EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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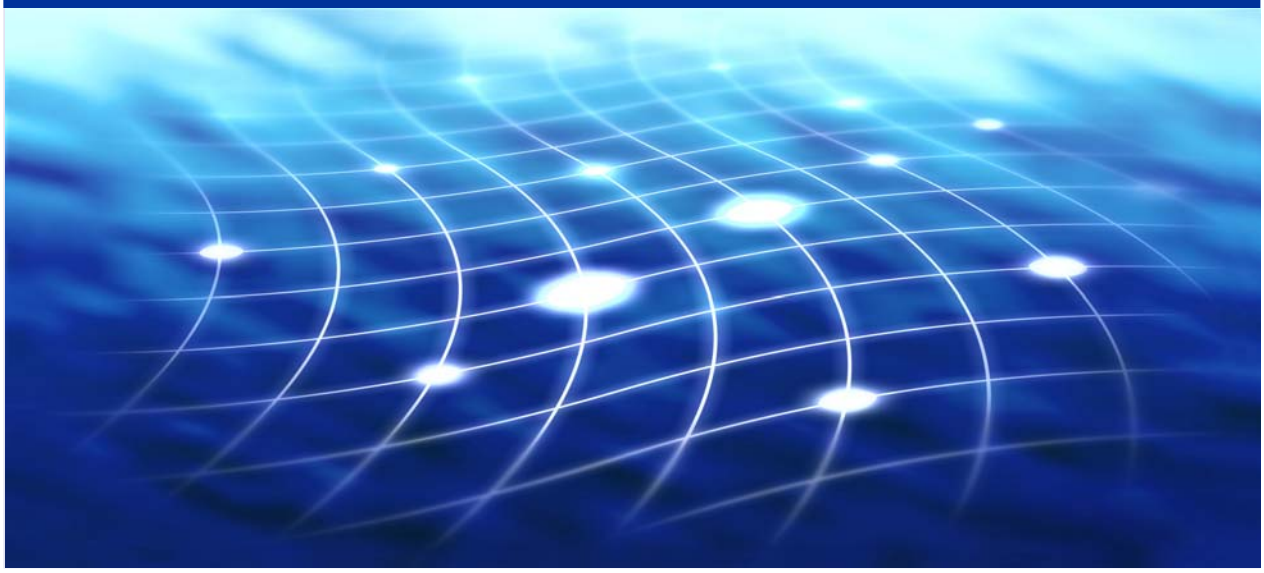
Executive Director

Work programme
2011

Adopted by the Management Board on 16 December 2010



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 2011 provided in the charts in this document are estimates.

Table of contents

Introduction by the Executive Director

Thomas Lönngren

The European Medicines Agency's 'Road Map to 2015' sets three strategic areas of focus for the years ahead: addressing public-health needs, facilitating access to medicines, and optimising the safe and rational use of medicines. The current work programme starts and continues the implementation of activities relevant to those areas.

In 2011, a number of existing and new business environmental factors will shape the Agency's priorities and objectives. The adoption of the new pharmacovigilance legislation will have a major impact on the Agency. In 2011, the Agency will focus on preparing for the application of the new measures in 2012 by preparing new procedures and planning important IT developments.

The Agency will also be affected in the longer term by the ongoing debate within the institutions of the European Union (EU) about the falsified medicines legislation. The debate on the future of the Clinical Trials Directive will continue. We will contribute to the debate and will monitor possible impact on our activities. Some development of the legislative proposal on information to patients may take place, and the Agency will follow and contribute to the progress. As recognised in the road map, EU initiatives in the field of relative effectiveness of pharmaceuticals will also impact on the Agency.

Amid the change and progress, our main priority will remain the management, in an efficient and effective way, of core business activities, which will further increase in 2011. In addition, the Agency will work to advance a number of long-term goals set out in the road map. The focus for 2011 will include:

- successful implementation of new legislation, with the pharmacovigilance legislation being most relevant for 2011;
- effective monitoring of the balance of benefits and risks of medicines, while contributing to a more rational use of medicines;
- communicating and engaging with stakeholders, empowering patients and enabling their participation in healthcare decisions, as well as increasing transparency of the Agency's activities;
- contributing to international activities and responding to globalisation of pharmaceutical research, development and manufacturing;
- responding to public-health needs, including the availability of medicines;
- fostering the European regulatory network.

Effective monitoring of the balance of benefits and risks is an ongoing priority area for the Agency. Initiatives will continue to be implemented in the context of the European Risk Management Strategy, with emphasis on the operation of the EU regulatory system, improving signal detection and data analysis. The Agency will pursue initiatives in the framework of a proactive conduct of pharmacovigilance by supporting the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) as a functional network of centres for the monitoring of targeted authorised medicines. Engagement with the scientific community and academia will increase as part of this and other activities. Other initiatives outlined in the road map will be planned.

Engagement of the Agency's stakeholders, patient empowerment and participation in healthcare decisions is one of the themes and objectives of the road map. The Agency will continue building on its past work and achievements in the area, and will widen the scope of interaction with civil-society

representatives through the implementation of a revised framework of interaction with patients and a gradual implementation of the framework of interaction with healthcare professionals.

Transparency has been the Agency's priority for a number of years, and its importance and impact on the Agency continued to increase over the previous year. This area remains important in the new road map. The Agency will further increase transparency in the daily operation of its activities by implementing transparency measures in accordance with the implementation plan of its transparency policy. Agendas and minutes of scientific-committee and working-party meetings will be published, and work will be progressed to provide interested parties with access to certain information contained in clinical-trials and EudraVigilance databases.

There is an increasing expectation for closer interaction and collaboration between regulators and health technology assessment bodies. The Agency addresses those expectations in its road map and is planning initiatives in this field, while ensuring that cost/benefit assessment remains separate from the licensing process. Initiatives for 2011 include the work to improve European public assessment reports and the contribution to the European Commission's and Member States' joint action.

Globalisation of pharmaceutical research, development and manufacturing is a predominant theme. In addition to the Agency's strong bilateral cooperation with a number of international regulatory authorities, the Agency is particularly involved in the areas of clinical trials, manufacturing of active pharmaceutical ingredients and medicinal products, and ongoing regulatory collaboration with its international partners. We will work to extend international partnerships in the areas of good-manufacturing-practice (GMP) and good-clinical-practice (GCP) inspections, will extend initiatives with the US Food and Drug Administration (FDA) on GCP and on GMP inspections of finished products, and will extend the active pharmaceutical ingredient inspection programme. Moreover, we will identify further opportunities for a strengthening of the interaction with our bilateral partners and international institutions such as the World Health Organization and the World Organisation for Animal Health (OIE).

In the field of public health, we will continue to strengthen the Agency's input into European activities regarding medicinal products for use in the elderly population. In the field of animal health, attention will remain focused on maintaining and improving the availability of veterinary medicines, particularly for minor species/minor uses (MUMS)/limited markets, and we will continue our contribution to the Community Animal Health Strategy where this relates to the use of medicines. Covering medicines for both man and animals, the Agency is particularly well placed to implement in practice the concept of 'One World, One Health', whereby promoting health in animals promotes health in man. In this context, the Agency will continue in 2011 to focus effort in the field of reducing the risk of antimicrobial resistance arising as a result of the use of antibiotics in man and animals.

In light of the approaching end of the transitional period for registration of traditional herbal medicinal products, the Agency will address, depending on available resources, specific challenges in the field, such as the need to improve the output of the Committee on Herbal Medicinal Products in terms of monographs and list entries, and to respond to any actions arising from the end of the transition period by which Member States shall apply the provisions of Directive 2004/24/EC. The transitional period for submission of gene- and cell-therapy medicinal products subject to the legislation on advanced therapy medicinal products will also expire.

The Agency will continue to foster fruitful cooperation with the national authorities and experts. In this context, the Agency will continue to support various initiatives undertaken by the Heads of Medicines Agencies aimed at strengthening the existing cooperation and ensuring the continuous availability of top-quality scientific expertise, which is of paramount importance to the success of this and future work programmes.

1. The European Medicines Agency in Europe and the world

1.1. European medicines network

Trends and new issues

Support to the development of the European medicines network is a priority area for the Agency. Over recent years, the workload within the network has grown significantly and a number of initiatives have been and need to be implemented to assure continuous availability of expertise in various existing and emerging scientific fields.

A better perspective of the future architecture of the European medicines network may be available by 2011-2012, following on from the current reflection and review. The role of the Agency in clinical-trials authorisation and provision of information in the Member States will be clarified. In 2011, one of the major challenges for the network will be the implementation of the new pharmacovigilance legislation.

Objective
Continue efforts to ensure the availability of top-quality scientific expertise for the Agency's scientific committees and their working parties and scientific advisory groups through the full implementation of the revised policy on the handling of conflicts of interests of CxMP members/experts.

Objective	
Continue supporting capacity-building on non-clinical safety and on alternative testing methods in light of the 3R principles (replacement, refinement and reduction).	
Performance indicators for the objective	**Target**
Establish an ad hoc multidisciplinary 3R working group.	Mandate and work plan of the group finalised.

Preparations for future enlargement

Activities to prepare for enlargement will continue in 2011 within the framework of the Instrument for Pre-accession Assistance (IPA) programme, designed to support participation of the beneficiary countries Albania, Bosnia-Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Kosovo under UNSC Resolution 1244/99, Montenegro, Serbia and Turkey in the Agency's activities.

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

Meetings at the Agency

Trends and new issues

The Agency expects that the number of reimbursed delegates will be around 9,100, representing a 4.8% increase from 2010 (8,685), and the estimated number of meetings will be around 600, as in 2010.

A large number of meetings places significant demands on the scientific resources of the national competent authorities. In 2011, the Agency will reflect on ways to further increase the uptake of

virtual meetings, substituting some of the conventional meetings. The experience gained in this domain following transport disruptions due to the volcanic ash cloud in 2010 will be taken into account.

The number of virtual meetings is expected to increase to 350 in 2011, compared to 270 in 2010.

Core performance indicators for the area	Target
Satisfaction of delegates and interested parties regarding support provided by the Agency.	95% of respondents to be satisfied or very satisfied.

1.2. European cooperation

Trends and new issues

Vaccine-related activities due to the novel H1N1 influenza pandemic will continue into 2011.

Further work on vigilance and traceability of tissues and cells, particularly those used for advanced therapy medicinal products, will be necessary, and there may be important implications for the Agency and for its interaction with ECDC, depending on the strategic orientations taken by DG Sanco and the Management Boards of the two agencies.

Interaction and communication with health technology assessment (HTA) bodies initiated in 2010 through the European Commission and Member States' joint action (EUnetHTA) will continue, particularly in the field of improving European public assessment reports (EPAR) and scientific advice.

Ongoing debate about the adequacy of relevant regulatory frameworks (i.e. for medicines and medical devices), including issues surrounding oversight of borderline in vivo products and combinations of medicines and in vitro diagnostics, and sophisticated and high-added-therapeutic-value products, is expected to have a high impact on HTA bodies and on relative-effectiveness considerations.

In the veterinary field, the European Commission will consider the response received to its consultation on the need for changes in the regulatory framework for veterinary medicines, with the objective of reducing administration and increasing availability. The Agency will assist with these considerations, particularly in terms of coordinating activities with the network, as appropriate and required. The Agency will continue the pilot phase of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Project, to collate data at EU level on sales of veterinary antimicrobials, and will review with partners and the European Commission the outcome of the pilot.

Objective	
Contribute to activities on core health technology assessment/relative effectiveness with European Commission and EUnetHTA Joint Action.	
Performance indicators for the objective	**Target**
Assessment report templates implementing agreed changes.	Templates rolled out.
Action plan for further EPAR improvement.	Plan developed.
Contribution to the core work packages of the Joint Action.	100% as identified.

Objective	
Enhance cooperation with ECDC in the area of pharmacovigilance and risk management for vaccines.	
Performance indicators for the objective	**Target**
Agree on a strategy for strengthening the monitoring of safety and effectiveness of vaccines with ECDC.	Strategy agreed, Q4.
Objective	
Collate data on sales of veterinary antimicrobials within the EU in the context of the ESVAC project.	
Performance indicators for the objective	**Target**
Review operation of the pilot project.	Report produced, Q4.

1.3. International cooperation

Trends and new issues

The Agency will focus on the further development and implementation of its international strategy during 2011. Interactions with the FDA, Health Canada and the Japanese MHLW/PMDA in the context of the existing bilateral confidentiality arrangements are expected to continue to intensify during 2011, with increasing product-related interactions, development of new cluster activities, and specific pilot projects on assessment-related matters with the FDA. Actions related to the GMP and GCP inspection pilots with the FDA will be reviewed with a view towards defining next steps. Similarly, the activities of the Transatlantic Task Force on Antimicrobial Resistance are scheduled to be completed in 2011. Periodic reports of ongoing interactions will be published.

Activities in ICH and VICH will continue, with increased focus on improving global outreach and harmonisation beyond the current ICH and VICH members. Maintenance of guidelines and further improvement of efficiencies will also be addressed within ICH.

Collaboration with authorities in countries such as China, India and Russia will continue to increase, as will interactions on clinical-trial aspects with countries where increasing numbers of patients are recruited. The Agency will continue to work with the Commission, national authorities and the network to contribute to capacity-building and training activities. Collaboration with the WHO will continue to be important with respect to contacts with these countries and in the context of its opinions on products intended to be used outside the Community, for example in developing countries (so-called Article 58 procedures). Supporting the WHO to contribute to capacity-building with respect to the network of Paediatric Medicines Regulatory Agencies will continue to be a priority. The Agency will provide support to the Commission in addressing the threat of counterfeit medicines, particularly in the context of its legislative proposal on falsified medicines.

At an internal organisational level, work will focus on better coordination of international activities between the scientific committees and with the staff of the Agency, improving transparency and developing tools (videoconferencing, training DVDs) to facilitate contacts and networks with international regulatory partners.

It is likely that 2011 will see the adoption of the identification of medicinal products family of standards and the individual case safety report by ISO. The Agency makes major contributions to the finalisation of these standards, working with the Member States and with the national standards boards. The Agency will also need to prepare for implementation on these standards.

1.4. Communication, provision of information and transparency

Provision of information

Trends and new issues

The Agency will further strengthen core activities relating to the provision of information, focusing on product information, with the objective of further contributing to the safe use of medicines. This will integrate some preparatory work on the implementation of the new pharmacovigilance legislation, especially by developing mechanisms and measures to minimise the risk of medication errors.

In order to make further progress in the area of communication and provision of information, the Agency will start implementing its communication strategy within the context of the European regulatory network, focusing on benefit/risk of medicines evaluated by the Agency, thereby building on current achievements and on the basis of users' research feedback.

The Agency will continue to strengthen and widen the scope of interactions with its stakeholders by implementing the revised framework for interaction with patients, and by gradually implementing the framework for interaction with healthcare professionals.

It is expected that the number of requests for information about the activities undertaken by the Agency will increase, as it is seen as an authoritative source of information. An estimated 5,500 requests for information (2010: 4,987) are expected.

Objective	
Further strengthen the Agency's communication on medicines evaluated by the Agency for syndication to the EU regulatory network.	
Performance indicators for the objective	**Target**
Adopt a communication strategy on benefit/risk of medicines evaluated by the Agency, integrating all communication aspects and establishing reinforced links with NCAs.	Q4.
Objective	
Further integrate civil-society representatives in the Agency's activities.	
Performance indicators for the objective	**Target**
Adopt a revised framework for interaction with patients.	Q4.
Gradual implementation of the framework for interaction with healthcare professionals.	Q4.

Core performance indicators for the area	Target
Percentage of summaries of opinions published at the time of the CHMP press release.	90% of summaries of opinion.
Percentage of initial EPARs published within 4 weeks of the Commission decision.	90% of marketing authorisations granted.
Percentage of EPAR summaries in a language understandable to the public, published together with the EPAR.	90% of EPARs.
Percentage of withdrawal question-and-answer (Q&A) documents published at the time of the next appropriate CHMP monthly report.	90% of Q&A documents.
Percentage of refusal Q&A documents published at the time of the CHMP opinion.	90% of Q&A documents.
Publication of Agency decisions on PIPs or waivers within 6 weeks.	95% of decisions.

Transparency

Trends and new issues

The Agency aims to finalise its transparency policy and start a gradual implementation of the agreed transparency measures. The milestones will include the publication of scientific-meeting agendas and minutes, progress in preparing to provide access to EudraVigilance reports and work to improve information in EPARs. The latter initiative relates to the Agency's cooperation with health technology assessment bodies.

It is expected that 120 requests for access to documents (2010: 114) will be received. The increase in requests needs to be matched by improved processes and tools to handle requests for access to documents and information. A proposal for improving the handling of requests for access to documents and information will be prepared.

Objective	
Further increase transparency in the daily operation of the Agency's activities.	
Performance indicators for the objective	**Target**
Adoption of transparency policy by Management Board.	Q4.
Implementation of initial measures to improve the EPAR as per the outcome of the EPAR usability project.	Q4.
Implementation of content-related measures in the EPAR.	Q4.

Objective
Increase transparency of clinical trials in EudraCT and on the Agency's website by commencing prospective publication of all paediatric trials.

Objective	
Optimise the use of the Agency's resources needed to provide access to documents and information.	
Performance indicators for the objective	**Target**
Plan developed.	Q4.

