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Work programme 2010 of the European Medicines Agency

Adopted by the Management Board in December 2009.

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Introduction by the Executive Director

Thomas Lönngren

The work programme for 2010 is set against a dynamic background of changes in the Agency's legislative and business environment. This year completes the implementation of the Agency's long-term strategy (Road Map to 2010) adopted by the Management Board in December 2004, and lays the ground for the new strategy document, which will span to 2015. Taking into account the achievements to date, the trends and changes in the Agency's environment, the following areas of focus are identified for this year's work programme:

- conducting the Agency's core activities to the highest quality standards, amid the increasing volume and complexity of activities;
- successfully implementing tasks vested by new legislation;
- strengthening the European medicines network;
- continuing to improve the safety-monitoring of medicines;
- cooperating with international partners and contributing to international activities;
- fostering communication, provision of information and increasing transparency;
- contributing to an environment that stimulates innovation and improved availability of medicines.

Due to the nature of the work of the Agency, following the authorisation of new medicinal products, there is a cumulative increase in the work needed to supervise those products, carry out pharmacovigilance activities and conduct other post-authorisation tasks. Therefore, the volume of activities, as well as their complexity, is growing from year to year, and has to be accommodated by the Agency and its network of partners. Some of these areas that will influence the Agency's resource distribution in 2010 include complex interactions between the six scientific committees of the Agency, increases in post-authorisation, referral, safety-of-medicines-related activities, and provision of information.

Following the recent legislation on advanced therapy medicinal products, a number of additional legislative changes have already come into effect, or will soon. These include the revision of the Variations Regulation, which brings new ways of handing variations, but also has implications for the Agency's financing, and the revised Maximum Residue Limits (MRL) Regulation, which promotes MRL extrapolation and extends the scope to cover biocidal products, as well as products used under the prescribing 'cascade'. The Agency will also commence preparations for possible future legislative changes in the areas of pharmacovigilance and counterfeit medicines.

The global nature of drug development and research, coupled with the high regard of the Agency in the international arena, mean that the Agency's international commitments will not only remain high on its agenda, but will also grow in importance and volume. Fields of activity include: the implementation of initiatives relating to clinical trials and manufacturing of active ingredients in China and India, and to international work-sharing activities in the field of GMP and GCP inspections; further collaboration with non-EU regulators in the context of confidentiality arrangements and mutual-recognition agreements; and contribution to international standardisation activities.

As in previous years, significant attention will be given to further work in the field of safety-monitoring of medicines. The focus in 2010 will include further implementation of the European risk-management

strategy (ERMS), data-quality improvement in EudraVigilance, and support to the European Network of Centres for Pharmacovigilance and Pharmacoepidemiology.

The Agency will continue its contribution to an environment that stimulates innovation and availability of medicines through its core activities, such as provision of scientific advice to companies developing new medicines and implementation of the various policies supporting development of medicines. At the same time, the Agency's experts contribute to the Innovative Medicines Initiative (IMI) – the pan-European work aimed at supporting innovation. As part of this contribution, the Agency leads a five-year collaborative European project with the goal of developing innovative methods in pharmaco-epidemiology and pharmacovigilance. For veterinary medicines, the Agency provides input to the European Technology Platform for Global Animal Health and the Action Plan for the Community Animal Health Strategy.

The Agency's activities in the field of communication and transparency will see further significant development. The Agency will start implementing its Transparency Policy, developed in 2009, and will continue discussions within the EU regulatory network to have, as far as possible, a common approach in the field of transparency. Further initiatives relating to provision of more information on benefit-risk assessment and rationale for decision-making will be implemented. This work will result in the provision of better and more useful information to interested parties, including the health-technology-assessment bodies. The Agency will launch its redesigned public website, which will provide easier access to information for patients, healthcare professionals and enterprises.

The same challenges that affect the Agency also affect the network, amid growing pressure on scientific resources of the national competent authorities. This trend is strengthened by the increasing number and complexity of applications across most of the Agency's activities, not least those relating to the recent legislation on advanced therapy medicinal products and paediatric medicines. Implementation of the new remuneration system may take place in 2010, following the pilot project completed in 2009. This transition will be managed with care, in order to ensure that any changes ensure strong participation of Member State national competent authorities in the work of the Agency.

1. European Medicines Agency in Europe and the world

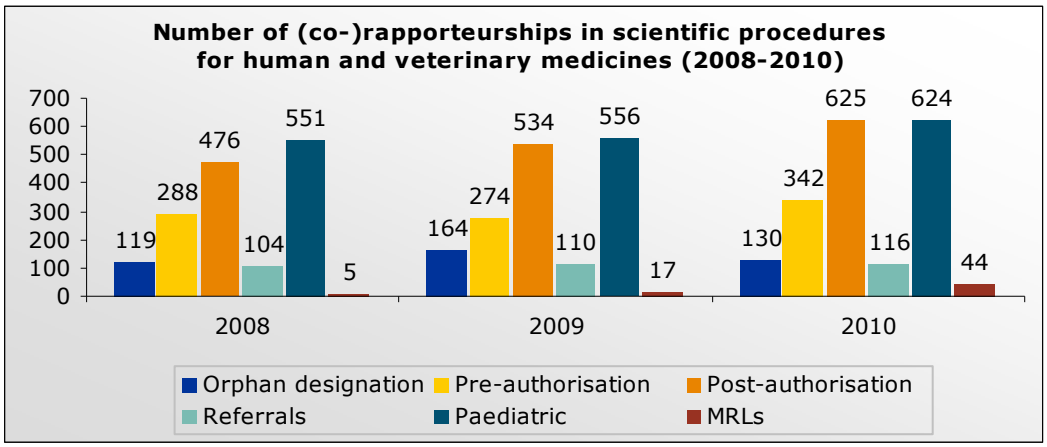
1.1. European medicines network

The European medicines network allows the mobilisation and coordination of scientific resources to the benefit of patients throughout the EU. It includes partnership with national competent authorities in areas such as training of assessors and strengthening of the European network of regulatory authorities. It also covers preparatory activities with pre-accession countries. Support to the development of the European medicines network is a priority area for the Agency.

The following trends and new issues will influence activities of the network in 2010:

- Due to high pressures on the existing scientific resources, the work on further rationalising their use, including further promoting alternative meeting solutions, will need to continue.
- Subject to the decision of the Management Board, a new payment system may be implemented and its impact analysed.

The Agency expects that the number of (co-)rapporteurs and coordinators from the European medicines network contributing to Agency procedures will increase by 14% to 1,881[1].



The following specific objectives will be targeted:

Objective	
Complete the Road Map to 2015 to provide a long-term plan for the development of the Agency	
Performance indicators for the objective	**Target**
Road map	Endorsed by the Management Board; Work programme 2011 takes into account the new road map

[1] This figure includes the number of rapporteurs, co-rapporteurs and coordinators in the procedures mentioned in the chart. The figure does not include coordinators in the working parties, scientific advisory groups and other areas.

Objective	
Monitor in a systematic way the use of resources put at the Agency's disposal thus contributing to an efficient use of resource of the network (related to the work of the HMA group on resources)	
Performance indicators for the objective	**Target**
Relevant data on resource use	Data provided to Agency management and the HMA resource group at agreed intervals

Objective	
Implement the new payment system to national competent authorities (NCAs) (depending on the decision of the Management Board) to adapt to legislative requirements and support the work of the network.	
Performance indicators for the objective	**Target**
Payment to NCAs for (co)rapporteurships using the new system	100% of all payments

Meetings at the European Medicines Agency

The Agency provides facilities and services for meetings of the committees, working party and other expert groups meetings. The Agency assists delegates with logistics and practical arrangements.

Trends and new issues:

- The Agency expects that the number of reimbursed delegates should remain the same in 2010 as in 2009, estimated at 9,200. The estimated number of meetings will be around 600.

Performance indicators for the activity area:

Performance indicator	Target
Satisfaction of delegates and interested parties regarding support provided by the Agency	95% of respondents to be satisfied or very satisfied

Preparations for future enlargement

A new 3-year Instrument for pre-accession assistance programme for pre-accession activities designed for the Balkan countries (Croatia, the former Yugoslav Republic of Macedonia, Serbia, Albania, Montenegro, Kosovo and Bosnia Herzegovina) and Turkey started in 2009.

Under this programme, the Agency builds contacts and relationships between the European Medicines Agency and the Candidate and Potential Countries for future collaboration in the Agency's activities and its relationship with Member States. In 2010, the project will include participation of Candidate and Potential Candidate Countries in selected meetings and trainings as observers, in order to familiarise the national competent authorities with the work performed by the European Medicines Agency, and organisation of conferences.

1.2. European cooperation

This covers contribution to new legislation initiated by Directorates-General of the European Commission, partnership with European Commission Directorates-General, namely DG Enterprise and Industry, DG Health and Consumer Protection (DG Sanco), DG Research and DG Development, and cooperation with EU Agencies, namely the European Centre for Disease Prevention and Control (ECDC), European Food Safety Authority (EFSA), European Chemicals Agency (ECHA) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

The Agency provides support and collaborates on a wide variety of topics. Some of the topics relevant for 2010 include: current novel H1N1 influenza pandemic, research on and development of off-patent paediatric medicines, rare diseases, risk assessment, database on medicinal products to be used against bioterrorism agents, harmonisation of vaccination schedules, surveillance and pharmacovigilance of vaccines, antimicrobial resistance, cooperation to ensure consistency of scientific opinions, anti counterfeiting, provision of information, contribution to discussions on added therapeutic value, use of medicines in the food chain and for zoonotic diseases.

An impact assessment of the existing regulatory framework for veterinary medicines will be launched by the European Commission in 2009. The European Medicines Agency will actively contribute to this process to ensure that the particular needs of the veterinary sector are taken into account when considering if there is a need to amend existing legislation.

The Agency also works with a number of EU bodies (ECDC, EFSA, DG SANCO, ECHA, EEA) to finalise an overarching document on collaboration of EU agencies working in similar fields. The bodies will also develop working arrangements in specific areas. These efforts will help to ensure consistency of scientific opinions among the scientific committees of the EU bodies.

In addition to the activities listed above, the following specific objective will be targeted:

Objective	
Implement the Pharmaceutical Forum conclusions on EPAR improvements to contribute to assessment of relative effectiveness by health technology assessment (HTA) bodies	
Performance indicators for the objective	**Target**
Establishment of collaboration with DG Sanco-Member States joint action on HTA	Established by Q1 2010
Identification of EPAR improvements	Identified by Q4 2010

Objective	
Intensify activities in cooperation with the European Commission and other stakeholders intended to minimise the risk of antimicrobial resistance arising from the use of veterinary medicines	
Performance indicators for the objective	**Target**
Follow up priority areas for action identified in the 'short report' produced for the European Commission in cooperation with EFSA, ECDC and SCENIHR	CVMP strategy on AMR updated as necessary by Q4 2010
Launch pilot project on collation of data on sales of veterinary antimicrobials in participating Member States	Collection of data started by Q4 2010 with a view to producing first report in 2011

1.3. International cooperation

These activities cover co-operation at European level, collaboration with the Organisation for Economic Co-operation and Development (OECD) and cooperation with the European Directorate for the Quality of Medicines and HealthCare (EDQM). At international level, the European Medicines Agency participates in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (including work with Standards Development Organisations (SDOs) and the Council for International Organizations of Medical Sciences (CIOMS)), works with the World Health Organization (WHO), the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), the Codex Alimentarius, the World Organisation for Animal Health (OIE), the US Food and Drug Administration (US FDA), the US Department of Agriculture (USDA) and the Japanese, Canadian and Australian authorities and with other non-ICH regulatory authorities. Work in this field also covers interactions with China, India and Russia.

Interactions with US FDA and Health Canada in the context of the existing bilateral confidentiality arrangements covering both human and veterinary products are expected to continue to intensify during 2010, with increasing actions related to the pandemic crisis, increasing cluster activities, optimisation of liaison placements and specific activities related to antimicrobial resistance, worksharing on GMP and GCP inspections, risk management concepts and collaboration on rare and neglected diseases, to name but a few. The arrangements with US FDA are due for renewal in 2010.

Interactions are also expected to increase in the context of bilateral arrangements with the health authorities in Japan and the recently signed one with Australian authorities cover human medicinal products only.

The impact of globalisation affecting activities such as the location of clinical trials and manufacturing activities, in particular of active pharmaceutical ingredients is a driver for the development of better relationships with authorities in countries such as China, India and Russia and collaboration with these countries are expected to continue to increase. The Agency will work with the Commission and national authorities, within the network to contribute to capacity building and training activities for these and other countries. Collaboration with WHO will be important in this regard. The Agency will also support the Commission in addressing the threat of counterfeit medicines, particularly in the context of its legislative proposal on falsified medicines.

The Agency will continue to contribute to the work on international standardisation, clinical trials registries, individual case safety reporting and identification of medicinal products. Implementation of agreements reached will be undertaken. Work in the context of the international harmonisation will contribute to the future of the ICH. The Agency also plans to host an international conference on priority topics related to authorisation and maintenance of veterinary medicines.

The Agency will continue to streamline its work with the WHO. The work will cover a number of activities, including the cooperation in scientific advice and assessment in the framework of medicinal products for use non-EU markets (so-called Article 58 procedures). Experts nominated by WHO and concerned regulatory authorities will be involved in all such procedures.

See also section 4.1 on inspection activities.

Certificates

The purpose of the European Medicines Agency's scheme for certificates of medicinal products is to support the work of health authorities outside the European Union, in particular in developing countries. Certificates are issued by the Agency, on behalf of the European Commission, to confirm the marketing authorisation status of products authorised by the European Commission through the centralised procedure or products for which a centralised application has been submitted to the Agency. The certificates also confirm compliance with good manufacturing practice (GMP) at the manufacturing site(s) where the medicinal product is produced in bulk pharmaceutical form. Health authorities can rely on centralised assessments to support marketing in their own countries, thus facilitating access to these medicines and avoiding the need for costly and duplicative assessment work. The Agency issues certificates also for products evaluated by the European Medicines Agency in the context of co-operation with the WHO (Art. 58 of Regulation (EC) No 726/2004).

Trends and new issues

- The number of certificate requests will increase by approximately 19 % (from 2,144 in 2009 to 2,554 in 2010), due to the increased number of approved marketing authorisations, cooperation with the WHO and authorisation of more generic medicinal products.

In addition to the core activities in the certification scheme, the Agency will discuss with WHO possible revisions of the scheme to take into account changing stakeholder needs and expectations.

Performance indicators for the activity area:

Performance indicator	Target
Percentage of certificates of medicinal products issued to requesting parties within the timeline	90% compliance

Mutual recognition and other agreements

Mutual recognition agreements (MRAs) between the European Union and partner (third) countries include specific annexes relating to medicinal products and GMP. These allow EU Member States and the MRA partner to mutually recognise conclusions of inspections of manufacturers carried out by the respective inspection services of the other party, and to mutually recognise the manufacturers' certification of conformity to specifications for each batch without re-control at import. The European Medicines Agency is responsible for implementation and operational aspects of these MRAs. MRAs with Australia, New Zealand, Switzerland, Canada and Japan are currently operational, but with slightly different provisions as to scope and applicability.

With regards to MRAs and other agreements, the Agency will work in the following domains:

- The changing of international environment on acceptance of GMP results as exemplified by the various pilot inspection programmes, the Commission's counterfeit legislation and negotiations on conformity acceptance agreements are expected to create a need to re-examine some of the existing MRA agreements to ensure a globally consistent approach.
- Possible accession to the EU of new partner countries will impact on bilateral discussions with existing MRA partners.
- Development of the third country inspection planning module of EudraGMP will create further opportunities to share non-paper based information with MRA partners.

- Impact of advanced therapy medicinal products on the current application and scope of existing MRAs.
- The Agency will work to implement a newly established sectoral annex on GMP, which was established within the context of the Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) between the Community and Israel.

1.4. Communication, provision of information and transparency

The pharmaceutical legislation gives the European Medicines Agency and the European network as a whole a mandate to increase the transparency of its activities and strengthen communication with its stakeholders. The areas of transparency and communication are a priority for the Agency.

The Agency provides targeted, understandable and accessible information for patients and healthcare professionals.

The Agency also coordinates the review of the quality of all product-related information submitted by sponsors and marketing authorisation holders.

Provision of information

The following trends and expectations will influence the Agency's work in this area:

- The Agency's stakeholders expect to consume online information in an easy and fast way in a format that they can use and understand.
- One of aims of the European Medicines Agency's Road Map to 2010 is to strengthen the Agency's collaboration with the EU national regulatory agencies in the area of provision of information as per current Community legislation, as well as developing an appropriate structure for this within the EU Regulatory System Network.
- The Agency will strengthen and widen the scope of interactions with its stakeholders with the objective to further contribute to the safe use of medicines.
- Access to information activities will see a further increase in the number of requests for information, which may grow by around 12% (from 4,290 in 2009 to forecast 4,800 in 2010).

In addition to the core activities in this area and addressing the above factors, the following specific objectives will be targeted:

Objective	
Establish the necessary systems and programmes to improve the quality and accessibility of the Agency's written information	
Performance indicators for the objective	**Target**
User research feedback	Feedback obtained
Identified systems/programmes	Implemented

Objective	
Further strengthen the Agency's communication for medicines evaluated by the Agency for syndication to the EU regulatory network	
Performance indicators for the objective	**Target**
Develop a Communication strategy for medicines evaluated by the Agency	Communication strategy developed

Objective	
Further integrate patients, consumers and healthcare professionals (HCPs) in Agency activities	
Performance indicators for the objective	**Target**
Revised framework of interaction with patients.	Implemented Q4
Development of framework of interaction with HCPs.	Q4

Performance indicators for the activity area:

Performance indicator	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 2 weeks of the Commission decision	80% 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 & Answer" (Q&A) documents published at the time of the next appropriate CHMP monthly report	90% of Q&A documents
Percentage of refusal "Question & Answer" (Q&A) documents published at the time of the CHMP opinion	90% of Q&A documents
Percentage of "Question & Answer" (Q&A) documents for Article 31, 36, and 107(2) procedures at the time of the CHMP opinion	90% of Q&A documents
Percentage of external requests for information processed within established timelines	90%

Transparency

The following trends will influence the Agency's work in this area:

- Access to documents activities will see a further substantial increase in the number of requests (incl. appeals), which may grow by around 12 % (from 116 in 2009 to forecast 130 in 2010).
- Following on from preliminary discussions with Health Technology Assessment Bodies, further actions to increase transparency to substantiate the scientific rationale for opinion-making will have to be developed.

In 2010, the European Medicines Agency will finalise its Transparency Policy as well as its Access to Documents Policy following the public consultation. The Agency will also continue discussions within

the EU regulatory network to have as much as possible a common approach in the field of transparency on key issues such as the concept of commercial confidential information. The implementation of the EudraVigilance Access Policy, which will extend access to data to healthcare professionals, patients and consumers, marketing authorisation holders, and sponsors of clinical trials will be a key activity in the field of transparency on safety related aspects. To increase efficiency of operations, the responsibility for responding to requests for access to documents and information will be centralised within a newly created Department for Data Management.

The following specific objective will be targeted:

Objective	
Further increase transparency in the daily operation of Agency activities	
Performance indicators for the objective	**Target**
Transparency Policy	Finalised Q3
Access to Documents Policy	Finalised Q2

1.5. Support for innovation and availability of medicines

This relates to activities contributing to innovation and availability of medicines for human use via the European Medicines Agency Innovation Task Force and CHMP working parties' activities, continuing cooperation with the European Commission in the context of the Innovative Medicines Initiative (IMI) and the 7th Framework Programme, and continuing participation as observer in US Critical Path Institute's initiatives. For veterinary medicines, the Agency provides input to the European Technology Platform for Global Animal Health and the Action Plan for the Community Animal Health Strategy.

The following activities also contribute to innovation and availability of medicines: continued implementation of orphan, advanced therapy and paediatric medicines policies, reinforcement of activities on medicines for geriatric populations, provision of scientific advice, operation of procedures shortening regulatory timeframes, stimulation of applications for products intended for non-EU markets in the context of cooperation with the WHO, support to veterinary pharmaceutical companies developing products indicated for minor uses/minor species (MUMS)/limited markets, contribution to the implementation of the action plans arising from the Heads of Medicines Agencies' Taskforce on Availability of Veterinary Medicinal Products and the Community Animal Health Strategy.

Small and medium sized enterprises (SMEs) operating in the human and veterinary pharmaceutical sectors are often innovative companies that can notably benefit from the pooling of scientific expertise at Community level. Regulations (EC) Nos 726/2004, (EC) 1394/2007 and Commission Regulation (EC) No 2049/2005 make provisions for incentives in the form of fee reductions or deferrals and administrative assistance by the Agency's SME Office.

Trends and new issues:

- Implementation of the Innovative Medicines Initiative will indirectly raise SMEs awareness of the regulatory framework for medicines developed by SMEs. This will result in increased requests for information, incentives, initial and renewal SME assignment and requests for regulatory assistance from the SME Office and European Medicines Agency Innovation Task Force.

Objective	
Promote regulatory support to innovative drug development by increasing knowledge transfer	
Performance indicators for the objective	**Target**
Percentage of scientific advice requests on new methodologies for drug development	10% increase over 2009
Participation in Innovative Medicines Initiative-related projects and as observers in C-path initiatives	Participation in 8 projects

Objective	
Deliver the five-year PROTECT project (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium) conducted under the Innovative medicines initiative	
Performance indicators for the objective	**Target**
Project implementation	In line with agreed plans

Objective	
Complete the review of European Medicines Agency-CHMP think-tank exercise on innovation and report on the outcome	
Performance indicators for the objective	**Target**
Close off obsolete actions and finalise remaining actions	All actions in plan addressed

Objective	
Reinforce the Agency's input in European activities in the field of medicines used in geriatric populations	
Performance indicators for the objective	**Target**
Establishment of CHMP ad hoc group of experts on geriatric medicines	The group of experts established

Objective	
Promote the new procedure intended to increase submission of applications for authorisation of products for minor use minor species (MUMS/limited markets)	
Performance indicators for the objective	**Target**
Number of enquiries and applications for all activities related to authorisation of products for MUMS/limited market	Increase of 25% in the number of requests received compared to previous years

1.6. Methodology and outcomes assessment projects

Trends and new issues:

- A need for developing the capacity for performing regulatory outcomes assessment in some areas is grounded in the Agency's Standards for Internal Controls that require the Agency to carry out evaluation of its activities.

