European Medicines Agency

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Work programme for the

European Medicines Agency

2008

Adopted by the Management Board on 13 December 2007

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Introduction by the Executive Director

Thomas Lönngren

The constantly evolving environment in which the Agency operates will shape its priorities and work in 2008. Elements affecting the environment include the adoption of new EU legislation in the field of pharmaceuticals, challenges faced by researchers in the development of new therapies, globalisation of the regulatory environment and steady intensification of work within the Agency's existing areas of responsibility.

While last year the Agency focused its efforts on implementing the Paediatric Regulation, the dominant regulatory issue in 2008 will be the implementation of a new regulation on advanced-therapy medicinal products. This will provide much-needed regulatory tools for improving the availability of innovative medicines in Europe. The EMEA will work throughout the year to prepare for its entry into force, by setting up a sixth scientific committee — the Committee for Advanced Therapies — and by introducing the necessary procedures for evaluating advanced-therapy medicines.

Increasing globalisation of the regulatory environment for medicines means that the EMEA needs to extend its activities in the international arena. The Agency will step up its interactions with international organisations and increase its contribution to scientific and regulatory discussions at the international level. This will include building on its successful collaboration with the US Food and Drug Administration (FDA) as a model for co-operation with the Japanese and Canadian authorities.

The European Union has launched a number of initiatives that aim to help researchers to overcome certain bottlenecks in the development of medicines. The Agency will continue to contribute to these efforts, in particular through its support to the Innovative Medicines Initiative, the 7th Framework Programme and the European Technology Platform for Global Animal Health. In addition, the Agency will work to implement initiatives proposed by the EMEA/CHMP Think-Tank on innovative drug development, will continue its support to small and medium-sized enterprises, and will undertake projects to assess the impact and consistency of the Agency's scientific opinions.

The workload of the Agency continues to increase steadily, as a result of new regulatory initiatives and increasing activity in existing core areas of responsibility. On top of this, there is the increasing complexity of activities stemming from advances in pharmaceutical research and development techniques. The Agency and its partners in the European medicines network must ensure that they have the scientific resources necessary to address these challenges, both in the short term and further into the future. Work is progressing in this area and additional proposals on how to tackle this issue will be considered in the revised Road Map which the EMEA will develop to steer the Agency's course from 2010 to 2013.

Also important in 2008 will be a focus on initiatives to improve the monitoring of risks of medicines, facilitate the availability of medicines for human and veterinary use, and strengthen transparency, communication and provision of information to stakeholders, in particular patients and healthcare professionals.

Priorities and key objectives for 2008

Improve the conduct of the Agency's core activities

- The effective conduct of the Agency's core responsibilities, in cooperation with all members of the European medicines network, in the areas of scientific advice, evaluation and supervision of medicinal products to the highest quality standards will continue to constitute the Agency's overall priority. This work is carried out in the face of increasing volume and complexity of activities. IT systems will be updated or newly developed to support the core activities.

Continue to improve the safety-monitoring of medicines for human and veterinary use

- Continue to apply a proactive approach to safety of medicines throughout their lifecycle, through initiatives undertaken in the context of the European Risk-Management Strategy (ERMS), in particular by implementing the ENCePP (European Network of Centres of Pharmacovigilance and Pharmacoepidemiology) project, by further developing EudraVigilance as a cornerstone of the EU Pharmacovigilance System, and by further improving the concept of risk-management plans for medicines for human use.
- Improve the methodology for determining benefit-risk balance of both human and veterinary medicinal products in order to improve predictability and consistency of the Agency's scientific opinions; place more emphasis on benefit-risk issues in the post-authorisation phase.
- Promote the supervision of veterinary medicines once authorised, through effective and targeted pharmacovigilance, including further development and use of the EudraVigilance veterinary database for continuous surveillance, and establishment of the concept of risk-management plans as it applies to the veterinary context.

Contribute to earlier availability of medicines for human and veterinary use

- Implement the new legislation on advanced-therapy medicinal products and establish a new Committee for Advanced Therapies.
- Consolidate and enhance activities relating to medicinal products for paediatric use, building on the experience gained in the first year of operation of new procedures; commence work on the implementation of the strategy for the network of paediatric research.
- Improve liaison with the World Health Organization and developing countries' regulatory authorities for the effective use of opinions on medicinal products intended for non-EU markets.
- Implement initiatives in cooperation with the Heads of Veterinary Medicines Agencies aimed at facilitating greater availability of veterinary medicines, particularly through measures to assist micro, small and medium-sized veterinary enterprises and companies seeking to authorise products for minor species and/or limited markets.

