estimate for 2011: 126; actual for 2010: 118).

Objectives

| | |
|---|--|
| Objective | |
| Ensure the implementation and coordination of risk-based pharmacovigilance-surveillance procedures for all adverse-event reports within EVVet related to centrally authorised products. | |
| Performance indicators for the objective | Target |
| Organise, coordinate and track risk-based surveillance of EVVet data | Surveillance procedures to cover 100% of adverse-event reports for CAPs |
| Training of Member States and MAHs | Training provided |
| Objective | |
| Ensure the availability of EU product data and relevant recoding. | |
| Performance indicators for the objective | Target |
| Continued updates of available product information and recoding | 100% recoding for CAPs 80% availability of all non-CAP product information 80% recoding of non-CAP product information (provided that the relevant data are made available by Member States or industry) |
| Objective | |
| Improve and simplify the EVVet data input and surveillance tools for the Agency and Member States, and align the system to internationally agreed standards. | |
| Performance indicators for the objective | Target |
| New and improved central pharmacovigilance database and surveillance tools for veterinary medicines provided | Release of first version of EVVet3 |
| Objective | |
| Make EVVet3 available for testing with stakeholders. | |
| Performance indicators for the objective | Target |
| Release of EVVet3 in test and release of test programme | 80% finalisation of testing with Member States and industry representatives |
| Objective | |
| Implement EVVet data access for general public. | |
| Performance indicators for the objective | Target |
| Specific data-warehouse queries to be built | Data warehouse queries made available, tested and 100% operational |

| Objective | |
|---|--------|
| Contribute to the review of legislation in the area of pharmacovigilance (road map activity). | |
| Performance indicators for the objective | Target |
| Technical advice provided to the European Commission on developing a framework for post-authorisation risk-management of veterinary medicinal products that is adapted to the needs, expectations and resources of the veterinary sector. | Q2 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|-------------|-------------|
| Percentage of PSURs evaluated within the established timelines | 90% | 93% |
| Percentage of adverse-event reports for CAPs monitored within the established timelines | 90% | 100% |

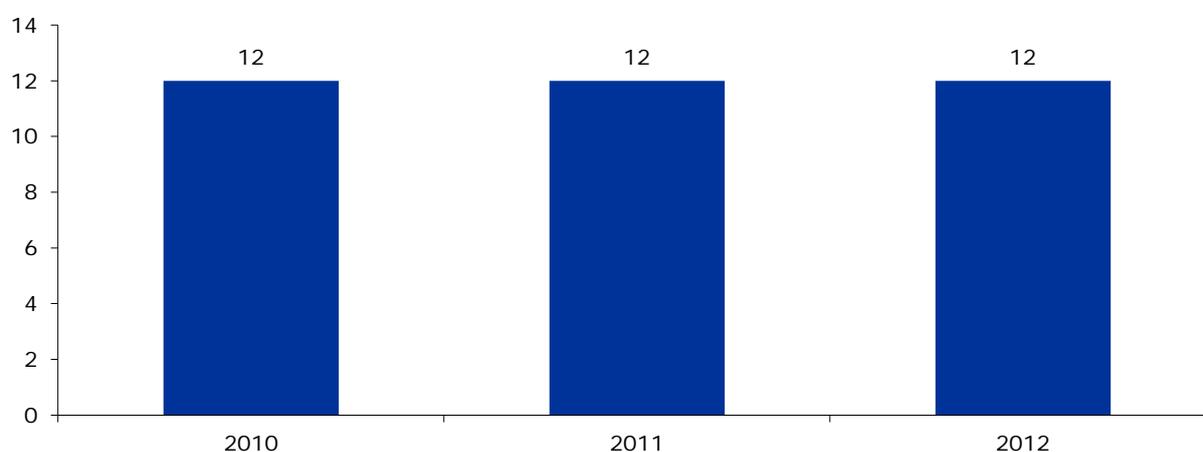
3.6. Arbitration, Community referrals and opinions on scientific matters

Trends and new issues

The Agency will continue to support efforts by the CVMP, CMDv and HMA to tackle issues with a potential for serious risk to animal or public health, or where there is disagreement in approach. Where appropriate, this will be by referral to the CVMP, but efforts will continue to avoid unnecessary or inappropriate referrals.

It is expected that, by 2012, agreement on prioritisation of referrals and harmonisation activities will have been reached between the Agency/CVMP, CMDv, HMA and the European Commission. As a result of this, a certain number of referrals related to harmonisation of products with significant public-health implications may arise, involving a large number of products. Notable amongst these will be class referrals intended to ensure harmonisation of the conditions of use of antimicrobials critically important for use in man, to assure their prudent use in animals, in line with the CVMP Strategy on Antimicrobials. It is not currently possible to predict the number and timing of such referrals, which will be dependent on the European Commission and/or Member States as the potential triggering parties, and it therefore remains difficult to predict the total number of referrals and resources required.