- Stakeholders put forward new demands to the Agency, such as requests for detailed justification of benefit-risk assessments done by the Agency's Committees, or the need to assess the impact of regulatory action on public health.

Taking the above into account, the following projects will be initiated/conducted in 2010:

- Develop new methodology for benefit-risk assessment on the basis of experience gained during pilot phase and finalise a number of case studies.
- Implement a system for measuring the effectiveness of risk management plans.
- Develop and test concept: electronic structure and maintenance of key SPC drug information to be applied in E-Prescribing services at point of health care (in collaboration with Karolinska Institutet, Sweden).
- Assess the content of Benefit-Risk communication – expectations from key opinion leaders (in collaboration with Kings College London, United Kingdom) and produce a final report.
- Assess the impact of scientific advice on the outcome of marketing authorisation applications for human medicinal products, set up a methodology and publish a final report.
- Expand the Scientific Memory Database (SMD).
- Improve methodologies for assessing the post marketing benefits and safety of medicinal products, by Comparison of new and established methodology for signal detection, development of linkage for drug exposure during pregnancy and congenital malformation data and completing an Inventory of drug utilisation data.
- Develop collaborative projects with European universities and other research organisations to enable the conduct of scientific projects pertinent to the Agency's core activities, and to enhance the Agency's visibility within the scientific community.

1.7. Integrated management at the European Medicines Agency

An integrated management system forms the backbone in providing management assurance about the Agency's processes and output. Central elements of this system, that is marked by continuous improvement, are: a quality management system; a risk management system; an Audit Advisory Committee; self-assessments, audits, internal controls and management reviews; benchmarking with partners in the European network of medicines agencies (BEMA); human resource management; business and financial management; health and safety, and environmental policies; and business continuity planning.

Trends and new issues:

- Changes to the European Medicines Agency's organisational structure to be further implemented in 2010.
- The introduction of the new computerised financial system (SAP) will have significant consequences for many budget and account-related activities of the Agency. The impact will be strengthened by potential changes to the remuneration system for scientific activities.
- Accommodation planning to match the increase in the number of staff and delegates as well as additional meetings; the number of visitors is forecast to increase by around 10% from 63,358 in 2009 to an estimated 70,000 in 2010.

In addition to the core activities in this area and work to address the above developments, the following specific objectives will be targeted:

Objective	
Complete the implementation of the Agency's revised organisational structure	
Performance indicators for the objective	**Target**
The new structure	Fully in place in line with a new organisation chart
Management positions	All positions filled
Updating of standard operating procedures and work instructions	Updating of 50% of procedures completed

Objective	
Create a Sector for Product Data Management to integrate business and administrative support to the scientific functions of the Agency	
Performance indicators for the objective	**Target**
First phase of creation of department	Implemented by Q2
Vision for second phase of implementation	Vision adopted by Q3
Enterprise Information Architecture project	Business input for Phase 1 completed Q1 2010 Project plan for Phase 2 prepared Q2 2010

Objective	
Develop the competence of Agency staff	
Performance indicators for the objective	**Target**
Scientific training programme	Initiated
Courses on statistics and clinical trial methodology	Procurement completed Q2
Training in line with the training profiles	60% compliance

Objective	
Further enhance the effectiveness of the Agency's integrated management system	
Performance indicators for the objective	**Target**
Review of the experience with the system	Completed Q1
Implementation of action plan, as appropriate	Completed in line with set timelines

2. Medicines for human use

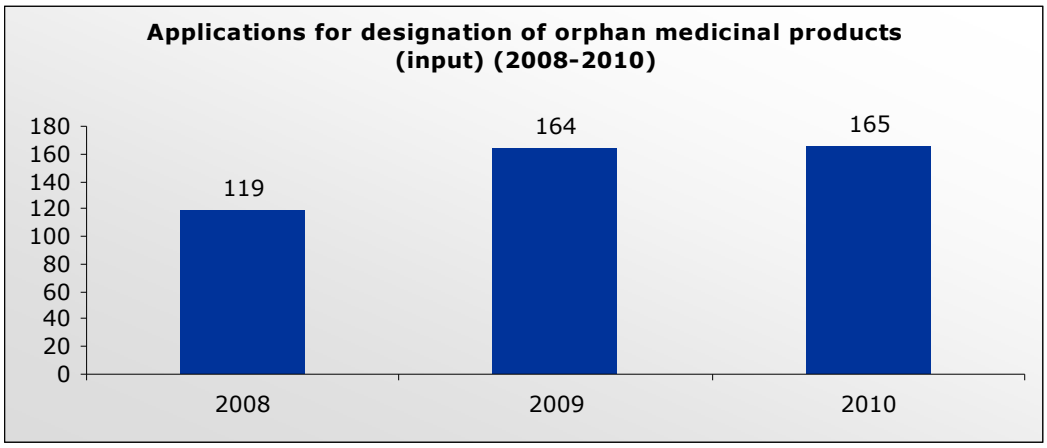
2.1. Orphan medicinal product designation

Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Community, or where for economic reasons such medicines would not be developed without incentives.

The Agency contributes significantly to the creation of an environment stimulating innovation and research and availability of medicines to treat rare diseases through the implementation of the orphan medicinal products policy. As part of this work, the Agency provides financial incentives during the development, initial marketing authorisation and, in the case of SMEs, post-authorisation phases. Protocol assistance remains a priority area for such incentives.

Trends and new issues:

- Increasing percentage of molecular and personalised medicines and of advanced therapies in the orphan product segment.
- Continued international collaboration with regulatory authorities: implementation of European Medicines Agency/US FDA common application form, expected increase in parallel submissions with the US FDA, analysis of different designation practices between the US FDA and the European Medicines Agency.



In addition to core activities relating to the evaluation of applications for designation and international collaboration in this area, particularly with the US FDA, the Agency will target the following specific objectives:

Objective	
Increase communication related to orphan designation activities	
Performance indicators for the objective	**Target**
Procedure and templates for public assessment report on review of designation criteria at the time of marketing authorisation	Procedure and templates implemented
COMP recommendation to European Commission on publication of data on clinical trials for rare diseases	Draft recommendation

Objective	
Review and analyse the first 10 years of activities in the field of rare diseases since the entry into force of Regulation (EC) No 141/2000 on orphan medicinal products	
Performance indicators for the objective	**Target**
Report on review and analysis	Final report published

Performance indicators for the activity area:

Performance indicator	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 one month of the European Commission's decision on marketing authorisation	80%

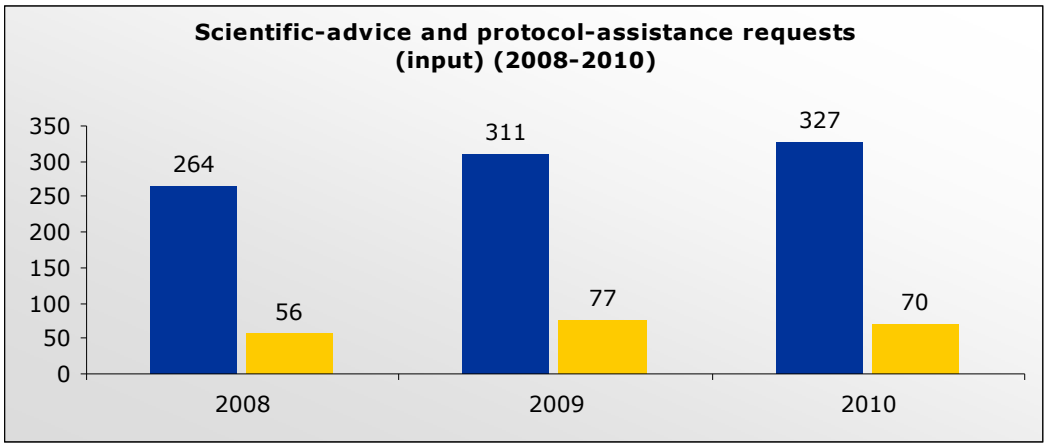
2.2. Scientific advice and protocol assistance

The Agency provides scientific advice and protocol assistance to sponsors during the phase of research and development of medicinal products. Scientific advice is provided on any aspect of research and development relating to quality, safety or efficacy of medicinal products. In addition, the Agency provides advice to sponsors of designated orphan medicines in the form of protocol assistance, which can include advice on the significant benefit of a product. The Agency has more recently introduced a qualification process for innovative development methods.

Scientific advice and protocol assistance are key areas of activity for the Agency, in particular with respect to fostering new innovative technologies and therapies. The Agency considers scientific advice as a means to facilitate and improve earlier availability of medicinal products to patients and healthcare professionals, and as a means to foster innovation and research.

Trends and new issues:

- The number of initiated scientific advice and protocol assistance procedures has been increasing steadily. An increase in the number of requests for scientific advice on topics such as innovative statistical approaches and adaptive clinical study designs is expected.
- The qualification of biomarkers procedure is expected to be well established by 2010. However, the extent to which sponsors will engage in this procedure is difficult to foresee at this point in time.



In addition to core activities relating to the provision of quality scientific advice to applicants, the Agency will work to respond to the needs of the small and medium-sized enterprises, advanced therapy medicinal products and biomarkers. The following specific objectives will be targeted:

Objective	
Support SMEs in developing high-quality data on advanced therapy medicinal products for certification and initial evaluation procedures	
Performance indicators for the objective	**Target**
Percentage of certification procedures preceded by scientific advice	50% of certification procedures
Percentage of initial evaluation procedures for advanced therapy medicinal products preceded by scientific advice (excluding procedures preceded by certification)	20% of initial evaluation procedures for advanced therapy medicinal products

Objective	
Initiate reassessment of biomarker qualification procedure to determine impact of procedure on qualification of novel methodologies	
Performance indicators for the objective	**Target**
Action plan for reinforcement of process	Finalised action plan

Performance indicators for the activity area:

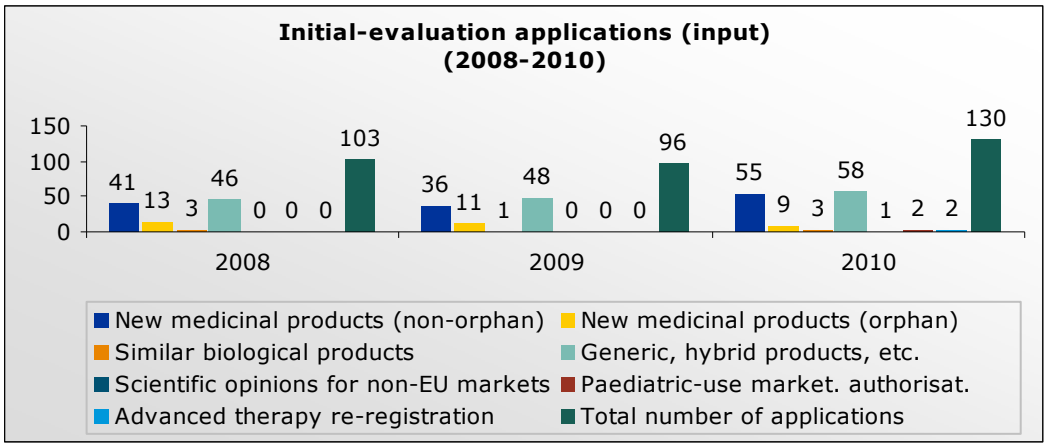
Performance indicator	**Target**
Scientific advice and protocol assistance requests evaluated within the procedural timelines	100% of requests
External experts involved in procedures	40% of SA and PA requests

2.3. Initial evaluation

This covers Agency activities relating to the processing of applications for centralised marketing authorisations from pre-submission discussion with future applicants, through evaluation by the CHMP for the issuance of a scientific opinion, to the granting of a marketing authorisation by the European Commission. These activities culminate in the production of the European Public Assessment Report (EPAR). Applications for certification of Plasma Master Files (PMF) and Vaccine Antigen Master Files (VAMF) are processed in a similar manner but without the production of an EPAR. Applications for opinions on ancillary blood derivatives and medicinal substances in devices are processed similarly to new applications.

Trends and new issues:

- The number of marketing authorisation applications for new products is expected to stabilise at 60-65.
- The number of generic applications will continue to increase in 2010 as more companies use the centralised procedure.
- The proportion of biologicals, which during recent years was around 20-25%, should increase.
- Marketing authorisation applications for advanced therapy medicinal products will be dominated by cell-based medicinal products.



In addition to the core activity of evaluating applications for marketing authorisation, attention will be given to geriatric populations, quality of assessment and clinical trials. The following specific objectives will be targeted:

Objective	
Further reinforce the regulatory and scientific consistency and transparency of initial evaluation CHMP opinions in line with agreed quality criteria	
Performance indicators for the objective	**Target**
Percentage of application procedures started in 2010 that undergo improved documented quality control in line with agreed criteria	80% of applications

Objective	
Implement more detailed assessment of clinical data relating to geriatric populations and reflect this in the assessment report of initial evaluation procedures	
Performance indicators for the objective	**Target**
Percentage of applications started in 2010 with detailed assessment and reporting on geriatric populations	50% of assessment reports on products with geriatric data

Objective	
Improve consistency in the assessment of identical applications for generic products between procedures at Agency level and at decentralised / national level	
Performance indicators for the objective	**Target**
Clear guidance for industry, marketing authorisation holders and assessors on generic and hybrid applications	Guidance document agreed
Questions and answers document on quality aspects of generics revised	Final document published

Performance indicators for the activity area:

Performance indicator	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% of applications

2.4. Post-authorisation and maintenance activities

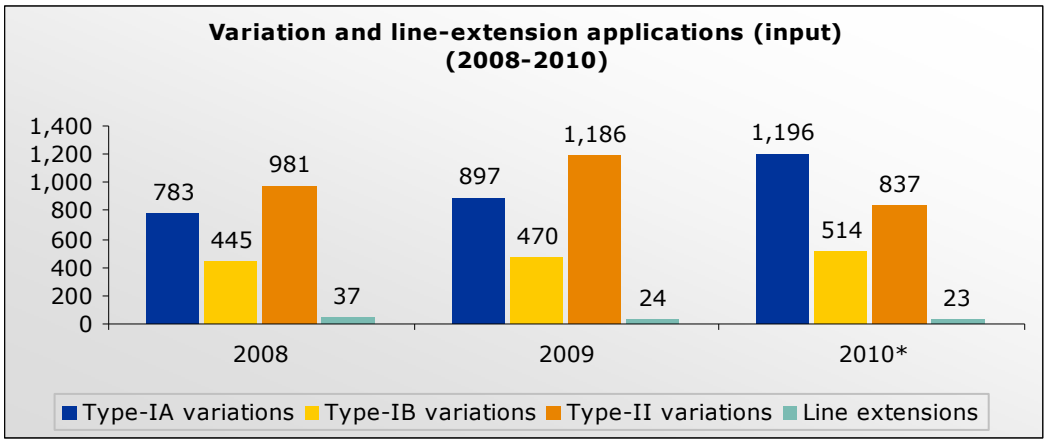
Post-authorisation activities relate to variations, line extensions and transfers of marketing authorisations. Variations to marketing authorisations can be either minor (type-IA or IB) or major (type-II) changes. These variations concern quality, (non-)clinical and pharmacovigilance related aspects, including extensions of indications and risk management plans.

This area also covers a number of maintenance activities relating to post-authorisation commitments (specific obligations, follow-up measures), renewal applications, conditional renewals, annual reassessments and Official Medicines Control Laboratories (OMCL) and Pharmacopoeia issues.

Trends and new issues:

- 2010 will be the first year of application of the new provisions arising from the revised variations Regulation, particularly grouping of variations and worksharing within the European regulatory network.

The Agency will see further increase in the number and the complexity of post-authorisation procedures, including procedures for generic/ biological similar medicinal products, extensions of indications to paediatric populations, legal status switches (prescription to non-prescription) and the first post-authorisation procedures for advanced therapy medicinal products.



* 2010 figures based on revised reclassifications.

In addition to the core activity of handling post-authorisation activities and continuous development and updating of procedural advice documents, the Agency will operate the revised Variations Regulation and will introduce further quality assurance measures. The following specific objectives will be targeted:

Objective	
Strengthen the quality assurance for major marketing authorisation changes (extensions of indications and line extensions)	
Performance indicators for the objective	**Target**
A peer-review system at CHMP level for the (co-)rapporteurs' assessment reports for major marketing authorisation changes	Introduced Q4

Performance indicators for the activity area:

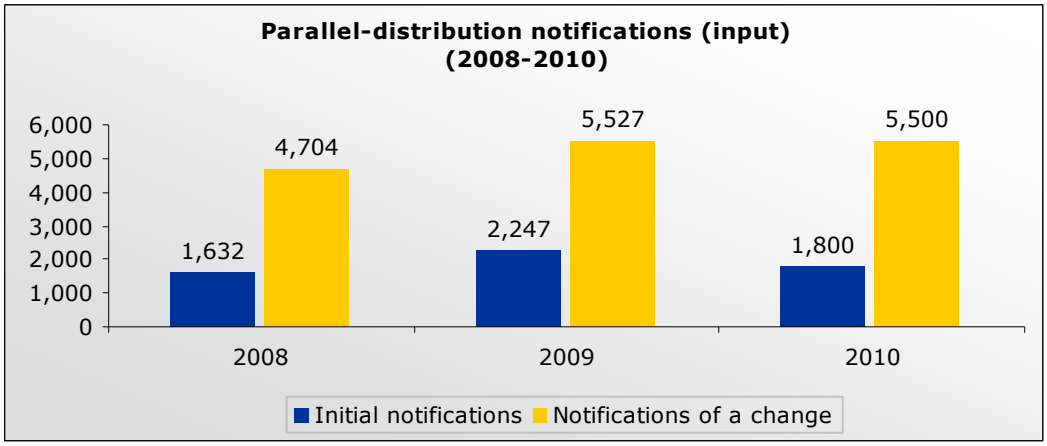
Performance indicator	**Target**
Percentage of applications for post-authorisation procedures evaluated within the regulatory and procedural timelines	100% of applications
Percentage of Agency recommendations on classification of variations delivered in the procedural timelines	80% compliance
Submission of assessment reports for post-authorisation commitments (PACs) to applicants/MAHs within 2 weeks of the CHMP meeting	90% of reports
Percentage of grouping and worksharing procedures completed in the procedural timelines	100% compliance
Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications

2.5. Parallel distribution

Parallel distribution is the distribution of a centrally authorised medicinal product from an EU-EEA Member State to another Member State by a pharmaceutical company independent of the marketing authorisation holder. The task of the European Medicines Agency is to check compliance of products parallel distributed with the conditions laid down in Community legislation on medicinal products and in the marketing authorisation of the centrally authorised product.

Trends and new issues:

- The number of initial notifications is expected to be comparable to that of 2009. A 10% increase in notifications of a change is estimated in 2010 due to the wide range of products distributed by parallel distributors and the regular update of the product information for centrally authorised products.



In addition to the core activity of checking that the conditions laid down in the Community marketing authorisations are observed for parallel-distributed centrally authorised medicinal products and guidance and information on parallel distribution activities are provided, the following specific objective will be targeted:

Objective	
Improve the handling time for initial notifications and for notifications of a change.	
Performance indicators for the objective	**Target**
Percentage of initial notifications checked for compliance within the regulatory timeline of 35 working days (validation and regulatory check)	Improve the compliance with the set timeline compared to 2009

Performance indicators for the activity area:

Performance indicator	**Target**
Percentage of initial notifications checked for compliance within the regulatory timeline of 35 working days (validation and regulatory check)	80%
Number of parallel distributed products sampled on the EU market checked for compliance with the Notices issued by	20 products

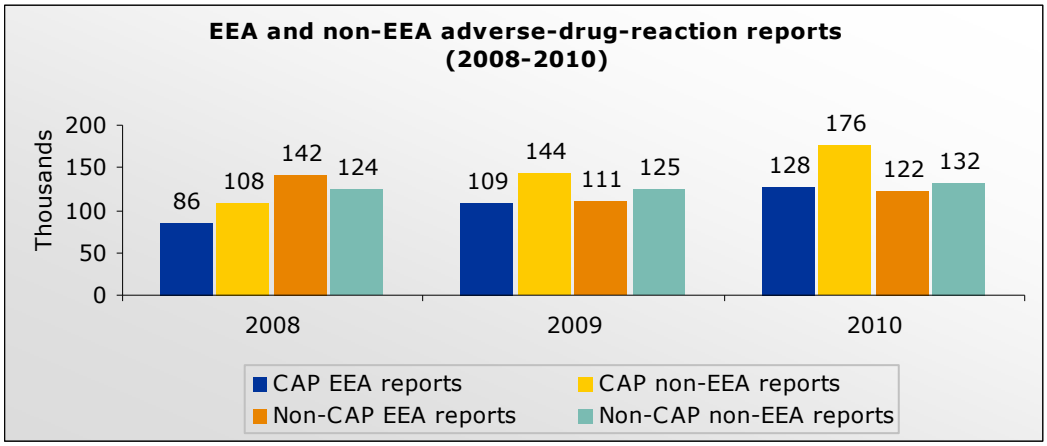
Performance indicator	Target
the European Medicines Agency	

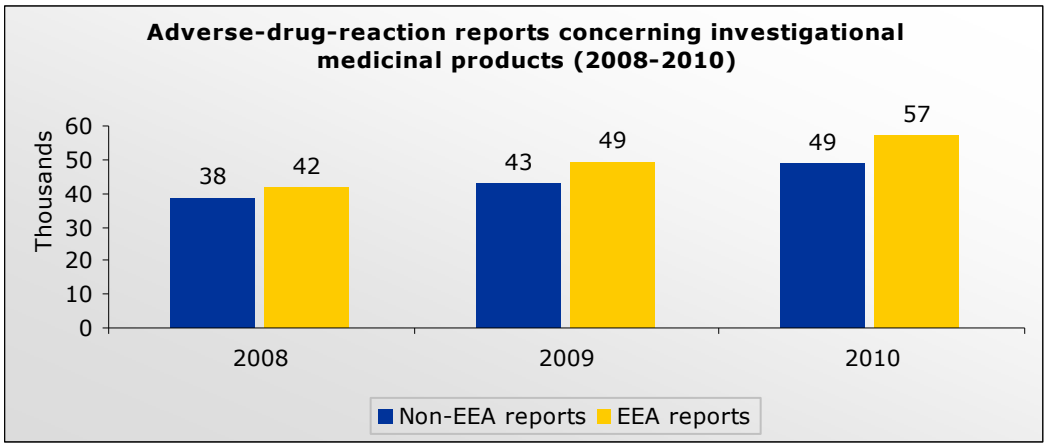
2.6. Pharmacovigilance activities

Pharmacovigilance activities include the management of suspected adverse drug reactions in the pre- and post-authorisation phase (individual case safety reports (ICSRs)), periodic safety-update reports (PSURs), risk-management plans (RMPs) and post-authorisation safety and efficacy/effectiveness studies. They further encompass support to detection and management of signals for centrally authorised medicinal products, the support to the EU Risk Management Strategy (ERMS) and the coordination of monitoring of the safety of medicines in the EU.