1.5. Support for innovation and availability of medicines

Trends and new issues

Several major policy initiatives (e.g. Small Business Act, 'Lisbon Strategy after 2010' consultation, etc.) focusing on innovation should stimulate the creation of small and medium-sized enterprises (SMEs) in the EU.

Despite uncertainties in economic recovery, the number of existing SMEs registering with the Agency for the first time is expected to continue to grow, as awareness about EU SME incentives increases.

Regarding veterinary medicines, activities in relation to availability are focused in particular on providing advice and other incentives provided by the Agency under Article 79 of Regulation (EC) No 726/2004 for products for minor uses and minor species (MUMS) and limited markets. The first review of this new scheme in 2010 showed that it has met with considerable success since its launch in September 2009, and it will be reviewed again in 2011 to assess the ability of the Agency to provide the necessary resources. In terms of innovation, the Agency continues to contribute to the DISCONTOOLS project within the European Technology Platform for Global Animal Health (ETPGAH).

Objective	
Obtain feedback on the SME initiative, five years after its implementation, with a view to reviewing and continually improving the services provided by the Agency's SME Office.	
Performance indicators for the objective	**Target**
Survey of SME companies and stakeholders on SME incentives and the various support measures in place.	Finalise survey.
Consultation with SME stakeholders.	One meeting.

Objective	
Contribute to European Commission and Innovative Medicines Initiative (IMI) projects.	
Performance indicators for the objective	**Target**
Coordinate the EU PROTECT project on pharmacovigilance and benefit-risk monitoring.	EU PROTECT annual report to IMI.
Participation in workshops organised by the EC in the areas of toxicology, translational medicine and personalised medicine.	Three workshops.

Participate in working groups within the DISCONTOOLS project of the ETPGAH.	Participation as requested.

Objective	
Continue strengthening Agency input to European activities regarding medicinal products for use in the elderly population.	
Performance indicators for the objective	**Target**
CHMP ad hoc group of experts on geriatrics.	Group in operation.
Report on the analysis of applications started in 2010 regarding the assessment of clinical data on geriatric population.	Final report.

1.6. Methodology and outcomes-assessment projects

Trends and new issues

The Agency has established a programme aiming to evaluate outcomes and the impact of regulatory actions on the Agency's stakeholders and public health in general. The programme also aims to provide methodologies for a more detailed justification of benefit-risk assessments done by the Agency's Committees.

The Agency will make the case for research funding into linking vaccination with health outcomes, with the long-term aim of establishing a fully operational vaccine data-link.

Objective	
Utilise the ENCePP network to enhance outcome assessment related to medicines' regulation.	
Performance indicators for the objective	**Target**
A study on outcome assessment through the ENCePP network initiated.	Q3.

Objective	
Further enhance the system for measuring the effectiveness of risk-management plans.	
Performance indicators for the objective	**Target**
Key outcomes for four medicinal products.	Identified by Q4.
Effectiveness of measurements performed by the MAHs for products with risk-minimisation plans that were introduced in 2008 and 2009.	Effectiveness evaluated, Q3.

Objective	
Conduct gap analysis of outcome measures for paediatric clinical trials.	
Performance indicators for the objective	**Target**
Gap analysis report.	Completed, Q4.
Objective	
Finalise project on methodologies for benefit-risk assessment of medicinal products.	
Performance indicators for the objective	**Target**
Consultative workshop with interested stakeholders.	One workshop.
Training programme for regulatory assessors (work package 5).	Develop programme.
Objective	
Define impact of emerging science on marketing authorisations in the period 2007-2010 as a follow-up to the Agency-CHMP think-tank report.	
Performance indicators for the objective	**Target**
Report on impact.	Published on website, Q4.

1.7. Governance

Trends and new issues

A new Executive Director will take office in the second part of 2011. The Agency will put in place preparations for the effective handover of responsibilities.

The introduction of a new enterprise resource project (ERP) based on an SAP database will have far-reaching consequences for all financial and budgetary operations. The deployment of SAP will also create significant changes in terms of processes, responsibilities, organisational structures, business and control activities, as well as communication means.

The outcome of the review of the fee regulation is expected to impact on the drafting of a revised fee regulation during 2011.

The leases of the Agency's office accommodation expire in 2014. A project to manage the options to ensure that the Agency has adequate office facilities is ongoing.

Objective	
Implement the ERP system.	
Performance indicators for the objective	**Target**
For timelines please refer to Chapter 5 'Information technology'.	

Functionality of the system in line with project plan.	100% of planned functionality.

Core performance indicators for the area	Target
Budget implementation.	Minimum of 95% implementation rate.
Staff recruitment (long-term positions).	4% vacancy rate by year end.
Testing of business continuity arrangements.	Annual test ensuring involvement of different staff members each year.

Product data and application management

Trends and new issues

An important consequence of the Agency's growing area of responsibilities is that its tasks have become much more complex. In this context, the Agency revises its processes to enable it to work more efficiently to reduce internal complexity, wherever possible, without compromising on the quality of core activities.

With the increasing number of applications, there is a significant increase in the volume of product information received. Data-quality assurance and control processes are needed to ensure reliability and consistency across the Agency, to support its scientific role, decision and opinion-making, and forecasting exercise. The Agency is working to harmonise the business processes and modernise how the information is managed as an asset, thereby further strengthening the Agency's core business activities and further reducing the administrative burden.

Objective	
Develop and initiate the implementation of the strategy for effective organisational support according to the agreed incremental implementation plan.	
Performance indicators for the objective	**Target**
Implementation of the agreed strategy according to plan.	80% of planned activities.

Objective	
Develop the implementation plan by Q2 with the aim of strengthening cross-Agency collaboration as part of the efficiency-improvement initiative.	

Objective	
Optimise processes for efficient and effective operation in view of the implementation of new IT systems (SIAMED II and a revised financial system) and the implementation of the Agency's records-management policy.	
Performance indicators for the objective	**Target**
Implementation of revised business processes according to project plans.	95% of planned processes.

Objective	
Develop and implement a data-quality-assurance system for SIAMED II.	
Performance indicators for the objective	**Target**
Quality assurance for SIAMED II developed, implemented and operational.	80% of planned activities.

Objective
Develop a common cross-Agency product-information architecture, governance strategy and implementation plan by Q4 as part of the enterprise information architecture.

2. Medicines for human use

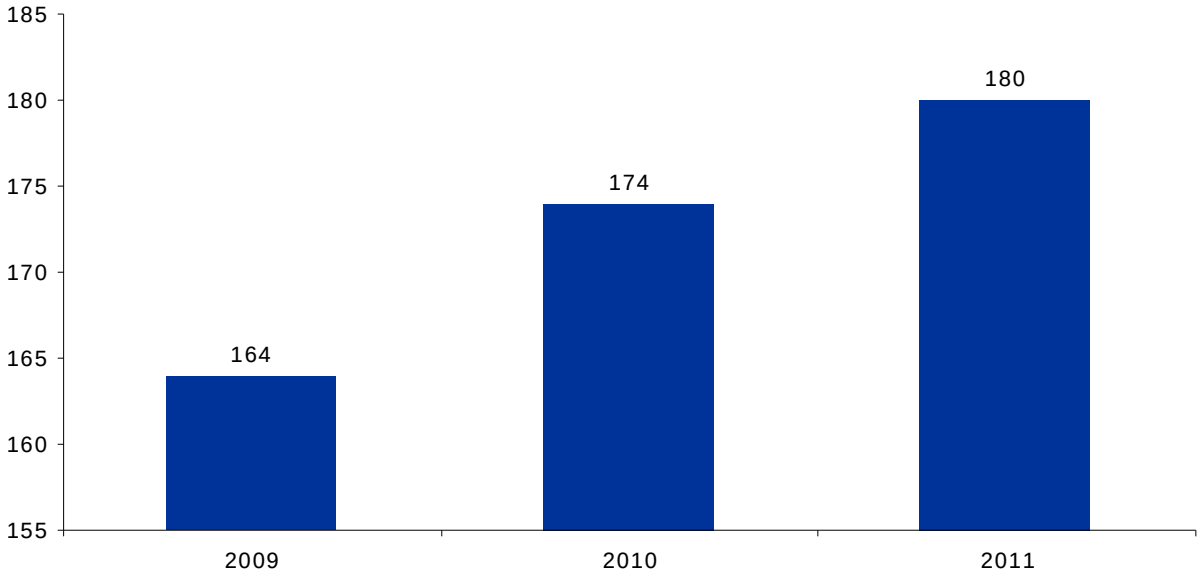
2.1. Orphan medicinal product designation

Trends and new issues

The number of applications for designation of orphan medicinal products will continue to increase as a consequence of the Agency's rare diseases policy (including due to collaboration with the FDA and continuous support to rare diseases provided by DG Research and DG Health and Consumers).

Follow-up activities of the Pharmaceutical Forum with health technology assessment bodies for orphan medicines are expected, in particular through the Clinical Added Value of Orphan Drugs (CAVOD) initiative.

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



Objective
Reach agreement on the framework for collaboration as part of the developing collaboration with the Commission and Member States HTA bodies on added value of orphan medicinal products.

Core performance indicators for the area	Target
Percentage of designation applications evaluated within 90-day timeline.	100%.
Percentage of summaries of opinion published within 1 month of the Commission decision on designation.	90%.
Percentage of public assessment reports (on review criteria) published within 1 month of the European Commission's decision on marketing authorisation.	80%.

2.2. Scientific advice and protocol assistance

Trends and new issues

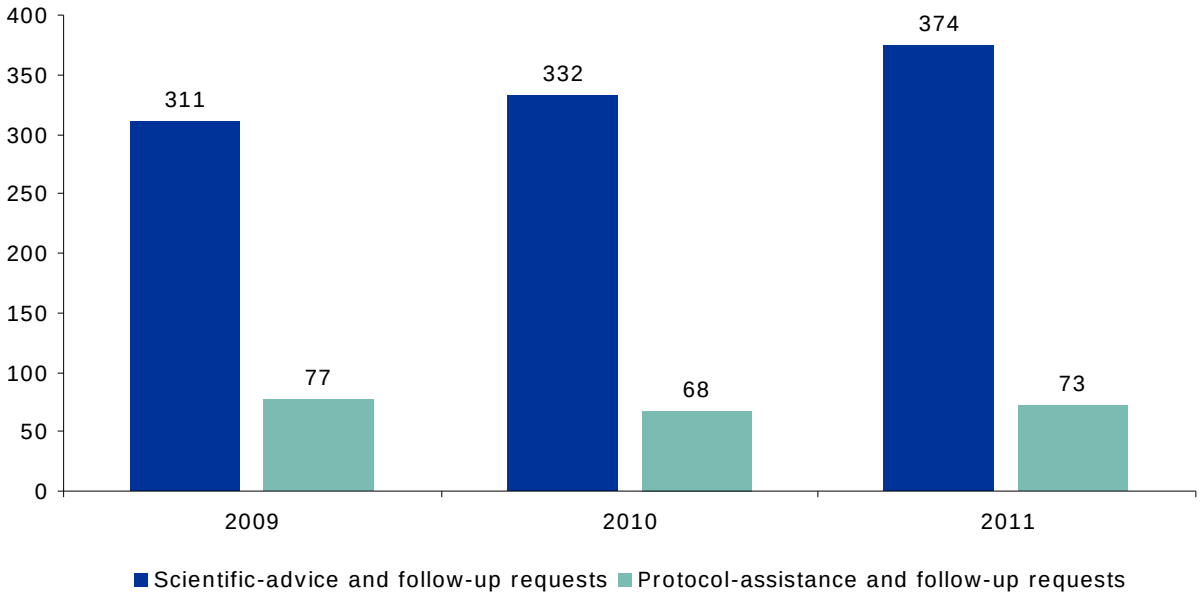
Acknowledging that the scientific advice provided by the Agency, if adhered to by the sponsor, increases the proportion of successful marketing-authorisation applications, the Agency will continue its efforts to reinforce the scientific-advice process.

Topics featuring high on the scientific-advice agendas will be adaptive and other innovative designs of clinical trials and use of biomarkers as endpoints in clinical trials.

Increasing uptake of biomarker qualification and the novel-methodologies procedure is expected.

Interactions with health technology assessment bodies and with national authorities providing scientific advice will become more important.

Figure 2. Scientific-advice and protocol-assistance requests



Objective
Implement action plan for reinforcement of biomarker-qualification procedure, based on outcome of assessment of impact of procedure on qualification of novel methodologies.

Core performance indicators for the area	Target
Scientific-advice and protocol-assistance requests evaluated within the procedural timelines.	100% of requests.
External experts involved in procedures.	30% of scientific-advice and protocol-assistance requests.
Percentage of marketing-authorisation applications for new technology products having received scientific advice/protocol assistance.	50% of applications.

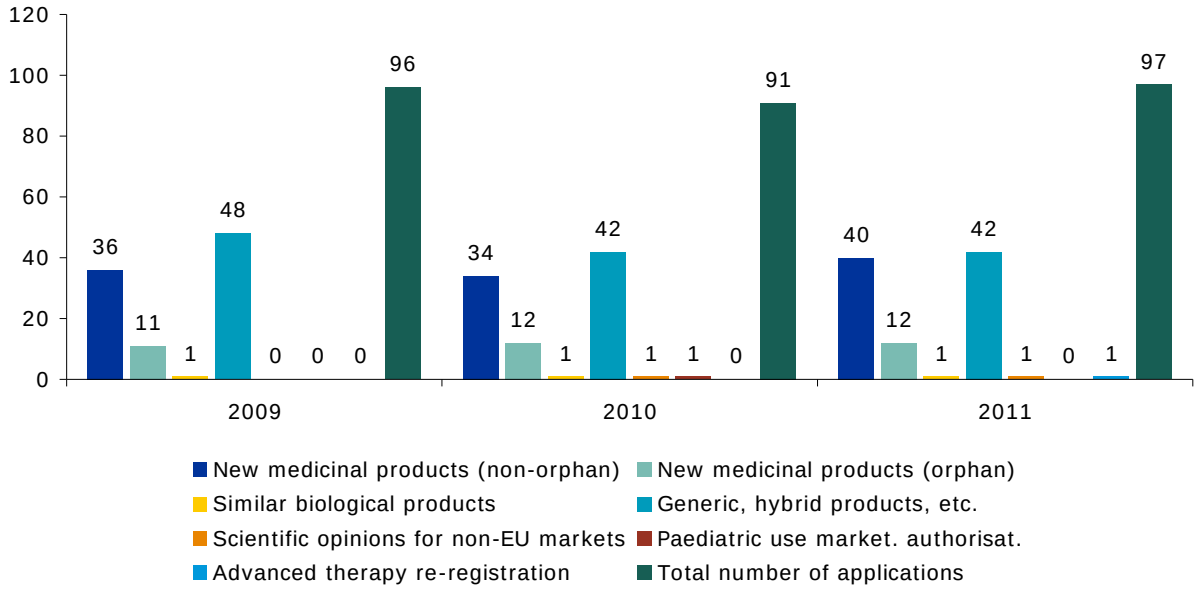
2.3. Initial evaluation

Trends and new issues

The general trend in research and development (R&D) is to narrow the scope of business pipelines (e.g. focus on oncology, immunology and metabolic disorders). In time this will result in less R&D in more and more therapeutic areas, which will increase the gap between the availability of medicines and unmet medical needs.

Generic applications are expected over the next few years due to patent expiration in 2011-2012. The number of similar-biological applications is expected to stay at a low level in the short term. Few applications for advanced-therapy medicinal products (ATMPs) are expected.

Figure 3. Applications for initial evaluation



Objective	
Strengthen peer-review process for generic marketing-authorisation applications and plan for increasing focus on bioequivalence.	
Performance indicators for the objective	**Target**
Process for improved Agency peer review of generic marketing-authorisation applications.	Process operational by Q4.

Core performance indicators for the area	**Target**
Percentage of applications evaluated within the regulatory timeline Marketing-authorisation applications (210 days). Accelerated-assessment applications (150 days). Plasma-master-file applications.	 100% of applications. 100% of applications. 100% of applications.

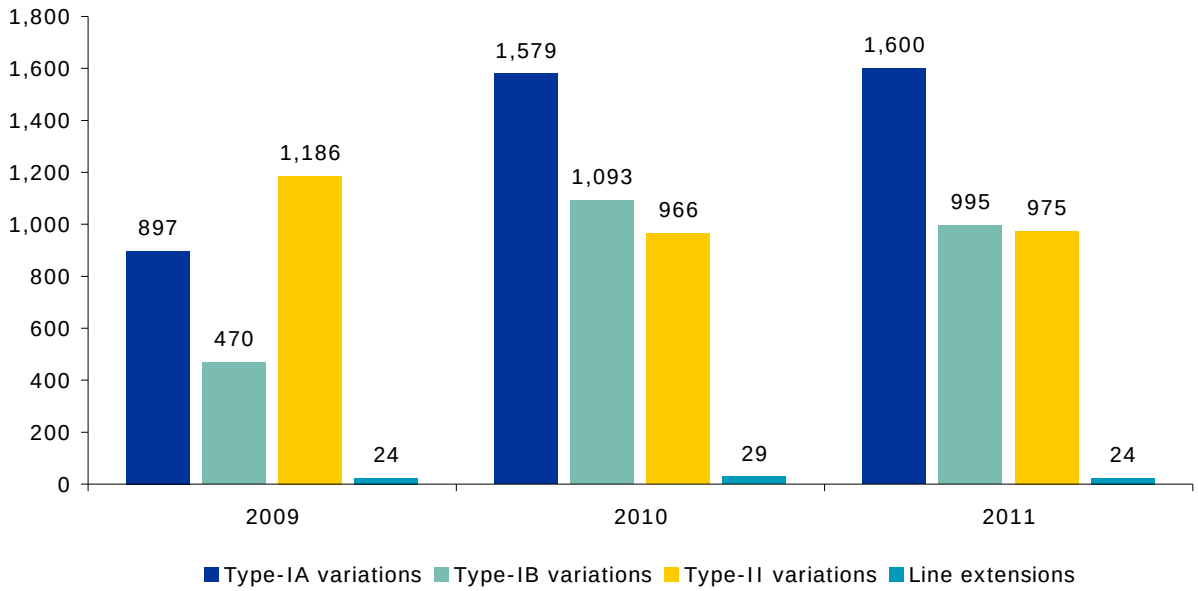
Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days.	100% compliance.