Figure 11. Arbitration and Community referrals



Objectives

| Objective | |
|---|---|
| Work with the network to develop a strategy for progressive harmonisation of existing products that minimises the need for referral to the CVMP and ensures that issues are prioritised on the basis of public and animal health (road map activity). | |
| Performance indicators for the objective | Target |
| Further develop strategy by joint CVMP/CMDv Task Force on referrals and harmonisation, where appropriate | Revised strategy document |
| Objective | |
| Ensure all arbitrations and referrals are handled in compliance with recommendations from the Joint Task Force on Referrals. | |
| Performance indicators for the objective | Target |
| CVMP opinions successfully adopted by the European Commission | 90% of opinions adopted by EC without requests for substantial change |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|--------------------|-------------|
| Percentage of arbitration and referral procedures managed within the legal timeline | 100% of procedures | 100% |

3.7. Scientific committees and working parties

Trends and new issues

The wide range of activities related to veterinary medicines described earlier in this chapter will continue to generate an extremely high workload for the CVMP. The Committee will continue its focus on the quality and consistency of opinions, and on embedding in them the principles of benefit-risk assessment.

Among its many activities, the CVMP — with the support of its Scientific Advisory Group on Antimicrobials and in line with its strategy on antimicrobials for 2010-2015 — will continue its contribution to the work of the EU scientific committees and international organisations in the priority area of minimising the potential for the development of antimicrobial resistance to arise through the use of antibiotics in animals. Pending a solution with regard to sustainable resourcing, the Agency will continue with the pilot phase of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, and will produce an annual report for 2010 on the collection of data on sales and use of antimicrobial veterinary medicinal products in a number of Member States of the EU.

The working parties will continue to provide scientific support to the Committee, in particular to develop and update guidelines, but also to provide advice on specific requests in relation to applications and enquiries from companies. Matters relating to the availability of veterinary products will remain a focus. Following a request from the European Commission, the development of new scientific recommendations on extrapolation of maximum residue limits to other food species and food commodities will be a priority. Advice to applicants on how the Agency will handle new biological veterinary innovations will require further consideration by the Committee.

Participation in the ongoing review by the European Commission of the veterinary legislation is also of high priority to the Committee.

The CVMP, with the support of its working parties, will continue to provide scientific input to prepare the EU position regarding international activities, in particular VICH and Codex Alimentarius.

3.8. Coordination group

Trends and new issues

The number of applications via the decentralised route is expected to continue to increase gradually.

There is a need for the Co-ordination Group for Mutual Recognition and Decentralised Procedures Veterinary (CMDv) to have an active role in effecting the maintenance of harmonisation achieved via Commission decisions following CVMP referrals, and in 2012, the CMDv will most likely start pilot procedures for the transfer of purely national MAs to MRP status following positive Commission decisions for Article 34 referrals.

It is expected that the number of referrals to the CMDv will continue at its present rate of approximately 10 products per year (counting all strengths as one product), of which roughly 4 products are forwarded for arbitration by the CVMP. Almost all referrals to the CMDv concern generics and the issues raised by the objecting Member States are well known to be problematic, e.g. environmental risk-assessment for older reference products, definition of bioequivalence for certain types of product.

Implementation of the new Variations Regulation will result in additional responsibilities for the Group (e.g. Article 5 - recommendation on unforeseen variations).

The CMDv will further develop its transparency initiatives and the secretariat will continue to promote a common approach through the work of the joint Agency/CMDv Working Group. This group will produce guidance on how the principles developed largely by the HMA/Agency group on transparency for documentation related to human applications will be applied in practice for veterinary documentation.

Objectives

| Objective | |
|--|--|
| Support the CMDv in the drafting and publication of new documents. | |
| Performance indicators for the objective | Target |
| CMDv to take over responsibility from EC for the information on national requirements currently held in Chapter 7 of the Notice to Applicants (NtA) | Assistance provided in publishing the previous Chapter 7 requirements on the CMDv website after CMDv rapporteurs have collected updated national information for new and post-authorisation applications |
| Potential review of relevant CMDv best-practice guides if scope of Variations Regulation is extended to purely national MAs | Assist CMDv rapporteurs in updating and publishing necessary CMDv guidance before implementation of any revised legislation |
| Objective | |
| Ensure effective liaison with the CVMP in the interests of the continued availability of veterinary medicines and the smooth functioning of the network. | |
| Performance indicators for the objective | Target |
| Acceptance by the CVMP of procedures initiated by the CMDv | 90% of procedures initiated by the CMDv accepted by the CVMP |

4. Compliance and inspections

Trends and new issues

Responding to the globalisation of clinical trials and of manufacturing of active pharmaceutical ingredients (APIs) and finished products, the Agency will work to extend its international partnerships in the areas of good-manufacturing-practice (GMP) and good-clinical-practice (GCP) inspection, and will work with its partners on tools, agreements and networks to support training and capacity-building, information-sharing and the planning, conduct and follow-up of inspections. The Agency will aim to consolidate its cooperation with the FDA in these domains and begin to extend this cooperation to pharmacovigilance inspection. The Agency will also work to extend the API-inspection programme in conjunction with international partners.