Trends and new issues:

- Patient safety and new methodologies for continuous evaluation of benefit and harm are high on the political and academic agenda, which will impact on the European Medicines Agency with regard to the transparency initiatives and the further development of scientific excellence and operational efficiency of pharmacovigilance.
- Pandemic pharmacovigilance will be a key activity for the Agency in line with the European Strategy for Influenza A/H1N1 Vaccine Benefit-Risk Monitoring.
- Transmission of ICSRs to EudraVigilance is projected to increase by about 36% pre-authorisation (clinical trials) and 12% post- authorisation between 2009 and 2010.
- Implementation of the Advanced Therapies legislation with respect to the post-authorisation follow-up of efficacy, the adverse reaction monitoring and risk management.
- The Agency is coordinating a network of pharmacoepidemiology and pharmacovigilance centres (ENCePP) to facilitate scientific evaluation of drug safety issues.
- In addition, the Agency is coordinating a programme of pharmacovigilance research funded by the Innovative Medicines Initiative.
- Work will be undertaken to prepare for the implementation of the new EU Pharmacovigilance legislation, especially as regards to the coordinating role of the Agency and further strengthening of the collection and management of adverse reaction reports in EudraVigilance.





In addition to the core responsibilities in the field of pharmacovigilance, the Agency will focus its resources on the following:

- Contributing to the implementation of the European risk management strategy (ERMS) in line with the 2010-2011 work plan.
- Supporting the EU Regulatory System Incident Management Plan.
- Performing signal detection for centrally authorised products in liaison with (Co-)Rapporteurs.
- Facilitating signal detection for non-centrally authorised medicinal products.
- Supporting the Member States' PSUR work-sharing initiative.
- Collaborating with DG Research to identify specific drug safety issues needing publicly funded studies.
- Further developing the EU Pharmacovigilance Issues Tracking Tool (EPITT).

The following specific objectives will be pursued:

Objective	
Maintain and strengthen EudraVigilance to support proactive pharmacovigilance	
Performance indicators for the objective	**Target**
Retrospective ICSR data quality improvement in EudraVigilance for centrally authorised products	Completed Q4
Proactive improvement of quality of ICSRs by implementing improved business rules across the EEA	To be initiated in Q2

Objective	
Support ENCePP as a functional network of centres for the monitoring of targeted authorised medicines	
Performance indicators for the objective	**Target**
Deliver publicly available database of research centres and data sources	Q2
Deliver publicly available database on pharmacovigilance and	Q3

Objective	
pharmacoepidemiology studies	

Objective	
Provide support to SMEs regarding electronic adverse reaction reporting	
Performance indicators for the objective	**Target**
Training on the use of EudraVigilance for electronic reporting purposes	10 training sessions provided

Performance indicators for the activity area:

Performance indicator	Target
Percentage of risk management plans (RMP) that are peer reviewed as part of the assessment of the initial marketing authorisation application	80% of applications
Percentage of RMPs that are peer reviewed by the Agency as part of the assessment of variations and line extensions which result in a significant change to a marketing authorisation	80% of RMPs
Percentage of ICSRs reported electronically for CAPs	100%

2.7. Arbitration, Community referrals and opinions on scientific matters

Article 20 procedures (Regulation (EC) 726/2004) require a CHMP opinion on the measures necessary to ensure the quality, safe and effective use of a centrally authorised product.

Arbitration procedures (either under Article 29(4) of Directive 2001/83/EC as amended or Articles 6(12) and 6(13) of Commission Regulation (EC) No 1084/2003) are initiated because of disagreement between Member States or because of disagreement of the marketing authorisation holder with the Member States in the framework of the mutual-recognition (MRP) or decentralised procedures.

Article 30 referrals (Directive 2001/83/EC) are mainly initiated in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by the Member States.

Article 31 and 36 referral procedures (Directive 2001/83/EC) are mainly initiated in case of Community interest and generally for safety-related issues.

Article 16c(1)(c) referrals are initiated by Member States regarding herbal medicinal products with a traditional use of at least 30 years, including at least 15 years in the Community, in order to obtain an opinion on the adequacy of evidence of the long-standing use. Article 16c(4) are initiated by Member States regarding herbal medicinal products with a traditional use of less than 15 years in the Community in order to obtain an opinion on the eligibility to the simplified procedure.

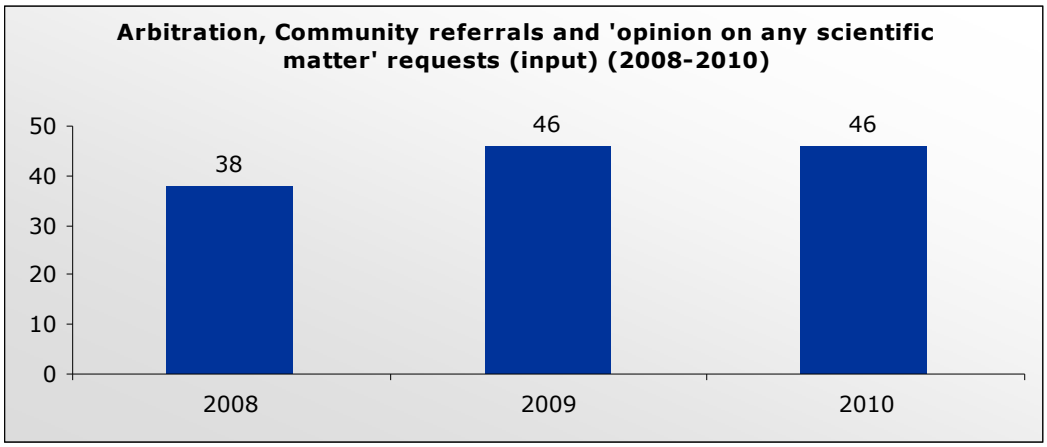
Article 107 of Directive 2001/83/EC, as amended, referrals are initiated to obtain a rapid CHMP opinion further to an envisaged suspension or revocation of the marketing authorisation (or optionally a variation to the marketing authorisation) of a medicinal product in a Member State as a result of pharmacovigilance data.

Article 5(3) procedures (Regulation (EC) 726/2004) require a CHMP opinion on any scientific matter raised by the European Medicines Agency, the European Commission or a Member State.

Article 29 procedures (Regulation (EC) No 1901/2006) require a CHMP opinion on authorisation of a new indication, new pharmaceutical form or new route of administration relating to paediatric use.

Trends and new issues:

- The complexity of referral procedures is expected to increase in the coming years. The cumulative number of referrals under Articles 29(4) and 30 is expected to stabilise within the range of 15 to 22 per year. The number under Article 29 (paediatric use) and Article 31 are expected to increase.
- New referral procedures stemming from the proposed Community legislation in the field of pharmacovigilance will, if maintained, come into force in 2012. However, preparatory work for this implementation will be undertaken in 2010-2011.



In addition to effective evaluation of arbitrations and referrals, the following specific objectives will be targeted:

Objective	
Increase consistency, efficiency and transparency of referrals procedures	
Performance indicators for the objective	**Target**
Identification of areas where consistency, efficiency and transparency can be increased	Measures identified and plan for the implementation of the improvement measures
New structure for referrals CHMP assessment reports	Changes implemented
Guidelines revised	Final documents agreed

Performance indicators for the activity area:

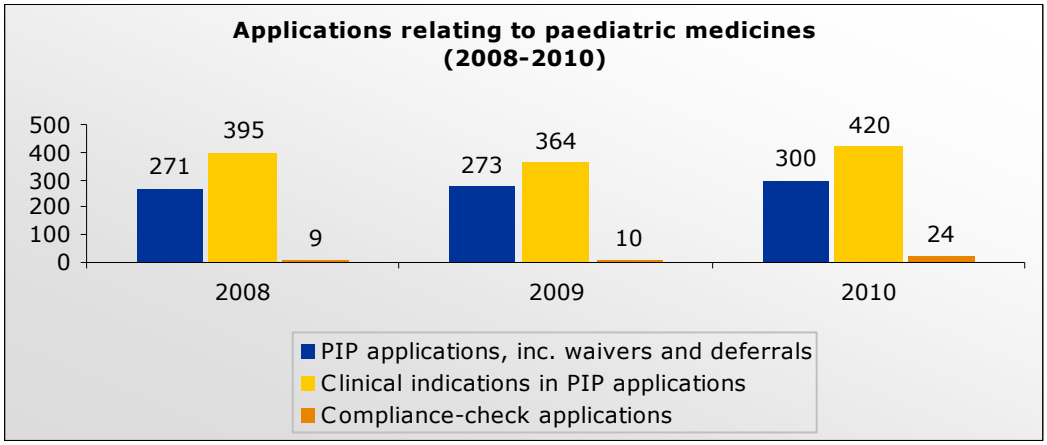
Performance indicator	**Target**
Percentage of arbitrations and referrals evaluated within the legal timeline	100%
Publication of the CHMP Opinion and Assessment Report for Art. 5(3) procedures at the time of the CHMP Opinion	100%

2.8. Medicines for paediatric use

This covers Agency activities relating to the assessment of, agreement of and verification of compliance with paediatric investigation plans and waivers by the Agency's Paediatric Committee in line with Regulation (EC) No. 1901/2006. An agreed paediatric investigation plan may lead to information on the paediatric use of medicines being included in a centralised or a national marketing authorisation for new medicinal products and in a paediatric-use marketing authorisation for off-patent products. Activities also include agreement on the strategy for the establishment of the European network of paediatric research and the provision of information on clinical trials performed in children.

Trends and new issues:

- The full implementation of the paediatric regulation by 2010-12 will have a major impact on Agency activities.
- Modifications of agreed PIPs are expected to increase to at least 20% of overall paediatric activities. These modifications are necessary as long-lasting plans may turn out to be no longer appropriate or workable.
- Systematic validation of paediatric requirements for marketing authorisation applications, variations and line extensions will have a significant impact on paediatric activities.
- PIP compliance checks could reach a significant portion of paediatric activities, including also referrals to PDCO by Member States.
- The network of paediatric research to be established and recognition criteria set up. This would lead to higher expectations for meetings and workshops.
- EudraCT to be fully implemented with full search and publication facilities, and electronic workflow should be in place; maintenance of EudraCT will be necessary.



In addition to the Agency's core activities in relation to paediatric medicines, the following specific objectives will be targeted:

Objective	
Develop and disseminate specific guidance for conduct of paediatric medicinal product development	
Performance indicators for the objective	**Target**
Guidance documents published for consultation or as final documents	75% of work plan

Objective	
Reinforce interaction between the Committee on Advanced Therapies and the Paediatric Committee on paediatric aspects of advanced therapy medicinal products	
Performance indicators for the objective	**Target**
Proportion of PIP applications for advanced therapy medicinal products discussed with the Committee on Advanced Therapies	70 % of PIPs for advanced therapies

Objective	
Improve interactions with applicants on paediatric-related activities	
Performance indicators for the objective	**Target**
Pre-submission meetings and teleconferences organised with applicants for PIPs / waivers	20% of applications

Objective	
Initiate implementation of process improvement measures relating to the handling of quality aspects of PIPs	
Performance indicators for the objective	**Target**
Implementation of actions according to agreed plan	100% of actions

Performance indicators for the activity area:

Performance indicator	**Target**
Number of paediatric investigation plan or waiver opinions and decisions within legal timelines.	100% of opinions/decisions
Percentage of Agency decisions on paediatric investigation plans/waivers published within 4 weeks of the decision	95%

2.9. Herbal medicinal products

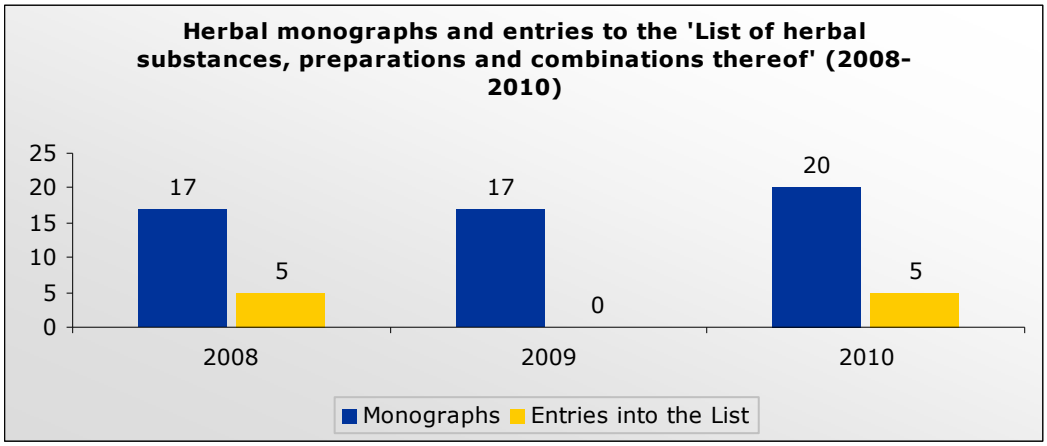
The Agency's activities in the area of herbal medicines include the provision by the Committee on Herbal Medicinal Products of scientific opinions on questions relating to herbal medicines, the establishment of Community herbal monographs for traditional and well-established herbal medicinal products, the establishment of a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, the provision of opinions on herbal substances at the request of the CHMP, and the evaluation for referral and arbitration procedures on traditional herbal medicinal products.

Trends and new issues:

- The Agency expects that it may need to address 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). Moreover, should there be an extension of the scope of Directive 2004/24/EC, the Agency would need to respond to these changes.

In addition to core activities relating to herbal medicines and the above developments, the following specific objective will be targeted:

Objective	
Improve the output of the Committee on Herbal Medicinal Products, in particular by increasing the quality and ensuring the quantitative output in form of monographs and list entries	
Performance indicators for the objective	**Target**
Community herbal monographs	20
Community list entries	5



2.10. Advanced therapies and other emerging therapies and new technologies

This area of activity relates to advanced therapy medicinal products (ATMP: gene therapy, somatic cell therapy or human tissue engineered products) that fall within the scope of Regulation (EC) No. 1394/2007. The main tasks of the Committee for Advanced Therapies, established by the Regulation, are to provide in relation to advanced therapy medicinal products draft opinions to the CHMP on the evaluation of MAAs, specific expertise and advice to the European Medicines Agency, CHMP and/or the European Commission, input to the certification of quality and non-clinical data, to scientific recommendation on classification, and to CHMP scientific advice. Other emerging therapies and new technologies that are outside the scope of the Regulation are also covered in this strategic area.

Trends and new issues:

- The volume of new certifications of quality and non-clinical data to be issued by the Agency is difficult to predict as the procedure was only fully implemented in mid-2009.
- The number of requests for recommendation on ATMP classification is expected to increase further in 2010.
- Increased demand for expertise on advanced therapies needed from both Agency secretariat and network of EU experts.
- The Committee for Advanced Therapies will, by virtue of its involvement in scientific advice requests and recommendations on classifications, continue to build its experience on advanced therapies.
- The first MAAs for ATMPs legally on Member States' markets could be submitted for evaluation in 2010.

In addition to the core activities in this area, including the provision of EudraVigilance data to national competent authorities regarding medical devices, the following specific objectives will be targeted:

Objective	
Initiate review of advanced therapy medicinal products processes on the basis of experience gained in the first year of operations	
Performance indicators for the objective	**Target**
Gap analysis performed and areas for improvement / strengthening identified	Analysis finalised and report agreed
Guidance on interaction with Notified Bodies on combined ATMPs	Document drafted and finalised Q4

Performance indicators for the activity area:

Performance indicator	**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

2.11. Scientific committees, working parties and scientific advisory groups

Trends:

- As a consequence of the increased complexity of the Agency's committee and working party structure, the Agency's secretariat will have a strong role to ensure appropriate collaboration between committees and working parties in areas of common interest (e.g. in relation to the development of guidelines, assessment of products, sharing of expertise).
- Increasing complexity of the applications means that European Medicines Agency has an increasing guiding role for committees and working parties in the process of managing and co-ordinating their work.
- Scientific advisory group and ad-hoc expert group meetings for product evaluation should increase in number due to earlier involvement, the complexity of procedures, a higher number of re-examinations and increased public scrutiny.

Specific objectives relating to the work of scientific committees, working party and scientific advisory groups:

Objective	
Further develop the interaction between the CHMP and the Paediatric Committee and the new Committee on Advanced Therapies	
Performance indicators for the objective	**Target**
Preparation of procedures detailing the interaction between individual Committees	Procedures finalised Q3

Objective	
Increase early active consultation with interested parties such as academia, learned societies, healthcare professionals and patients during the development of clinical guidelines particularly those of public health interest.	
Performance indicators for the objective	**Target**
Criteria for identifying public health interest guidelines and interested parties	Criteria agreed and implemented

Objective	
Modify working party framework according to the CHMP-European Medicines Agency analysis and proposals report	
Performance indicators for the objective	**Target**
Implementation of the action plan	All main actions implemented

Objective	
Optimise the composition of and availability of experts for SAGs, their governance and policy for consultation by CHMP and PDCO	
Performance indicators for the objective	**Target**
Implementation of the actions agreed by the Agency and committees concerned	All actions implemented

2.12. Coordination group

The Agency provides secretarial support to the Coordination group for mutual recognition and decentralised procedures (human products) (CMD)(h) and its sub-groups/working groups in accordance with the approved rules of procedure.

Trends and new issues:

- A consolidation of the CMD(h) activities will continue to be undertaken, in particular, in the area of referrals to CMD(h), including referrals to CMD(h) for type II variations and worksharing, arising from the implementation of the revised Variations Regulation and the list of products for SPC harmonisation, laid down on a yearly basis by the CMD(h).

In addition to the activities in the area and within the context of the above trends the following specific objectives will be pursued:

Objective	
Further improve the functioning of the CMD(h), including its interaction with the European Medicines Agency's scientific and working parties	
Performance indicators for the objective	**Target**
The implementation of the action plan following the evaluation of the functioning of the CMD(h)	Finalised by Q4.
A procedure on the interaction between the CMD(h) and the Agency's scientific committees and working parties	Procedure developed Q4

Objective	
Fully implement the revised Variations Regulation at the level of the CMD(h)	
Performance indicators for the objective	**Target**
Draft and/or revise the CMD(h) secretariat's procedures in relation to: - CMD(h) 60-day referral procedure for variations - Procedure for providing advice on unclassified variation; - Worksharing procedure.	Procedures developed Q4

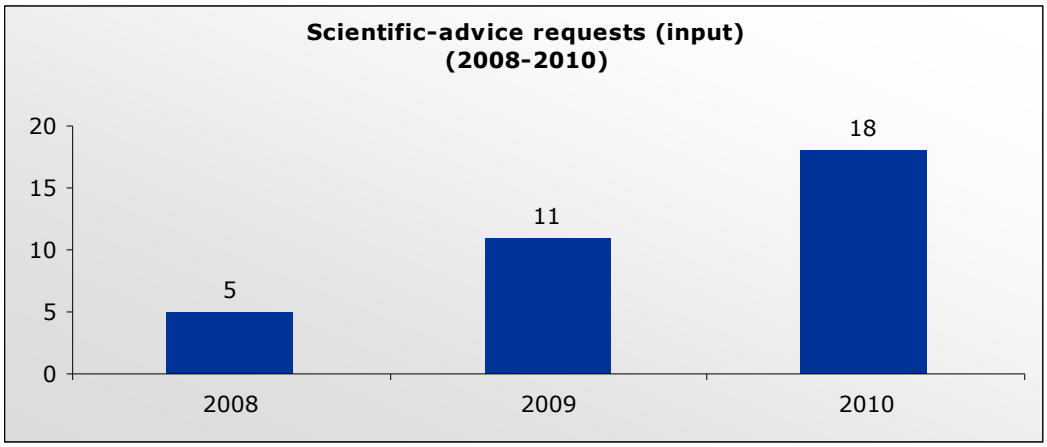
3. Veterinary medicines

3.1. Scientific advice

This relates to the provision of scientific advice to sponsors during the research and development of medicinal products. Scientific advice is a priority area for the Agency and is provided on any aspect of research and development relating to quality, safety or efficacy of medicinal products, and to the establishment of maximum residue limits.