2.4. Post-authorisation and maintenance activities

Trends and new issues

The transitional period for implementation of Directive 2009/53/EC by Member States for alignment of variations to nationally authorised products with the revised Variations Regulation ends in January 2011. There is potential for an increase in the number of national products included in worksharing procedures with centrally authorised products, once the scope of Regulation (EC) No 1234/2008 is extended to encompass medicinal products authorised via national procedure.

Figure 4. Post-authorisation applications received



Note: 2010 and 2011 figures based on revised classification.

Objective	
Initiate review of variations processes on the basis of experience gained in the first year of operation of the Variations Regulation.	
Performance indicators for the objective	**Target**
Gap analysis and areas for improvement / strengthening identified.	Analysis finalised and implementation plan agreed by Q4.
Review of the classification of variations.	Review finalised and changes identified by Q4.

Core performance indicators for the area	Target
Percentage of applications for post-authorisation procedures evaluated within the regulatory and procedural timelines.	100% of applications.
Percentage of the Agency's recommendations on classification of variations delivered within the regulatory timelines.	100% compliance.
Percentage of grouping and worksharing procedures completed within the procedural timelines.	100% compliance.
Submission of outcome reports for post-authorisation commitments (PACs) to applicants/MAHs within 2 weeks of the CHMP meeting.	90% of reports.
Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check.	100% of applications.

2.5. Pharmacovigilance activities

Trends and new issues

The main change in the field of pharmacovigilance is the new pharmacovigilance legislation that will come into effect in 2012. Preparations for the implementation will be carried out in 2011.

The Agency will further deploy initiatives in the context of the European Risk Management Strategy (ERMS), and it is envisaged that the forward-looking ERMS work plan will prioritise collaboration with the Member States in preparation for the new pharmacovigilance legislation. There will be new standards for electronic submission of individual case safety reports (ICSRs) and for the identification of medicinal products. The first results on new pharmacovigilance methods from the Innovative Medicines Initiatives Protect project will become available. There will be a drive to better integrate benefit and risk monitoring in the post-authorisation phase.

In EudraVigilance, the focus will be on further strengthening signal detection, data analysis and risk management, and on enhancing the system to meet the needs of the new pharmacovigilance legislation.

The Agency will support pan-European research activities in the field of pharmacovigilance by providing support to DG Research on priorities in the field of drug-safety research needing public funding, by co-ordinating the PROTECT project under the Innovative Medicines Initiative.

Objective	
Prepare for the implementation of the new EU pharmacovigilance legislation.	
Performance indicators for the objective	**Target**
Status report on implementation actions stemming from the 2010 implementation plan.	Prepared, Q4.

Objective	
Maintain and strengthen EudraVigilance to support proactive pharmacovigilance.	
Performance indicators for the objective	**Target**
Complete activities carried out by the third-party service provider to improve the EudraVigilance data quality for centrally authorised products in the context of the EudraVigilance Data Quality Management tender.	Q4.
Objective	
Improve the monitoring of pharmacovigilance compliance.	
Performance indicators for the objective	**Target**
An enhanced compliance-monitoring strategy prepared and presented to the Heads of Medicines Agencies (HMA).	Q3.
A report on reporting compliance of MAHs and NCAs submitted to the Management Board.	Q4.
Objective	
Progress the European Signal Management initiative towards an integrated EU system.	
Performance indicators for the objective	**Target**
Reaction-monitoring reports to support signal detection and evaluation.	Monthly reports provided to (co-)rapporteurs and national competent authorities.
Sixth-monthly reports on signal-detection activities.	Submitted to the Management Board, Q2 and Q4.

Core performance indicators for the area	Target
Percentage of risk-management plans (RMPs) that are peer reviewed as part of the assessment of the initial marketing-authorisation applications.	90% of applications.
Percentage of RMPs that are peer reviewed by the Agency as part of the assessment of variations and line extensions that result in a significant change to a marketing authorisation.	90% of applications.
Percentage of ICSRs reported electronically for centrally authorised products (CAPs).	100%.
Percentage of CAPs monitored at least monthly by the signal-detection group.	100%.

2.6. Arbitration, Community referrals and opinions on scientific matters

Trends and new issues

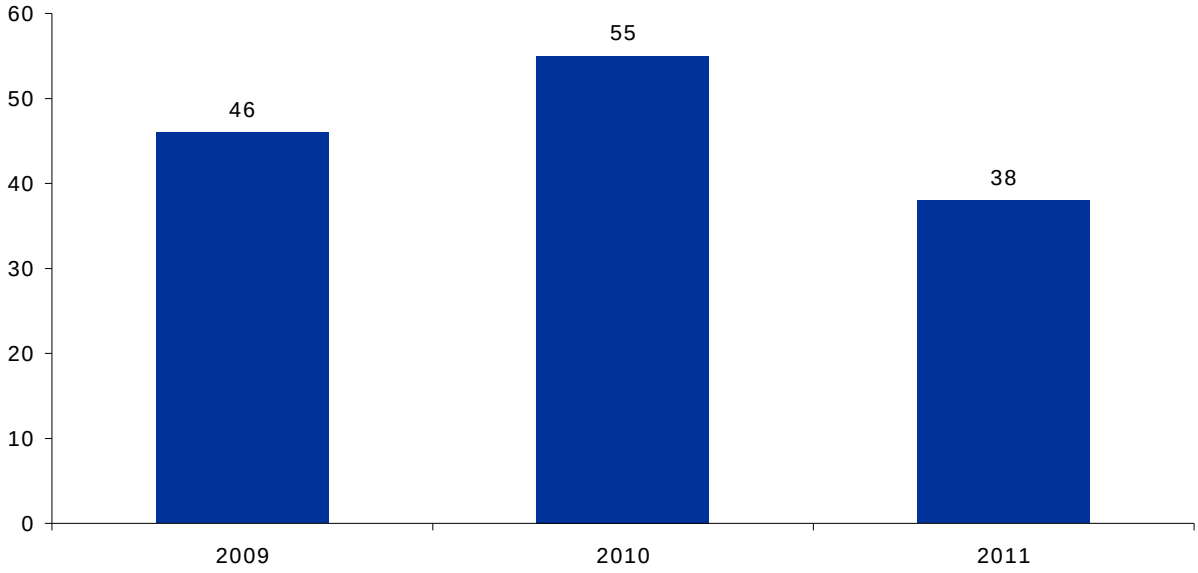
New referral procedures (Article 107i) stemming from the proposed Community legislation in the field of pharmacovigilance will come into force in 2012. However, preparatory work for this implementation will be undertaken in 2011.

Article 29 (paediatric use) procedures are particularly demanding, not only because of the short timeframe for assessment but also because of the issues related to validation.

The number of Article 20 procedures is expected to increase and the procedures are expected to be triggered earlier.

The cumulative number of referrals under Articles 29(4) and 30 is expected to decrease and the number of Article 31 referrals is expected to stabilise.

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



Objective	
Prepare for the implementation of Article 107i of the new pharmacovigilance legislation.	
Performance indicators for the objective	**Target**
Draft revision of the guidance document.	Provided to the European Commission, Q4.
Objective	
Monitor the implementation of the Article 29 paediatric procedure and adapt procedural guidance where necessary.	

Performance indicators for the objective	Target
Report on the outcome of the monitoring of the practical implementation.	Report completed, Q4.

Core performance indicators for the area	Target
Percentage of arbitration and referral procedures evaluated within the legal timeline.	100%.
Publication of question-and-answer documents for Community-interest referral procedures (Art. 31, 36, 107(2)) and Art. 20 procedures at the time of the CHMP opinion.	100%.
Publication of the CHMP opinion and assessment report for Art. 5(3) procedures at the time of the CHMP opinion.	100%.

2.7. Medicines for paediatric use

Trends and new issues

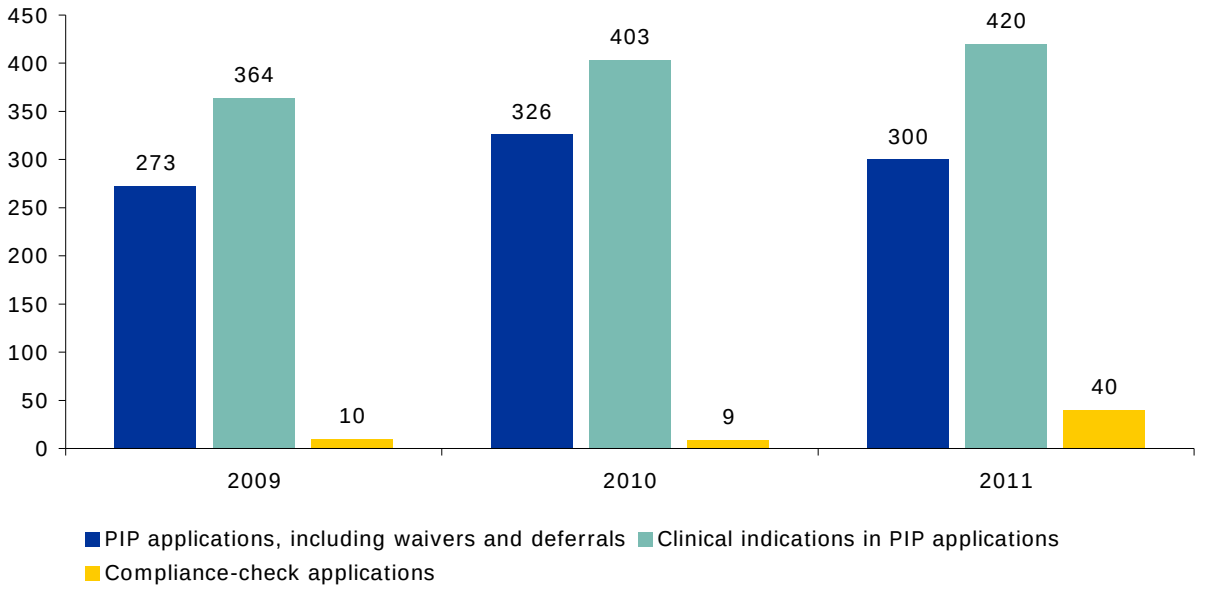
Availability of medicines for unmet medical needs, which includes the paediatric population, is high on the Agency's agenda. The implementation of the paediatric legislation is largely complete. However, work on consolidating and improving the activities in this field will continue, with a view to further promoting the availability of high-quality medicines for children.

The number of applications is expected to increase compared to 2009. However, this trend is obscured by the additional 70 PIP applications submitted in 2010 following a change in German law.

Experience shows that clinical-trial methodology and non-clinical issues are critical aspects of the evaluation of applications.

Feasibility of clinical trials and availability of patients are key topics in conditions that are rare or not highly prevalent in children.

Figure 6. Paediatric investigation plans and related applications



Objective	
Finalise development of specific guidance for conduct of paediatric medicinal-product development.	
Performance indicators for the objective	**Target**
Publication of standard PIPs.	2 standard PIPs.
Finalisation of guidance documents.	100%.

Objective	
Create a network coordination group to strengthen established European paediatric network (EnprEMA).	
Performance indicators for the objective	**Target**
Group established.	Q2.

Core performance indicators for the area	**Target**
Number of PIP or waiver opinions and decisions within legal timelines.	100% of opinions/ decisions.
Percentage of Agency decisions on paediatric investigation plans/waivers published within 6 weeks of the decision.	95%.
Expert workshops on specific diseases / therapeutic areas.	3 meetings.

2.8. Herbal medicinal products

Trends and new issues

The issues raised in the European Commission's report on the experience acquired as a result of the application of the provisions of Chapter 2a of Directive 2001/83/EC (introduced by Directive 2004/24/EC) on specific provisions applicable to traditional herbal medicinal products need to be addressed. In particular, improvement concerning the genotoxicity data situation shall be sought.

The Member States will face the end of the transition period by which they shall apply the provisions of Directive 2004/24/EC to traditional herbal medicinal products that were already on the market on 30 April 2004.

Regular reports on the uptake of the traditional-use-registration scheme in the Member States shall be undertaken, in cooperation with the CMDh.

Objective	
Improve the output of the Committee on Herbal Medicinal Products, in particular by increasing the quality and number of monographs and list entries.	
Performance indicators for the objective	**Target**
Adjustment to the needs of the market operators of the priority list of herbal substances, preparations and combinations thereof for assessment.	The list adjusted in collaboration with stakeholders, Q4.
Implementation of the orientation concerning the genotoxicity data situation chosen in 2010. Possible options include the use by the HMPC of unpublished data available on a national level and transparent labelling with regard to genotoxicity information.	Implemented, Q4.
Implementation of the HMPC policy for the systematic assessment of the need for revision of final Community herbal monographs, aiming that they remain up to date (scientific state of the art).	Implemented, Q4.
Community herbal monographs • Final. • Released for public consultation.	 • 20. • 20.
Community list entries • Transmitted to the European Commission. • Released for public consultation.	 • 10*. • 10*. *Pending success of performance indicator regarding genotoxicity-data situation.

Objective	
Report on the uptake of the traditional-use-registration scheme.	
Performance indicators for the objective	**Target**
Publication and updating on 6-monthly basis of an overview of applications received, under evaluation and registrations granted per Member State (name of product, herbal substance, preparation or combination thereof used and the therapeutic indication(s) granted).	Publication (in collaboration with the CMDh), Q2 and Q4.
Report on impact of published Community herbal monographs upon assessment of marketing authorisations and traditional-use registrations granted by the Member States.	Report delivered (in collaboration with the CMDh), Q4.

2.9. Advanced therapies and other emerging therapies and new technologies

Trends and new issues

In 2011, manufacturers and Member States will face the end of the transitional period by which, according to the provision of the ATMP Regulation (Art. 29), all ATMPs other than tissue-engineered products (which were legally on the European market at the time of entry into force of the Regulation) have to be centrally authorised. The uptake of the ATMP-classification procedure was already high in 2010 and is expected to increase further in 2011. There will also be an increase in the number of applications for certification of quality and non-clinical data for ATMPs developed by SMEs, even though it is difficult to predict an accurate number of such certification applications. The Committee for Advanced Therapies (CAT) has developed its work programme for 2010-2015, identifying the key objectives and actions of the Committee. These include actions related to: products legally on the market; further strengthening the CAT's interactions with all its interested parties, including SMEs, academia, hospitals and research groups developing ATMPs; promoting access to marketing-authorisation procedures; contributing to efforts to foster innovation and promote access and availability of ATMPs for EU patients.

With regard to emerging therapies and new technologies, the area is subject to gradual change, and the Agency will have to address new challenges in fields like nanotechnologies, personalised medicine, borderline products and other complex areas, such as the combination of medicines and medical devices as single integral products, leading to further reflection on the criteria to address borderline issues and develop the most appropriate guidelines and regulatory oversight. The concept of personalised medicine is rapidly moving from a theoretical concept to everyday reality. In this area, the scientific/technical and regulatory challenges will be very significant, and will have to be addressed in the longer term. Likewise, scarce expertise in the area of new technologies will need to be

addressed, to enable the European regulatory network to respond to future regulatory needs in the area.

Objective	
Promote Agency and European network competence-development in the area of nanomedicines.	
Performance indicators for the objective	**Target**
Training sessions for working parties during plenary meetings.	3 sessions.
Content and outcome of training published on website and in journals.	1 paper published.
Objective	
Review impact of pharmacogenomic tests and biomarkers in regulatory procedures to promote development and regulatory adaptations in the field.	
Performance indicators for the objective	**Target**
Report published in a peer review journal.	1 report submitted for publication.
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**
Procedure on the consultation of notified bodies for the evaluation of combined ATMPs.	Implemented, Q4.

Core performance indicators for the area	**Target**
Percentage of 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.
Scientific recommendations on advanced-therapy classification provided within the legal timeline.	100% of requests.
Certification of quality and non-clinical data issued within the procedural timelines.	100% of requests.
Innovation Task Force briefing meetings organised within 60 days from receipt of a request.	80% of meetings.
Percentage of regulatory-advice requests and ITF regulatory advice on new, emerging and borderline medicinal products (excluding ATMPs) given within 60 days.	80% of requests.

2.10. Scientific committees, working parties and scientific advisory groups

Trends and new issues

A critical element will continue to be the sustainability of the system, due to the demand on scientific resources for all committees and procedures. Due account will have to be taken of the outcome of the results of the evaluation of the Agency carried out in 2009.

The internal coordination of the well-established scientific committees of the Agency, their working parties and satellite groups, and the more recently established Paediatric Committee and Committee for Advanced Therapies, will continue in 2011 as a priority, to ensure collaboration throughout the lifecycle of medicinal products.