Contribute to the creation of an environment that stimulates innovation

- Continue the contribution to pan-European efforts to facilitate innovation and research, and thus to increase availability of medicines, in particular through participation in the work of the Innovative Medicines Initiative for human medicines, the European Technology Platform for Global Animal Health for veterinary medicines, and the continued implementation of recommendations of the EMEA/CHMP Think-Tank Group on innovative drug development.
- Conduct an assessment of the impact and consistency of the Agency's scientific opinions.

Strengthen the European medicines network

- Enhance collaboration with the Heads of Medicines Agencies and national competent authorities, thereby contributing to the network of excellence, in particular through initiatives in the fields of safety of medicines, resource planning, competence development, the medical information network, transparency, communication, paediatric medicines and the benchmarking of European medicines agencies (BEMA).
- Continue to support the European Commission in implementing its 'Better Regulation' initiative in the field of pharmaceutical legislation.
- Continue implementation of the EMEA Road Map and contribute to the implementation of the Heads of Medicines Agencies strategy paper; commence preparation of the EMEA Road Map 2010-2013.

Foster transparency, communication and provision of information

- Develop and implement the EMEA communications strategy and information-related aspects of the EMEA Road Map in order to adapt the current EMEA information practices and improve the provision of information to all stakeholders.
- Improve the transparency of EMEA activities; provide access to EudraVigilance data, information on clinical trials, data held in EudraGMP and EMEA documents in general, in line with agreed access policies.
- Reinforce the Agency's interaction with patients and healthcare professionals, building on the initiatives undertaken in 2006 and 2007 and taking due account of satisfaction surveys.

Increase the Agency's contribution to international regulatory activities

- Review and further strengthen collaboration with the FDA in the context of the EU/US FDA confidentiality arrangements; implement the EU/Japanese Health Authorities and EU/Health Canada confidentiality arrangements.
- Focus on the international issues related to inspections, in particular with regard to avoiding where possible the duplication of inspections internationally; ensure consistency of standards for manufacture of active substances and finished products, and consistency of ethical standards for the conduct of clinical trials outside the EU.
- Maintain ongoing international cooperation in human and veterinary fields and explore possibilities for extending cooperation to other non-EU countries on important public-health matters.
- Participate in international standardisation activities.

1. EMEA IN THE EUROPEAN SYSTEM

1.1 Management Board

In addition to discharging its statutory responsibilities, the Management Board will target the following objectives:

- Further strengthen effective functioning and engagement of the Management Board.
- Increase transparency of the Management Board activities.
- Review the system of remuneration for the work of (co-)rapporteurs.

Main initiatives

- Implement remaining recommendations of the EMEA Management Board task force on role and responsibilities.
- Implement a procedure for publication of adopted, non-confidential documents (Road Map initiative).
- Continue discussion on alternative options for establishing a new remuneration scheme for scientific services provided by (co-)rapporteurs taking into account the Community financial regulations (Road Map initiative).

1.2 European medicines network

The support and 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:

- Growing strains within the national competent authorities on human resources that are necessary for the effective functioning of the networking model. The growing workload of existing activities at the level of the centralised procedures and addition of new tasks as described in this work programme increases workload for the national competent authorities and strengthens this trend.
- Implementation of both the EMEA Road Map and the Heads of Medicines Agencies (HMA) strategy paper with special attention to areas where there is a high level of overlap (risk management, provision of information, transparency and communication).
- The second phase of the Benchmarking of European Medicines Agencies will require contributions from EMEA related to logistics, assessments and seminars on behalf of the Heads of Medicines Agencies.

Objectives and main initiatives

- Formalising the process for workload and resource planning, resulting in an agreement at HMA and EMEA Management Board level (Road Map initiative).
- Streamline the participation of EU experts in the activities of the scientific committees and working parties and increase the use of video- and teleconferencing tools. Implement working-party meetings with flexible operation designs, which include a mix of face-to-face and electronic tools.
- Ensuring the availability at EU level of top-quality scientific expertise (including the establishment of an EU-wide up-to-date inventory of the available scientific expertise for all aspects of human and veterinary medicines regulation) (Road Map initiative).

- Participate in the Joint HMA/EMEA Training Project Team and organise training of the EU network (new and senior assessors) in the use of electronic tools for the performance of scientific activities (Think-tank Report initiative).
- Find optimal ways to harmonise training and continuous education initiatives for NCAs and EMEA secretariat (Road Map and Think-tank Report initiatives).
- Strengthen cooperation between Member States on inspection performance and outcomes in order to optimise compliance with Community requirements in relation to GMP, GCP, GLP, pharmacovigilance and GDP.

1.3 Transparency and communication

The areas of transparency and communication are a priority for the Agency. The following trends will influence the Agency's work in this area:

- Expectation of stakeholders and the public on transparency of opinion-making process and desire of patients' representatives to participate in regulatory processes.
- Expected interest of the public in receiving information on paediatric medicines and paediatric clinical trials.
- Access-to-documents activities will continue and the number of requests will increase substantially.