Trends and new issues:

- The Agency is keen to promote early applications for scientific advice in relation to the development of veterinary medicines. Following a decrease or static numbers of scientific advice applications in 2007 and 2008 a range of improvements have been introduced successfully in the procedure and the number of applications has doubled in 2009. The availability of the scientific advice procedure has also been more widely publicised with industry. Uptake has been strong from SME companies (about 60% of total figures in 2009) taking advantage of the incentives offered. An increase in applications for products not to be authorised via the centralised procedure was also seen, reflecting the efforts made to attract applications for decentralised/mutual recognition procedures. External experts have been appointed to assist co-ordinators in certain applications where additional expertise was needed.
- The criteria for providing free scientific advice in relation to the development of products indicated for MUMS/limited markets was amended in 2009. The new MUMS policy came into force on 1 September 2009 with the possibility to request classification of a product intended as MUMS/limited markets by CVMP. It is anticipated that this will provide an incentive for developing such products and increase the number of scientific advice applications for this type of product thus contributing to availability of products for MUMS and limited markets. A new category of scientific advice was introduced, where an applicant can ask for a general review of the data requirements for a specific product intended for MUMS/limited markets in line with adopted guidelines on MUMS data requirements. The expected increased workload in 2010 will need to be monitored to ensure availability of co-ordinators to assess the applications within the agreed timeframes.



In addition to the Agency's core activities in relation to the provision of scientific advice and support to the scientific advice working party, the following objectives will be targeted:

Objective	
Promote the European Medicines 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	Remains at the previous years' level or increases

Objective	
Increase cooperation with FDA and other international partners in the context of existing arrangements to promote parallel scientific advice as a measure of assistance to industry	
Performance indicators for the objective	**Target**
Parallel scientific advice with FDA	One request received

Objective	
Promote scientific advice in relation to products for minor use minor species (MUMS/limited markets)	
Performance indicators for the objective	**Target**
Scientific advice request related to MUMS/limited markets	Increase by 25% in the number of request(s) received as compared to previous years

Performance indicators for the activity area:

Performance indicator	**Target**
Scientific advice requests evaluated within the procedural timelines	100% of applications

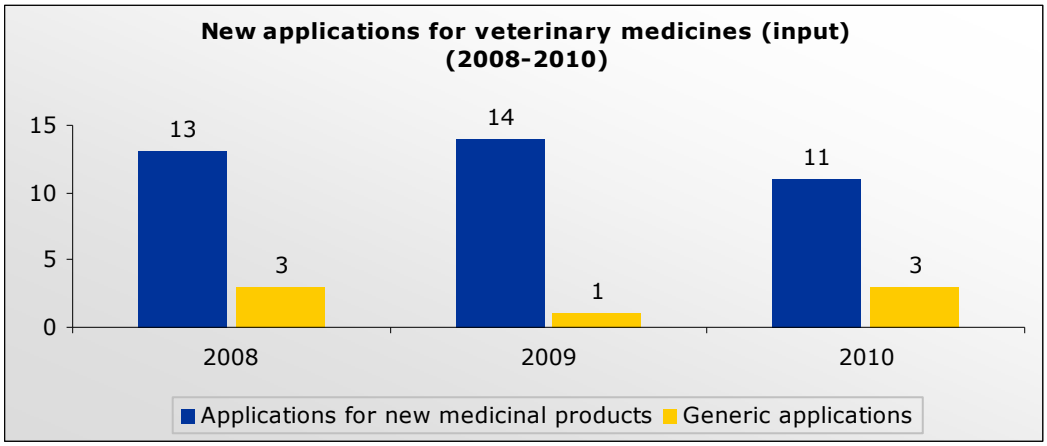
3.2. Initial evaluation

The initial evaluation phase covers a number of Agency activities ranging from pre-submission discussions with future applicants, through evaluation by the CVMP, to the granting by the European Commission of the marketing authorisation. The Agency publishes a European public assessment report (EPAR) once the Commission decision has been taken.

Trends and new issues:

- The Agency predicts a continuation of the long-term trend for a gradual increase in the number of applications for marketing authorisations when averaged out over several years. The level of generics is expected to increase in line with the number of innovative reference products reaching the end of the 10-year period of data exclusivity.
- There has been a dramatic increase in recent years in terms of requests for authorisation under exceptional circumstances for 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 of the Community in relation to exotic diseases.

- 2010 will be the first 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. A gradual increase in the number and scope of applications for MUMS/limited market products is anticipated and there will be an increase in demand for CVMP to consider requests for classification and, thereby, eligibility for assistance.



In addition to core activities in the area, the Agency will work in the area of further strengthening of the quality assurance system in respect of CVMP procedures to ensure the quality and consistency of the scientific assessments conducted. 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'. Assistance will be provided to the Commission in considering the particular needs of the veterinary sector with respect to authorisation of veterinary medicinal products.

Objective	
Strengthen the quality assurance system in respect of CVMP procedures to ensure the quality and consistency of the scientific assessments conducted (Road Map initiative)	
Performance indicators for the objective	**Target**
Submission of CVMP peer review reports	80%

Performance indicators for the activity area:

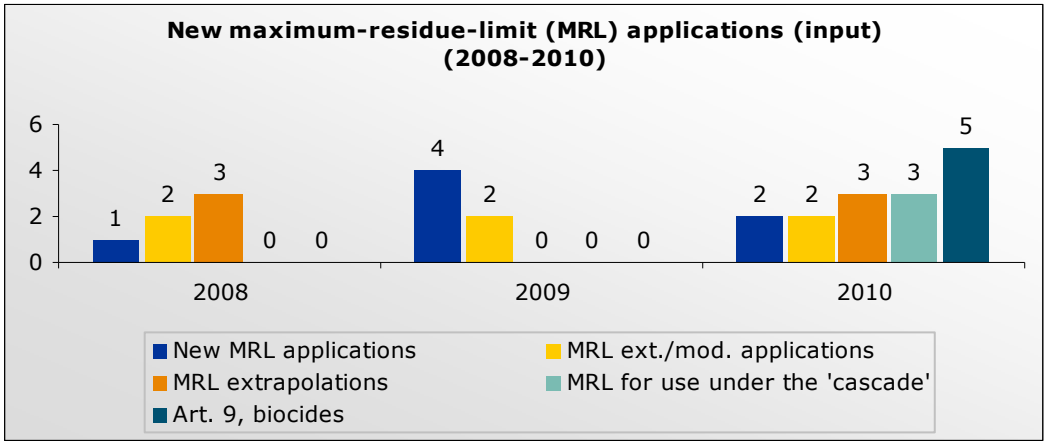
Performance indicator	**Target**
Percentage of products evaluated within the regulatory timeline of 210 days	100% of applications

3.3. Establishment of maximum residue limits

The use of veterinary medicinal products in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. Before a veterinary medicinal product can be authorised, an evaluation of the safety of residues must be carried out. The Agency establishes maximum residue limits (MRLs) for pharmacologically active substances used in veterinary medicinal products as well as biocidal products used in animal husbandry, to provide for the safe use of foodstuffs of animal origin, including meat, fish, milk, eggs and honey.

Trends and new issues:

- The Agency's offer to extend MRLs to other species without a fee by way of extrapolation (provided the scientific criteria described in CVMP guidance are met) has not been much taken up in the last years. It is expected that in 2010 more such requests will be made by Member States following the approval of the revised MRL legislation providing specific emphasis and a legal basis for extrapolations.
- Applications for MRLs for products classified by the CVMP as indicated for limited markets may be forthcoming in response to the assistance provided by the Agency in accordance with Article 79 of Regulation (EC) No 726/2004.
- Applications for the establishment of MRLs are expected in the future from Member States or the European Commission under Article 9 of the new MRL regulation, as well as 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, which will be stretched over several years. For 2010 five of such applications are predicted.
- A number of applications from Member States, the European Commission or interested parties and organisations for the establishment of MRLs for substances that are intended for use under Article 11 of Directive 2001/82/EC (the "cascade") and for which no MRLs have been established yet in the foodstuff or species concerned are also expected.



In addition to the core activity of high-quality assessment of MRL applications, extrapolation of MRLs to other species and related activities, the following objectives will be targeted:

Objective	
Further strengthen the quality assurance system in respect of CVMP procedures, including MRL assessment, and foster systems for peer review of the quality and consistency of scientific assessments (Road Map initiative).	
Performance indicators for the objective	**Target**
Submission of comments by CVMP peer reviewers	80% of the number of applications

Objective
Complete the development of up-to-date scientific and regulatory guidance for the implementation of

Objective	
the new MRL regulation, as basis for measures foreseen in new regulation.	
Performance indicators for the objective	**Target**
Review and revision of existing guidance for the establishment of MRLs for veterinary medicinal products and preparation of guidance for establishment of MRLs for biocides	Submitted to the European Commission
Preparation of proposals for modification of standard withdrawal periods for use of veterinary medicines under the cascade	Submitted to the European Commission

Performance indicators for the activity area:

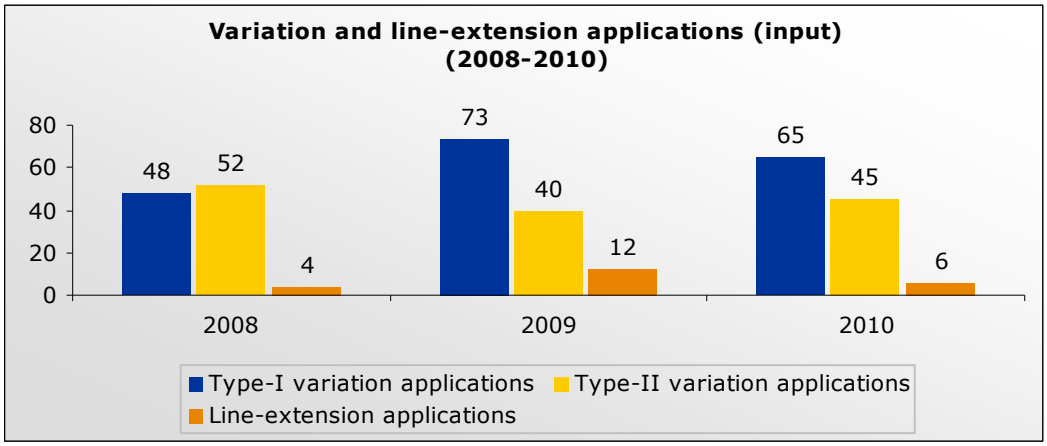
Performance indicator	Target
Percentage of MRL applications evaluated within the legal timeline	100% of applications

3.4. Post-authorisation activities

Post-authorisation activities relate to variations, line extensions and transfers of marketing authorisations. Variations to marketing authorisations can be either minor (type-I) or major (type-II) changes.

Trends and new issues:

An increased workload is foreseen with the coming into force of the new Variations Regulation. The new concepts of work-sharing and grouping of variations are expected to have a major impact on post-authorisation activity within the veterinary area. These new measures are intended to simplify and speed up regulatory procedures related to the maintenance of authorisations. These changes should therefore be welcomed by industry which should start to reap the benefits in 2010.



In addition to the Agency's core activities in relation to post-authorisation area, the following objective will be targeted:

Objective	
Implementation of the new Variations Regulation	
Performance indicators for the objective	**Target**
Appropriate guidance	In place with the coming into force of the new variations regulation

Performance indicators for the activity area:

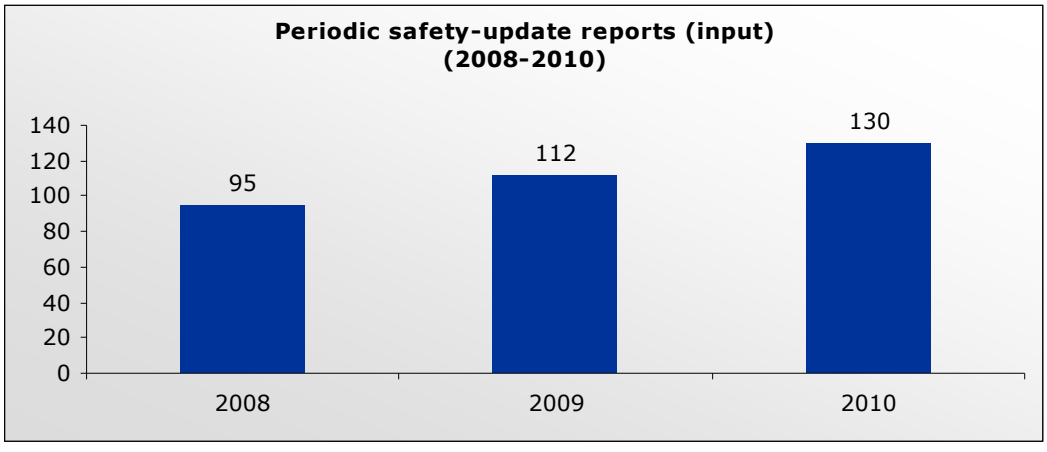
Performance indicator	Target
Post-authorisation applications processed in accordance with legal requirements	100% of applications

3.5. Pharmacovigilance and maintenance activities

This activity relates to pharmacovigilance information, including suspected adverse reaction (SAR) reports and periodic safety-update reports (PSURs). Pharmacovigilance remains a high priority for the Agency in 2009, to ensure that post-authorisation monitoring and effective risk management are continuously applied to veterinary medicines throughout the EU.

Trends and new issues:

- The number of serious adverse reaction and human reaction reports has increased continuously over the last years and assuming a 40% increase for 2010, as in the previous years, the number of spontaneous reports received on an annual basis may reach a number over 4,000, with approximately 130 PSURs being submitted.
- Following the full implementation of the EudraVigilance Veterinary Data Warehouse in 2009, 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 (Road Map initiative) initially with emphasis on centrally authorised products.
- Implementation of policy on access to EudraVigilance Veterinary following public consultation on the Agency's proposal.
- Agreements on international harmonisation within VICH on pharmacovigilance in 2009 will require updating of EudraVigilance Veterinary in the future.



In addition to the Agency's core activities in relation to pharmacovigilance and maintenance activities, the Agency will continue its collaboration with the Member States to optimise efficiency in the EU regulatory network for veterinary pharmacovigilance for all medicinal products authorised in the Community, will support targeted pharmacovigilance and introduce guidance on risk management plans for veterinary medicines.

The following specific objective will be targeted:

Objective	
Improve processing of pharmacovigilance information and access to veterinary EudraVigilance data	
Performance indicators for the objective	**Target**
Signal detection tools	Available and used by the Agency and NCAs
Access to EVVet data	EVVet access for general public in line with Agency policy

Performance indicators for the activity area:

Performance indicator	**Target**
Percentage of PSURs and SARs evaluated within the established timelines	80% of PSURs; 100% of SARs

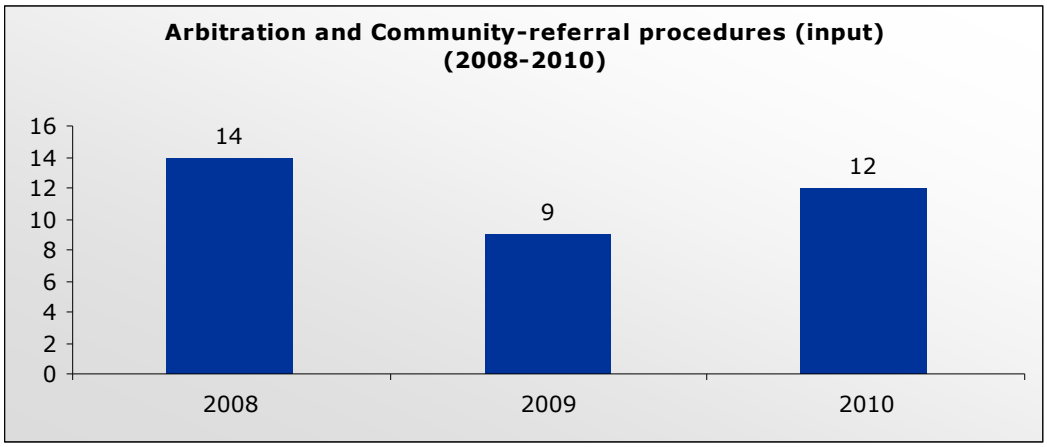
3.6. Arbitration and Community referrals

Arbitration procedures are initiated because of disagreement between Member States within the framework of the mutual-recognition or decentralised procedure (Article 33 of Directive 2001/82/EC, as amended).

Referrals are initiated either in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by Member States (Article 34 of Directive 2001/82/EC) or in cases where there is a Community interest or other safety-related issue (Articles 35 and 40 of Directive 2001/82/EC)

Trends and new issues:

- A significant proportion of referrals relate to authorisation of generic products. Authorisation of generics is more complex for veterinary medicines than human medicines due to a number of additional factors that need to be considered including use of the same product in different species and consumer protection.
- 1-2 referrals under Article 34 or 35 due to discrepancies of withdrawal periods for veterinary medicinal products for food producing animals with the aim to harmonise withdrawal periods and ensure consumer safety are expected to be submitted. These referrals usually concern large number of products and require considerable resources to process.
- Depending on the outcome of actions ongoing within the European Regulatory Network, one or more referrals to 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. If such referrals arise, they are likely to be extensive and relate to classes of antimicrobials encompassing large numbers of authorisations.



In addition to the Agency's core activities in relation to provision of high-quality opinions arising from arbitration and referral procedures, the European Medicines Agency will continue to support efforts by CVMP, CMD(v) and HMA to tackle issues that have a potential for disagreement in approach and develop common understanding, with the aim to avoid inappropriate referrals.

Performance indicators for the activity area:

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

3.7. Scientific committee

The Committee for Medical Products for Veterinary Use (CVMP) is responsible for preparing the Agency's opinions on all questions concerning veterinary medicinal products, in accordance with Regulation (EC) No 726/2004.

- In addition to its core tasks of providing opinions on veterinary medicinal products, the Committee will continue to contribute to various topics in the areas of public and animal health and the availability of medicines.
- 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 quantity as well as scope the CVMP will continue to review working practices and consider establishing specialised scientific advisory groups to support the Committee.
- The publication by the European Commission of a revision of Annex I to Directive 2001/82/EC in 2009 updating the technical requirements for authorisation of veterinary medicinal products results in a programme of updating of existing CVMP guidelines which has started in 2009 and extend into 2010.
- 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.

- The European Medicines Agency will work to strengthen liaison with other EU scientific committees, in particular with those within the EFSA to ensure consistency of scientific opinions and to provide appropriate input when EFSA scientific committees prepare opinions related to the use of veterinary medicinal products in the food chain or for animal health.

Specific objective:

Objective	
Provide scientific advice to inform risk management decisions related to minimising the risk to man from resistance arising as a result of the use of antimicrobials in animals	
Performance indicators for the objective	**Target**
Scientific advice reports (prepared in liaison with other EU bodies)	Submitted to the European Commission within specified timeframe
Compilation of EU data on sales and use of antimicrobials in veterinary medicinal products.	Tbd

Objective	
Complete the programme of updating of existing CVMP guidelines in line with a revision of Annex I to Directive 2001/82/EC	
Performance indicators for the objective	**Target**
Updating of guidelines	Completed (updating started in 2009)

3.8. Coordination group

The Agency provides secretarial support to the Coordination group for Mutual recognition and Decentralised procedures (veterinary) (CMDv) and its sub-groups/working groups.

Trends and new issues:

- Some specific issues affecting the smooth functioning of the network, such as packaging and labelling, divergent interpretation of legislation and national validation requirements, require continued work by the CMDv with support from the 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.
- Implementation of the new variations regulation will result in additional responsibilities for the Group (e.g. Article 5 - recommendation on unforeseen variations).

Specific objective:

Objective	
Assist the committee in promoting consistency of decision-making	
Performance indicators for the objective	**Target**
Regulatory database to track decisions	Explore options for delivery by Q4 2010
Implementation of Variations Regulations	Procedures in place for the role of the secretariat

Objective	
Support the group in the development of a procedure to promote prioritised harmonisation of SPCs	
Performance indicators for the objective	**Target**
Harmonisation scheme agreed	Q2 2010

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

4. Inspections

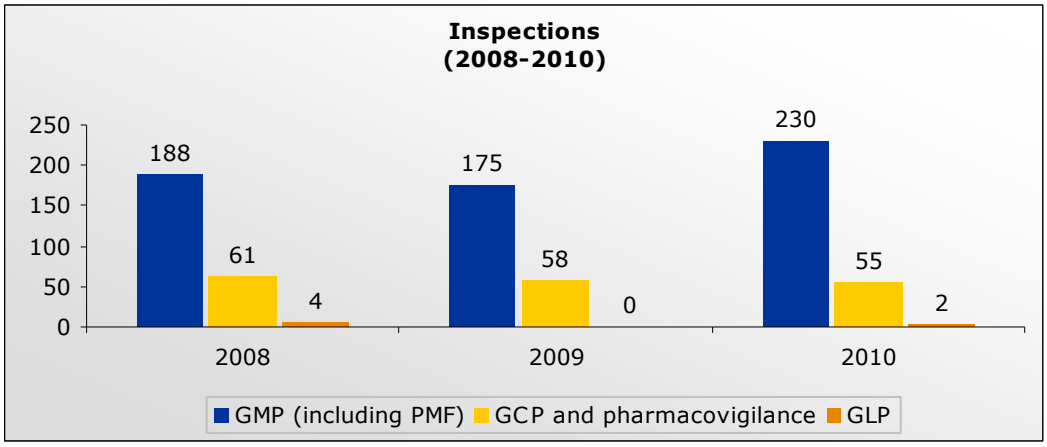
4.1. Inspections

The European Medicines Agency coordinates the verification of compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP) and good laboratory practice (GLP), and with certain aspects of the supervision of authorised medicinal products in use in the Community. It does this through inspections requested by the CHMP or CVMP in connection with the assessment of marketing authorisation applications and/or the assessment of matters referred to these committees in accordance with Community legislation. These inspections may be necessary to verify specific aspects of the clinical or laboratory testing or manufacture and control of the product, and/or to ensure compliance with GMP, GCP or GLP and quality assurance systems.