Not only has the number of procedures increased, but the complexity of applications has too, in view of the legislation on paediatric medicines, advanced therapies and variations, as has the interaction between the various committees. Following the review of the functioning of the working parties, some outstanding actions may need to be dealt with in 2011. Various implemented initiatives for assuring effectiveness of processes, in particular concerning new therapeutic working parties, are to be monitored.

Objective	
Finalise ongoing implementation of the working-parties framework as agreed with the CHMP.	
Performance indicators for the objective	**Target**
Outstanding actions in plan are completed.	Q4.
Objective	
Monitor implementation of optimisation of functioning of scientific advisory groups.	
Performance indicators for the objective	**Target**
Analysis of implementation.	Report completed.
Objective	
Monitor the interaction between committees and further develop the interaction between the CHMP and the other committees, in particular the Paediatric Committee and the Committee for Advanced Therapies.	
Performance indicators for the objective	**Target**
Procedure on interaction between CHMP and PDCO.	Reviewed, Q3.

2.11. Coordination group

Trends and new issues

Following the adoption of the new pharmacovigilance legislation, the role of the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) will be strengthened, resulting in new tasks for the CMDh and the CMDh Secretariat.

Objective	
Prepare for the Agency's activities in relation to the implementation of the legislative proposal to strengthen the EU system for the safety-monitoring of medicines (pharmacovigilance) with regard to the CMDh.	
Performance indicators for the objective	**Target**
The implementation plan for the CMDh Secretariat.	Plan finalised, Q4.

3. Veterinary medicines

The theme for 2011 will be one of putting into place concrete actions, following a period of reflection and review in 2010. With respect to veterinary medicines, the European Medicines Agency will be assisting the European Commission in preparing detailed proposals as a result of the consultation with stakeholders and impact assessment on the veterinary legislation that took place during 2010.

The Commission's consultation provided an opportunity to address the current structural difficulties that the sector is facing. In particular, it is hoped that as a result, changes can be developed that will permit regulatory focus to be concentrated more on issues of high priority for animal and human health, such as stimulating innovation, retaining animal health R&D within the EU and tackling antimicrobial resistance, and less on dealing with avoidable referrals and other issues arising from historical differences in the market for veterinary medicines across the European Union. In this context, continued focus on maintaining and improving the availability of veterinary medicines, both in general and particularly those for minor uses/minor species (MUMS)/limited markets, will be given. The Agency will continue to play a role in fostering solutions through the secretariats of the Committee for Medicinal Products for Veterinary Use (CVMP) and the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv), and ensuring effective liaison between the two fora.

The trend for the Agency and the CVMP to be asked to contribute more widely and with a higher profile on a wide range of topics related to veterinary medicines at EU and international level – such as antimicrobial resistance, MRLs, risk-assessment methodology, and harmonisation of standards and requirements – is expected to continue. The veterinary sector will therefore need to strictly prioritise its activities, and ensure that these are in line with the international strategy being developed by the Agency.

3.1. Scientific advice

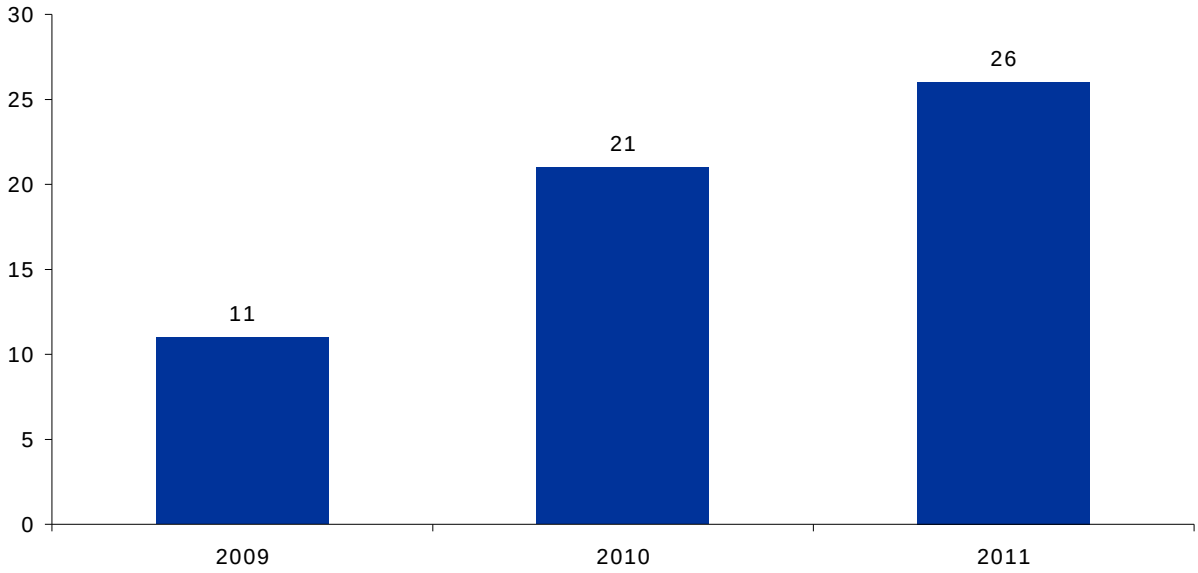
Trends and new issues

The Agency is keen to promote early applications for scientific advice in relation to the development of veterinary medicines. The availability of the scheme has recently been more widely publicised with industry. Uptake has been particularly strong among SMEs taking advantage of the incentives offered (about 60% of total figures in 2009 and 2010), and this trend is expected to continue in 2011. An increasing number of applications are being received for products not intended to be authorised via the centralised procedure, reflecting the awareness of industry that the procedure is also applicable to other routes of authorisation.

The criteria for providing free scientific advice in relation to the development of products indicated for MUMS/limited markets were amended in 2009. The new MUMS/limited-market policy came into effect on 1 September 2009, with the possibility to request classification of a product intended as MUMS/limited markets by the CVMP. This policy is intended to provide an incentive for developing such products. It resulted in an increase in the number of scientific-advice applications for this type of product, thus contributing to the availability of products for MUMS and limited markets. A new category of scientific advice has been introduced, whereby applicants can request confirmation of the general data requirements for an application in line with the adopted MUMS data guidelines.

Following the doubling in the total number of applications in 2009 and again in 2010, the increase in applications is now expected to slow down. The continuous collaboration with the FDA under the Confidentiality Agreement strongly supports applications for parallel scientific advice. It is hoped that 2011 will show an uptake of this type of activity.

Figure 7. Scientific-advice requests



Objective	
Continue promoting the Agency as the central point of contact for scientific advice in relation to 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.	Increase by at least 10% in total.

Core performance indicators for the area	Target
Scientific-advice requests evaluated within the procedural timelines.	95% of applications.

3.2. Initial evaluation

Trends and new issues

The large increase of new applications seen in 2010 may not be sustained, and the Agency predicts a stabilisation in the number of applications for marketing authorisations, reflecting the current economic environment. The low level of generics is expected to increase only slightly, in line with the number of innovative reference products reaching the end of the 10-year period of data exclusivity, but this is dependent on whether innovative reference products have achieved high-volume sales and return on investments.

The year 2011 will be the second full year of operation of the measures to assist applications related to products indicated for MUMS/limited markets under Art. 79 of Regulation (EC) No 726/2004, which

attracted high interest in terms of requests for MUMS/limited-market classification. A continued increase in classification requests is anticipated. However, as these requests are made at an early stage of product development, the first applications for MUMS/limited-market products eligible for assistance are expected to be submitted in 2011/2012 at the earliest.

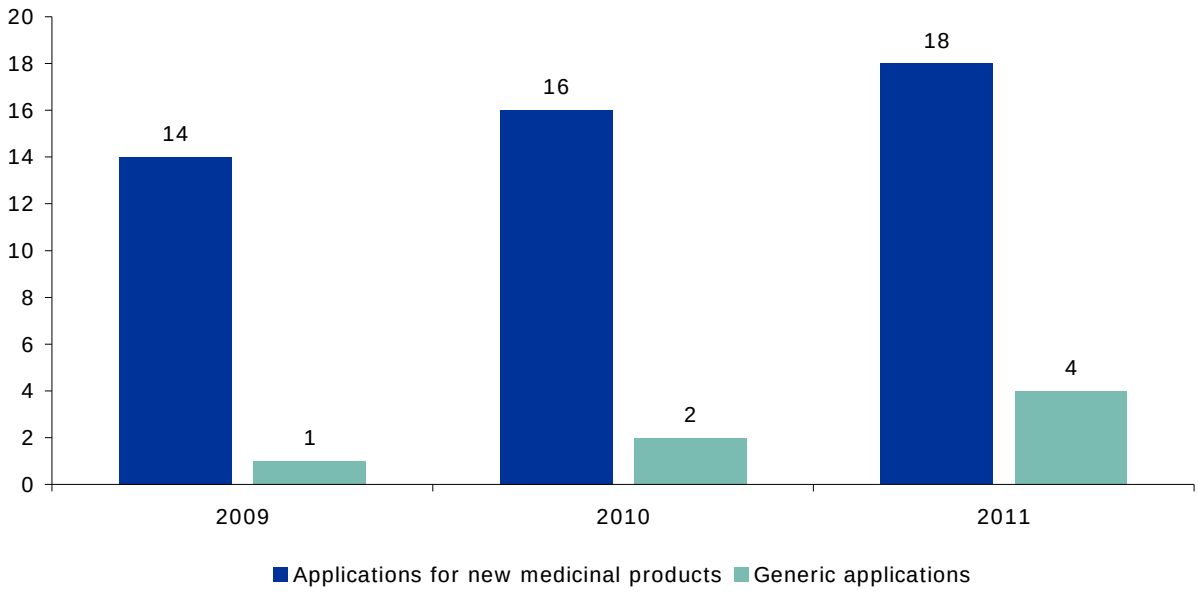
In addition to ensuring effective and efficient core activities in the area, the Agency will continue to put emphasis on the quality-assurance system in respect of CVMP procedures, to ensure the quality and consistency of the scientific assessments conducted.

There has continued to be an increase in recent years in the number of requests for authorisation under exceptional circumstances of vaccines against epizootic diseases of livestock (avian influenza and bluetongue, in particular). The demand for such authorisations will depend on the evolution of the epidemiological situation in the EU in relation to exotic diseases. In principle, this situation has the potential to deteriorate as global warming extends the geographical limit of vector species and as the trend to globalisation of trade increases the potential for exposure to new or (re)emerging pathogens.

The Agency will continue to promote authorisation through the centralised procedure of vaccines against epizootic disease of livestock by actively engaging in the Community Animal Health Strategy 'Prevention is better than cure'.

There has been an increased demand for advice with respect to the submission of innovative products for veterinary medicine through the centralised procedure, including a number of medicines containing active substances of biological origin, such as biologically active proteins and novel vaccines. The CVMP hopes to receive at least one application based on advanced therapies in the veterinary area in 2011 or 2012.

Figure 8. New applications for veterinary medicines



Objective	
Promote authorisation through the centralised procedure of vaccines against epizootic diseases of livestock.	
Performance indicators for the objective	**Target**
Completion of activities within the Community Animal Health Strategy 'Prevention is better than cure'.	Activities completed in line with action plan.

Core performance indicator for the area	Target
Percentage of products evaluated within the regulatory timeline of 210 days.	100% of applications.

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, resulting in a steady state of applications for maximum residue limits (MRLs). For 2011, the same number of MRL applications as in 2010 is forecasted.

The number of extensions has been largely unchanged over the past years, despite the initiatives taken by the CVMP to facilitate the authorisation of products for minor uses and minor species.

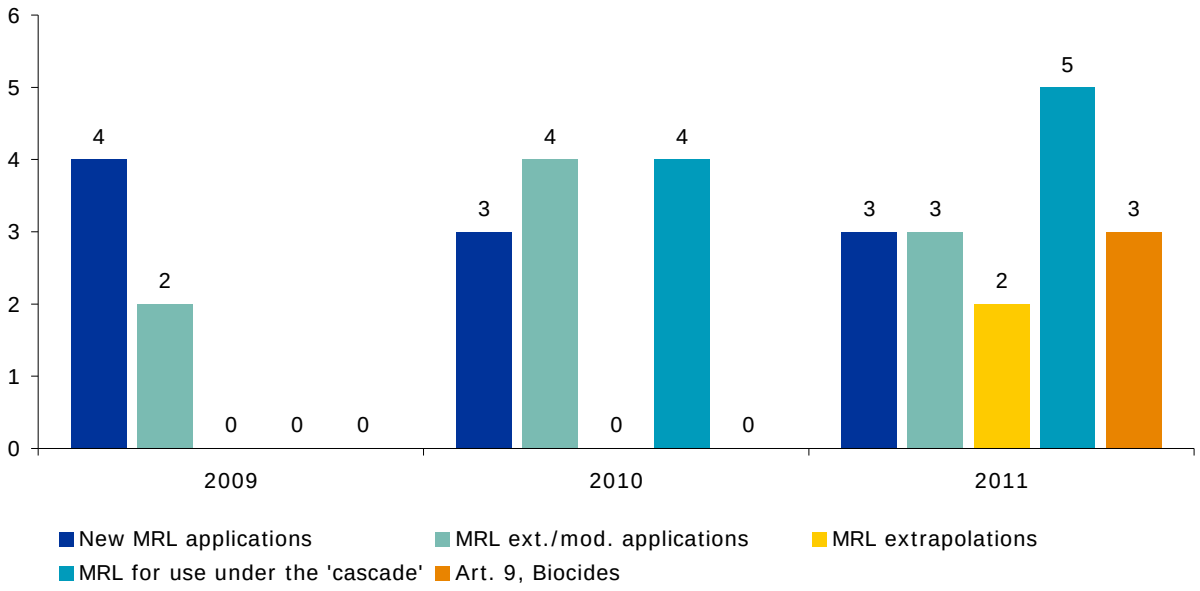
While the new MRL Regulation provides specific emphasis on extrapolations, and allows Member States, the European Commission and interested parties to submit requests to the Agency without payment of fees, little use has yet been made of this incentive, indicating that there continues at present not to be much interest in developing products for minor species based on existing major-species products, presumably due to a lack of expected return on investment.

The new MRL Regulation foresees that the Codex MRLs are automatically adopted by the European Union, provided that there were no objections from the EU delegations to the decision of the Codex Alimentarius Commission. The Agency/CVMP will be requested to evaluate the MRLs proposed by Codex in order to substantiate the EU position. Based on current requests to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for establishment of MRLs, the number of such assessments is estimated to be between 5 and 7 substances in 2011.

The new legislation allows for the establishment of MRLs for substances used under the so-called 'cascade', based on applications from Member States. Assuming that the pending procedural issues for such applications are resolved, applications for over 50 substances may potentially be made by Member States over the coming years, with 5 estimated in 2011.

With the new MRL Regulation, the Agency became responsible for substances included in biocidal products that are used in animal husbandry, for which MRLs should be established in accordance with Directive 98/8/EC. The evaluation of substances that are already on the market will be stretched over several years. In addition, applications for new substances are also expected. Overall, up to 3 such applications are expected in 2011.

Figure 9. New applications for maximum residue limits (MRLs)



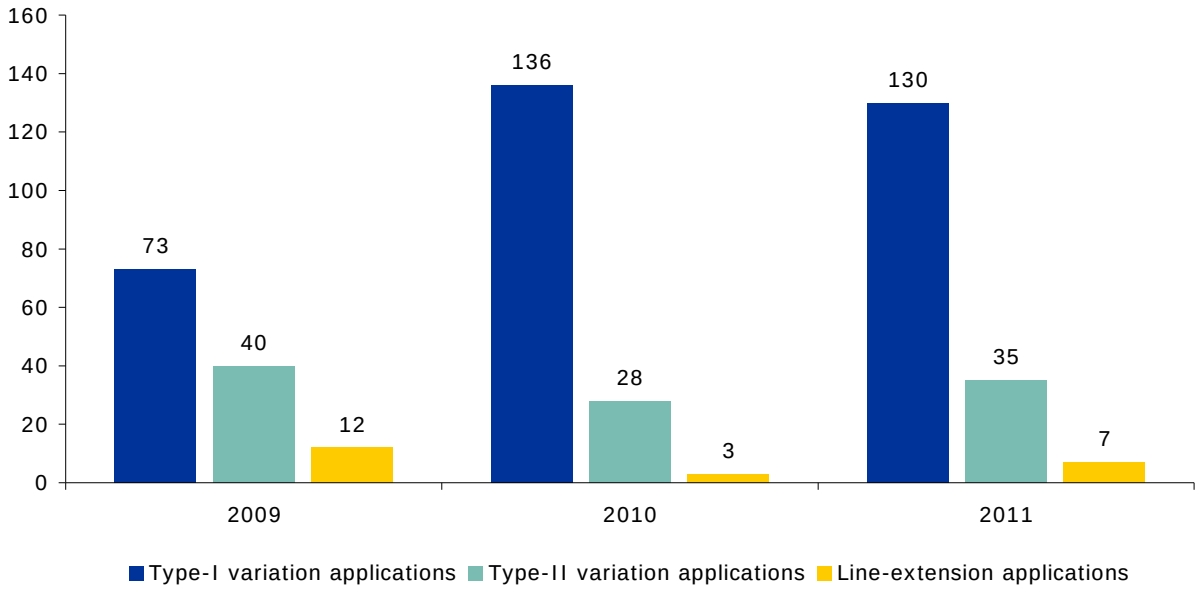
Core performance indicator for the area	Target
Percentage of MRL applications evaluated within the legal timeline.	100% of applications.