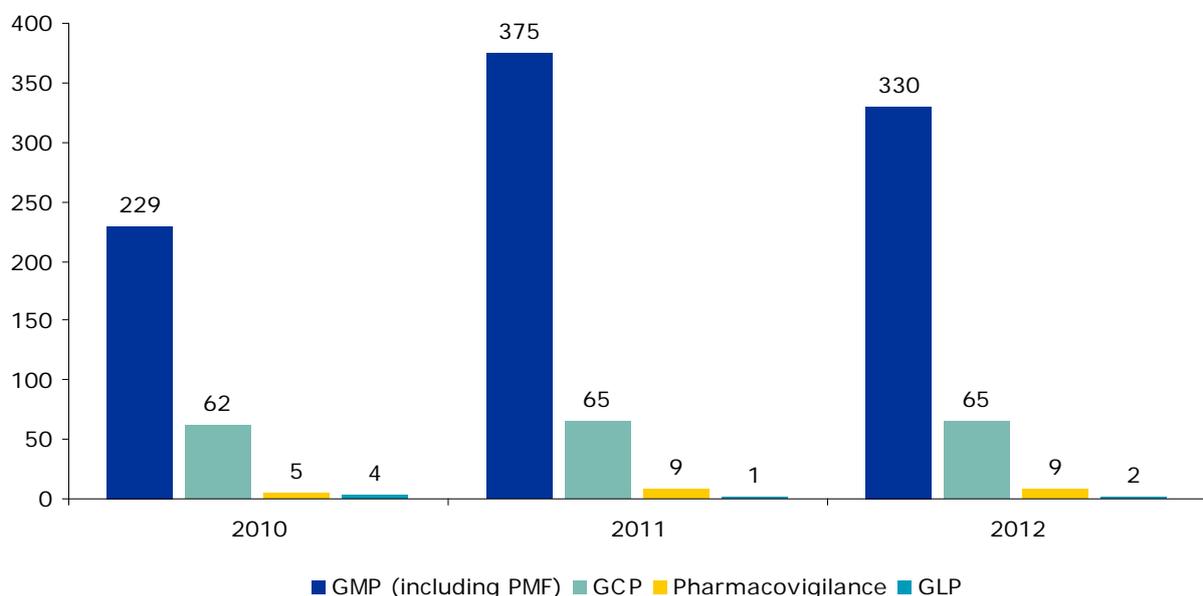
Quality defects are a key concern, with increasingly complex follow-up at EU and international level. A root-cause-analysis project and follow-up on its implementation will be a major activity.

Over the past years, the EU has increasingly been confronted with acute and chronic supply shortages of medicinal products, caused by GMP-compliance problems. This has resulted in changes to prescribing information and patient-allocation programmes.

Implementation of the new pharmacovigilance legislation and preparation for the implementation of the new legislation on falsified medicines will necessitate preparatory work in the area of inspections.

Transparency of clinical-trial information remains a key issue with the anticipated inclusion of summaries of clinical-trial results in EudraCT and in EudraPharm's EU Clinical Trials Register.

Figure 12. Number of inspections



PMF = plasma master file.

4.1. Manufacturing and quality compliance

For trends and new issues, please see above.

Objectives

| | |
|---|----------------|
| Objective | |
| Include new partners in the international cooperation project for API inspections. | |
| Performance indicators for the objective | Target |
| One new partner added, subject to agreement of existing partners | Q3 |
| Objective | |
| Continue Agency/FDA GMP-inspection initiative. | |
| Performance indicators for the objective | Target |
| Joint inspections conducted | 4 by Q4 |
| Identify differences in GMP interpretation, with harmonisation on these points published | Q1–Q4 |
| Objective | |
| Prepare for the implementation of the anti-falsification legislation. | |
| Performance indicators for the objective | Target |
| Implement the Agency's action plan, including the following: | Q4 |
| <ul style="list-style-type: none"> • support the Commission's preparation of requirements and procedures for listing of third-country API GMP regulatory frameworks and related intermediate processes; • processes for cooperation on international inspection planning developed; • revision of good-distribution-practice (GDP) guidelines finalised; • implementation of work plan for GMP/GDP Inspections Working Group. | Q4 Q3 Q4 |
| Objective | |
| Complete the sampling and testing programme. | |
| Performance indicators for the objective | Target |
| The 2012 sampling and testing programme completed in cooperation with the EDQM | Q1-Q4 |
| The 2013 sampling and testing programme prepared | Q2 |
| Objective | |
| Manage the mutual-recognition agreements (MRAs) with third countries | |
| Performance indicators for the objective | Target |
| Review MRA activities as appropriate in line with new legislation and objectives of each MRA | Q1-Q4 |
| Objective | |
| Undertake initiatives to address product-supply shortages caused by GMP-compliance problems | |
| Performance indicators for the objective | Target |
| The reflection paper on product-supply shortages finalised | Q1 |
| Discuss this reflection paper with the European Commission and the HMA | Q2-Q3 |
| The implementation plan finalised | Q4 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|--|----------------------------------|-------------|
| Management of inspections within legislative timelines (see Fig. 12) | 100% | 100% |
| Complete the sampling and testing programme (41 products) | 100% of samples taken and tested | 100% |