Similarly, the Agency coordinates pharmacovigilance inspections requested by the scientific committees and inspections of blood establishments within the plasma master file (PMF) certification framework. Communication and action by Member States in response to suspected quality defects and counterfeit medicines relating to centrally authorised medicines are also coordinated by the Agency.

Trends and new issues:

- Increasing numbers of generic applications as well as activities related to advanced therapies are expected to have an impact on GMP inspection numbers.
- GCP and pharmacovigilance inspections are expected to continue to increase in 2010 taking into account the activities relating to the advanced therapy regulation, increasing numbers of generic applications, and increased inspections of third country sites.
- International collaboration on worksharing of all types of inspections, as well as greater focus on risk based approaches and on contributions to capacity building are increasingly important activities.
- New legislative proposals on counterfeits and pharmacovigilance are expected to impact approaches to GMP and pharmacovigilance inspections.
- Greater focus on GDP.



In addition to core activities relating to effective coordination of inspections and management of quality defects the Agency will assess the impact of the new legislative proposals on counterfeits and pharmacovigilance and initiate steps to facilitate implementation. The following specific objectives will be targeted:

Objective	
Progress pilot projects on joint inspections with FDA in both GMP and GCP areas and international collaboration on inspections of active pharmaceutical ingredients in third countries	
Performance indicators for the objective	**Target**
Joint inspections with FDA	Successful completion of 5 GMP and 3 GCP inspections by end 2010

Objective	
Continue policy and procedures development in the area of pharmacovigilance inspections (Human and Veterinary) and address international collaboration	
Performance indicators for the objective	**Target**
Policies and procedures	2 policies/procedures revised/published

Objective	
Implement revised procedures for quality defect management and handling of rapid alert information	
Performance indicators for the objective	**Target**
Revision of the two procedures	Implemented and applied

Objective	
Further develop and implement the Agency's strategy for acceptance of clinical trials conducted in third countries, including the development of advice and guidance on ethical and data quality requirements and on the assessment, inspection and transparency processes relating to these trials.	
Performance indicators for the objective	**Target**
Implementation of the action plan 2008-2011	100% implementation of 2010 actions

Performance indicators for the activity area:

Performance indicator	**Target**
Management of inspections within legislative timelines	100% of inspections

Meetings of GMDP, GCP, GLP, and pharmacovigilance inspectors working groups and Joint CHMP/CVMP quality working party

The inspectors groups will focus their efforts in the following areas:

- Coordination of approaches to investigations and inspections arising from crises with potential impact throughout the Community.
- Supervision of active substances and supply chains in collaboration with international partners.
- Inspection of clinical trials in collaboration with international partners.
- Training activities.

- Cooperation between inspection and assessment functions.
- Capacity building in clinical trials and quality/manufacturing areas in developing countries.

4.2. Sampling and testing

The objectives of the sampling and testing programme, derived from the legal requirements, are to supervise the quality of centrally authorised medicinal products placed on the market and to check compliance of these with their authorised specifications. This ensures that the products actually on the market continue to meet public and animal health requirements. Sampling from the market in different countries is carried out by national inspectorates and testing is performed by official medicines control laboratories coordinated through the EDQM (European Directorate for the Quality of Medicines and Healthcare). A selection of centrally authorised products is included in each annual programme.

Trends and new issues:

- Risk-based approaches under development within the HMA product testing taskforce.
- Experience from first year of implementation of risk-based approach to selection of human medicinal products and from development of analogous approach for veterinary medicinal products.
- Experience from first year of inclusion of testing of parallel distributed products.
- Impact of generic and similar biological products on the centrally authorised products sampling and testing programmes.

In addition to core activities relating to the sampling and testing of centrally authorised products, the Agency will review its experience with the new approaches and evaluate the impact of new trends relating to advanced therapy medicinal products, similar biological and generic products.

Performance indicators for the activity area:

Performance indicator	Target
Percentage of planned products (43) actually tested	95% of planned products

4.3. Implementation of the Clinical Trial and GCP Directives

Trends and new issues:

- Voluntary harmonisation procedure in operation at the level of the Clinical Trials Facilitation Group (CTFG).
- Greater need for links between marketing-application assessment and clinical-trials-supervision processes (CHMP/CTFG).
- Increased public transparency of clinical-trial information from EudraCT (including both protocol and result-related information) and related international standardisation activities with respect to information for inclusion in clinical-trial registries.
- Potential revision of clinical-trial legislation, depending on priorities identified by the European Commission.

In the field of the implementation of the Clinical Trials Directive, the Agency will work in the areas of: the development of harmonised procedures, implementation of actions arising from the 2007 conference on clinical trials, the provision of support to the Clinical Trials Facilitation Group and development of data management and analysis capabilities for the EudraCT database.

5. Information technology

(Support for EU telematics and internal activities)

5.1. EU telematics

The EU telematics strategy for pharmaceuticals is agreed between Member States, the European Medicines Agency and the European Commission. In order to implement European pharmaceutical policy and legislation, the various initiatives aim to increase efficiency, enhance transparency, and support and facilitate the operation of procedures established by legislation.

The implementation strategy concentrates on a number of projects with high European added value. These projects have been agreed as being EudraNet, EudraVigilance, EudraPharm, electronic submissions, EudraCT and Good Manufacturing Practice (GMP) databases. In addition, the Telematics Steering Committee has endorsed a set of horizontal services that are necessary to support the implementation of the systems mentioned.

Trends and new issues:

- The new legislation on pharmacovigilance and anti-counterfeiting measures will require the enhancement of existing and the development of new IT systems. This will be addressed in the Telematics master plan.
- Improvement of the communications capabilities across the network and transparency are key elements of the work programme 2010.
- Contributing to the work on international standardisation, including the development of the following standards: ISO Individual Case Safety Report (ICSR) standard, Regulated Product Submission (RPS) standard, Health Level 7 (HL7) pre-standard for Clinical Trials Registries and Reporting, Identification of Medicinal Products (IDMP) standards.

The following projects and objectives will be pursued (Please refer to the Telematics master plan for further information):

Objectives	
Maintain and strengthen EudraVigilance to support Pharmacovigilance	
Performance indicators linked to objective	**Target**
EV Vet 3 requirements gathering phase completed EV Vet Access policy implemented EV Human Access policy implemented EV data management (backlog) 70% completed	Q4
Eudra Data Warehouse finalisation of inclusion of medicinal products for human use in the updated data warehouse.	Q2

Objectives	
Maintain and strengthen EudraCT to support the European Commission and the NCAs in the registration and oversight of Clinical Trials	
Performance indicators linked to objective	**Target**

Objectives	
Release version 8	Q3
Release version 8.5	Q4

Objectives	
Implement eCTD for all applications for marketing authorisation to the European Medicines Agency to increase the efficiency of centralised procedures	
Performance indicators linked to objective	**Target**
Implementation completed	Q1

Objectives	
Implement e-Application Form project	
Performance indicators linked to objective	**Target**
Implementation completed	Q2

Objectives	
Provide enhanced ICT support to processes contributing to communication and provision of information within the European medicines network by developing the following set of projects:	
Performance indicators linked to objective	**Target**
Light Authoring Tool PIM Review System Data Validation Engine Reference Data Model V3	Complete development phase for centrally authorised products providing final versions by Q3
Note: Migration of centrally authorised products is planned for Q4 2011.	

5.2. Implementation and operation of corporate IT

Trends and new issues:

- Following a period of six years during which priority has been given to the development of EU Telematics systems the Agency must now focus on modernising its corporate IT systems as an essential support for the Agency's process improvement initiative.
- Continuation of the European Medicines Agency Information Architecture assignment with detailed business modelling and analysis on core activities translated in to IT Systems.

The following projects and objectives will be pursued:

Objective	
Enhance and develop ICT systems supporting the efficient conduct of the Agency's core activities	
Performance indicators linked to objective	**Target**
Continue development of applications tracking system (SIAMED II) Implementation of support for the processing of marketing authorisation applications	Q4
Implement Enterprise Resource Planning	

Objective	
system Support of go-live for financial modules. Blue printing for human resource(hr) modules Realisation phase for human resource modules	Q3 Q1 Q3
Complete Phase II of Agency information architecture and Enterprise Information Management projects	Q4
Build a new system to plan, manage, document and evaluate GXP inspections Implementation in production	 Q4

Objective	
Improve the operation of the Eudra and Corporate IT user support	
Performance indicators linked to objective	**Target**
Preparation of service level agreements	Created and agreed with business Q1
Metrics and monthly reporting to management	Metrics created; reports provided Q2
SOP on Incident Management	Created Q3
Compliance with Service level agreement	Met according to definition Q4

Activities in the following area will be undertaken:

Ensuring the provision of reliable and robust IT services to delegates, users of pan-European systems and Agency staff.

Ensuring the maintenance of reliable and robust IT Disaster Recovery facilities.

Progressing the development of the best practice support processes based on the IT Infrastructure Library (ITIL) service management.

Conducting the testing of the Agency's Business Continuity systems with users and new IT Systems and Applications. It is essential that these systems are fully tried and tested on a regular basis to ensure that they are effective in a disaster scenario.

Improving the support and Service Desk functions and the archiving and back-up of data while maintaining a high level of security and confidentiality for all data held on Agency systems.

Performance indicator related to core business	Target
Telematics and corporate IT systems availability measured against Agency working hours	98%

Service Desk - meeting of service level agreements per system/ priority level:

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

Performance indicator for projects	Target
Projects delivered on time	85%
Projects delivered to original specifications	100%
Projects delivered within budget	80%

[2] Response Time means the time within which the Service Desk will inform the user what it is intending to do to resolve the problem.
[3] Resolution Time means the time within which the support team (1st, 2nd & 3rd line) should resolve the problem and have closed it.

Annex 1 Establishment plan 2008-2010

Function group & Grade	Posts 2008				Posts 2009		Posts 2010	
	Authorised		Actual as per 31.12.2008		Authorised		Authorised	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	1				1		1
AD 15	-	3		1		3		4
AD 14	-	4		4		4		5
AD 13	-	5		5		6		6
AD 12	-	34		27		36		37
AD 11	-	33		29		34		36
AD 10	-	33		14		34		32
AD 9	-	22		34		35		35
AD 8	-	42		26		40		43
AD 7	-	43		11		38		38
AD 6	-	23		62		34		39
AD 5	-	9		30		17		34
Total grade AD	*0*	*252*	*0*	*243*		*282*		*310*
AST 11	-	-		1		-		2
AST 10	-	6		1		6		4
AST 9	-	2		2		5		8
AST 8	-	11		3		12		13
AST 7	-	14		13		15		18
AST 6	-	33		16		38		35
AST 5	-	34		15		39		35
AST 4	-	56		28		46		46
AST 3	-	26		51		30		36
AST 2	-	21		16		25		40
AST 1	-	26		80		32		20
Total grade AST	*0*	*229*		*226*		*248*		*257*
Grand Total	**0**	**481**	**0**	**469**	**0**	**530**	**0**	**567**

CONTRACT AGENTS	Actual as per 31.12.2008	Planned FTE 2009	Planned FTE 2010
FG IV	27	35	51
FG III	8	10	15
FG II	30	39	57
FG I	1	1	2
Total	**66**	**85**	**125**

NATIONAL EXPERTS	Actual as per 31.12.2008	Planned FTE 2009	Planned FTE 2010
Total	**12**	**28**	**19**

Annex 2 Revenue and expenditure overview 2008-2010

		2008[4]		**2009**[5]		**2010**[6]	
		€ '000	*%*	€ '000	*%*	€ '000	*%*
	Revenue						
100	Fees	132,179	*70.16*	140,966	*72.52*	152,780	*77.09*
200	General EU contribution	34,408	*18.26*	36,390	*18.72*	28,280	*14.27*
200	Surplus from previous year (reserve)	7,977	*4.23*	[7]4,900	*2.52*	4,332	*2.19*
201	Special EU contribution for orphan medicinal products	3,755	*1.99*	5,500	*2.83*	4,500	*2.27*
300	Contribution from EEA	956	*0.51*	888	*0.46*	935	*0.47*
600	Community programmes	576	*0.31*	360	*0.19*	400	*0.20*
500+900	Other	8,541	*4.53*	5,385	*2.77*	6,960	*3.51*
TOTAL REVENUE		**188,392**	*100.00*	**194,389**	*100.00*	**198,187**	*100.00*

Expenditure							
Staff							
11	Staff in active employment	49,200	*28.40*	54,898	*27.85*	62,489	*31.53*
13	Mission expenses	605	*0.35*	789	*0.41*	789	*0.40*
14	Socio-medical infrastructure	429	*0.25*	570	*0.29*	640	*0.32*
15	Exchange of civil servants and experts	1,866	*1.08*	3,910	*2.01*	2,847	*1.44*
16	Social welfare	92	*0.05*	114	*0.06*	145	*0.07*
17	Entertainment and representation expenses	33	*0.02*	38	*0.02*	50	*0.03*
18	Staff insurances	1,573	*0.91*	1,867	*0.96*	2,133	*1.08*
	Total Title 1	*53,798*	*31.06*	*62,186*	*31.99*	*69,093*	*34.86*
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	18,641	*10.76*	16,754	*8.62*	17,707	*8.93*

[4] 2008 as per final accounts.
[5] 2009 Budget as per 31 December 2009 (incl. AB 01-2009).
[6] 2010 Budget as finally adopted by the Management Board taking account of revised contribution from the EU budget as adopted by the European Parliament on 17 December 2009.
[7] With AB 01-2009 of total reserve €3.7 million were allocated to I200 and €1.2 million to I201.

21	Expenditure on data processing	25,375	*14.65*	29,595	*15.22*	22,071	*11.14*
22	Movable property and associated costs	1,668	*0.96*	2,779	*1.43*	1,456	*0.73*
23	Other administrative expenditure	778	*0.45*	1,264	*0.65*	1,063	*0.54*
24	Postage and communications	771	*0.45*	848	*0.44*	664	*0.34*
25	Expenditure on formal and other meetings	63	*0.04*	104	*0.05*	143	*0.07*
	Total Title 2	*47,296*	*27.31*	*51,344*	*26.41*	*43,104*	*21.75*
Operational expenditure							
300	Meetings	7,259	*4.19*	8,059	*4.15*	8,930	*4.51*
301	Evaluations	60,181	*34.74*	67,419	*34.68*	72,075	*36.37*
302	Translation	3,937	*2.27*	4,345	*2.24*	4,329	*2.18*
303	Studies and consultants	82	*0.05*	80	*0.04*	80	*0.04*
304	Publications	281	*0.16*	298	*0.15*	176	*0.09*
305	Community programmes	379	*0.22*	300	*0.15*	400	*0.20*
	Total Title 3	*72,120*	*41.64*	*80,501*	*41.41*	*85,990*	*43.39*
Provisional appropriation							
900	Provisional appropriation	0	0.00	358	0.19	p.m.	0.00
	Total Title 9	*0*	*0.00*	*358*	*0.19*	*p.m.*	*0.00*
TOTAL EXPENDITURE		173,213	*100.00*	194,389	*100.00*	198,187	*100.00*

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).

CHMP Biologics Working Party

Reference Number	**Document Title**	Status
EMEA/410/01 rev 4	Note for guidance on minimising the risks of TSE transmission via medicinal products	For finalisation
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	For revision of guideline
EMA/CHMP/BWP/534898/2008	Guideline on biological quality aspects of biological medicinal products to be used in Clinical Trials	For consultation in 2010, finalisation in 2011
EMEA/CPMP/BWP/269/95 rev 4	Note for guidance on Plasma derived medicinal products	For finalisation
EMEA/CPMP/BWP/3794/03	Guideline on the scientific data requirements for a plasma master file (PMF)	Templates for finalisation
CHMP/BWP/481473/2008	Annex to Guideline on cell culture Inactivated influenza vaccines	Release of draft guideline and finalisation
EMEA/CHMP/BWP/2879/02	Position Statement on Creutzfeldt-Jakob disease and plasma-derived and urine-derived medicinal products	For consultation and finalisation
EMEA/CPMP/BPWP/BWP/561/03	Note for Guidance on the warning on transmissible agents in Summary of Product Characteristics and package leaflets for plasma-derived medicinal products	Need for revision of guideline to be considered
	Revision of guideline on the use of transgenic animals in the manufacture of biological medicinal products for human use	Initiation of development of guideline

Reference Number	Document Title	Status
EMEA/CPMP/BWP/125/04. rev 1	Guideline on epidemiological data on blood transmissible infections	For finalisation
EMEA/CPMP/BWP/2758/02	Guideline on pharmaceutical aspects of the product information for human vaccines	Scientific input for revision of guideline
EMEA/CHMP/BWP/466097/2007	Guideline on the Chemical and Pharmaceutical Quality Documentation concerning Biological Investigational Medicinal Products in Clinical Trials	Draft guideline to be published for external consultation
EMEA/CPMP/BWP/268/95	Guideline on virus validation studies: The design, contribution and interpretation of studies validating the inactivation and removal of viruses	Clarification concerning GLP/GMP for initiation
	Guideline on development of live recombinant vector vaccines	Development of quality aspects of the guideline
	Guideline on stability data for cumulative storage periods for vaccines/intermediates	Development of quality aspects of the guideline
EMEA/CHMP/BWP/3088/99	Guideline on quality, preclinical and clinical aspects of gene transfer medicinal products	Development of quality aspects of the guideline
EMEA/CHMP/BWP/83508/2009	Guideline on xenogeneic cell-based medicinal products	Development of quality aspects of the guideline
EMEA/CAT/486831/2008/corrr	Guideline on the minimum quality and non-clinical and clinical development of cell-based medicinal products	Development of quality aspects of the guideline
	Annex to guideline on Radiopharmaceuticals based on monoclonal antibodies	Revision of annex

CHMP Blood Products Working Party

Reference Number	Document Title	*Status*
EMEA/CHMP/BPWP/144533/2009	Guideline on the Clinical investigation of recombinant and human plasma-derived Factor VIII	For finalisation

Reference Number	Document Title	*Status*
	products	
EMEA/CHMP/BPWP/144552/2009	Guideline on the Clinical investigation of recombinant and human plasma-derived Factor IX products	For finalisation
CPMP/BPWG/388/95 rev 1	Note for guidance on the Clinical investigation of Human normal immunoglobulin for intravenous administration (IVIg)	For finalisation
CPMP/BPWG/283/00	Note for guidance on the Clinical investigation of Human normal immunoglobulin for subcutaneous and intramuscular use	Concept paper for publication
	Guideline on the Clinical investigation of alpha$_1$-proteinase inhibitor (alpha$_1$ antitrypsin)	Revision for consultation
	Guideline on the Clinical investigation of recombinant Factor VIIa (eptacog)	If required, publication of concept paper
	Guideline on the Clinical investigation of human C1 inhibitor	If required, publication of concept paper
EMEA/CHMP/BPWP/161104/2009	Guideline on the Clinical investigation of Human specific immunoglobulins	Revision for consultation
CPMP/BPWG/1619/99	Core SmPC for Human plasma derived and recombinant coagulation Factor VIII products	Revision for finalisation
CPMP/BPWG/1625/99	Core SmPC for Human plasma derived and recombinant coagulation Factor IX products	Revision for finalisation
CPMP/BPWG/859/95 rev 2	Core SmPC for Human normal immunoglobulin for intravenous administration (IVIg)	Revision for finalisation
CPMP/BPWG/282/00	Core SmPC for Human normal immunoglobulin for subcutaneous and intramuscular use	Review and possible revision.
	Warning on transmissible agents for SmPCs and patient leaflets	Review of guideline.
	Guideline on the Core SmPC for alpha1-proteinase inhibitor (alpha1	Revision of concept paper for consultation

Reference Number	Document Title	*Status*
	antitrypsin)	
	Guideline on the Core SmPC for human C1 inhibitor	If required, publication of concept paper

CHMP Efficacy Working Party

Reference Number	Document Title	Status
EMEA/CHMP/EWP/342691/2009	Guideline on Gastroparesis and Gastroesophageal Reflux Disease (GERD)	For finalisation
CPMP/EWP/1080/00	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Diabetes Mellitus	For consultation
	Guideline on Renal Insufficiency	For consideration
CPMP/EWP/1343/01	Points to Consider on the Clinical Evaluation of New Agents for Invasive Fungal Infections	For finalisation
CPMP/EWP/558/95 Rev 2	Guideline on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections	For consultation
EMEA/CHMP/EWP/14377/2008	Addendum to the Note for Guidance on Evaluation of Medicinal Products Indicated for Treatment of Bacterial Infections CPMP/EWP/558/95 Rev 2 to Specifically Address the Clinical Development of New Agents to Treat Disease Due to Mycobacterium Tuberculosis	Final addendum for consultation
EMEA/CHMP/EWP/520088/2008	Appendix 2 to the Guideline on the evaluation of Anticancer Medicinal Products in Man (CPMP/EWP/205/95 Rev. 3) on Haematological Malignancies	Finalisation of appendix
	Guideline on Lupus and Lupus Nephritis	For consultation
CPMP/EWP/569/02	Note for guidance on evaluation of anticancer medicinal products in man Addendum on Paediatric Oncology	For consideration
EMEA/CHMP/EWP/356954/2008	Guideline on the Clinical Investigation of Medicinal Products	Paediatric addendum for consultation