3.4. Post-authorisation and maintenance activities

Trends and new issues

The increased workload for the Agency and the EU regulatory network foreseen with the coming into force of the new Variations Regulation will continue in 2011. While these measures will undoubtedly represent a reduction in bureaucracy to industry, there is a corresponding increase in the complexity of the regulatory procedure for regulatory authorities. The ability to further streamline variation procedures will be assessed in 2011.

Figure 10. Post-authorisation applications



Objective	
Streamlining of procedures, following the implementation of the new Variations Regulation.	
Performance indicators for the objective	**Target**
Review operation of new variations legislation in light of experience gained.	Review completed, Q4.

Core performance indicator for the area	Target
All post-authorisation procedures processed in accordance with legal requirements.	100% of applications.

3.5. Pharmacovigilance and maintenance activities

Trends and new issues

Further to the steady increase in the number of spontaneous serious adverse reaction and human reaction reports in the past years, this trend is expected to decelerate in 2011, with 6,500 reports expected (nearly 5,000 for 2010). Improving the surveillance strategy for all adverse-event reports submitted will remain one of the key objectives for 2011.

The number of periodic safety update reports (PSURs) being submitted in 2011 for centrally authorised products is expected to increase slightly, with 126 being forecast (117 in 2010).

The new version of EudraVigilance Veterinary (EVVet 3.x), which provides for improved and simplified data input, a tracking facility for surveillance analysis, and alignment to internationally agreed standards, is expected to reach testing phase in 2011.

Following the full implementation of the EudraVigilance Veterinary Data Warehouse in 2010, the coordinating role of the Agency in processing and analysing pharmacovigilance information will be further rationalised, with the focus on optimising tools for signal detection, to establish the Agency's surveillance role within the EU, initially with emphasis on centrally authorised products.

Objective	
Support targeted pharmacovigilance and implement the signal-detection tools developed in the data warehouse for centrally authorised products, with an increased role of the PhVWP-V in line with its mandate.	
Performance indicators for the objective	**Target**
Full signal detection implemented for CAPs.	Q4.

Core performance indicators for the area	**Target**
Percentage of PSURs evaluated within the established timelines.	80%.
Percentage of suspected adverse reactions monitored within the established timelines.	100%.

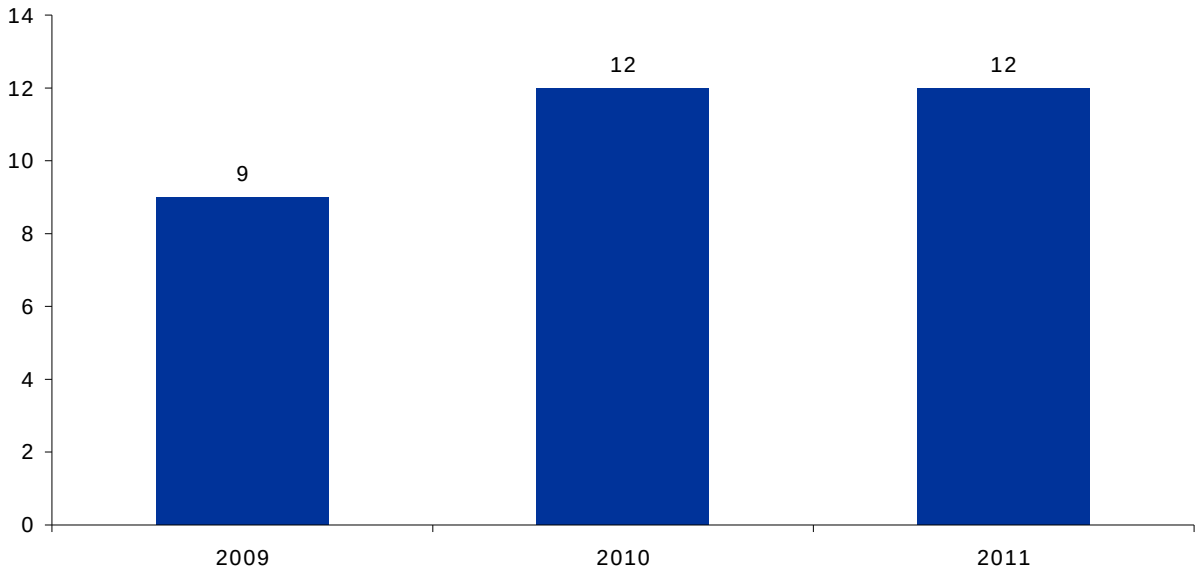
3.6. Arbitration, Community referrals and opinions on scientific matters

Trends and new issues

Trends remain in line with those expected for 2010. While the number of Article 33 referrals has decreased over the years, indicating that some differences in interpretation of legislation or guidelines seem to have been overcome, and that the recommendations given previously by the CVMP are being accepted by Member States, a significant number of referrals are expected to continue to relate to mutual-recognition or decentralised procedures (submitted under Article 33 and Article 34). A significant proportion of referrals relate to authorisation of generic products. It is expected that 1 or 2 referrals will be submitted under Article 34 or 35 due to discrepancies of withdrawal periods for veterinary medicinal products for food-producing animals, with the aim of harmonising withdrawal periods and ensuring consumer safety. These referrals usually concern large numbers of products and require considerable resources to process. One or more referrals to the CVMP may be initiated under Article 35 in relation to minimising the risk of the development of resistance arising from the use of antimicrobials in animals. Although few in number, experience has shown that such referrals are challenging, both in terms of the number of products potentially involved and the amount of data requiring assessment to enable the Committee to reach a conclusion.

The Agency will continue to support efforts by the CVMP, CMDv and Heads of Medicines Agencies (HMA) to tackle issues that have potential for disagreement in approach, and develop a common understanding, with the aim of avoiding inappropriate referrals.

Figure 11. Arbitration and Community referrals



Objective	
Ensure all arbitrations and referrals are handled in compliance with recommendations from the Ad-hoc Group and Task Force.	
Performance indicators for the objective	**Target**
CVMP opinions successfully adopted by the European Commission.	90% of opinions adopted by the European Commission without requests for substantial change.

Core performance indicators for the area	Target
Percentage of arbitration and referral procedures managed within the legal timeline.	100% of procedures.

3.7. Scientific committees and working parties

Trends and new issues

The CVMP working parties will continue to provide scientific support to the CVMP, in particular to develop and update guidelines, but also to provide advice on specific requests in relation to applications and technical and scientific enquiries from companies under consideration by both the CVMP and the Coordination Group.

Considering the continued increase of workload, in terms of both quantity and scope, the CVMP will continue to review working practices, and will consider establishing specialised scientific advisory groups to support the Committee.

The CVMP, with the support of its Scientific Advisory Group on Antimicrobials, 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 through the use of antibiotics in animals. The Agency's secretariat will produce a report on the collection of data on sales and use of antimicrobial veterinary medicinal products in the EU.

The Agency will continue to strengthen its interaction with other scientific committees, in particular those within EFSA, with the objective of ensuring consistency of assessment approaches and scientific opinions, as well as providing appropriate input when EFSA scientific committees prepare opinions related to the use of veterinary medicinal products in the food chain or to animal health.

3.8. Coordination group

Trends and new issues

Some specific issues affecting the smooth functioning of the EU regulatory network, such as packaging and labelling, divergent interpretation of legislation, and national validation requirements, require continued work by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv), with support from the Agency's secretariat.

The current level of referrals is expected to continue and may increase. There is a need to continue the analysis of the underlying drivers, to ensure that referrals are prioritised according to the needs of public and animal health and the environment. Work with the CVMP on strategic considerations regarding referrals, including prioritisation criteria, is ongoing.

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

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

Objective	
Ensure effective liaison with the CVMP in the interests of consistency, the continued availability of veterinary medicines and the smooth functioning of the network.	
Performance indicators for the objective	**Target**
Acceptance by CVMP of procedure initiated by CMDv.	90% of procedures initiated by CMDv accepted by CVMP.

4. Compliance and inspections

Trends and new issues

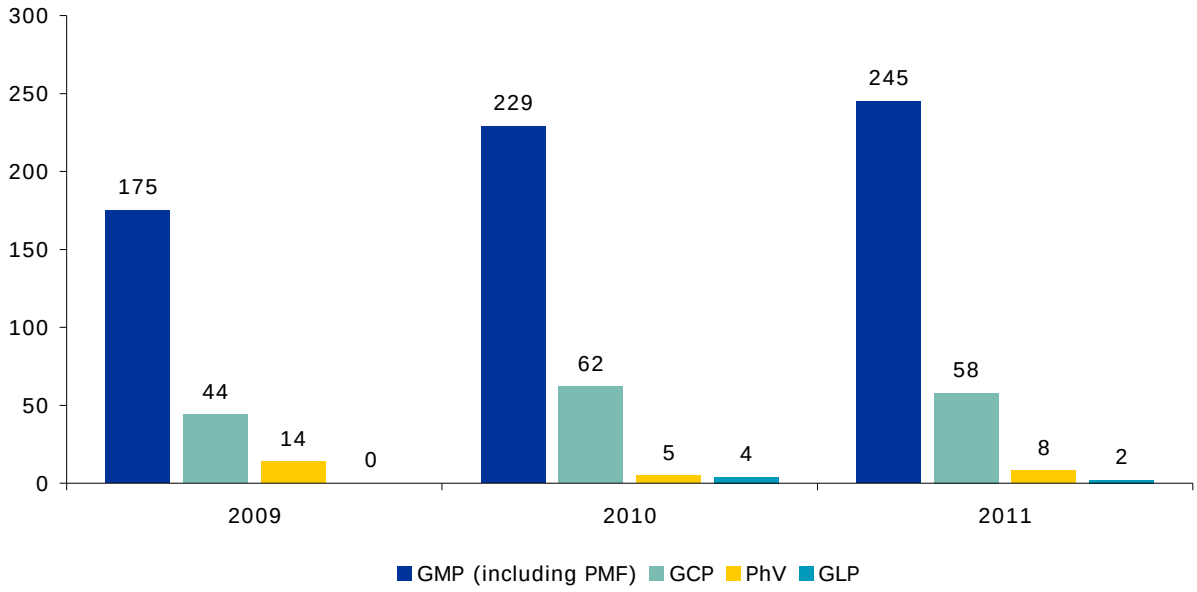
Globalisation of clinical trials and of manufacturing of active pharmaceutical ingredients (APIs) and finished products remains one of the trends in the area of inspections. With that in mind, the Agency will extend its international partnerships in the areas of good-manufacturing-practice (GMP) and good-clinical-practice (GCP) inspections, and work with the partners on tools and agreements to support training, capacity-building, information sharing and inspection planning. Within the same context of globalisation, the pilot phase of the joint Agency-FDA initiative on GCP will have been completed. Longer-term cooperation will be explored after reviewing the process and scope of the initiative. Cooperation on GMP inspections of finished-product manufacturers will be further developed, as will international cooperation in the field of pharmacovigilance inspections.

Transparency of clinical-trial information remains a key issue with the release of the EU Clinical Trials Register and the Agency's plans to make summaries of clinical-trial results public.

Quality defects are a key concern, with increasingly complex follow-up at EU and international level. A major activity in this area will be to conduct and follow up on a project to analyse the root causes.

The European Commission is expected to publish proposals for revision of the clinical-trials legislation in the first semester of 2012. The Agency will contribute as required to these developments.

Figure 12. Number of inspections



4.1. Manufacturing and quality compliance

For trends and new issues, please see above.

Objective	
Enhance collaboration on international GMP agreements with regulatory partners.	
Performance indicators for the objective	**Target**
Acceptance of new Member States within the agreements.	Q4 for 2004 enlargement (10).
Increase in the number of international partners linked to EudraGMP.	All MRA partner authorities connected with read and write access, and paper exchange of certificates discontinued, Q4.
Objective	
Prepare for the implementation of the new EU legislation on falsified medicines.	
Performance indicators for the objective	**Target**
Preparation of an action plan on implementation of the new legislation.	Status report prepared following publication of the agreed legislative package.
Revised guidance on good distribution practice.	Revised guidance submitted to the European Commission for public consultation, Q3.
Objective	
Implement a trial strategy on sampling and testing of generic medicinal products.	
Performance indicators for the objective	**Target**
Conduct of a pilot testing programme for generics authorised in the centralised procedure.	A pilot testing programme carried out.
Objective	
Include checking of packaging and labelling of centrally authorised products as part of the sampling and testing programme.	
Performance indicators for the objective	**Target**
Inclusion of a selection of parallel distributed products in the programme (both for package-label checking and for sampling and testing).	3 products included.
Carry out a trial programme of general label conformance checks on samples (non-parallel distributed).	Trial conducted and evaluated.

Core performance indicators for the area	Target
Management of inspections within legislative timelines.	100% of inspections.
Number of products of the sampling and testing programme for centrally authorised products actually tested.	52.

4.2. Clinical and non-clinical compliance

For trends and new issues, please see above.

Objective	
Develop operational the international network of GCP inspection services.	
Performance indicators for the objective	**Target**
International workshop on GCP inspection.	Workshop conducted, Q3.
Contribution to a coordinated international approach to training and capacity-building for GCP inspectors and other GCP-related areas.	Contribution provided, Q4.
Objective	
Progress pilot project and extend the Agency-FDA GCP initiative following completion of the pilot phase.	
Performance indicators for the objective	**Target**
Preparation of a report on the pilot phase and an action plan for the extension of the initiative.	Report prepared and action plan agreed.
Providing regular information exchanges with the FDA.	Monthly exchanges held.
Planning of inspections and information sharing for products of mutual interest.	6 products included.
Objective	
Develop international cooperation in the field of pharmacovigilance inspection.	
Performance indicators for the objective	**Target**
A pilot initiative on PhV inspection.	Initiative implemented, Q3.

Objective	
Initiate steps to facilitate implementation of the inspection-related aspects of the new legislation on pharmacovigilance.	
Performance indicators for the objective	**Target**
Preparation of an action plan on the steps to be taken to facilitate the implementation.	Action plan prepared, Q1.

Core performance indicator for the area	Target
Management of inspections within legislative timelines.	100% of inspections.

4.3. Clinical-trials support

Trends and new issues

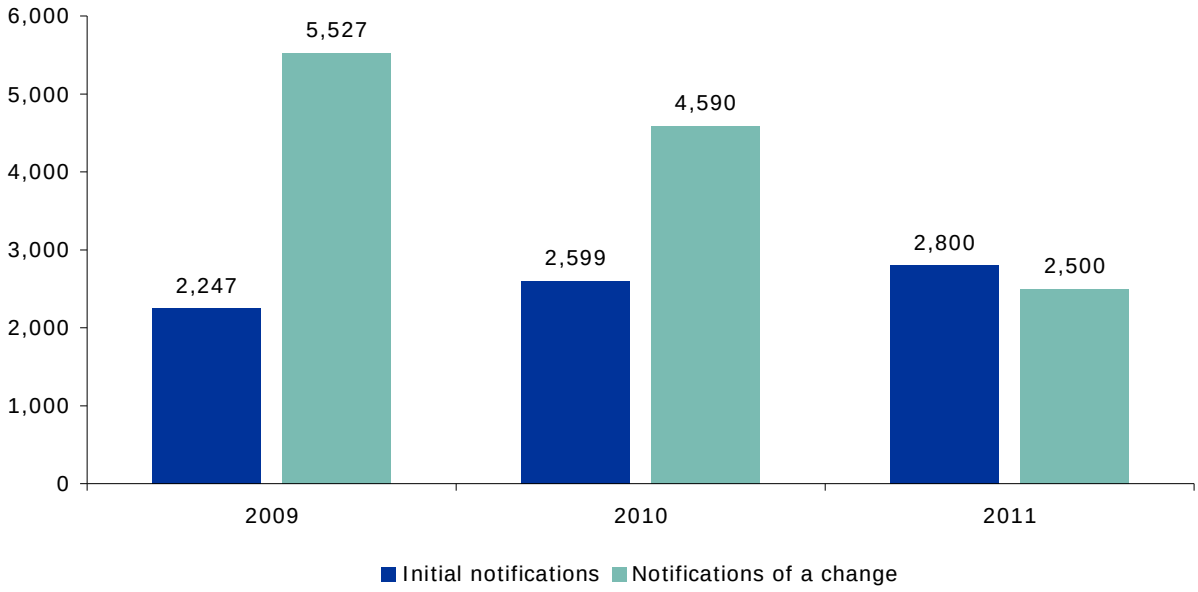
Globalisation of clinical trials is among the main topics in the environment and on the Agency's agenda in this area. Many activities therefore have an international dimension. These include implementation of the Agency's strategy for acceptance of clinical trials conducted in third countries, work on international standardisation of clinical-trials registries, and cooperation in the field of GCP inspections. Other activities in this domain concern implementation of the programme of GCP inspections and continued development of risk-based approaches to the quality-management of clinical trials.

Objective	
Implement the Agency's strategy for acceptance of clinical trials conducted in third countries.	
Performance indicators for the objective	**Target**
Publication of the reflection paper on acceptance of clinical trials conducted in third countries.	Paper published, Q3.
Preparation of a report on the first year of implementation of regulatory actions identified in the reflection paper on acceptance of clinical trials conducted in third countries.	Report prepared, Q4.
Objective	
Implement the Agency-HMA/CTFG action plan relating to interactions throughout the lifecycle of medicinal products – pre and post-marketing authorisation.	
Performance indicators for the objective	**Target**

Development and implementation of procedures for communication between the Agency, its scientific committees, the CTFG and its members on product-related matters.	Procedures implemented, Q3.