4.2. Clinical and non-clinical compliance

For trends and new issues, please see above.

Objectives

| Objective | |
|---|--------|
| Continue Agency/FDA GCP-inspection initiative and progress with harmonisation issues and information exchanges. | |
| Performance indicators for the objective | Target |
| The scope of joint inspections reviewed | Q1 |
| Collaborative inspections conducted (observational and joint inspections) | 6 |
| Initiate extension of the scope of the initiative to bioequivalence inspections | Q1-Q4 |
| Initiate extension of the scope of the initiative to pharmacovigilance inspections | Q1-Q4 |
| Objective | |
| Extend international collaboration on GCP inspections to other international partners. | |
| Performance indicators for the objective | Target |
| Partners of interest identified | Q1-Q4 |
| The scope of the collaboration identified | Q1 |
| The network of GCP inspectors consolidated, building on links with GCP-inspector/clinical-trial networks in other regions | Q1-Q2 |
| Objective | |
| Prepare for the implementation of the new pharmacovigilance legislation and implement that legislation when it comes into force in July 2012. | |
| Performance indicators for the objective | Target |
| In conjunction with the national competent authorities, finalise GVP sections on quality systems, inspection and pharmacovigilance system master file | Q2 |
| Support the development of inspection-planning and information-sharing systems (including for pharmacovigilance inspection reports) | Q1-Q4 |
| PhVIWG workplan topics to revise inspection procedures in line with the new legislation | Q1-Q4 |

Core performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|--|---------------------|-------------|
| Management of inspections within legislative timelines (see Fig. 12) | 100% of inspections | 100% |

4.3. Clinical-trials support

The European Commission is reflecting on the future of the clinical-trials legislation. The Agency will provide its support to the European Commission in this domain.

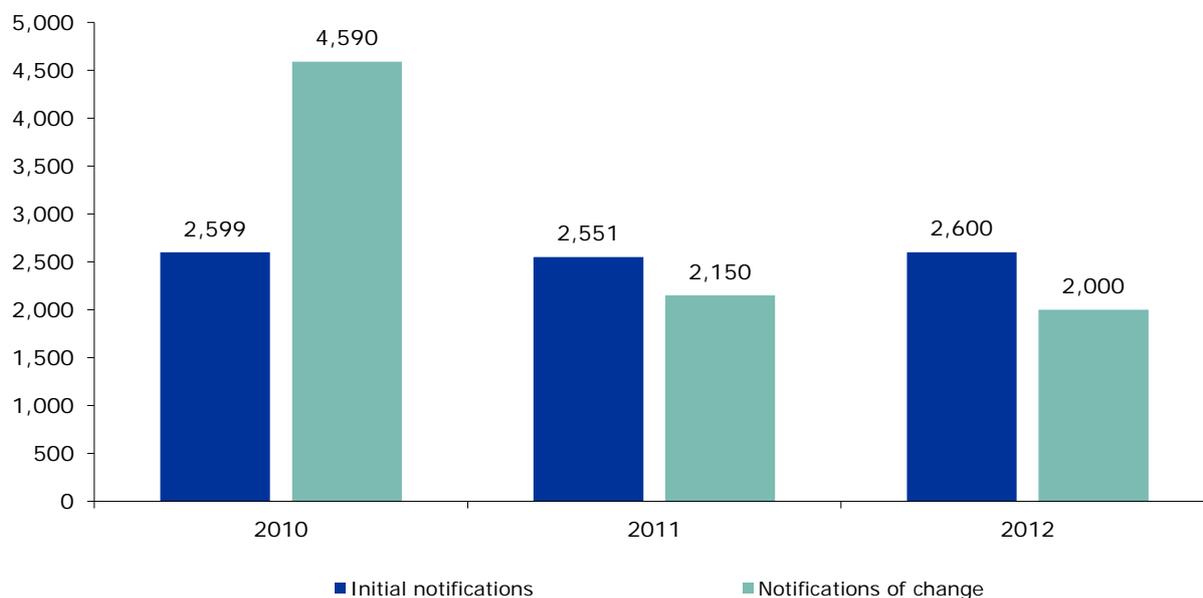
In response to the globalisation of clinical trials, work on further implementing the Agency's strategy on acceptance of clinical trials conducted in third countries will continue, in conjunction with international partners and networks.