Reference Number	Document Title	Status
	for the Treatment of Pulmonary Hypertension	
EMEA/CHMP/EWP/352438/2008	Addendum to the Note for Guidance on Antiarrhythmics (CPMP/EWP/237/95) on Atrial Fibrillation	For finalisation
	Guideline on the Prevention of Thromboembolic events in Atrial Fibrillation	For consideration
CPMP/EWP/238/95 Rev. 3	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Hypertension	For finalisation
	Guidelines on Clinical Investigation of Medicinal Products in the Treatment of Hypertension (CPMP/EWP/238/95 Rev. 3) 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.	For consultation
CPMP/EWP/3020/03	Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders: Revision on imaging surrogate endpoints	For consultation
CPMP/EWP/2986/03	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	Concept paper for finalisation, addendum for consultation
CPMP/EWP/238/95 Rev. 3	Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Hypertension	Paediatric addendum for consultation
CPMP/EWP/3020/03	Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Lipid Disorders	Paediatric addendum for consultation
	Paediatric Addendum to the Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Pulmonary Hypertension	Paediatric addendum for consultation
CPMP/EWP/784/97 Rev. 1	Guideline on Clinical Investigation of	For finalisation

Reference Number	Document Title	Status
	Medicinal Products used in the Treatment of Osteoarthritis	
CPMP/EWP/552/95 Rev. 2	Guideline on the Evaluation of Medicinal Products in the treatment of Primary Osteoporosis	Addendum on secondary disease for consideration
CPMP/EWP/556/95	Points to Consider on the Clinical Investigation of Medicinal Products other than NSAIDs in Rheumatoid Arthritis	Revision to be considered
CPMP/EWP/422/04	Guideline on Clinical Investigation of Medicinal Products for the Treatment of Juvenile Idiopathic Arthritis	Revision to be considered
EMEA/CHMP/EWP/20097/2008	Guideline on the Development of Medicinal Products for the Treatment of Alcohol Dependence	For finalisation
EMEA/CHMP/EWP/431734/2008	Guideline on the clinical Investigation of Medical Products for the Treatment of Attentional Deficit Hyperactivity Disorder (ADHD)	For finalisation
	Guideline on the Treatment of Premenstrual Dysphoric Disorders (PMDD)	For consultation
CPMP/EWP/566/98 Rev. 2	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders	For finalisation
EMEA/16274/2009	Guideline on Medicinal Products for the Treatment of Insomnia	For finalisation
CPMP/EWP/559/95	Note for guidance on the Clinical Investigation of Medicinal Products in the Treatment of Schizophrenia	Revision to be considered, guideline for consultation
CHMP/EWP/518/97 Rev. 1	Note for Guidance on the Clinical Investigation of Medicinal Products in the Treatment of Depression	Draft guideline for consultation
CPMP/EWP/QWP/1401/98 Rev. 1	Guideline on the Investigation of Bioequivalence	For finalisation
CPMP/EWP/560/95	Note for Guidance on the Investigation of Drug Interactions	For consultation
CPMP/EWP/280/96	Note for guidance on Modified Release Oral and Transdermal Dosage Forms: Section II	Revision to be considered

Reference Number	Document Title	Status
	(Pharmacokinetic and Clinical Evaluation)	
CPMP/EWP/2922/01	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Asthma	For consultation
CPMP/EWP/562/98	Guideline on Clinical Investigation of Medicinal Products in the Chronic Treatment of Patients with Chronic Obstructive Pulmonary Disease (COPD)	For consultation
CPMP/EWP/18/01	Note for Guidance on the Clinical Investigation of Medicinal Products for the Treatment of Urinary Incontinency in Women	Revision to be considered
EMEA/CHMP/EWP/12052/2008	Harmonisation and Update of the Clinical Aspects in the Authorised Conditions of Use for Radiopharmaceuticals and other Diagnostic Medicinal Products	Core SPCs for consultation
EMEA/CHMP/EWP/158625/2007	Appendix I to the Guideline on Conditional Marketing Authorisation (EMEA/509951/2006) on Methodological Considerations	For consultation
	Reflection Paper on the Bioequivalence Criteria for Narrow Therapeutic Index Drugs	For consideration
	Guideline on the Use of Subgroup Analyses in Confirmatory Clinical Trials	For consideration
	Guideline on Thrombocytopenia	Concept paper for finalisation
CPMP/EWP/1776/99 Rev. 1	Guideline on Missing Data	For finalisation
	Reflexion Paper on Pegylated and Liposomal Formulations	Concept paper for finalisation
	Guideline on the Validation of Analytical Methods	For finalisation
	Reflection Paper on Statistical and Methodological Issues Associated with PG biomarkers	For consultation
	Guideline on the Use of Pharmacogenomic Methodologies in	For finalisation

Reference Number	Document Title	Status
	the Pharmacokinetic Evaluation of Medicinal Products	

CHMP Gene Therapy Working Party

Reference Number	Document Title	Status
EMEA/GTWP/58311/2007	Guideline on the quality, preclinical and clinical aspects of medicinal products containing genetically modified cells	For consultation and finalisation
EMEA/CHMP/GTWP/587488/2007	Reflection paper on quality, pre-clinical and clinical issues relating specifically to recombinant adeno-associated viral vectors	For consultation and finalisation
EMA/CHMP/GTWP/BWP/234523/2009 (concept paper)	Revision of the Note for guidance on quality, preclinical and clinical aspects of gene transfer medicinal products	Concept paper for finalisation, revision of draft guideline
EMEA/CHMP/GTWP/44236/2009	Regulatory Reflections on gene therapy product changes during development	Status for consideration (reflection paper or scientific publication)
EMEA/CHMP/GTWP/212377/2008	Question and Answer documents on current topics in gene therapy	For updating

CHMP Pharmacogenomics Working Party

Reference Number	Document Title	Status
	Guideline on the use of PG in PK studies (in collaboration with the EWP-PK group)	For finalisation
	Reflection paper on co-development of PG biomarkers and test platforms	For finalisation
	Reflection paper on statistical and methodological issues associate with PG biomarkers (in collaboration with the EWP)	For finalisation
	Reflection paper on genomics and personalised medicines	For consultation and finalisation

CHMP Pharmacovigilance Working Party

Reference Number	Document Title	Status
	Volume 9A of the Rules Governing Medicinal Products in the European Union – Revisions	In 2010: Finalisation of the revision 2009 (mainly concerning EU-RMP, EU Signal Management, PSUR AR) following public consultation. Further chapters of Volume 9A, in addition to those specified below, may be updated as necessary during the revision 2010, in particular with regard to worksharing between Member States on PSUR assessment and also in follow-up of initiatives taken by the European Commission for the strengthening of the EU pharmacovigilance system, for public consultation.
	Volume 9A Chapter II.2.A: Conduct of Pharmacovigilance for Centrally Authorised Products	In 2010: Revision taking into account revised CHMP/PhVWP procedures, for public consultation.
	Volume 9A Chapter II.2.B: Crisis Management Plan for Centrally Authorised Products	In 2010: Revision on the basis of the EU Incident Management Plan, after pilot running from mid-2009 to mid-2010, for public consultation.
	Guidelines in relation to transparency at the level of the PhVWP	In 2010: Development of guidance and policies, in particular for the PhVWP Monthly Report, , in the context of the overall Transparency Policy, in order to further implement the Legislation and taking into account the Agency's report "Information on Benefit-Risk of Medicines: Patients', Consumers' and Healthcare Professionals' Expectations", also in the light of ongoing

Reference Number	Document Title	Status
		discussions at the level of the Head of Agencies and initiatives taken by the European Commission for the strengthening of the EU pharmacovigilance system.
As allocated by EV EWG Secretariat	Guidelines in relation to EudraVigilance	In 2010: Contribution to development of guidelines as requested by the EudraVigilance Expert Working Group (EVEWG).
As allocated by PhVIWG Secretariat	Guidelines in relation to pharmacovigilance inspections	In 2010: Contribution to development of further guidance in accordance with the Work Programme of the Ad Hoc Pharmacovigilance Inspectors Working Group (PhVIWG) through their PhVWP Subgroup and discussion at PhVWP plenary level.
EMEA/359381/2009 EMEA/468326/2009	Guidelines in relation to the outbreak of the novel Influenza A (H1N1) virus	In 2010: Monitoring of implementation and revising guidance as necessary provided in the framework of pharmacovigilance strategies developed in 2009 for vaccines and antivirals.
As allocated by respective Secretariat	Other CHMP Guidelines	In 2010: Contribution and commenting on Guidelines prepared by other Working Parties as considered necessary by the CHMP.
As allocated by EC	Other EC Guidelines	In 2010: Contribution and commenting on Guidelines as requested by the European Commission. This may include guidance on the safety of excipients.
ICH-E2B(R3)	Clinical Safety Data Management - Data Elements for Transmission of Individual Case Safety Reports / IS ICSR: International Standard: Health informatics - Pharmacovigilance -	In 2010: Contribution to the development of ICH-E2B into an international standard (ISO/CEN).

Reference Number	Document Title	Status
	Individual Case Safety Report	
ICH-E2C(R2)	Clinical Safety Data Management – Periodic Safety Update Reports (PSURs)	In 2010: Contribution to the possible revision of ICH-E2C(R) in the light of the final ICH-E2F guideline on Development Safety Update Reports (DSURs).
ICH-M1	Medical Dictionary for Drug Regulatory Activities (MedDRA)	In 2010: Contribution to MedDRA maintenance and user guidance documents as requested by the EC.
ICH-M5	Data Elements and Standards for Drug Dictionaries / IS IDMP: International Standard: Health informatics - Identification of Medicinal Products	In 2010: Contribution to the development of ICH-M5 as international standard (ISO/CEN).
ICH-M6	Standard Operating Procedures for Maintenance of ICH Terminology Lists	In 2010: Contribution to this guideline.
	Regulatory guidance issued by the European Medicines Agency	In 2010: Commenting as requested by Agency.
	Guidelines and Standard Operating Procedures issued by the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human (CMD(h)) or developed jointly by the CMD(h) and the PhVWP	In 2010: Implementation of the PhVWP & CMD(h) Best Practice Guide (BPG) on Communication and Implementation of Safety Information. Implementation of the Mandate of the CMD(h)-PhVWP Joint Working Group and development of guidance documents for the co-operation between the CMD(h) and the PhVWP as needed. Development of guidance documents supporting the worksharing between Member States of the assessment of Periodic Safety Update Reports through the Joint PhVWP-CMD(h) Working Group on PSUR Assessment

Reference Number	Document Title	Status
		Worksharing and discussion at PhVWP plenary level. Commenting on CMD(h) guidance documents as requested by the CMD(h) through the Joint CMD(h)-PhVWP Working Group and discussion at PhVWP plenary level.
As allocated by EC	Recommendations and guidelines in relation to the Commission Regulation Concerning the Examination of Variations to the Terms of Marketing Authorisations for Medicinal Products for Human Use and Veterinary Medicinal Products	In 2010: Contribution to implementing guidelines as requested by the European Commission. Development of timeframes for implementation of safety-related variations and criteria for recall and repackaging following urgent safety restriction and variation procedures for consideration by CHMP and EC.

CHMP Safety Working Party

Reference Number	Document Title	Status
EMEA/CHMP/SWP/150115/2006	Reflection Paper on Drug-Induced Hepatotoxicity	For finalisation
EMEA/CHMP/SWP/302413/2008	Note for Guidance on Single Dose Toxicity (Eudralex vol. 3B3BS1A)	Q&A document for adoption
CPMP/372/01	Points to Consider on the Non-Clinical Assessment of the Carcinogenic Potential of Insulin Analogues	Revision to be considered
CPMP/SWP/2145/00	Note for Guidance on Non-Clinical Tolerance Testing of Medicinal Products	Concept paper for revision of guideline for adoption
	Environmental Risk Assessment of Medicinal Products for Human Use: Q & A document	Q&A document for adoption
CPMP/SWP/398/01	Note for Guidance on Photosafety	Guideline to be developed as

Reference Number	Document Title	Status
	Testing	ICH topic
CPMP/SWP/728/95	Replacement of Animal Studies by *in vitro* Models	Concept paper for revision of guideline for adoption
CPMP/SWP/2145/00	Note for Guidance on the Non-Clinical Local Tolerance Testing of Medicinal Products	Concept paper for revision of guideline for adoption
EMEA/CHMP/431994/2007	Genotoxic Impurities: Q & A document	Revision to be considered

CHMP Similar Biological (Biosimilar) Medicinal Products Working Party

Reference Number	Document Title	Status
(EMEA/CHMP/BMWP/301636/2008)	Revision of Guideline on Similar Biological Medicinal Products containing Recombinant Erythropoietins	For finalisation
	Guideline for monoclonal antibodies for the CHMP Guideline on Immunogenicity Assessment of Therapeutic Proteins	For preparation
	Reflection Paper on non-clinical and clinical development of similar biological medicinal products expressed in novel/different expression systems	For preparation
	Guideline for Follitropin alpha	For preparation
	Guideline for Biosimilar Monoclonal Antibodies	For preparation

CHMP Vaccine Working Party

Reference Number	Document Title	Status
EMEA/CHMP/VWP/141697/2009	Guideline on Quality, Non-clinical and Clinical aspects of live recombinant viral vectored vaccines	For finalisation

CHMP Working Party on Cell-based Products

Reference Number	Document Title	Status
EMA/CHMP/CPWP/571134/2009	Reflection paper on stem cell products	For finalisation

Reference Number	Document Title	Status
EMA/CHMP/CPWP/708420/2009	Concept paper on the Guideline on the application of the risk-based approach for advanced therapy medicinal products according to Annex I, part IV of Dir. 2001/83/EC.	For consultation
	Guideline on the application of the risk-based approach for advanced therapy medicinal products according to Annex I, part IV of Dir. 2001/83/EC.	For initiation
EMA/CHMP/CPWP/573420/2009	Reflection paper on clinical aspects specific to regenerative medicines	For finalisation
EMEA/CAT/CPWP/288934/2009	CAT Reflection paper on quality, Nonclinical and Clinical aspects specific to autologous chondrocyte medicinal products	For finalisation
	Guideline on Clinical Post-marketing surveillance for cell-based medicinal products	For initiation
	Reflection paper on the use of animal cells in manufacturing	For initiation
	Question and Answer document on pharmaceutical, non-clinical and clinical development of cell-based medicinal product.	For initiation

CHMP Working Group with Health-Care Professionals' Organisations

Reference Number	Document Title	Status
EMEA/384343/2007	Framework on the interaction between the European Medicines Agency and healthcare professionals' organisations	Expected to be finalised in 4Q2009/1Q2010 (HCP WG contribution)
EMEA/42240/2007	Criteria to be fulfilled by healthcare professionals' organisations involved in Agency activities	Expected to be finalised in 4Q2009/1Q2010(HCP WG contribution)
EMEA/421182/2006	Mandate, Objectives and Rules of Procedure for the European Medicines Agency CHMP Working Group with	Expected to be finalised in 1/2Q 2010

Reference Number	Document Title	Status
	healthcare professionals' organisations	
EMEA/483439/2008 *rev. 1*	Rules of involvement of members of patients', consumers', and healthcare professionals' organisations in committees related activities	Revision expected in 3/4Q2010 (HCP WG contribution)

CHMP Name Review Group

Reference Number	Document Title	Status
EMA/648795/2009	NRG Position Paper (DRAFT) - Re-use of invented names of medicinal products	For finalisation

Committee for Advanced Therapies (CAT)

Reference Number	Document Title	Status
CAT/CPWP/288934/09	Reflection paper on in-vitro cultured chondrocytes for cartilage repair of the knee	For finalisation

Committee on Herbal Medicinal Products (HMPC)

Reference Number	Document Title	Status
EMEA/HMPC/186645/2008	Reflection paper on level of purification of extracts to be considered as herbal preparations	For finalisation 1-2 Q
	Guidance on comparability of herbal substances/preparations (e.g. extracts using different solvents)	Draft to be released for public consultation 3-4 Q
EMEA/531300/2008	List of questions & answers (Q&A) on quality issues emerging for herbal medicinal products	Update in 2010
EMEA/HMPC/CHMP/CVMP/287539/2005 Rev.1	Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products	For finalisation 1-2 Q
EMEA/HMPC/3626/2009	Reflection paper on stability testing of herbal medicinal products and traditional herbal medicinal products	For finalisation 1-2 Q

Reference Number	Document Title	Status
EMEA/HMPC/85114/2008	Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products	For finalisation 1-2 Q

HMPC Working Party on Community monographs and Community list

Reference Number	Document Title	Status
EMA/HMPC/144006/2009	Community herbal monograph on Agni casti fructus	For finalisation 1-2 Q
EMA/HMPC/600717/2007	Community herbal monograph on Cimicifugae rhizoma	For finalisation 1-2 Q
EMA/HMPC/688216/2008	Community herbal monograph on Echinaceae angustifolia radix	For finalisation 1-2 Q
EMA/HMPC/577784/2008	Community herbal monograph on Echinaceae purpureae radix	For finalisation 1-2 Q
EMA/HMPC/580539/2008	Community herbal monograph on Mate folium	For finalisation 1-2 Q
EMA/HMPC/281496/2009	Community herbal monograph on Orthosiphonis folium	For finalisation 1-2 Q
EMA/HMPC/142986/2009	Community herbal monograph on Ribis nigri folium	For finalisation 1-2 Q
EMA/HMPC/235453/2009	Community herbal monograph on Rosmarini aetheroleum	For finalisation 1-2 Q
EMA/HMPC/13633/2009	Community herbal monograph on Rosmarini folium	For finalisation 1-2 Q
EMA/HMPC/131901/2009	Community herbal monograph on Thymi aetheroleum	For finalisation 1-2 Q
EMA/HMPC/585558/2007	Community herbal monograph on Valerianae radix/Lupuli flos	For finalisation 1-2 Q
EMA/HMPC/16635/2009	Community herbal monograph on Vitis viniferae folium	For finalisation 1-2 Q
EMA/HMPC/444035/2009	Public statement on *Urtica dioica* L.; *Urtica urens* L., radix	For finalisation 1-2 Q
EMA/HMPC/579663/2009	Public statement on *Centella asiatica* (L.) Urban., herba	For finalisation 1-2 Q
EMA/HMPC/41843/2009	Public statement on *Salvia officinalis* L., aetheroleum	For finalisation 3-4 Q
EMA/HMPC/727465/2009	Public statement on *Euphrasia*	For finalisation 3-4 Q

Reference Number	Document Title	Status
	officinalis L. and *Euphrasia rostkoviana* Hayne, herba	
EMA/HMPC/726698/2009	Public statement on *Echinacea angustifolia* DC., radix	For finalisation 3-4 Q
	Community herbal monograph on Agropyri repentis rhizoma	Draft to be released for public consultation
EMA/HMPC/246763/2009	Community herbal monograph on Arctii radix	Draft to be released for public consultation
	Community herbal monograph on Arnicae flos	Draft to be released for public consultation
	Community herbal monograph on Capsella bursa-pastoris herba	Draft to be released for public consultation
EMA/HMPC/369802/2009	Community herbal monograph on Chelidonii herba	Draft to be released for public consultation
	Community herbal monograph on Cichorii intybi folium	Draft to be released for public consultation
	Community herbal monograph on Cichorii intybi radix	Draft to be released for public consultation
	Community herbal monograph on Cinnamomi cortex	Draft to be released for public consultation
	Community herbal monograph on Cucurbitae semen	Draft to be released for public consultation
EMA/HMPC/150218/2009	Community herbal monograph on Cynarae folium	Draft to be released for public consultation
EMA/HMPC/246819/2009	Community herbal monograph on Euphrasiae herba	Draft to be released for public consultation
	Community herbal monograph on Foenugraeci semen	Draft to be released for public consultation
	Community herbal monograph on Hederae helices folium	Draft to be released for public consultation
	Community herbal monograph on Juniperi aetheroleum	Draft to be released for public consultation
	Community herbal monograph on Lavandulae aetheroleum	Draft to be released for public consultation
	Community herbal monograph on Lavandulae flos	Draft to be released for public consultation
	Community herbal monograph on	Draft to be released for public

Reference Number	Document Title	Status
	Marrubii herba	consultation
	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
	Community herbal monograph on Millefolii flos	Draft to be released for public consultation
EMA/HMPC/290284/2009	Community herbal monograph on Millefolii herba	Draft to be released for public consultation
EMA/HMPC/430507/2009	Community herbal monograph on Oleae folium	Draft to be released for public consultation
EMA/HMPC/277792/2009	Community herbal monograph on Oenotherae biennis oleum	Draft to be released for public consultation
	Community herbal monograph on Plantaginis lanceolatae folium	Draft to be released for public consultation
EMA/HMPC/3203/2009	Community herbal monograph on Quercus cortex	Draft to be released for public consultation
EMA/HMPC/572846/2009	Community herbal monograph on Symphyti radix	Draft to be released for public consultation
EMA/HMPC/587578/2009	Community herbal monograph on Tanaceti parthenii herba	Draft to be released for public consultation
	Community herbal monograph on Thymi herba/Primulae radix	Draft to be released for public consultation
EMA/HMPC/573460/2009	Community herbal monograph on Uvae ursi folium	Draft to be released for public consultation
EMA/HMPC/131734/2009	Community herbal monograph on Violae tricoloris herba	Draft to be released for public consultation
EMA/HMPC/246792/2009	Community herbal monograph on Visci albi herba	Draft to be released for public consultation
	Community herbal monograph on Zingiberis rhizoma	Draft to be released for public consultation
	Instructions for the preparation of herbal teas	For finalisation 1-2 Q
	Reflection paper on possible initiatives to stimulate the conduct of clinical studies with herbal medicines in the paediatric population	Draft to be released for public consultation in 2010

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

Reference Number	Document Title	Status
EMEA/354515/2005-Final	Framework on the interaction between the European Medicines Agency and patients' and consumers' organisations	Revision expected in 2/3Q 2010 (PCWP contribution)
EMEA/259449/2009	Third report on the progress of the interaction with patients' and consumers' organisations during 2009	Finalisation expected in 2Q2010 (PCWP contribution)
EMEA/483439/2008 *rev. 1*	Rules of involvement of members of patients', consumers', and healthcare professionals' organisations in committees related activities	Revision expected in 3/4Q2010 (PCWP contribution)
EMEA/115803/2007	Training manual for patients and consumers participating in the review of information on medicinal products	Revision expected in 2/3Q2010 (PCWP contribution)