4.4. Parallel distribution

Figure 13. Parallel-distribution notifications



Objective	
Implement a system for electronic submission and handling at the Agency of notifications of parallel distribution.	
Performance indicators for the objective	**Target**
Development of an electronic form to support online submission.	Q3.
90% of submission being received electronically.	Q4.

Core performance indicators for the area	**Target**
Percentage of initial notifications checked for compliance within the regulatory timeline: paper submission validation and regulatory check 35 days	80%
Number of parallel distributed products sampled on the EU market checked for compliance with the Notices issued by the Agency	20 products

4.5. Certificates

Trends

The number of certificate requests submitted is expected to be similar to the number for 2010, with an estimated 2,500 requests being foreseen.

Objective	
Further develop the process of issuing certificates, following discussions with WHO and stakeholders in 2010.	
Performance indicators for the objective	**Target**
A proposal for revisions to the process.	Proposal prepared, Q2.

Core performance indicator for the area	**Target**
Percentage of certificates of medicinal products issued to requesting parties within the timeline.	90% compliance.

5. Information and communications technology

This chapter covers support for both internal activities and EU Telematics.

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

Trends and new issues

Budget cuts announced by the Budgetary Authority, coupled with new tasks vested in the Agency (as at the date of this document), as well as the continuous drive for increased efficiency, have resulted in the financial resources available for further ICT development being subject to contention. Accordingly, not all the projects needed to meet all the urgent requirements of the Agency will be carried out, but only those listed below.

The expiry of the Agency's lease on its premises necessitates a considerable investment in planning over the coming year, and may require substantial additional investment in ICT infrastructure in 2012 and 2013.

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

Overall objectives for the area

1. Consolidate the current ICT landscape.

Over the lifetime of the Agency, a number of ICT systems have been put into place to support the Agency's processes. In order to increase efficiency in terms of support for these systems, it is necessary to rationalise the architecture of the ICT systems, and improve communication at the systems level.

2. Assure the coherent technical implementation of legislation.

In furtherance of the first objective, increased emphasis will be placed on ensuring the complementary nature of new developments and enhancements.

Projects improving the efficiency of the Agency

Resource-management projects

- The first financial module (known as FIN 1) of the enterprise-resource-planning (ERP) system will be launched in Q1, to replace several different legacy systems. One of the principal benefits will be an improvement in the quality of data provided for decision making.
- Phase 1 of the human-resource module of the ERP system will be implemented in Q3, and the realisation (construction) work on Phase 2 will be completed in Q4. The system will improve the administration of human resources within the Agency.

Projects improving management of processes

- Deliver the system to support procedure and workload management for marketing-authorisation and post-authorisation applications (SIAMED II) by Q3.
- Complete the first implementation of electronic signatures in Q4.
- Complete the first implementation of electronic workflows for publication in Q4.
- Deliver a system to support plasma-master-file applications in Q4.

Projects improved quality of data input, processing and management

- Launch Electronic Application Form (EAF) into production for initial applications and variations in Q2.
- Implement improvements to systems supporting electronic submissions in Q4.
- Complete Phase 2 (Q2) and initiate phase 3 (Q4) of EMA Enterprise Information Architecture.
- Complete pilot for the Unique Product Identifier by Q3.
- Launch the first release of the updated version of the Eudra Common Directory in Q4.

Implementation of legislation

Regulation (EC) 1049/2001 on access to documents:

- Launch document register by Q4.
- Implement tracking support in Q4.

Automated publication of experts' declarations of interests:

- Implement the register in Q2.

Performance indicator	Target
Projects delivered on time.	85%.
Projects delivered to original specifications.	100%.
Projects delivered within budget.	85%.

5.2. EU Telematics

Trends and new issues

The factors affecting the potential for investment in EU Telematics systems are the same as those outlined above in respect of the Agency's administrative and operational systems.

The implementation of the systems specifically foreseen in the legislation and the communication needs across the European medicines network to assure full use of these systems require specific support. This is achieved through the definition and implementation of standards, and the establishment of infrastructure. Neither of these is specifically foreseen in the legislation. The EU Telematics programme proposed is therefore a balance between explicitly legislated systems and infrastructure systems limiting expenditure to available appropriations.

The severity of the structural risk that funding may not be maintained in accordance with the requirements of the portfolio of projects taken forward in any given year is on an increasing trend. Planning activities are therefore undertaken in the context of a number of uncertainties. The targets set out in this work programme are based on a number of assumptions that may not hold, and accordingly adjustments will be required after publication of this document.

The new pharmacovigilance legislation will apply from 2012. The legislation necessitates major IT investment, including in: EudraVigilance (human); the European Pharmacovigilance Issues Tracking Tool (EPiTT) to support PSURs and RMPs; a web portal; the ENCePP database of non-interventional studies. The implications of the new legislation are, however, significant across all systems supporting European processes.

Objectives for systems supporting the European medicines network

Improved communication

- Publish a new version of the Telematics website for the European medicines network in Q2.
- Implement the Management Board Telematics Committee strategy for increasing use of virtual meetings technology by Q4.
- Review the governance structure of EU Telematics by Q3.

Efficient and interoperable platform

- Make available a first iteration of partially-ISO compatible medicinal products and substances database within EUTCT by Q2.
- Next version of the Eudra Common Directory available in Q4.
- Launch a revised data warehouse offering business intelligence functionality on EudraVigilance Human data by Q4.
- Launch a data warehouse offering business intelligence functionality on EudraCT data by Q3.

Efficient Telematics systems that are fit for purpose

- Complete EV data management (backlog) 100% by Q4.
- Implement EV data access policy by Q4.
- Progress implementation of new legislative functionality in EV (human), the data warehouse and the eSubmissions systems.
- EudraCT version 8.x: New CTA Paediatrics Protocol, EU Clinical Trials Register and delivering increased electronic communication between registries and other stakeholders by Q3.
- EudraCT version 9: Complete analysis and design, and deliver a first prototype by Q4.

Improved capacity for performance measurement

- Implement automated key performance indicators by Q4.

Increasing the Agency's contribution to international regulatory activities

Improved assimilation of EU requirements leading to a coherent EU position.

There will be significant Agency and EU regulator contributions to achieving the following in the context of standards-development organisations:

- ISO ICSR (individual case safety report) standard available Q2.
- RPS (regulated product submission) release 3 ballot package available Q4.
- Test results of CTR&R (clinical trial registration and results) draft standard for trial use satisfactory for EU requirements Q2.
- ISO IDMP (identification of medicinal products) standard available Q4.

Objectives for assuring the coherent technical implementation of legislation

Interoperability of systems

- EUTCT: All Telematics systems using at least 10% of their necessary CTLs in Q4.
- EUTCT: 70% of national competent authorities (NCAs) using at least one list from EUTCT in Q4.

Redundant input of information

- EAF (Electronic Application Form) in production for initial applications and variations Q2.

Increased efficiency of pharmacovigilance activities

- Tools supporting improved data for the identification of medicinal products in place Q2.

Increased transparency, communication and provision of information

- EudraPharm: publishing medicinal product information from 55% of NCAs in Q4.

Performance indicator	Target
Projects delivered on time.	85%.
Projects delivered to original specifications.	100%.
Projects delivered within budget.	85%.

5.3. Maintenance and support of ICT

Core business performance indicators for the area (covers EU Telematics and corporate IT)

Performance indicator	Target
Telematics and internal IT systems availability measured against Agency's working hours.	98%.
Service Desk (Eudra) - meeting of service level agreements per system/priority level.	See table below.

Service Desk (Eudra): Performance indicators for meeting service level agreements per system/priority level

Severity rating	Description	Response time	Target	Resolution time	Target
1. Critical	Users unable to use system.	30 min.	90%.	4 hours.	80%.
2. Severe	System operational but severely restricting use.	1 hour.	90%.	1 business day.	80%.
3. Important	System operational but one or more functions restricted.	1 day.	90%.	10 business days.	80%.
4. Minor[1]	System operational and no functions restricted.	3 days.	90%.	120 business days.	80%.

[1] 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 2009-2011

Function Group & Grade	Authorised for 2009		Occupied as at 31.12.2009			Authorised for 2010		Authorised for 2011[2]	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts		Permanent posts	Temporary posts	Permanent posts	Temporary posts
				Grade filled	Actual grade				
AD 16	-	1	-	1	-	-	1	-	1
AD 15	-	3	-	3	1	-	4	-	4
AD 14	-	4	-	4	4	-	5	-	5
AD 13	-	6	-	6	6	-	6	-	7
AD 12	-	36	-	36	27	-	37	-	37
AD 11	-	34	-	34	28	-	36	-	36
AD 10	-	34	-	34	15	-	32	-	32
AD 9	-	35	-	32	37	-	35	-	38
AD 8	-	40	-	34	26	-	43	-	43
AD 7	-	38	-	38	19	-	38	-	42
AD 6	-	34	-	32	68	-	39	-	32
AD 5	-	17	-	15	36	-	34	-	33
Total AD	***0***	***282***	***0***	***269***	***267***	***0***	***310***	***0***	***310***
AST 11	-	-	-	-	1	-	2	-	2
AST 10	-	6	-	5	1	-	4	-	4
AST 9	-	5	-	5	2	-	8	-	8
AST 8	-	12	-	12	3	-	13	-	13
AST 7	-	15	-	14	13	-	18	-	19
AST 6	-	38	-	38	16	-	35	-	35
AST 5	-	39	-	39	16	-	35	-	35
AST 4	-	46	-	46	34	-	46	-	49
AST 3	-	30	-	28	50	-	36	-	36
AST 2	-	25	-	24	21	-	40	-	40
AST 1	-	32	-	31	87	-	20	-	16
Total AST	***0***	***248***	***0***	***242***	***244***	***0***	***257***	***0***	***257***
TOTAL	**0**	**530**	**0**	**511**	**511**	**0**	**567**	**0**	**567**

[2] As revised for draft establishment plan endorsed by the Budgetary Authority.

Annex 2 Revenue and expenditure overview 2009-2011

		2009[3]		2010[4]		2011[5]	
		€ '000	%	€ '000	%	€ '000	%
	Revenue						
100	Fees	141,023	71.9	152,780	73.3	161,041	77.1
200	General EU contribution	36,320	18.5	28,280	13.6	28,042	13.4
200	Surplus from previous year	4,900	2.5	[6]14,532	7.0	5,477	2.6
201	Special EU contribution for orphan medicinal products	5,632	2.9	4,500	2.2	4,901	2.3
300	Contribution from EEA	873	0.4	935	0.4	784	0.4
600	Community programmes	103	0.1	460	0.2	560	0.3
5+9	Other	7,283	3.7	6,900	3.3	8,058	3.9
TOTAL REVENUE		**196,135**	**100.0**	**208,387**	**100.0**	**208,863**	**100.0**
	Expenditure						
Staff							
11	Staff in active employment	51,988	27.8	63,039	30.3	67,186	32.2
13	Mission expenses	663	0.4	789	0.4	800	0.4
14	Socio-medical infrastructure	535	0.3	615	0.3	647	0.3
15	Exchange of civil servants and experts	2,636	1.4	2,332	1.1	2,999	1.4
16	Social welfare	97	0.1	145	0.1	152	0.1
17	Entertainment and representation expenses	37	0.0	95	0.0	35	0.0
18	Staff insurances	1,786	1.0	2,078	1.0	2,130	1.0
	Total title 1	***57,741***	***30.9***	***69,093***	***33.2***	***73,949***	***35.4***
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	16,056	8.6	19,066	9.1	16,945	8.1
21	Expenditure on data processing	29,589	15.8	30,802	14.8	7,701	3.7
22	Movable property	2,598	1.4	1,486	0.7	1,599	0.8
23	Other admin. expenditure	1,128	0.6	1,103	0.5	1,236	0.6
24	Postage and communication	818	0.4	694	0.3	959	0.5
25	Expenditure on other meetings	92	0.0	153	0.1	138	0.1
	Total title 2	***50,281***	***26.9***	***53,304***	***25.6***	***28,578***	***13.7***
Operational expenditure							
300	Meetings	7,660	4.1	8,820	4.2	8,471	4.1
301	Evaluation of medicines	66,487	35.6	71,106	34.1	74,925	35.9
302-304	Translation, studies and consultants, publications	4,251	2.2	4,615	2.2	4,751	2.4
305	Community programmes	272	0.1	480	0.2	500	0.2
310	Expenditure on data processing related to product lifecycle					5,792	2.8
311	Expenditure on data processing for special programmes					11,897	5.7
	Total title 3	***78,670***	***42.1***	***85,021***	***40.8***	***106,336***	***50.9***
Provisional appropriation							
900	Provisional appropriation	0	0.0	969	0.5	0	0.0
	Total title 9	***0***	***0.0***	***969***	***0.5***	***0***	***0.0***
TOTAL EXPENDITURE		**186,693**	**100.0**	**208,387**	**100.0**	**208,863**	**100.0**

[3] 2009 as per final accounts.
[4] Budget 2010 as of 31 December 2010 (incl. AB 01-2010).
[5] Budget 2011 as adopted by the Management Board on 16 December 2010.
[6] EUR 3.7 million of surplus are used to compensate for orphan medicines fee reductions (AB 01-2010).

Annex 3 Working-party guidelines

In addition to the guidelines listed below, the European Medicines Agency's scientific committees and their working parties actively contribute on behalf of the European Union to the development of guidelines by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH).

Committee for Medicinal Products for Human Use (CHMP)

CHMP Biologics Working Party

Reference number	Document title	Status
EMEA/CPMP/BPWP/BWP/561/03	Note for Guidance on the warning on transmissible agents in Summary of Product Characteristics (SPCs) and package leaflets for plasma-derived medicinal products	Revision for publication
EMA/CHMP/BWP/534898/2008	Guideline on the Requirements for Quality Documentation concerning Biological Investigational Medicinal Products in Clinical Trials	For publication
EMEA/CPMP/BWP/269/95 rev 4	Note for guidance on Plasma derived medicinal products	For publication
EMA/CHMP/BWP/68803/2010	Guideline on quality aspects on the isolation of candidate influenza vaccine viruses in cell culture	For publication
EMEA/CHMP/BWP/2879/02	Position statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products	For finalisation
EMEA/CHMP/BWP/353632/2010	Position Statement on Creutzfeldt-Jakob disease and advanced therapy medicinal products	For finalisation
3AB7a	Revision of guideline on the use of transgenic animals in the manufacture of biological medicinal products for human use	For consultation and finalisation
EMEA/CHMP/BWP/1793/2001	Note for guidance on the use of bovine serum used in the manufacture of human biological	To initiate discussions on need to review guideline in respect of testing requirement for BVD

	medicinal products	
EMEA/CHMP/BWP/3088/99	Guideline on quality, preclinical and clinical aspects of gene transfer medicinal products	*To be developed jointly with GTWP.* Development of quality aspects of the guideline
CHMP/GTWP/671639/2008	Draft Guideline on the quality, nonclinical and clinical aspects of medicinal products containing genetically modified cells	*To be developed jointly with GTWP and CPWP.* For finalisation
EMA/CAT/571134/09	Reflection paper on stem cell-based medicinal products	*To be developed jointly with CPWP.* Development of quality aspects of the guideline
EMEA/CAT/486831/2008/corrr	Scientific guideline on the minimum quality and non-clinical data for certification of advanced therapy medicinal products.	*To be developed jointly with CPWP and GTWP.* Review of guideline in the light of experience of certification procedures
CHMP/CPWP/708420/09	Guideline on risk-based approach according to Annex I, part IV of Directive 2001/83/EC applied to Advanced Therapy Medicinal Products	*To be developed jointly with CPWP and GTWP.*
Not yet assigned	Guideline on development of DNA vaccines	Development of quality aspects of multidisciplinary guideline
3AB1A	Production and quality control of medicinal products derived by recombinant DNA technology. Maintenance of guideline; update in the light of scientific developments e.g. reflection papers on peptide mapping test, qualification of tests for residual host cell proteins and residual DNA, particulate matter (in line with guideline on monoclonal antibody, filiation, requirements for process changes, specifications, etc.	Discussions to be initiated on need to develop reflection papers
EMEA/CHMP/BWP/49348/2005	Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substances: Quality issues	Review of guideline in light of experience gained in area of products containing biotechnology-derived proteins as active substances
Not yet assigned	Concept paper on potency declaration / labelling for biological medicinal products	For publication

	modified proteins for which an International Standard exist for the non-modified product	
3AQ21a	Guideline on radiopharmaceuticals based on monoclonal antibodies	Scientific input for the revision of the guideline
CHMP/BWP/99698/2007	Procedural advice on the submission of variations for annual update of Human Influenza inactivated vaccines applications in the centralised procedure	For publication
	Guidelines on influenza vaccines in the light of the lessons learnt during the pandemic	For review
Not yet assigned	Strain composition of the influenza vaccine for the forthcoming annual vaccination campaign	To propose strain composition
	Article 5(3) regarding any potential public health concern arising from detection of genomic fragments from endogenous and adventitious viral agents in live attenuated vaccines and the need to revise available guidance on biologicals.	On-going review of guidelines

CHMP Pharmacovigilance Working Party

Reference number	Document title	Status
N/a	Volume 9A of the Rules Governing Medicinal Products in the European Union – Revisions of the guidelines on EU RMP, Risk Communication, Signal Management, PSUR Management and Assessment, and 'Pharmacovigilance Urgent Measures' under Article 107	Finalisation of the revision 2010
N/a	ICH-E2B(R3): Clinical Safety Data Management – Data Elements for Transmission of Individual Case Safety Reports	Contribution to the project to develop ICH-E2B into an international standard (ISO/CEN)
N/a	ICH-E2F: Development Safety Update Reports	Contribution to finalisation following public consultation
N/a	ICH-M1: Medical Dictionary for	Contribution to MedDRA

	Drug Regulatory Activities (MedDRA)	maintenance and user guidance documents
N/a	ICH-M5: Data Elements and Standards for Drug Dictionaries	Contribution to the project to develop ICH-M5 as international standard (ISO/CEN)
N/a	ICH-E2C(R2): Clinical Safety Data Management – Periodic Safety Update Reports (PSURs)	Contribution to the revision of the current ICH-E2C Guideline throughout 2011
N/a	Guidelines in relation to public communication of pharmacovigilance information and transparency: PhVWP Monthly Reports, publication of DHPC, guidance on risk communication	In progress
N/a	Guidance on PhVWP Assessment Report	In progress
N/a	Guidelines in relation to pharmacovigilance inspections	Contribution to development of further guidance in accordance with the Work Programme of the Ad Hoc Pharmacovigilance Inspectors Working Group (PhVIWG)
N/a	Guidelines in relation to EudraVigilance	Contribution to development of guidelines as requested by the EudraVigilance Expert Working Group (EV EWG)
N/A	Best Practice Guidance for NCAs and Guidance for MAHs on submission and assessment of PSURs under PSUR worksharing scheme	Contribution to the revision of the BPG and guidance document.