Objectives

| Objective | |
|---|--------|
| Support the activities of the European Commission in relation to the ongoing development of their proposal on the revision of the clinical-trials legislation. | |
| Performance indicators for the objective | Target |
| Agency input to the European Commission provided as required, including written contributions, attendance and contribution to workshops, stakeholder meetings and technical meetings | Q1-Q4 |
| Objective | |
| Implement the Agency's strategy for acceptance of clinical trials conducted outside the EU. | |
| Performance indicators for the objective | Target |
| The international network for GCP inspections and GCP-related activities expanded | Q1-Q4 |
| Conduct or support capacity-building activities for inspectors, NRAs and ethics committees | Q1-Q4 |
| Objective | |
| Provide support to CTFG activities (including Voluntary Harmonised Procedure) and ensure communication on decisions taken at Agency level with impact on clinical trials, and at CTFG level with impact on trials included in marketing-authorisation applications or post-authorisation follow-up. | |
| Performance indicators for the objective | Target |
| EudraCT data warehouse reports developed and used | Q1-Q4 |
| Data-management support for EudraCT content provided by NCAs and by sponsors improved | Q1-Q4 |

4.4. Parallel distribution

Figure 13. Parallel-distribution notifications



Notifications of change have decreased due to process improvements that have reduced the requirement for submitting notifications of change to those that have an impact on safety and/or quality.

Objectives

| Objective | |
|---|--------|
| Simplify the regulatory requirements for notifications of a change. | |
| Performance indicators for the objective | Target |
| A risk-based approach implemented | Q2 |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|-------------|---|
| Percentage of initial notifications checked for compliance within the regulatory timeline: paper submission, validation and regulatory check: 35 days | 90% | 64% It was not possible to meet the target due to the increasing workload and the historical backlog |
| 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.

4.5. Certificates

Trends

The number of certificate requests is expected to be around 3,000 (same as the anticipated actual number for 2011).

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|-------------|-------------|
| Percentage of certificates of medicinal products issued to requesting parties within the timeline | 90% | 90.5% |

5. Information and communications technology

Trends and new issues

The implementation of the new pharmacovigilance legislation influences significantly the nature of projects undertaken by the Agency. It should be noted that a significant part of the implementation of the legislation has been deferred to 2013-2014.

The expected entry into force of the falsified medicines legislation will also impact the ICT projects.

The Agency and the network are also working to respond to the increasing demand on their resources. The ICT projects that can increase the efficiency of the Agency and the network are foreseen for 2012.

A number of projects planned for 2012 are ones that were started in the past and need to be brought to completion.

Periodic testing and upgrading of business-continuity infrastructure will continue to be undertaken.

5.1. Implementation and operation of ICT in support of internal activities

Objectives

| Objective | |
|---|---|
| Implement the projects that will improve the efficiency of the Agency's activities. | |
| Performance indicators for the objective | Target |
| Resource-management projects | Phase 2 of HR project. The system will improve the administration of human resources within the Agency. Phase 2 is planned to follow on from the successful delivery of HR 1 in October 2011. The second phase of the FIN project will be started in 2012. |
| Projects improving management of processes | Siamed II: Extend Siamed II to allow Siamed I to be phased out by Q3. Electronic signatures. A system allowing the Agency to receive and produce electronic signatures for electronic applications will be available by the end of Q4. Gateway: Automation of manual processes covering submission via the Gateway (receiving, validation, registration) by Q3. |
| Projects improving quality of data input, processing and management | Records management will be rolled out across further processes by Q2 2012. Enpr-EMA: A system to support the European Network of Paediatric Research will be made available in Q3. Quick Wins: A total of 15 systems with limited functionality, scalability and user community will be implemented. |

| Objective | |
|--|---|
| Implement systems facilitating public access to documents and information. | |
| Performance indicators for the objective | Target |
| Regulation (EC) 1049/2001 on access to documents | Ask EMA: Deliver in Q4 a system to support the Agency policy on access to documents in line with Regulation 1049/2001 |
| Requests for information | Ask EMA: Deliver in Q4 a system to support the Agency policy on requests for information |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|-------------|---|
| Projects delivered on time | 85% | 67% by number; 63% by value. The main reasons for the performance being lower than planned are that a number of projects started late, others were more technically challenging than initially estimated, and others suffered from a lack of available resource. |
| Projects delivered to original specifications | 100% | 54% by number; 84% by value. The performance of a number of projects was reduced because, despite being delivered to specification, they did not include lessons learnt and closure reports. Lack of available resource also impacted planned delivery of projects to original specifications. |
| Projects delivered within budget | 85% | 85% by number; 72% by value. The lower performance by value is due to some projects proving to be more technically challenging than anticipated and to modifications in contractors' seniority and rate. |