Other Agency Scientific Committees and Working Party Guidelines

Reference Number	Document Title	Status
	Updated Post-Authorisation Procedural advice to reflect the detailed operation of the new Variation Regulation in the Centralised procedure	Revision to be finalised 1Q2010

Agency contribution to EC Guidelines

Reference Number	Document Title	Status

CVMP Efficacy Working Party

Reference Number	Document Title	Status
EMEA/CVMP/019/00-Rev.1	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 (Q 2-3 2010)
Revision of current GL	Veterinary medicinal products controlling Varroa destructor parasitosis in bees (7AE16a, Volume 7A)	Revision of existing guideline Guideline to be finalised following public consultation Q4 2010)
Revision of current GL	Guideline on Efficacy of veterinary medicinal products for use in farmed aquatic species (7AE22a Volume 7A)	Revision of existing guideline Guideline to be finalised following public consultation (Q 4 2010) Focus Group meeting with interested parties scheduled for Q1 2010
Revision of current GL	Conduct of efficacy studies for intramammary products for use in cattle (EMEA/CVMP/344/99)	Concept paper to be prepared for public consultation (Q2-3 2010)
	Palatability Guideline	Concept paper to be prepared for public consultation (Q2-3 2010)
Revision of current GL	Conduct of efficacy studies for NSAIDs (EMEA/CVMP/273/01)	Revision of existing guideline Draft Concept paper for the revision of guideline to be prepared for adoption by CVMP for public consultation (Q1-2 2010)
Revision of current GL	Statistical principles for veterinary clinical trials (EMEA/CVMP/83804/2005)	Revision of existing guideline Draft guideline for the revision of guideline to be prepared for adoption by CVMP for public consultation (Q4 2010)

CVMP Environmental Risk Assessment Working Party

Reference Number	Document Title	Status
	Guideline on fate of veterinary medicinal products in manure	Draft for consultation to be published during 2010
	Guideline on higher tier testing of antiparasitics to dung organisms	Draft for consultation to be published at the end of 2010
	Environmental information for the SPC and risk mitigation. Consideration of effectiveness of risk mitigation practices and SPC standard risk mitigation phrases (section 4.5.iii of the SPC) and environmental information (section 5.3) and on EPAR and Scientific Discussion templates in respect to environmental risk assessment	Considerations to be published during 2010

CVMP Immunologicals Working Party

Reference Number	Document Title	Status
EMEA/CVMP/IWP/219089/2006	Guideline on requirements for in-use stability claims	Guideline to be adopted for implementation Q1 2010
	Guideline on the need for requiring data to demonstrate the influence of maternally derived antibodies on the vaccination of very young animals	Reflection paper to be published Q1/2 2010
	Revised Guideline on requirements for combined veterinary vaccines	Draft Guideline to be released for consultation by Q2/3 2010
	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
	Guideline on the requirements for multistrain dossiers	Guideline to be published in March 2010
	Validation of batch potency tests and establishing pass criteria	Concept paper to be released for consultation by IWP/CVMP Q1/2 2010

Reference Number	Document Title	Status
	Revision of all guidelines for IVMPs	Draft Guidelines to be released for consultation in 2010/2011

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference Number	**Document Title**	**Status**
	Volume 9B of the Rules Governing Medicinal Products in the European Union – Pharmacovigilance of veterinary medicinal products	Finalisation of the draft Volume 9B following end of public consultation and request from the European Commission
EMA/CVMP/471721/2006	Recommendation on the use of data in EudraVigilance Veterinary (EVVet)	To be finalised and released for public consultation in 2010. Following finalisation of the guidance, it is foreseen for inclusion in Volume 9B.
EMEA/CVMP/VICH/647/01	VICH GL30: Pharmacovigilance of Veterinary Medicinal Products: Controlled list of terms	To be finalised in 2000, on the basis of the VICH position paper developed in 2007
EMEA/CVMP/VICH/123940/2006	VICH GL35: Pharmacovigilance of Veterinary Medicinal Products: Electronic standards for transfer of data	To be developed and finalised in 2010 following developments related to GL35 (HL7/ISO) and GL30 (GL30, GL35 and GL42 are considered as one package)
EMEA/CVMP/VICH/355996/05	VICH GL42 Step 7: Guideline on Pharmacovigilance of Veterinary Medicinal Products: data elements for submission of adverse event reports	Possible update in 2010 following developments related to GL35 (HL7/ISO) and GL30 (GL30, GL35 and GL42 are considered as one package)
EMEA/CVMP/10418/2009 Rev.1 EMEA/CVMP/553/03 – Rev. 4 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 Veterinary Medicinal Products; List of Species and Breeds for Electronic reporting of adverse reactions in Veterinary	Expected date(s) of drafting/expert group: 28 April 2010.

Reference Number	Document Title	Status
	Pharmacovigilance; CVMP List on Additional Controlled Terminology for Electronic Submission of Reports on Adverse Reactions to Veterinary Medicinal Products	
EMEA/CVMP/552/03	Guideline on Harmonising the approach to causality assessment for adverse reactions to veterinary medicinal products	Concept paper to be developed and finalised in 2010 aiming at revision of the guideline (to be reclassified as a CVMP recommendation). The revised recommendation will be considered for inclusion in Volume 9B in due course.
EMEA/CVMP/126726/2007	Reflection paper on detailed descriptions of risk management systems for centrally authorised veterinary medicinal products	Reflection paper to be finalised in 2010 following public consultation.

CVMP Safety Working Party

Reference Number	Document Title	Status
EMEA/CVMP/SWP/355689/2006	Guideline on the pharmacological ADI	Guideline to be finalised after consultation (Q3/Q4)
EMEA/CVMP/543/03	Revision of the guideline on user safety	Revised guideline to be finalised after consultation (Q1)
EMEA/CVMP/516817/2009	Guidance on data to be provided in support of a request to include a substance in the list of substances not considered as falling within the scope of Regulation (EC) 470/2009	Revised guideline to be developed after consultation (Q1 2011)
EMEA/CVMP/016/00-REV.1	Conduct of bioequivalence studies for veterinary medicinal products Multidisciplinary guideline: Involved WPs are EWP, SWP and QWP	Guideline to be finalised after consultation (Q2/Q3)
	Review of alternative reference limits	Continue developing reflection papers during 2010 (not for publication)

	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)
	Volume 8	Revise guidance for publication for consultation (Q2)
	Guidance on the development of MRLs for biocide substances used in animal husbandry	Develop draft guidance for release for consultation (Q2/Q3)
	Review of risk assessment concepts (including 'utilization of the full ADI for individual tissues' and 'one meat plus eggs plus milk' concepts)	Reflection paper to be developed during 2010
	(VICH) Guidelines on metabolism and residue kinetics: Metabolism study to determine the quantity and identify the nature of residues (VICH GL 46) Comparative metabolism studies in laboratory animals (VICH GL 47) Marker residue depletion studies to establish product withdrawal periods (VICH GL48) Validation of analytical methods used in residue depletion studies (VICH GL49)	Following release of guidelines for consultation support EU position during 2010
	(VICH) Guideline on elaboration of Acute Reference Dose for Veterinary Medicinal Products	Support to EU position during 2010
EMEA/CVMP/VICH/467/03	*(VICH) Guideline on the microbiological ADI (VICH GL36)*	Support to EU position during 2010
	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	Guidance for companies requesting scientific advice	Review SOP and Guidance document in 2008/9 and revise where necessary in view of experience gained with the procedure
SOP/V/4016	SOP on Scientific Advice to be given by the CVMP for veterinary medicinal products	Review SOP and Guidance document in 05/2009 and revise where necessary in view of experience gained with the procedure

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
	Use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union: development of resistance and impact on human and animal health (concept paper to be prepared)	Publication reflection paper during 2010
	Considerations on MRSP in companion animals	Publication of a reflection paper during 2010

CVMP General

Reference Number	Document Title	Status
EMA/CVMP/50745/2005-Rev.1	Procedural advice on the re-examination of CVMP opinions	Coming into effect following review of comments received during public consultation
EMA/CVMP/38660/2010	CVMP review of current legislation and considerations on the possible evolution of the legal framework concerning veterinary medicinal products	In development, for finalisation by 1-2Q 2010.
EMEA/CVMP/115769/2005-Rev.1	Revision of the Guideline for an assessor preparing assessment reports	In development, for finalisation in 1-2Q/2010

Joint CHMP/CVMP Quality Working Party

Reference number	Document title	Status
CPMP/QWP/576/96 Rev 1 EMEA/CVMP/373/04	(Joint) CHMP/CVMP Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation	Revision of the guidelines in the light of the new variation regulation
	CHMP Guideline on Pharmaceutical Development of Medicines for Paediatric Use	Release of a draft guideline for public consultation.
CPMP/QWP/3309/01 EMEA/CVMP/961/01	(Joint) CHMP/CVMP Note for Guidance on the Use of Near Infrared Spectroscopy	Finalisation of revision.
CHMP/QWP/848/96 EMEA/CVMP/598/99	(Joint) CHMP/CVMP Guideline on Process Validation	Publication of a Concept Paper and revision of the guideline (to take into account continuous validation and monitoring).
CPMP/ICH/367/96 3A Q11a Vol. IIIA CPMP/QWP/2820/00 Rev.1 EMEA/CVMP/815/00 Rev.1	CHMP and CVMP Guidelines on Specifications	Consideration of the impact of new technologies and approaches as described in ICH Guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality Systems).
CPMP/QWP/486/95 & EMEA/CVMP/126/95	(Separate) CHMP and CVMP Guidelines on the Manufacture of the Finished Dosage Form	
CPMP/QWP/130/96 Rev 1 & EMEA/CVMP/541/03	(Separate) CPMP and CVMP Guidelines on the Chemistry of New Active Substances	
CPMP/QWP/3015/99 (Human)	CPMP Guideline on Parametric Release	Release of the draft revised CHMP guideline, including Real Time Release concepts, for external consultation. (Consideration of revision of the CVMP guideline later.)
	(Joint Human & Vet) Guidance on the Assessment of the Quality of Medicinal Products Containing Existing/Known Active Substances	Finalisation after end of public consultation.
EudraLex 3AQ21A (Human)	CHMP Guideline on Radiopharmaceuticals based on Monoclonal Antibodies	Release of a draft guideline for public consultation.

Reference number	Document title	Status
EMEA/CHMP/167068/2004-ICH EMEA/INS/GMP/157614/2005-ICH ICH Q10	ICH Guidelines on Pharmaceutical Development (Q8), Quality Risk Management (Q9) and Pharmaceutical Quality System (Q10)	Contribution to the implementation in the EU
	ICH Q11 guideline on development and manufacture of the active substance	Contribution to the development or the guideline.
		Contribution to the discussion on Common technical document (ICH topic M4)
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.
EMEA/CVMP/VICH/581467/2007 (Vet)	VICH GL45 - Guideline on Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products	Finalisation after end of public consultation.
	VICH Guideline on the Evaluation of Stability Data	Contribution to the development.
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.
	(Joint) CHMP/CVMP Guideline on Setting Specifications for Related Impurities in Antibiotics	Release of a draft guideline for public consultation.

Annex 4 Personality profiles

Pat O'Mahony, Chair of the Management Board, n. Irish

Education: Pat O'Mahony is a qualified veterinary surgeon from University College Dublin with a post graduate research Masters Degree in Veterinary Medicine. Pat was awarded an MBA degree from the Michael Smurfit Graduate School of Business, University College Dublin in 2001.

Career to date: Pat O'Mahony is Chief Executive at the Irish Medicines Board, a position he took up in December 2002. Having initially spent a number of years in private practice and four years as technical manager in the pharmaceutical industry in Ireland and the U.K, Pat worked in public health and was Director of Consumer Protection for five years at the then newly established Food Safety Authority of Ireland. He is a member of the European Medicines Agency's Management Board since 2003 and Chair since 2007. He is also a member of the Board of the Food Safety Authority of Ireland, and a member of the Board of the Irish National Accreditation Board.

Lisette Tiddens-Engwirda, Vice-chair of the Management Board, n. Dutch

Education: Lisette Tiddens–Engwirda has a Masters degree in Law and Political Science from Katholieke Universiteit Brabant in Tilburg in the Netherlands.

Career to date: Lisette Tiddens -Engwirda has been active as a lobbyist in many different policy areas. After finishing her Masters degree in Law and Political Science she worked for the Union of Local Authorities in the Netherlands. From there she went to Bennis/BPR as a senior consultant in which capacity she handled a wide range of different client accounts. As partner of this PR/PA firm she was also responsible for the Public Affairs department. Before coming to the CPME she was Secretary General of the European Organisation of Community Pharmacists, PGEU. Lisette Tiddens-Engwirda is the co-author of different books on issues related to politics in the Netherlands. Through the years she has been active as a politician and a member of a variety of different boards of national and international organisations. She was appointed Secretary General of the CPME in November 2001.

Thomas Lönngren, Executive Director, n. Swedish

Education: Qualified pharmacist from the University of Uppsala Faculty of Pharmacy. MSc in social and regulatory pharmacy. Post-graduate studies in management and health economics. Honorary Member of the Pharmaceutical Society of Great Britain since 2003 and Honorary Fellow of the Royal College of Physicians since 2004. In recognition of his work in regulatory science he was awarded in 2008 an honorary PHD by the University of Uppsala

Career to date: From 1976 to 1978, lecturer at University of Uppsala. Mr Lönngren was with the National Board of Health and Welfare, Sweden, from 1978 to 1990 during which time he was responsible for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. He acted as senior pharmaceutical consultant for the Swedish health cooperation programme in Vietnam from 1984 to 1994. He joined the Swedish Medicinal Products Agency in 1990, serving as Director of Operations and later as Deputy Director-General. He is Executive Director of the European Medicines Agency since January 2001.

European Medicines Agency scientific committees

Eric Abadie, Chair of the CHMP, n. French

Education: Qualified medical doctor from the University of Paris.

Post-graduate qualifications in internal medicine, endocrinology, diabetology and cardiology. He also holds an MBA.

Career to date: From 1981 to 1983 Dr Abadie held a number of clinical and laboratory positions, before joining the pharmaceutical industry in 1983. He was Director of Medical Affairs of the French pharmaceutical trade association from 1985 to 1993. He returned briefly to the pharmaceutical industry from 1993 - 1994, before joining the French medicines agency in 1994 as Director of Pharmacotherapeutic Evaluation, until 2007.Currently he works as a Scientific Adviser to the General Director at AFSSAPS.

He became a member of the CHMP in 1997, and was elected Vice chair in 2001. He was elected Chair in 2007.He has been a consultant in cardiology and diabetology since 1984.

Tomas Salmonson, Vice-chair of the CHMP, n. Swedish

Education: Qualified pharmacist from University of Uppsala, Sweden. Post graduate research at School of Pharmacy, UCSF, San Francisco. Obtained a PhD in internal medicine 1990 (pk/pd of erythropoietin) from Uppsala University.

Career to date: Following his PhD, Dr Salmonson worked for 9 months as a visiting assessor at the Therapeutic Goods Administration, Canberra. Upon returning to Sweden he was appointed Head of Section, Pharmacokinetics at the Medical Products Agency (MPA), Sweden in 1991. He joined the pharmaceutical industry for a short period in 1994-95. On his return to the MPA, he was appointed Head of Pre-clinical and Clinical Unit I. He was also acting Director at the MPA for 18 months and became a member of the CPMP in 1999.

Dr Salmonson was elected Vice-chair in 2007.

Gérard Moulin, Chair of the CVMP, n. French

Education: PhD in Microbiology from the University of Lyon.

Career to date : From 1981 to 1984, Dr Moulin worked in the Bovine Pathology Laboratory in Lyon. In 1984, he joined the Veterinary Medicines Laboratory in Fougères where he was assessor and rapporteur for marketing authorisation dossiers. He was also responsible for a laboratory unit. In 1997, he was appointed as Head of the Pharmaceuticals Assessment Unit of the French veterinary agency (AFSSA-ANMV). In 2002, he was appointed as Director Delegate of International Affairs and in 2006 he became Head of the Marketing Authorisation Department. He was appointed as Deputy Director of the French veterinary agency (AFSSA-ANMV) in 2008. He is a CVMP member since 1997, he was elected Vice-chair of CVMP in 2001. He was first elected Chair of the CVMP in January 2003. He was then elected Chair of the new CVMP in 2004, following the publication of the review of the EU legislation, and re-elected in 2007.

Anja Holm, Vice-chair of the CVMP, n. Danish

Education: Veterinarian (DVM) from the Royal Veterinary and Agricultural University of Copenhagen in January 1994.

Career to date: In 1991 to 1993 Dr Holm worked at the Department of Toxicology at H Lundbeck A/S in Copenhagen. From 1994 to 1998 she was a veterinary practitioner (small and large animals) in Denmark. In 1998 she was employed by the Danish Medicines Agency as safety and efficacy assessor for veterinary medicinal products including immunologicals. In 2001-2002 she joined the research section at the Virology Department at the Danish Veterinary Institute. In 2002, she returned to the Danish Medicines Agency as Senior Scientific Officer where she is involved in centralised, MRP and national procedures, clinical trials and pharmacovigilance. Member of CVMP since January 2004. Member of Pharmacovigilance Working Party from 1998 - 2003 and again in 2006. Member of Immunologicals Working Party in 2004 - 2006. Member of the Scientific Advice Working Party since 2004. Elected Vice-chair of CVMP in October 2006 and re-elected in October 2009.

Kerstin Westermark, Chair of the COMP, n. Swedish

Education: Qualified medical doctor from the University of Uppsala. PhD in endocrinology. Specialist in internal medicine and endocrinology. Professor of internal medicine at the University of Uppsala.
Career to date: From 1980 to 1996, Dr Westermark worked as a practitioner and a senior consultant in the Department of Internal Medicine of the University Hospital of Uppsala and held a position as Head of the Endocrinology and Diabetes Section (1995 to1996). In 1996 Dr Westermark joined the Medical Products Agency (MPA) of Sweden as a senior consultant in the Clinical Trials Department. She was Head of Department from 1997 to 2005 and since 2005 is as a senior expert at the MPA.

Since 1999 Dr Westermark has been a senior medical lecturer at the Department of Medical Sciences of the University of Uppsala and in 2008 she became adjunct professor.

Dr Westermark has been a COMP member since 2000 and was elected Chair in June 2006.

Birthe Byskov Holm, Vice-chair of the COMP, n. Danish

Education: Qualified lawyer from the University of Copenhagen

Career to date: From 1973 to 1980, Mrs Byskov Holm worked as an officer in the Tax Ministry and Administration in Denmark. In 1980 she became head of office in the Department of Internal Revenue and, in 1990, Regional Director of Customs and Tax in Denmark. Since 2002, she works for a private law firm.

Mrs Byskov Holm is a member of the Danish Osteogenesis Imperfecta Society and the Danish Alliance for Rare Disorders.

Mrs Byskov Holm has been a COMP member since 2003 and was elected vice-chair in June 2006.

Konstantin Keller, Chair of the HMPC, n. German

Education: Pharmacist, doctorate in natural sciences (Pharmacognosy) from the University of Saarbruecken.

Career to date: From 1978 to 1982, Dr Keller worked as a research and teaching assistant at the Institute for Pharmacognosy and Analytical Phytochemistry of the University of Saarbruecken. After serving as a pharmacist (Captain) in a pharmaceutical control laboratory of the German Army, he joined the former German Federal Health Office in 1983.

His main activities since then have been related to the pre-clinical and clinical review of old substances and the assessment of complementary / alternative medicines.

He is currently working within the Department for International Pharmaceutical Affairs at the German Ministry of Health where he is in charge of international anti-counterfeit activities, pandemic flu preparedness and contacts with WHO and Council of Europe in the area of pharmaceuticals. Dr Keller is member of the American Society of Pharmacognosy and the International Society for Medicinal Plant Research.

Ioanna Chinou, Vice-chair of the HMPC, n. Greek

Education: Pharmacist, doctorate in Pharmacognosy, University of Athens, Greece, post doctorate at the University of Nantes, France (Laboratoire de Recherche Therapeutique en Cancerologie - Lab. de Chimie Organique).

Career to date: From 1989 Lecturer and since 2002 Assoc. Prof. at the University of Athens, School of Pharmacy, Division of Pharmacognosy and Chemistry of Natural Products. Her main research activities have been related to phytochemical studies (isolation, structure elucidation) of bioactive natural products, including also bee-keeping products.

Dr Chinou is Vice-chair of the Committee of Greek Pharmacopoeia since 2003 and external assessor for herbal medicinal products at the Greek Medicines Agency.

Dr Chinou joined the HMPC (Herbal Medicinal Products Committee) in Nov 2005 and has been elected Vice-chair of the HMPC Working Party on Community Lists and Monographs (MLWP) in May 2006. She is reviewer of more than 20 International Journals, member of many Scientific Societies (PSE, GA, ISP, AFERP etc) and author of several publications (110) and chapters in scientific books (12). Since January 2009 she is observer on behalf of HMPC (European Medicines Agency) at EDQM (13A expert group) and has been elected Chair of MLWP.

Daniel Brasseur, Chair of the PDCO, n. Belgian

Education: Qualified medical doctor from the Free University of Brussels. Post-graduate degree in paediatrics and a PhD in nutrition.

Career to date: From 1976 to 1986 Dr Brasseur worked as a paediatrician at the University Sint Pieter Hospital in Brussels. He moved briefly to the pharmaceutical industry from 1986 to 1987, before returning to clinical work at the Queen Fabiola Children's University Hospital in Brussels as Head of the Nutrition and Pharmacodynamics Unit, a post he continues to hold today. He joined the Pharmaceutical Inspectorate of the Belgian Ministry of Public Health as head of medical assessors in 1997. He was appointed a member of the CPMP in 1997. Dr Brasseur has held a number of teaching

posts and is currently professor of nutrition and related diseases at the Free University of Brussels. He was CHMP Chair from 2001 to May 2007. He was elected Chair of the PDCO in September 2007.