Objectives and main initiatives

- Complete and adopt the EMEA communications strategy.
- Increase EMEA transparency in the field of safety of medicines (including access to EudraVigilance data, information on paediatric clinical trials) and non-product related issues. Provide more visibility of scientific activities of the EMEA and working parties through the Agency's website and other information activities.
- Create a new corporate identity for the Agency.
- Continue implementing access-to-documents activities without compromising core activities.

For activities in the area of provision of information, please refer to section 2.10 "Provision of information to and interaction with patients and healthcare professionals".

1.4 Support for innovation and availability of medicines

Objectives and main initiatives

- Conduct the following activities contributing to innovation and availability of medicines for human use: expand opportunities for scientific dialogue on innovative pharmaceutical research and development approaches via the EMEA Innovation Task Force and CHMP working parties' activities; implement the new regulation on advanced therapy medicinal products; continue to support orphan and paediatric medicines policies; expand the scope for provision of scientific advice; provide support to small and medium-sized enterprises; operate procedures with a shorter regulatory timeframe.
- Continue cooperation with the European Commission to foster innovation in the context of the Innovative Medicines Initiative (IMI) and 7th Framework Programme. Such cooperation will also lead to a new procedure for development of a clinical research grant for orphan medicinal

products programmes within the 7th framework programme. The Agency will continue its participation as observer in the US Critical Path Institute's initiative on validation of biomarkers.

- Continue to implement the actions arising from the final report of the EMEA/CHMP Think-Tank Group on innovative drug development (Road Map initiative).
- Provide further guidance (including specific needs for advanced therapies) for SMEs on the Agency's website and through the SME user guide. Continue to organise training on current issues.
- Further facilitate electronic reporting by SMEs of adverse drug data through the EudraVigilance system.
- Further support the concept of SME offices within the European network (Road Map initiative).
- Collaborate with academia and learned societies in the field of outcome assessment through the EMEA outcome assessment agenda.
- Implement relevant recommendations from the HMA(v) Task Force on Availability.
- Provide support to the European Technology Platform for Global Animal Health to support access-to-market for innovative veterinary medicines.
- Implement initiatives adopted by the EMEA Management Board aimed at facilitating greater availability of veterinary medicines through measures to assist companies seeking to authorise products for minor species and/or limited markets.

1.5 European public-health activities

Work on public health matters will involve continuing collaboration with institutional and European partners, including the European Commission (DG Enterprise and Industry, DG Health and Consumer Protection, DG Research), decentralised EU agencies (EFSA, ECDC, EMCDDA), and the European Directorate for the Quality of Medicines and HealthCare (EDQM).

Main activity areas

- The Agency will continue its work to tackle public health threats, including the development of antimicrobial resistance, influenza pandemic and avian influenza (as well as other epizootic diseases), microbicides, tropical diseases, neglected diseases, communicable diseases and new emerging diseases. The EMEA will continue its work in the field of environmental risk assessment and will provide support to programmes aimed at reduction of animal testing. The database on pathogenic agents that can be used in biological warfare will be maintained.
- The EMEA will also participate in the Pharmaceutical Forum and in activities related to pharmacovigilance of vaccines and disease modifiers.
- The Agency will support the European Commission in updating and further developing the 'Notice to applicants' and will provide support to other fora dealing with regulatory matters, e.g. the Pharmaceutical Committee.
- Within the context of the 7th Framework Programme, the EMEA will also participate in the work relating to studies on off-patent medicinal products used in children as well as studies on the safety of medicines and projects on rare diseases.
- The EMEA will also continue to collaborate with DG Enterprise in the Innovation Task Force in relation to borderline medicinal product issues and further participate in meetings of the Medical Device Expert Group on borderline products classification.
- Cooperation with EDQM on a wide range of quality and terminology related matters and, in particular, in the context of the sampling and testing programme for centrally authorised products will remain an important activity area.

1.6 Preparations for future EU enlargement

Trends

- EMEA will continue to work on a new transitional programme IPA (instrument for pre-accession) for supporting participation of Croatia, Turkey and the former Yugoslav Republic of Macedonia as observers in meetings, training courses, and workshops planned by the EMEA, in order to familiarise the National Competent Authorities with the work performed by the EMEA's scientific committees and their working parties. This will be followed by a larger IPA programme in 2009-2011 covering the remaining Balkan countries.

Objectives and main initiatives

- Build contacts and relationships between Croatia, Turkey, the former Yugoslav Republic of Macedonia and the EMEA for future collaboration in EMEA activities.
- Ensure appropriate involvement of Croatia, Turkey and the former Yugoslav Republic of Macedonia in the EU Telematics initiatives (i.e. EudraNet, EudraVigilance, EudraPharm and the European review system).
- Enable participation of Croatian, Turkish and the former Yugoslav Republic of Macedonia representatives in selected meetings, training courses and conferences organised by the EMEA (Road Map initiative).