5.2. EU telematics

Objectives

| Objective | |
|---|--|
| Support the European medicines network through ICT systems. | |
| Performance indicators for the objective | Target |
| Improved communication | EudraLink: A new version will be made available in 2012. |
| Efficient telematics systems that are fit for purpose | EudraVigilance Vet v3.0: Quarterly releases are 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 guidelines and enhanced processes. |
| Projects improving quality of data input, processing and management | Central repository: Make available a central repository of marketing-application dossiers to the national competent authorities by Q3 and a next version in Q4. |

| | |
|--|--|
| | eSubmission gateway: Make available a system for piloting electronic submission of marketing-authorisation dossiers in Q1. Subject to the conclusion of the pilot and desirability of this by the EMRN, move into full production mode before end Q4. eAF: Put in production four EU forms by Q2. |
|--|--|

Objective

| Assure the coherent technical implementation of legislation. | |
|--|---|
| Performance indicators linked to objective | Target |
| Reducing redundant input of information | EUTCT – Full ISO compliance is scheduled, and interoperability across a number of systems is to be achieved. This will reduce the terminology maintenance burden. |
| Increased transparency, communication and provision of information | eSPC: By end Q4, documented requirements and a proof-of-concept model will be provided to prove the applicability and use of information in the summary of product characteristics in clinical systems (e-Prescribing; decision support). |
| EV MS edition | The Agency will continue to support this system in collaboration with the national competent authorities. |
| EudraCT programme | Further releases of EudraCT 8.x: Version 8.2 in Q1 and version 8.3 in Q2. Release 1.2 of the EU Clinical Trials Register (EU CTR) in Q1. Make available iterative releases of EudraCT 9.x, providing support for processing CT results. |
| EudraGDP | The good-distribution-practice database, foreseen in the legislation to support anti-falsification activities, is planned for the year. |
| EudraGMP | Conclude the inception phase of the good-manufacturing-practice database in Q1, the elaboration phase in Q2, and provide two construction iterations by end Q4. |

Objective

| Provide the Agency's contribution to international regulatory activities | |
|---|---|
| Performance indicators for the objective | Target |
| Improved assimilation of EU requirements, leading to coherent EU position | International standardisation: The identification of medicinal products will be finalised, and specifications for the risk-management information and periodic safety update reports are also scheduled for completion. The regulated product submission (vehicle to replace the eCTD) is scheduled to complete its trial-use period, and the registration part of the clinical-trial registration and results standard is scheduled to reach the final draft international standard stage. All will have been shaped by EU requirements. |
| Reference data model | Version 4 of the RDM will provide integration of ISO ICSR and ISO IDMP. |

Core business performance indicators for the area

| Performance indicator | Target 2012 | Actual 2010 |
|---|-------------|---|
| Projects delivered on time | 85% | 43% by number; 20% by value. Technical development issues held up various projects. Difficulties in technical resourcing held up testing projects. One other project was affected by a delay in the planned procurement procedure. |
| Projects delivered to original specifications | 100% | 61% by number; 62% by value. The nature of the functionality to be delivered was re-specified during the year. Lack of available resource resulted in some projects not being delivered. |
| Projects delivered within budget | 85% | 71% by number; 78% by value. The budget overrun is due to greater effort required to deliver original specifications and/or due to underestimating the overall cost of a project. |

5.3. Maintenance and support of ICT

Core business performance indicators (covers EU telematics and corporate ICT)

| Performance indicator | Target 2012 | Actual 2010 |
|--|-------------------|-------------|
| Telematics and internal ICT systems availability measured against Agency working hours | 98% | 98% |
| ICT Service Desk: meeting service-level agreements per system/priority level | (See table below) | |

ICT Service Desk: Performance indicators for meeting service-level agreements per system/priority level

| Severity rating | Description | Resolution time | Target |
|------------------------|--|-------------------|--------|
| 1. Critical | Users are unable to use the system | 4 hours | 80% |
| 2. Severe | The system is operational but use is severely restricted | 1 business day | 80% |
| 3. Important | The system is operational but one or more functions are restricted | 10 business days | 80% |
| 4. Minor ¹² | The system is operational and no functions are restricted | 120 business days | 80% |

¹² Although fixing the 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.