Gérard Pons, Vice-chair of the PDCO, n. French

Education: Qualified medical doctor from the University of Paris (Xavier Bichat). Post graduate degree in Paediatrics. PhD in pharmacology.

Career to date: Prof. Pons held positions in paediatric pharmacology in University of Minnesota, USA and in France. He is currently the Head of Department of Perinatal and Paediatric Pharmacology of Cochin St Vincent de Paul Hospital, and professor of clinical pharmacology at University Rene Descartes, Paris. He is President of the European Society for Developmental Perinatal and Paediatric Pharmacology. He is also the co-ordinator of the French paediatric research network (RIPPS) and the Chair of the French paediatric committee. He was elected Vice-chair of the PDCO in September 2007.

Christian Schneider, Chair of the CAT, n. German

Education: MD degree in Medical Biochemistry, Friedrich-Alexander University Erlangen-Nuremberg. Research Fellow, Institute of Clinical Immunology, Department of Internal Medicine III, Nikolaus-Fiebiger-Institut of Molecular Medicine, Erlangen. Postdoctoral Fellow, Department Neuroimmunology, Max-Planck-Institut of Neurobiology, Martinsried.

Career to date: Head of Division for EU Cooperation/Microbiology at the Paul-Ehrlich-Institut (PEI) in Langen, Germany. His areas of expertise include: quality and safety of biological medicines, including ATMP; clinical trials and risk mitigation strategies for first-in-man clinical trials; non-clinical development of biotechnology-derived medicinal products; unwanted immunogenicity of therapeutic proteins; concepts for comparability exercise for biotechnological medicinal products. He was elected Chair of the CAT in February 2009.

Paula Salmikangas, Vice-chair of the CAT, n. Finish

Education: M.Sc. in Biochemistry from University of Oulu, Department of Biochemistry. Ph.D. in Cell and Molecular Biology from the University of Helsinki, Department of Pathology.

Career to date: Senior researcher, responsible for marketing authorisations of biological medicinal products at the National Agency for Medicines in Finland. She is also Associate Professor in Biochemistry, University of Helsinki. Her area of expertise is focused on cell and molecular biology of various inherited diseases. She is a member of the Working Group 6 (Biological substances) Council of Europe. Chair of the Cell-based Products Working Party at the European Medicines Agency. Member of the Biologics Working Party at the European Medicines Agency.

Human Medicines Development and Evaluation Unit

Patrick Le Courtois, Head of Unit, n. French

Education: Qualified medical doctor from the University of Paris. PhD in public health from the University of Bordeaux. Post-graduate degrees in tropical medicine, clinical research and epidemiology.

Career to date: From 1977 to 1986, Dr Le Courtois worked as a general practitioner and as Director of a medical centre in Paris. In 1986 he joined the University of Bordeaux and was involved in research areas in public health including epidemiology, clinical research, pharmacovigilance, tropical and infectious diseases, health economy and health education. In 1990, he joined the Pharmacy Directorate of the French Ministry of Health and in 1993 the French Medicines Agency as CPMP rapporteur, Head of Unit of European Procedures and from January 1995 as French CPMP delegate. He joined the European Medicines Agency in September 1997 and was appointed Head of Sector for New Chemical Substances in June 1998, Head of Sector for Orphan Drugs and Scientific Advice in January 2001 and Head of Unit for the Pre-authorisation Evaluation of Medicines for Human Use in March 2001. Head of Human Medicines Development and Evaluation Unit since 2009.

Agnès Saint Raymond, Head of Sector for Human Medicines Special Areas, n. French

Education: Qualified medical doctor from the University of Paris. Post-graduate qualifications in paediatrics and methodology.

Career to date: Dr Saint Raymond held a position as paediatrician in a teaching paediatric hospital in Paris, followed by a number of years working for a number of pharmaceutical companies. In 1995 she joined the French Medicines Agency as Head of Unit for Pharmaco-Toxico-Clinical Assessment. She joined the European Medicines Agency in January 2000 and was appointed Head of Sector for Scientific Advice and Orphan drugs in December 2001. Dr Saint Raymond was also acting Head of Sector for Safety & Efficacy from October 2004 to December 2005. She is in charge of the implementation of the European regulation on medicinal products for paediatric use. She is the Head of Special Areas Sector, which includes Scientific Advice, Orphan Medicines, Paediatric Medicines, Scientific Support and Projects Sections and the Office for Small and Medium-Sized Enterprises.

John Purves, Head of Sector for Quality of Medicines, n. British

Education: Qualified as a pharmacist from Heriot-Watt University, Edinburgh. PhD in pharmaceutical microbiology from the University of Strathclyde, Glasgow.

Career to date: From 1972 to 1974, Dr Purves worked in the pharmaceutical industry. Between 1974 and 1996, he held posts in the UK Medicines Division and the Medicines Control Agency (MHRA - formally known as Medicines Control Agency), including inspector of pharmaceutical manufacture, reviewer of dossiers and manager of the Biotechnology and Biological Unit. He was the UK representative at the Quality Working Party and Biotechnology Working Party, involved in the generation of many guidelines relating to quality, biotechnology and biological products. He joined the European Medicines Agency in August 1996 as Head of Sector for Biotechnology and Biologicals. He was appointed Head of Sector for Quality of Medicines in January 2001. Since the restructuring of the Agency in 2009 the Sector consists of two sections; Chemicals and Biologicals.

Xavier Luria, Head of Sector for Safety and Efficacy of Medicines, n. Spanish

Education: Qualified medical doctor from the Autonomous University of Barcelona. Postgraduate fellowship in internal medicine and postgraduate qualifications in pharmaceutical medicine, in biostatistics and in clinical pharmacology, drug development and regulation.

Career to date: Dr Luria worked as a general practitioner and internal medicine physician, as assistant of the Physiology Department (Autonomous University of Barcelona), assistant in gastrointestinal and psychosomatic disorders and in the Internal Medicine Department at the Hospital Sant Pau. In 1987, he joined a pharmaceutical company as a medical doctor in clinical research and in 1990 became Head of Clinical Research. In 1995 he was nominated Medical Director with responsibility for clinical development, biometry, pharmacovigilance and global medical affairs. He has been a member of working groups in the Spanish (Farmaindustria) and European (EFPIA) Pharmaceutical Industry Associations. He participated in a number of ICH initiatives and was also a member of the DIA Steering Committee Europe until 2004. He joined the European Medicines Agency in December 2005 as Head of Sector for Safety and Efficacy of Medicines. Now the Sector includes five Sections distributed by therapeutic areas integrating pre- and post-authorisation procedures, and a group on research activities (benefit/risk and others).

Patient Health Protection Unit

Noël Wathion, Head of Unit, n. Belgian[8]

Education: Qualified pharmacist from the Free University of Brussels.

Career to date: Mr Wathion first worked as pharmacist in a retail pharmacy. He was later appointed to the Pharmaceutical Inspectorate (Ministry of Social Affairs and Public Health) in Brussels as a Chief Inspector, acting as Secretary of the Belgian Medicines Commission. He is a former Belgian member of both the CPMP and CVMP, and representative on the Pharmaceutical Committee, Standing Committee and Notice to Applicants Working Group. He joined the European Medicines Agency in August 1996 as Head of Sector for Regulatory Affairs and Pharmacovigilance and was appointed Head of the Human Medicines Evaluation Unit in September 2000. Further to the restructuring of the Human Medicines Evaluation Unit in 2001, he was appointed Head of Unit for the Post-Authorisation Evaluation of Medicines for Human Use. He was appointed Head of Patient Health Protection in 2009 following the Agency's restructuring, being responsible for pharmacovigilance and risk management, crisis handling, compliance and inspection, medical information, regulatory and procedural advice.

Fergus Sweeney, Head of Sector for Compliance and Inspection, n. Irish

Education: Degree in Physiology (Trinity College Dublin, Ireland, 1979), a Doctorat de Troisiéme Cycle in cancer biology (Université de Paris, 1982), and a PhD in Pharmacology (UCD, Ireland, 1986).

Career to date: Began his career in the laboratory of a phase I clinical trial unit in Dublin in 1982. From 1986 he worked mainly in the field of quality assurance, covering phase I-IV clinical research, pharmacovigilance and laboratory activities prior to joining European Medicines Agency. Joined the Agency's Inspection Sector in November 1999 and was appointed Head of Sector for Inspections on 1

[8] Currently directly responsible for post-authorisation safety & efficacy.

May 2009. The sector is responsible for GMP, GCP, GLP and Pharmacovigilance Inspection Co-ordination, Parallel Distribution, Certificates, the Quality Working Party and Mutual Recognition Agreement implementation. He is the Chair of the GCP and Pharmacovigilance Inspectors Working Group. Member of the European Commission's Expert Working Group on implementing guidelines for Directive 2001/20/EC and business analyst for the EudraCT database.

Isabelle Moulon, Head of Medical Information Sector, n. French

Education: Qualified medical doctor from the University of Grenoble, France. Specialist in endocrinology and metabolic diseases. Post-graduate studies in nutrition, statistics and methodology.

Career to date: Worked as a clinical endocrinologist in hospital until 1987 and then joined the Directorate of Pharmacy at the French Ministry of Health. She worked for the pharmaceutical industry from 1992 to 1995 before joining the European Medicines Agency in July 1995. She was responsible for Scientific Advice until December 2000. She was appointed Head of Sector for Safety and Efficacy of Medicines in January 2001. She has been Head of the Medical Information Sector since September 2005.

Peter Arlett, Head of Sector for Pharmacovigilance and Risk Management, n. British

Education: Qualified in medicine from University College London (UCL) in 1991 and after specialising in hospital medicine, in 1994 became a Member of the Royal College of Physicians (MRCP) of London. In 2002 became a member of the Faculty of Pharmaceutical Medicine (MFPM) of the Royal College of Physicians of London and in 2004 also became Honorary Senior Lecturer in the Department of Medicine at UCL. In 2007 became a fellow of the Faculty of Pharmaceutical Medicine (FFPM) of the Royal College of Physicians of London.

Career to date: After his basic training in medicine he worked as a hospital physician in Oxford and at the Hammersmith Hospital (Imperial College). Joined the UK Medicines Control Agency (now MHRA) in 1996 where he had various responsibilities as a specialist assessor and manager. In 2001 he was appointed UK delegate to the European Committee for Human Medicinal Products (CHMP). In 2003 he joined the Pharmaceuticals Unit, DG Enterprise and Industry of the European Commission as Principal Administrator where his responsibilities included: international relations, pharmacovigilance (including lead responsibility for the revision to legislation), implementation of new pharmaceutical legislation, medicines for children (including lead responsibility for the new legislation 'the paediatric regulation'). He joined the European Medicines Agency in 2008 as Head of Sector for Pharmacovigilance and Risk Management which since the restructuring of 2009 comprises sections on data collection and management, signal detection and data analysis, risk management and coordination and networking.

Tony Humphreys, Head of Sector for Regulatory Affairs and Organisational Support, n. Irish

Education: Qualified as a pharmacist, BSc (Pharm) and was granted a masters degree in pharmaceutics in the research area of microencapsulation from Trinity College Dublin.

Career to date: Since qualifying in 1983 Mr Humphreys has worked in the area of development pharmaceutics for a national branded generics manufacturer and an international research and

development company. In 1991 he joined the International Regulatory Affairs Division of Glaxo Group Research Limited where he was responsible for the development and submission of a series of international registration applications in a number of therapeutic areas. He joined the European Medicines Agency in May 1996 and is currently the Head of Sector for Regulatory, Procedural and Committee Support. Within this capacity he is currently responsible for provision of secretariat support to the CHMP, CMDh, HMPC and CAT, provision of regulatory advice and guidance concerning human medicinal products within the Agency and to applicants/marketing authorisation holders and co-ordination of Community Referral procedures.

Unit for Veterinary medicines and product data management

David Mackay, Head of Unit, n. British

Education: Graduated in veterinary medicine from the Royal Veterinary College, London. MSc in Immunology from the University of Birmingham and a PhD in Veterinary Immunology from the Royal Veterinary College, University of London. Member of the Royal College of Veterinary Surgeons of the United Kingdom. Honorary professor of the Royal Veterinary College, London.

Career to date: After a period in general veterinary practice in the UK, Dr Mackay returned to academia to gain an MSc followed by a PhD in veterinary immunology. This was followed by work as a research scientist, first for industry and subsequently as an expert in exotic viral diseases of livestock at the Pirbright Laboratory of the Institute for Animal Health, UK. Dr Mackay then worked for four years in regulatory affairs at the Veterinary Medicines Directorate, finishing in the post of Director of Licensing. He then returned to Pirbright as Head of Laboratory before taking up the post as Head of Unit in February 2006.

Head of Sector for product data management

This post is currently vacant.

Kornelia Grein, Head of Sector for veterinary medicines, n. German

Education: Doctorate in natural sciences (organic chemistry) from the Free University of Berlin. Diploma in chemistry and qualified pharmacist from the Free University of Berlin.

Career to date: From 1976 to 1981, Dr Grein held a position at the Free University of Berlin in Germany teaching and conducting research. This was followed by positions as a pharmacist. In 1987, she joined the German Environmental Agency as scientific administrator involved in risk assessment of industrial chemicals. Seconded to the European Commission in 1992, she was involved in the implementation of the EU legislation on existing chemicals and international harmonisation activities, and coordinated the development of the EU approach on risk assessment for chemicals. In 1995 she returned to Germany to the Ministry for Environment as senior administrator. She joined the European Medicines Agency in April 1996 as Head of Sector.

Information and Communications Technology (ICT)

Hans-Georg Wagner, Head of Unit for ICT, n. German

Education: Doctorate in natural sciences (applied physics and materials science) from Saarbruecken University, Diploma in physics from Tuebingen University, Master of Arts (mathematics) from the University of Cambridge, UK.

Career to date: Dr Wagner was a research and teaching assistant at Saarbruecken University from 1976 to 1981. He later taught as a lecturer and senior lecturer at the same university until he joined the European Commission in Luxembourg in January 1986. There he was responsible for a number of groups in the Technical Support Division of the Euratom Safeguards Directorate. Dr Wagner was appointed Head of Sector for IT in the same service in 1993. He joined the European Medicines Agency on 1 May 2002.

Tim Buxton, Head of Sector for ICT Development, n. British

Education*:* Bachelor of Laws from the University of Birmingham, qualified as a member of the Institute of Chartered Accountants in England and Wales.

Career to date*:* Tim Buxton completed articles with Touche Ross & Co in London in 1987. After a year in merchant banking, he was finance director of a private company from 1988 to 1995. He undertook long term assignments as a management consultant until January 1997, when he joined the European Medicines Agency. He was appointed Head of Sector on 1 May 2002.

Riccardo Ettore, Head of Sector for ICT User and Application Support, n. Italian

Education: Diploma in conference interpretation and translation from Scuola Superiore per Interpreti, Milan.

Career to date: Mr Ettore joined the European Commission as conference interpreter in 1976. During the 1980s, he developed a computer system to support the complex task of editing and managing the assignment of European Commission interpreters to meetings. By 1987, he had gradually moved from full-time interpreting to full-time software development. His published works include scores of articles in computer journals during the 1980s and several popular software packages. He joined European Medicines Agency in May 1995. He became Deputy Head of Sector IT in July 2003, with direct responsibility for IT Operations from July 2008. He was appointed Head of Sector on 1 September 2009.

David Drakeford, Head of Sector for ICT Infrastructure, n. Irish

Education: Honours degree in experimental physics, and MSc in electronic engineering from Trinity College Dublin.

Career to date: David Drakeford worked with Telecom Eireann where he managed the implementation of a national data communication network. In 1987, he joined Coopers & Lybrand where he was a senior management consultant specialising in the management and financial control of large, primarily IT-related, projects. He was also involved in numerous multinational project

management and business analysis assignments, including managing the implementation of a worldwide information management system for clinical trials on behalf of a Swiss-based pharmaceutical company. He joined the European Medicines Agency in February 1997 and has been Head of Sector IT since 2003.

Administration Unit

Andreas Pott, Head of Unit, n. German

Education: Masters Degree in political science, history and English from the University of Hamburg. Certificat de Hautes Etudes Européennes (economics) from the College of Europe, Bruges.

Career to date: From 1972 to 1989 Mr Pott held a number of teaching and research posts, including a research fellowship at the Institute of Peace Research and Security Policy, University of Hamburg. He joined the Secretariat of the European Parliament in 1989, serving on the secretariats of the Committee on Research, Technological Development and Energy, of the Committee on Budgets and latterly of the Parliament's Bureau and Conference of Presidents. He moved to the Translation Centre for Bodies of the European Union in 1999 as Head of the Department for Interinstitutional Cooperation. He joined the European Medicines Agency in May 2000.

Frances Nuttall, Head of Sector for Human Resources, n. Irish

Education: Master of Science in economics and Bachelor of Science in public administration from Trinity College Dublin.

Career to date: Ms Nuttall held several posts in the Irish Civil Service, serving in the Departments of Health, Finance and the Office of Public Works. Ms Nuttall then served with the Food and Agriculture Organisation of the United Nations from 1990 to 1995. She joined the Agency in May 1995.

Head of Sector for Finance and Budget

This post is currently vacant.

Sylvie Bénéfice, Head of Sector for Meeting and Conference Management , n. French

Education: Doctorate in physical sciences from Montpellier University; PhD in physical organic chemistry from Montpellier University, qualified in research management from Montpellier University; Masters degree in physical organic chemistry from Montpellier University; Degree in biochemistry from Nice University.

Career to date: From 1982 to 1986, Dr Bénéfice was a researcher at the University of Montpellier, France. In 1986 she joined the French National Scientific Research Centre (CNRS) as *Chargé de recherche 1 Class* and became officer for European affairs in 1991. From 1993 to 1997 she was seconded to the European Commission (DG Research) as Scientific Secretary for COST actions in the field of chemistry, with responsibility for coordination of research networks and organisation of

scientific conferences and workshops in Europe. She joined the European Medicines Agency in September 1997.

Sara Mendosa, Head of Sector for Infrastructure Services, n. British

Education: Business studies and languages at Loughborough Polytechnic

Career to date: From 1975 to 1990 Mrs Mendosa held a number of posts at the European Commission in Luxembourg, including the Conference Service, the Office for Official Publications and the Statistical Office. In 1991 Mrs Mendosa was transferred to the London office of the European Commission Representation in the UK. She joined the European Medicines Agency in November 1994 and was nominated as Head of Sector in November 2002.

Services attached to the Executive Director

Hans-Georg Eichler, Senior Medical Officer, n. Austrian

Education: MD from Vienna University Medical School, Austria, Master of Science in toxicology from the University of Surrey, Guildford, UK.

Career to date: Prof. Eichler was professor and chair of clinical pharmacology at the Medical University of Vienna, Austria, from 1992 until 2007. In 2003, he assumed the position of Vice Rector for Research and International Relations. He received his clinical training at Vienna University Hospital and the Poison Control Centre as well as at Stanford University in USA. He did research in several institutions in the USA, the UK and South Africa and gained experience in outcomes research as a visiting professor at the world headquarters of Merck & Co. Prof. Eichler was a member of several medical advisory boards at the Austrian Ministry of Health. From 2000 to 2006, he was President of the Vienna School of Clinical Research. Prof. Eichler was a member of the Committee for Orphan Medicinal Products from April 2000 to June 2002, and has twice served as a member of the CHMP Scientific Advice Working Party. He was appointed Senior Medical Officer on 1 February 2007.

Martin Harvey Allchurch, Head of the Office of the Executive Director, n. British

Education: Law degree from the University of Dundee, UK. Masters degree in European and international law from the Vrije Universiteit Brussel, Belgium.

Career to date: After a traineeship with the European Commission 1991-92, Martin Harvey Allchurch worked as a European affairs consultant in Brussels from 1992 to 1995. During this time he also worked as contributing editor for a European affairs publication and as Brussels correspondent for an American pharmaceutical journal. He joined the European Medicines Agency in September 1995. He was nominated as Press Officer in September 2001 and appointed Head of Executive Support in January 2004.

Vincenzo Salvatore, Head of Legal Service, n. Italian

Education: Law degree from the University of Pavia (I), PhD in European Law from the European University Institute of Florence (I), *Avvocato*, Chair Professor of International Law.

Career to date: From 1991 to 2004 Prof. Salvatore experienced as qualified lawyer in private practice both arbitration and litigation dealing mainly with public procurement, competition, international trade and contracts. He worked also as research assistant in International Law at the University of Pavia from 1992 to 1999, Associate Professor of International Law at the University of Insubria (Varese) from 1999 to 2003 and Chair Professor of International Law at the same University since 2004. He joined the European Medicines Agency as Head of Legal Sector on 16 November 2004. He was appointed Data Protection Officer in July 2005.

Edit Weidlich, Head of Internal Audit, n. Hungarian

Education: Doctor degree in Economics. PhD study in International Economics Relation - University of Economics, Budapest. Foreign Trade Expert Certificate from Foreign Institute of Budapest, Mathematics degree from University of Science. Certified Chartered Accountant from Chamber of Statutory Auditors and Certified Public Internal Auditor (CGAP) from Institute of Internal Auditors, Certified Validator of IA Quality Assessment from Institute of Internal Auditors

Career to date: Mrs Weidlich held several posts in the Hungarian Civil Service, serving in the Ministry of Industry and Trade, Ministry of Finance as Commissioner to the Minister, Government Audit Office as Vice President. Member of several professional organisations (IIA, ICGFM, FEE Public Sector Committee). She joined the Agency in May 2009.