CHMP Safety Working Party

Reference number	Document title	Status
CPMP/SWP/398/01	Note for Guidance on Photosafety Testing	Revision to be developed as an ICH topic
Not yet assigned	Reflection paper on the Impact of 3Rs in Pharmaceutical testing	For consideration
Not yet assigned	Reflection/position paper on available validated biomarkers	For consideration
CPMP/372/01	Points to Consider on the Non-Clinical Assessment of the Carcinogenic Potential of Insulin Analogues	Revision of the guideline for consideration
CPMP/SWP/2145/00	Note for Guidance on Non-Clinical Tolerance Testing of	Concept paper for the need of revision for publication

	Medicinal Products	
EMEA/CHMP/SWP/4447/00	Environmental Risk Assessment of Medicinal Products for Human Use	Revision of the guideline for consideration
CPMP/SWP/728/95	Replacement of Animal Studies by *in vitro* Models	Concept paper on the need for revision for publication
CPMP/463/00	Guideline on Excipients in the Label and Package Leaflet of Medicinal Products for Human Use	Revision of the guideline for consideration
CPMP/SWP/465/95	Note for guidance on pre-clinical Pharmacological and toxicological testing of vaccines	Revision of the guideline for consideration

CHMP Efficacy Working Party

The Efficacy Working Party has been replaced by new therapeutic working parties and drafting groups. See CHMP working parties and drafting groups below for relevant guidelines.

CHMP Biosimilar Medicinal Products Working Party

Reference number	Document title	Status
CHMP/437/04	Similar Biological Medicinal Product	For revision
EMA/CHMP/BMWP/94899/2010	Concept Paper on Similar biological medicinal products containing recombinant follicle stimulation hormone	Draft Guideline for publication
CHMP/BMWP/86572/10	Concept Paper on Similar biological medicinal product containing recombinant interferon beta	Draft Guideline for publication
CHMP/BMWP/632613/09	Similar biological medicinal products containing monoclonal antibodies	For publication
EMEA/CHMP/114720/2009	Immunogenicity assessment of monoclonal antibodies intended for in vivo clinical use	For publication

CHMP Biostatistics Working Party

Reference number	Document title	Status
EMA/CHMP/EWP/117211/2010	Guideline on the Use of Subgroup Analyses in Confirmatory Clinical Trials	Draft guideline to be developed in 2011.
EMEA/641698/2008	Reflection Paper on Methodological Issues Associated with PG biomarkers	Finalisation expected in 2011.

	in relation to clinical development and patient selection. Working parties involved: PGWP (leading), EWP	
EMEA/509951/2006	Annex to the Guideline on Conditional Marketing Authorisation on Methodological Considerations	Release for consultation expected Q2 2011.
N/A	Internal guidance document on the analysis and interpretation of survival data	Draft guidance document to be developed in 2011.

CHMP Blood Products Working Party

Reference number	Document title	Status
EMA/CHMP/BPWP/585257/2009	Guideline on the Clinical investigation of Human Plasma Derived Hepatitis-B Immunoglobulin	For consultation
CPMP/BPWG/283/00	Note for guidance on the Clinical investigation of Human normal immunoglobulin for subcutaneous and intramuscular use	Development of revised guideline
CPMP/BPWG/282/00	Core SmPC for Human normal immunoglobulin for subcutaneous and intramuscular use	Development of revised guideline
Not yet assigned	Reflection paper on the Clinical investigation of alpha1-proteinase inhibitor (alpha1 antitrypsin)	For consultation
Not yet assigned	Question and answer document relating to Guideline on Clinical Investigation of Plasma derived Fibrin Sealant/Haemostatic Products	For preparation
CPMP/BPWG/153/00	Core SmPC for plasma derived fibrin sealant / haemostatic products	Revision for consultation
EMA/CHMP/BPWP/BWP/360642/2010	Warning on transmissible agents for SmPCs and patient leaflets	Decision on whether to make specific reference to vCJD
Not yet assigned	Reflection paper on immune tolerance induction with FVIII and FIX products	For consultation
EMA/CHMP/BPWP/144533/2009	Guideline on the Clinical investigation of recombinant and human plasma-derived factor	For adoption and publication

	VIII products	
EMA/CHMP/BPWP/144552/2009	Guideline on the Clinical investigation of recombinant and human plasma-derived Factor IX products	For adoption and publication
CPMP/BPWG/1619/99	Core SmPC for Human plasma-derived and recombinant coagulation Factor VIII products rev. 1	For adoption and publication
CPMP/BPWG/1625/99	Core SmPC for Human plasma-derived and recombinant coagulation Factor IX products rev. 1	For adoption and publication

CHMP Cardiovascular Working Party

Reference number	Document title	Status
Not yet assigned	Guideline on the Prevention of Thromboembolic events in Atrial Fibrillation	To be developed
Not yet assigned	Guidelines on Clinical Investigation of Medicinal Products in the Treatment of Hypertension (CPMP/EWP/238/95) and of the Guideline on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (CPMP/EWP/3020/03): Need for Outcome Studies Basis on Safety Data at the Time of MAA.	To be developed
CPMP/EWP/3020/03	Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders (CPMP/EWP/3020/03): Revision on imaging surrogate endpoints	For finalisation
CPMP/EWP/2986/03/Rev. 1	Addendum on Acute Cardiac Failure of the Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Cardiac Failure (CPMP/EWP/235/95, Rev. 1)	For consultation
Not yet assigned	Paediatric Addendum to the Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Hypertension	To be developed

EMA/CHMP/213057/2010	Paediatric Addendum to the Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders	For finalisation
EMA/CHMP/EWP/213972/2010	Paediatric Addendum to the Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Pulmonary Hypertension	For finalisation
CPMP/EWP/1080/00 Rev.1	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Diabetes Mellitus	For finalisation

CHMP Central Nervous System Working Party

Reference number	Document title	Status
EMA/CHMP/607022/2009	Guideline on the Treatment of Premenstrual Dysphoric Disorders (PMDD)	For finalisation
EMA/CHMP/40072/2010 Rev. 1	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Schizophrenia	For finalisation
EMA/CHMP/185423/2010 Rev. 2	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Depression	For consultation

CHMP Infectious Diseases Working Party

Reference number	Document title	Status
EMEA/CHMP/EWP/30039/2008	Guidelines for the development of direct acting antiviral agents intended for treatment of chronic hepatitis C	Finalisation by Q3-4 2011
CPMP/EWP/558/95 Rev 2	Guideline on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections	Finalisation by Q3-4 2011
CPMP/EWP/2655/99	Points to Consider on Pharmacokinetics and Pharmacodynamics in the Development of Antibacterial Medicinal Products	Instead of revising this document, it is proposed to include a part on PK/PD in the revision of guideline CPMP/EWP/558/95.
EMEA/CPMP/EWP/633/02	Clinical Development of Medicinal Products for	Revision 3

	Treatment of HIV Infection	
EMA/CHMP/86004/2011	Guidance on the Nonclinical and Clinical Development of Medicinal Products for HIV Prevention including Oral and Topical Preexposure Prophylaxis	First draft reflection paper to be released for consultation by Q4 2011

CHMP Oncology Working Party

Reference number	Document title	Status
Not yet assigned	Guideline on Thrombocytopenia	To be developed
CPMP/EWP/205/95/Rev.4	Guideline on Evaluation of Anticancer Medicinal Products in Man	Revised guideline to be developed
CPMP/EWP/569/02	Addendum on Paediatric Oncology	Ongoing revision

CHMP Pharmacogenomics Working Party

Reference number	Document title	Status
EMEA/641698/2008	Reflection Paper on Methodological Issues Associated with PG biomarkers in relation to clinical development and patient selection: in collaboration with the BSWP	For consultation
EMA/CHMP/641298/2008	Reflection paper on co-development of pharmacogenomic biomarkers and Assays in the context of drug development	Released for consultation. Finalisation expected in 2011
EMA/CHMP/37646/2009	Guideline on the Use of Pharmacogenomic Methodologies in the Pharmacokinetic Evaluation of Medicinal Products. Working parties involved: in collaboration with PKWP	Released for consultation. Finalisation expected in 2011
EMEA/52482/2009	Reflection paper on genomics and personalised medicines	To be released for consultation in 2011

CHMP Pharmacokinetics Working Party

Reference number	Document title	Status
CPMP/EWP/560/95 Rev. 1	Note for Guidance on the Investigation of Drug Interactions	Revised guideline for publication
Not yet assigned	Appendix to the Guideline on Bioequivalence Regarding the Presentation of Biopharmaceutical and Bioanalytical Data in Application Dossiers	For consultation
EMA/CHMP/EWP/1303/2010	Note for guidance on modified release oral and transdermal dosage forms: section II (pharmacokinetic and clinical evaluation)	For consultation
Not yet assigned	Reflection Paper on the data requirements for Liposomal Products developed to be similar to an Innovator Product	For consultation
EMEA/CHMP/EWP/192217/2009	Guideline on Validation of Bioanalytical Methods	Revised guideline for publication

CHMP Rheumatology / Immunology Working Party

Reference number	Document title	Status
CPMP/EWP/556/95 REV. 1	Guideline on the Clinical Investigation of Medicinal Products other than NSAIDs in Rheumatoid Arthritis	Revision for consultation
Not yet assigned	Guideline on the clinical investigation of medicinal products intended for treatment of systemic and cutaneous lupus erythematosus	For consultation
Not yet assigned	Guideline on the clinical investigation of medicinal products to slow progression of renal insufficiency	For consultation
Not yet assigned	Addendum to the Guideline on the evaluation of medicinal products in the treatment of primary osteoporosis" (CPMP/EWP/552/95 Rev. 2): Clinical investigation of medicinal products intended for treatment of glucocorticoid-	For consultation

	induced osteoporosis	
CPMP/EWP/422/04	Guideline on the clinical investigation of medicinal products for treatment of juvenile idiopathic arthritis	Revision of the guideline to be considered

CHMP Vaccine Working Party

Reference number	**Document title**	**Status**
CHMP/308136/07	Guidance for DNA vaccines	Concept paper released for consultation July 2007 Guideline to be drafted in 2011
Not yet assigned	Non-Clinical and Clinical data requirements for the annual update of Live Attenuated Influenza Vaccines (LAIV)	New guidance to be developed
Not yet assigned	Core SmPC for trivalent influenza vaccines	New guidance
CHMP/VEG/193031/04	Core SmPC for pandemic influenza vaccines	For revision after lessons learnt exercise
CHMP/VWP/12544/2008.	Core SmPC for influenza vaccines with avian strains with a pandemic potential for human use	Draft guideline for finalisation
Not yet assigned	Reflection paper / Concept Paper on clinical investigation of influenza vaccines in children	Drafting of concept paper (guideline) and release for consultation
Not yet assigned	CP/Reflection paper on clinical investigation of influenza vaccines in pregnant women	Drafting of concept paper (guideline) and release for consultation
EMEA/CHMP/VEG/134716/2004	Guideline on adjuvants in vaccines for human use	To be revised after lessons learnt exercise
CHMP/VWP/244894/2006	Explanatory note on Immunomodulators for the Guideline on Adjuvants in vaccines for human use	To be revised after lessons learnt exercise
EMEA/CPMP/4986/03	Guideline on Submission of Marketing Authorisation Applications for Pandemic Influenza Vaccines through the Centralised Procedure	To be revised as required after lessons learnt exercise
EMEA/CPMP/VEG/4717/03 rev. 1	Guideline on Dossier Structure and Content for Pandemic Influenza Vaccine Marketing Authorisation Application	To be revised as required after lessons learnt exercise
CHMP/VWP/263499/06	Guideline on Influenza vaccines prepared from viruses with the	To be revised as required after lessons learnt exercise

	potential to cause a pandemic and intended for use outside of the core dossier context	

CHMP Gastroenterology Drafting Group

Reference number	Document title	Status
CHMP/EWP/342691/09	Guideline on the evaluation of medicinal product for the treatment of Gastroesophageal Reflux Disease	For publication

CHMP Radiopharmaceuticals Drafting Group

Reference number	Document title	Status
Not yet assigned	Core SmPC for Technetium (^{99m}Tc) Sestamibi Core PL for Technetium (^{99m}Tc) Sestamibi	For finalisation
Not yet assigned	Core SmPC for Technetium (^{99m}Tc) generator Core PL for Technetium (^{99m}Tc) generator	For finalisation
Not yet assigned	Core SmPC for sodium fluoride (^{18}F) Core PL for sodium fluoride (^{18}F)	For finalisation
Not yet assigned	Core SmPC for fluorodopa (^{18}F) Core PL for fluorodopa (^{18}F)	To be drafted
Not yet assigned	Core SmPC for Sodium iodide I 131 Core PL for Sodium iodide I 131	To be drafted
Not yet assigned	Core SmPC for gadopentetate dimeglumine Core PL for gadopentetate dimeglumine	To be drafted
Not yet assigned	Core SmPC for technetium (99mTc) nanocolloids Core PL for technetium (99mTc) nanocolloids	To be drafted
Not yet assigned	Core SmPC for technetium (99mTc) macrosalb Core PL for technetium (99mTc) macrosalb	To be drafted

CHMP Respiratory Drafting Group

Reference number	Document title	Status
CPMP/EWP/2922/01	Guideline on Clinical	For consultation

	Investigation of Medicinal Products in the Treatment of Asthma	
CPMP/EWP/562/98	Guideline on Clinical Investigation of Medicinal Products in the Chronic Treatment of Patients with Chronic Obstructive Pulmonary Disease (COPD)	Revised draft following public consultation for publication

CHMP Urology Drafting Group

Reference number	Document title	Status
CPMP/EWP/18/01	Note for Guidance on the Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinence	Draft revision for consultation

CHMP Working Group with Health-Care Professionals' Organisations

Reference number	Document title	Status
EMA/521899/2010	Framework of interaction between the Agency and Healthcare professionals' organisations	Finalisation by 4Q2010/1Q2011
	Criteria to be fulfilled by healthcare professionals' organisations involved in the European Medicines Agency.	Finalisation by 4Q2010/1Q2011
	Mandate and Rules of Procedure of the Healthcare professionals' organisations Working Group	Finalisation by 4Q2010/1Q2011
	Annual report of Agency's interaction with Healthcare professionals' organisations	Finalisation by 4Q2011

CHMP Name Review Group

Reference number	Document title	Status
EMA/17663/2010	Concept Paper on Names of radiopharmaceutical products – how to avoid mix-ups	In progress

Committee for Advanced Therapies (CAT)

CAT Gene Therapy Working Party

Reference number	Document title	Status
CHMP/GTWP/671639/2008	Draft Guideline on the quality, nonclinical and clinical aspects of medicinal products containing genetically modified cells	For finalisation
CHMP/GTWP/234523/09	Revision of the Note for guidance on quality, preclinical and clinical aspects of gene transfer medicinal products (CPMP/BWP/3088/99)	Review to be initiated
CHMP/CPWP/708420/09	Guideline on the application of the risk-based approach for advanced therapy medicinal products	For consultation
EMA/CHMP/GTWP/347737/2008	Draft reflection paper on changes during gene therapy medicinal product development	For consultation
CHMP/GTWP/212377/08	Questions and Answers on gene therapy	To initiate discussion on inclusion of additional Q&A

CAT Cell-based Products Working Party

Reference number	Document title	Status
CHMP/GTWP/671639/2008	Draft Guideline on the quality, nonclinical and clinical aspects of medicinal products containing genetically modified cells	For finalisation
CHMP/GTWP/234523/09	Revision of the Note for guidance on quality, preclinical and clinical aspects of gene transfer medicinal products (CPMP/BWP/3088/99)	For preparation
CHMP/CPWP/708420/09	Guideline on the application of the risk-based approach for advanced therapy medicinal products	For consultation
EMA/CHMP/GTWP/347737/2008	Draft reflection paper on changes during gene therapy medicinal product development	For consultation
CHMP/GTWP/212377/08	Questions and Answers on gene therapy	Inclusion of additional Q&A, when appropriate