Annex 1 Establishment plan 2010-2012

| Function Group & Grade | Authorised for 2010 | | Occupied as at 31.12.2010 | | | Authorised for 2011 | | Authorised for 2012 | |
|------------------------|---------------------|-----------------|---------------------------|-----------------|--------------|---------------------|-----------------|---------------------|-----------------|
| | 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 | - | 1 |
| AD 15 | - | 4 | - | 4 | 1 | - | 4 | - | 4 |
| AD 14 | - | 5 | - | 5 | 4 | - | 5 | - | 6 |
| AD 13 | - | 6 | - | 6 | 7 | - | 7 | - | 7 |
| AD 12 | - | 37 | - | 35 | 28 | - | 37 | - | 38 |
| AD 11 | - | 36 | - | 34 | 28 | - | 36 | - | 38 |
| AD 10 | - | 32 | - | 32 | 16 | - | 32 | - | 34 |
| AD 9 | - | 35 | - | 32 | 37 | - | 38 | - | 39 |
| AD 8 | - | 43 | - | 42 | 33 | - | 43 | - | 47 |
| AD 7 | - | 38 | - | 36 | 22 | - | 42 | - | 45 |
| AD 6 | - | 39 | - | 35 | 72 | - | 37 | - | 37 |
| AD 5 | - | 34 | - | 34 | 45 | - | 33 | - | 33 |
| Total AD | 0 | 310 | 0 | 296 | 293 | 0 | 315 | 0 | 329 |
| AST 11 | - | 2 | - | 2 | 1 | - | 2 | - | 2 |
| AST 10 | - | 4 | - | 4 | 3 | - | 4 | - | 5 |
| AST 9 | - | 8 | - | 8 | 0 | - | 8 | - | 7 |
| AST 8 | - | 13 | - | 13 | 5 | - | 13 | - | 13 |
| AST 7 | - | 18 | - | 18 | 15 | - | 19 | - | 20 |
| AST 6 | - | 35 | - | 33 | 10 | - | 34 | - | 33 |
| AST 5 | - | 35 | - | 35 | 22 | - | 35 | - | 35 |
| AST 4 | - | 46 | - | 45 | 38 | - | 49 | - | 51 |
| AST 3 | - | 36 | - | 34 | 51 | - | 32 | - | 37 |
| AST 2 | - | 40 | - | 38 | 30 | - | 40 | - | 40 |
| AST 1 | - | 20 | - | 20 | 78 | - | 16 | - | 18 |
| Total AST | 0 | 257 | 0 | 250 | 253 | 0 | 252 | 0 | 261 |
| TOTAL | 0 | 567 | 0 | 546 | 546 | 0 | 567 | 0 | 590 |

| | 2010 | 2010 | 2011 | 2012 |
|-------------------------|------------------------------|-------------------------|-------------|-------------|
| | Actual FTE ¹ used | Actual as at 31.12.2010 | Planned FTE | Planned FTE |
| Contract agents | | | | |
| FG IV | 40.3 | 41 | 68 | 55 |
| FG III | 9.7 | 6 | 15 | 16 |
| FG II | 45.9 | 46 | 64 | 61 |
| FG I | 1 | 1 | 3 | 0 |
| TOTAL | 96.9 | 94 | 150 | 132 |
| National experts | | | | |
| TOTAL | 14.2 | 16 | 20 | 15 |

¹ FTE = full-time equivalent.