Committee on Herbal Medicinal Products (HMPC)

Reference number	Document title	Status
	Mock-up of Module 3 of CTD for herbal medicinal products, as a future development of the HMPC 'Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products' (EMEA/HMPC/71049/2007)	Draft to be released for public consultation
	Guidance on comparability of herbal substances/preparations (e.g. extracts using different solvents)	Draft to be released for public consultation

HMPC Working Party on Community monographs and Community list

Reference number	Document title	Status
EMA/HMPC/262766/2010	Community herbal monograph on Bursae pastoris herba	For finalisation 1-2 Q
EMA/HMPC/369802/2009	Community herbal monograph on Chelidonii herba	For finalisation 1-2 Q
EMA/HMPC/706229/2009	Community herbal monograph on Cinnamomi aetheroleum	For finalisation 1-2 Q
EMA/HMPC/246774/2009	Community herbal monograph on Cinnamomi cortex	For finalisation 1-2 Q
EMA/HMPC/150218/2009	Community herbal monograph on Cynarae folium	For finalisation 1-2 Q
EMA/HMPC/289430/2009	Community herbal monograph on Hederae helicis folium	For finalisation 1-2 Q
EMA/HMPC/143181/2010	Community herbal monograph on Lavandulae aetheroleum	For finalisation 1-2 Q
	Community herbal monograph on Lavandulae flos	For finalisation 1-2 Q
EMA/HMPC/290284/2009	Community herbal monograph on Millefolii herba	For finalisation 1-2 Q
EMA/HMPC/143949/2009	Community herbal monograph on Millefolii flos	For finalisation 1-2 Q
EMA/HMPC/96911/2010	Community herbal monograph on Myrrha (Commiphora molmol)	For finalisation 1-2 Q
EMA/HMPC/277792/2009	Community herbal monograph on Oenotherae biennis oleum	For finalisation 1-2 Q
EMA/HMPC/430507/2009	Community herbal monograph on Oleae folium	For finalisation 1-2 Q
EMA/HMPC//2009	Community herbal monograph	For finalisation 1-2 Q

	on Plantaginis lanceolatae folium	
EMA/HMPC/587578/2009	Community herbal monograph on Tanaceti parthenii herba	For finalisation 1-2 Q
EMA/HMPC//2009	Community herbal monograph on Trigonellae foenugraeci semen	For finalisation 1-2 Q
EMA/HMPC/572846/2009	Community herbal monograph on Symphyti radix	For finalisation 1-2 Q
EMA/HMPC/573460/2009	Community herbal monograph on Uvae ursi folium	For finalisation 1-2 Q
EMA/HMPC/726698/2009	Public statement on Echinaceae angustifoliae radix	For finalisation 1-2 Q
	Community herbal monograph on Agrimoniae herba	Draft to be released for public consultation
	Community herbal monograph on Agropyri repentis rhizoma	Draft to be released for public consultation
	Community herbal monograph on Caryophyllii aetheroleum	Draft to be released for public consultation
	Community herbal monograph on Caryophyllii flos	Draft to be released for public consultation
EMA/HMPC/560734/2010	Community herbal monograph on Chamomillae romanae flos	Draft to be released for public consultation
EMA/HMPC/121819/2010	Community herbal monograph on Cichorii intybi folium	Draft to be released for public consultation
EMA/HMPC/121816/2010	Community herbal monograph on Cichorii intybi radix	Draft to be released for public consultation
EMA/HMPC/136024/2010	Community herbal monograph on Cucurbitae semen	Draft to be released for public consultation
EMA/HMPC/434894/2010	Community herbal monograph on Filipendulae ulmariae flos	Draft to be released for public consultation
EMA/HMPC/434881/2010	Community herbal monograph on Filipendulae ulmariae herba	Draft to be released for public consultation
	Community herbal monograph on Fumariae herba	Draft to be released for public consultation
	Community herbal monograph on Juglandis folium	Draft to be released for public consultation
EMA/HMPC/571119/2010	Community herbal monograph on Liquiritiae radix	Draft to be released for public consultation
EMA/HMPC/278814/2010	Community herbal monograph on Matricariae aetheroleum	Draft to be released for public consultation
	Community herbal monograph on Matricariae flos	Draft to be released for public consultation
EMA/HMPC/560961/2010	Community herbal monograph on Pelargonii radix	Draft to be released for public consultation
	Community herbal monograph on Rhodiolae roseae rhizoma	Draft to be released for public consultation
EMA/HMPC/130042/2010	Community herbal monograph on Thymi herba and Primulae	Draft to be released for public consultation

	radix	
	Community herbal monograph on Zingiberis rhizoma	Draft to be released for public consultation
EMA/HMPC/833398/2009	Reflection paper on the necessity of initiatives to stimulate the conduct of clinical studies with herbal medicinal products in the paediatric population	Finalisation 1-2 Q

Committee for Orphan Medicinal Products (COMP)

Reference number	Document title	Status
Not yet assigned	Reflection paper on biomarkers and subsetting of medical conditions for orphan designation	For preparation

Paediatric Committee (PDCO)

No work on guidelines planned for 2011.

Committee for Medicinal Products for Veterinary Use (CVMP)

Reference number	Document title	Status
EMA/CVMP/2128/2007-Rev.1	Procedural advice on the re-examination of CVMP opinions	To be presented to the Committee for adoption (pending the finalisation of the Veterinary SAG policy document (EMA/347137/2010))
EMA/CVMP/115769/2005-Rev.1	Revision of the Guideline for an assessor preparing assessment reports	In development
EMA/CVMP/430509/2009	Guideline on the change of classification of veterinary medicinal products authorised by the Community	To be finalised following public consultation
EMA/CVMP/328/98-Rev.3	Revision of the Guideline on the acceptability of names for veterinary medicinal products processed through the centralised procedure	In development

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMA/CVMP/SAGAM/741087/2009	Use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Revise reflection paper during 2011, following consultation period
EMA/CVMP/SAGAM/736964/2009	Reflection paper on meticillin-resistant *Staphylococcus pseudintermedius* (MRSP)	Revise reflection paper during 2011, following consultation period
	Concept paper on data requirement for new veterinary medicinal products for companion animals with respect to antimicrobial resistance	Publish a concept paper on the subject during 2011
	Use of pleuromutilins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Publish a concept paper on the subject during 2011
EMA/CVMP/627/01	Revision of the guideline demonstration of efficacy for veterinary medicinal products containing antimicrobial substances	Publish a concept paper on the subject during 2011

	Considerations on impact of off-label use of antimicrobials on resistance in food producing animals	To reflect on the subject during 2011

CVMP Efficacy Working Party

Reference number	Document title	Status
EMEA/CVMP/019/00-Rev.2	Conduct of bioequivalence studies for veterinary medicinal products *Multidisciplinary guideline: involved WPs are EWP, SWP and QWP*	Revision of existing guideline. Guideline to be finalised following public consultation (Q1 - 2 2011)
7AE22a Volume 7A	Guideline on Efficacy of veterinary medicinal products for use in farmed aquatic species	Revision of existing guideline Guideline to be finalised after consultation (Q1 - 2 2011)
EMEA/CVMP/344/99	Conduct of efficacy studies for intramammary products for use in cattle *Multidisciplinary guideline: Involved Working parties are EWP and SAGAM*	Revised guideline to be released for consultation (Q 1 2012)
EMA/CVMP/EWP/81987/2010	Demonstration of palatability of veterinary medicinal products	Public consultation of concept paper expected by Q1 2011. Focus Group meeting, if necessary.
EMEA/CVMP/273/01	Conduct of efficacy studies for NSAIDs	Revision of existing guideline Revised guideline to be released for consultation (Q4 2011)
EMEA/CVMP/83804/2005	Statistical principles for veterinary clinical trials	Revision of existing guideline; Public consultation of draft guideline until 31 March 2011 Guideline to be finalised after consultation (Q1 - 2 2012)

CVMP Environmental Risk Assessment Working Party

Reference number	Document title	Status
EMA/CVMP/ERA/409328/2010	Reflection paper on risk mitigation measures related to the environmental evaluation of veterinary medicinal products	Reflection paper to be published during 2011
EMA/CVMP/ERA/430327/2009	Guideline on fate of veterinary medicinal products in manure	Following the consultation period revised guidance to be published during 2011
EMA/CVMP/ERA/409350/2010	Guideline on higher tier testing	Consultation of guideline, and

	of antiparasitics to dung organisms	revised guidance during 2011
EMA/389867/2010	Assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine	To publish a reflection paper and revise it as required during 2011

CVMP Immunologicals Working Party

Reference number	Document title	Status
EMA/CVMP/IWP/206555/2010	Guideline for the production and control of bacterial and viral vaccines for veterinary use	Guideline to be adopted for consultation Q1 2011
EMA/CVMP/IWP/314550/2010	Guideline for the design of safety and efficacy studies in fish vaccines	Guideline to be adopted for consultation Q1 2011
EMA/CVMP/IWP/354949/2010	Table of extraneous agents to be tested for in relation to the guideline for the production and control of bacterial and viral vaccines for veterinary use	Table to be adopted for consultation Q1 2011
	Requirements for combined and associated immunological veterinary medicinal products	Draft Guideline to be released for consultation by Q1/2 2011
	VICH Guideline for the tests on the presence of extraneous viruses in veterinary viral vaccines	EU contribution to development of guideline
	VICH Guideline on the detection of mycoplasma	EU contribution to development of guideline
	VICH Guideline on the harmonisation of criteria to waive batch safety testing for inactivated vaccines for veterinary use	EU contribution to development of guideline

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference number	Document title	Status
EMA/CVMP/10418/2009 Rev.2 EMA/CVMP/553/03 – Rev. 5 EMEA/CVMP/PhVWP/556/04-Rev. 1	Annual review of standard lists used for reporting suspected adverse reactions: Combined VeDDRA List of Clinical Terms for Reporting Suspected Adverse Reactions in Animals and Humans to	Expected date(s) of expert group: 28 April 2011

	Veterinary Medicinal Products; List of Species and Breeds for Electronic reporting of adverse reactions in Veterinary Pharmacovigilance; CVMP List on Additional Controlled Terminology for Electronic Submission of Reports on Adverse Reactions to Veterinary Medicinal Products	
EMA/CVMP/471721/2006	Recommendation on the basic surveillance data in EudraVigilance Veterinary (EVVet) data	To be finalised and implemented following public consultation in 2010. Following finalisation of the guidance, it is foreseen for inclusion in a future revision of Volume 9B.
EMA/CVMP/PHVWP/5507/2011	Concept paper for revision of the guideline on harmonising the approach to causality assessment for adverse reactions to veterinary medicinal products	Concept paper to be drafted and released for public consultation.
EMEA/CVMP/552/03	Recommendation/guideline on harmonising the approach to causality assessment for adverse reactions to veterinary medicinal products	Revision of guideline/recommending to commence pending public consultation on above-mentioned concept paper
EMEA/CVMP/126726/2007	CVMP reflection paper on risk management plans for centrally authorised products	CVMP to determine the need for development of reflection paper and/or further guidance on this topic
EMEA/CVMP/VICH/123940/2006	VICH GL35: Pharmacovigilance of Veterinary Medicinal Products: Electronic standards for transfer of data	Continue to provide input to the experts of the VICH pharmacovigilance expert working group (EWG) for finalisation of the guideline

CVMP Safety Working Party

Reference number	Document title	Status
EMA/CVMP/90250/2010	Guidance on risk characterisation and assessment of maximum residue limits (MRL) for biocides	Guideline to be released for consultation (Q1-Q2)
EMEA/CVMP/SWP/122154/2005-CONSULTATION	Guideline on the pharmacological/pharmacodynamic data to establish a pharmacological ADI	Guideline to be released for consultation (Q3)
	Review of alternative reference limits	Continue developing/updating reflection papers during

		2011 (not for publication)
EMEA/CVMP/473/98-FINAL	Note for guidance for the determination of withdrawal periods for milk (and relevant parts of SPC guideline)	Develop a concept paper for the revision of the guideline (Q2/Q3)
EMA/CVMP/SWP/281676/2010	Review of residues risk assessment concepts (including 'utilization of the full ADI for individual tissues' and 'one meat plus eggs plus milk' concepts)	Further development of reflection paper (not for publication)
EMA/CVMP/SWP/693125/2010	Setting MRLs for muscle using a non-standard approach	Develop a concept paper (Q2/Q3)
	Scientific method for the risk assessment of groundwater	Develop recommendations for discussion at CVMP
	Volume 8 of the rules governing medicinal products in the EU	Revision of existing guidance following adoption of Reg 470/2009 (Q2 – timelines may be influenced by input from Commission)
EMEA/CVMP/VICH/463104/2009-CONSULTATION EMEA/CVMP/VICH/463202/2009-CONSULTATION EMEA/CVMP/VICH/463072/2009-CONSULTATION EMEA/CVMP/VICH/463199/2009-CONSULTATION	VICH metabolism and residue kinetics GLs (VICH GL 46-49)	Support for EU position following consultation procedure
	VICH Guideline on elaboration of Acute Reference Dose for Veterinary Medicinal Products	Support for EU position during guidance development
	VICH Guideline on bioequivalence	Support for EU position during guidance development
CVMP/VICH/467/03-FINAL-corr	VICH GL36: General approach to establish a microbiological ADI	Support for EU position during review of the guideline
	Review existing VICH GLs	Support EU position during 2010

CVMP Scientific Advice Working Party

Reference number	Document title	Status
EMEA/CVMP/172329/04-Rev.2	EMEA guidance for companies requesting scientific advice	

Other Agency scientific committee and working party guidelines

European Medicines Agency Human Scientific Committees Working Party with Patients and Consumers' Organisations

Reference number	Document title	Status
	Revision of the Framework of interaction between the Agency and patients' and consumers' organisations	Finalisation by 2/3Q2011
	Report from 1-year pilot phase of patients participation in SAGs meetings	Finalisation by 4Q2011
EMA/351803/2010 Rev. 3	The role and responsibilities of patients' representatives within EMA Human Scientific Committees	Finalisation by 4Q2010/1Q2011
EMA/363543/2010	Patient involvement in the Committee for Medicinal Products for Human Use (CHMP) assessments of the benefit/risk of medicinal products	Finalisation by 4Q2011
	Annual report of Agency's interaction with patients' and consumers' organisations	Finalisation by 4Q2011

Other guidelines

Reference number	Document title	Status
	Updated Post-authorisation Procedural Advice	Revision to be finalised by Q4 2011
	Updated Guidance on pre-submission meetings for initial marketing authorisation applications for human medicinal products in Centralised procedure	Revision to be finalised by Q4 2011
	Update of Procedural Advice documents on generics/hybrid medicinal products	Revision to be finalised by Q4 2011
	Procedural Advice documents on generics/hybrid medicinal products	Initiation in Q1 2011
	Guideline on Traceability for Advanced therapy medicinal products	Q4 2011

Agency contribution to European Commission guidelines

Reference number	Document title	Status
Notice To Applicants	NTA Chapter 1	Q2 2011
Notice To Applicants	(Electronic) Application forms for New applications and Variations	Q2 2011
Notice To Applicants	NTA Volume 9	Q4 2011
Notice To Applicants	Guideline on the Categorisation of Extension Application Vs Variations Applications	Q2 2011
Notice To Applicants	Commission guideline on the details of the various categories of variations	Q4 2011

Joint CHMP/CVMP Quality Working Party

Reference number	Document title	Status
CPMP/QWP/3309/01 & EMEA/CVMP/961/01	Guideline on the Use of Near Infrared Spectroscopy	Finalisation of revision
EudraLex 3AQ21A	Guideline on Radiopharmaceuticals Based on Monoclonal antibodies	Development of the Concept Paper for the revision of the guideline and of the draft revised guideline for public consultation
CPMP/QWP/3015/99	Guideline on Real Time Release Testing (formerly Guideline on Parametric Release)	Finalisation of revision. (Consideration of revision of the CVMP guideline later.)
CHMP/QWP/848/96 & EMEA/CVMP/598/99	Guideline on Process Validation	Development of the draft revised guideline for public consultation
Not yet assigned	Guideline on Pharmaceutical Development of Medicines for Paediatric Use	Development of the guideline for public consultation
EMA/CHMP/CVMP/QWP/199250/2009	Guideline on Setting Specifications for Related Impurities in Antibiotics	Finalisation after end of public consultation
Not yet assigned	(Joint) CHMP/CVMP Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation	Development of the draft revised guideline for public consultation
Not yet assigned	Guideline on Modified Release Products	Development of the draft revised guideline for public consultation
CVMP/VICH/502/99 (Vet)	VICH GL18 - Guideline on Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients	Contribution to the revision
New	VICH Guideline on the Statistical	Contribution to the development

	Evaluation of Stability Data	
EMEA/CVMP/016/00-Rev.1 (Vet)	CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products *Multidisciplinary guideline: involved WPs are EWP-V, SWP-V and QWP*	Contribution to finalisation of the revision of the existing guideline following public consultation
ICHQ11	Development and manufacture of drug substances (chemical entities and biotechnological entities)	EU contribution developed jointly with BWP
Not yet assigned	Reflection Paper on Liposomal Products	Finalisation
Not yet assigned	Reflection Paper on Injectable Micellar Systems	Finalisation