Annex 2 Revenue and expenditure overview 2010-2012

| | | 2010 (final) ¹ | | 2011 (budget) ² | | 2012 (budget) ³ | |
|--------------------------------|--|---------------------------|--------------|----------------------------|--------------|----------------------------|--------------|
| | | € '000 | % | € '000 | % | € '000 | % |
| Revenue | | | | | | | |
| 1+5 | Fees and charges | 160,566 | 76.7 | 168,639 | 80.7 | 181,905 | 81.8 |
| 200 | General EU contribution | 24,533 | 11.7 | 28,042 | 13.4 | 22,966 | 10.3 |
| 200 | Surplus from previous year | 14,532 | 6.9 | 5,477 | 2.6 | 9,875 | 4.4 |
| 201 | Special EU contribution for orphan medicinal products | 7,988 | 3.8 | 4,901 | 2.3 | 6,000 | 2.7 |
| 300 | Contribution from EEA | 826 | 0.4 | 784 | 0.4 | 753 | 0.3 |
| 600 | Community programmes | 580 | 0.3 | 560 | 0.3 | 640 | 0.3 |
| 5+9 | Other | 436 | 0.2 | 460 | 0.2 | 350 | 0.2 |
| TOTAL REVENUE | | 209,460 | 100.0 | 208,863 | 100.0 | 222,489 | 100.0 |
| Expenditure | | | | | | | |
| Staff | | | | | | | |
| 11 | Staff in active employment | 61,986 | 30.6 | 67,845 | 32.5 | 68,752 | 30.9 |
| 13 | Mission expenses | 597 | 0.3 | 570 | 0.3 | 835 | 0.4 |
| 14 | Socio-medical infrastructure | 521 | 0.3 | 612 | 0.3 | 597 | 0.3 |
| 15 | Exchange of civil servants and experts | 2,329 | 1.1 | 2,466 | 1.2 | 2,315 | 1.0 |
| 16 | Social welfare | 132 | 0.1 | 245 | 0.1 | 255 | 0.1 |
| 17 | Entertainment and representation expenses | 93 | 0.0 | 32 | 0.0 | 30 | 0.0 |
| 18 | Staff insurances | 2,038 | 1.0 | 2,141 | 1.0 | 2,262 | 1.0 |
| | Total title 1 | 67,695 | 33.4 | 73,911 | 35.4 | 75,046 | 33.7 |
| Building/equipment | | | | | | | |
| 20 | Investment in immovable property, renting of building and associated costs | 19,065 | 9.4 | 20,888 | 10.0 | 20,478 | 9.2 |
| 21 | Expenditure on admin. data processing | 30,789 | 15.2 | 8,864 | 4.2 | 9,135 | 4.1 |
| 22 | Movable property | 1,404 | 0.7 | 1,573 | 0.8 | 1,470 | 0.7 |
| 23 | Other admin. expenditure | 914 | 0.5 | 848 | 0.4 | 1,028 | 0.5 |
| 24 | Postage and communications | 621 | 0.3 | 514 | 0.2 | 493 | 0.2 |
| 25 | Expenditure on other meetings | 90 | 0.0 | 121 | 0.1 | 96 | 0.0 |
| | Total title 2 | 52,883 | 26.1 | 32,808 | 15.7 | 32,700 | 14.7 |
| Operational expenditure | | | | | | | |
| 300 | Meetings | 7,425 | 3.7 | 8,414 | 4.0 | 8,018 | 3.6 |
| 301 | Evaluation of medicines | 70,561 | 34.8 | 71,903 | 34.4 | 79,832 | 35.9 |
| 302 | Translations | 3,580 | 1.8 | 4,396 | 2.1 | 4,479 | 2.0 |
| 303 | Studies and consultants | 58 | 0.0 | 180 | 0.1 | 2,220 | 1.0 |
| 304 | Publications | 131 | 0.1 | 175 | 0.1 | 99 | 0.0 |
| 305 | Community programmes | 480 | 0.2 | 550 | 0.3 | 500 | 0.2 |
| 310 | Data processing related to product lifecycle | 0 | 0.0 | 5,674 | 2.7 | 5,816 | 2.6 |
| 311 | Data processing for special programmes | 0 | 0.0 | 10,852 | 5.2 | 13,779 | 6.2 |
| | Total title 3 | 82,234 | 40.5 | 102,144 | 48.9 | 114,743 | 51.6 |
| TOTAL EXPENDITURE | | 202,813 | 100.0 | 208,863 | 100.0 | 222,489 | 100.0 |

¹ Financial year 2010, as per final accounts.

² Financial year 2011, as per final budget.

³ Financial year 2012, as adopted by the Management Board on 15 December 2011.

Annex 3 Working-party guidelines

Working parties' work plans for 2012, which include information on guidelines, are available on the Agency's website via the links below.

Committee for Medicinal Products for Human Use (CHMP)

[CHMP Biologics Working Party](#)

[CHMP Pharmacovigilance Working Party](#)

[CHMP Safety Working Party](#)

[CHMP Biosimilar Medicinal Products Working Party](#)

[CHMP Biostatistics Working Party](#)

[CHMP Blood Products Working Party](#)

[CHMP Cardiovascular Working Party](#)

[CHMP Central Nervous System Working Party](#)

[CHMP Infectious Diseases Working Party](#)

[CHMP Oncology Working Party](#)

[CHMP Pharmacogenomics Working Party](#)

[CHMP Pharmacokinetics Working Party](#)

[CHMP Rheumatology/Immunology Working Party](#)

[CHMP Vaccine Working Party](#)

[CHMP Gastroenterology Drafting Group](#)

[CHMP Radiopharmaceuticals Drafting Group](#)

[CHMP Respiratory Drafting Group](#)

[CHMP Urology Drafting Group](#)

[CHMP Working Group with Healthcare Professionals' Organisations](#)

Committee for Advanced Therapies (CAT)

[CAT Gene Therapy Working Party](#)

[CAT Cell-based Products Working Party](#)

Committee on Herbal Medicinal Products (HMPC)

[HMPC Working Party on Community monographs and Community list](#)

Committee for Medicinal Products for Veterinary Use (CVMP)

[CVMP Scientific Advisory Group on Antimicrobials](#)

[CVMP Efficacy Working Party](#)

[CVMP Environmental Risk Assessment Working Party](#)

[CVMP Immunologicals Working Party](#)

[CVMP Pharmacovigilance Working Party \(PhVWP-V\)](#)

[CVMP Safety Working Party](#)

[CVMP Scientific Advice Working Party](#)

Other Agency scientific committee working parties

[Human Scientific Committees Working Party with Patients' and Consumers' Organisations](#)

[Joint CHMP/CVMP Quality Working Party](#)