1.7 International cooperation

Trends

- International activities will be a priority area for the Agency in 2008. The Agency will therefore continue its existing international activities and will aim to expand international collaboration.
- Through the ICH Global Collaboration Group, other regions have strongly expressed interest in the EU networking model of regulatory agencies. The Agency will progressively develop support to knowledge building.

Objectives and main initiatives

- Maintain relations with the EMEA international partners: WHO[1], ICH[2] and VICH[3] fora, Codex Alimentarius, OIE[4], FAO[5], US FDA[6], the Canadian and Japanese medicines authorities. Further interactions will develop with Chinese and Indian authorities. An extension of international cooperation to other non-EU countries will be explored in collaboration with the European Commission.
- Review and further strengthen collaboration with the FDA in the context of the EU/FDA Confidentiality Arrangements. Establish joint processes within the framework of the EMEA/FDA bilateral agreement. EMEA will also gain more experience of procedures for exchange of information on veterinary medicinal products with the US regulatory authorities.
- Develop an implementation plan and commence the implementation of the confidentiality arrangements between the EU and the Japanese as well as Canadian health authorities.
- Cooperate in the areas of pharmacovigilance, risk management, clinical data management and multidisciplinary topics in the framework of ICH. Explore the possibility to increase worksharing

[1] World Health Organization.
[2] International Conference on Harmonisation of Technical Requirements for Registration of Medicinal Products.
[3] Veterinary International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.
[4] World Organisation for Animal Health.
[5] Food and Agriculture Organization of the United Nations.
[6] US Food and Drug Administration.

on all types of inspection, taking into account ICH principles and guidelines (quality risk management, pharmaceutical quality systems). Following the decision that future ICH messaging standards would be developed by a joint initiative of ISO, CEN and HL7, the EMEA will participate in working group meetings of this initiative.

- Play an active role in the implementation of the strategy for phase II of VICH (2006-2010), following agreement on the priorities during 2007.
- Continue to contribute to the work of the WHO, including in the areas of priority medicines for children, medicinal products intended for markets outside the EU, quality matters, and international non-proprietary names (INN) for similar biological medicinal products.
- Participate in discussions and liaise with fora regarding Ayurvedic and traditional Chinese medicines. Support the work of the European Commission-Indian Government working party on Ayurvedic and biotech medicines.
- Increase the Agency's capability in the area of international activities.

1.8 EMEA outcome assessment

Trends and new issues

- A need for developing the capacity for performing assessments of the outcomes of regulatory actions in some areas is grounded in the EMEA Standards for Internal Controls (Code of Financial Conduct) that require the Agency to carry out evaluation of all its activities.
- Current tools available to the Agency are insufficient to address some of the emerging demands from EMEA's stakeholders. Such demands include, for example, mounting scrutiny of and requests for detailed justification of benefit-risk assessments performed by the Agency's committees, and a need to respond to challenges to past regulatory decisions by assessing the impact of regulatory actions on public health (e.g. based on healthcare databases).

Objectives

- Develop capability in clearly defined areas of regulatory sciences where: (i) regulators need to be actively engaged because methodology or knowledge cannot (usually) be developed by academia or industry and later adopted by regulators; and (ii) such sciences are expected to have an impact on how the EMEA evaluates and supervises medicines and delivers its services to its stakeholders, ultimately contributing to public and animal health.
- Initiate pilot projects for, amongst others, projects on benefit-risk, risk communication and scientific memory. Some of the projects are expected to fall within the scope of the Innovative Medicines Initiative (IMI) and 7th Framework Programme.

1.9 Integrated quality management at the Agency

Objectives/initiatives

- Following the planned completion of the two-year exercise aimed at identifying process improvements, continue to implement measures to optimise key processes, improve cost-effectiveness of the Agency's operations, and achieve higher satisfaction for the Agency's stakeholders.
- Consolidate existing management tools to improve the linkage between them and to provide for improved coordination of IQM[7] activities.

[7] Integrated quality management.

- Strengthen the advisory and counselling role of the EMEA audit advisory committee in respect of the management systems and management tools used at the Agency. This will add value to the already developed advisory role of the committee regarding the audits conducted at the Agency.
- As in previous years, carry out self-assessments and planned internal audits, review the level of implementation of standards for internal control, and evaluate the overall effectiveness of the IQM system. Conduct staff and stakeholder surveys at planned intervals.
- The Agency will consolidate its practices of conducting ex-post controls to support the reasonable assurance by the Executive Director on the effectiveness of the Agency's financial procedures and related controls.

2. MEDICINES FOR HUMAN USE

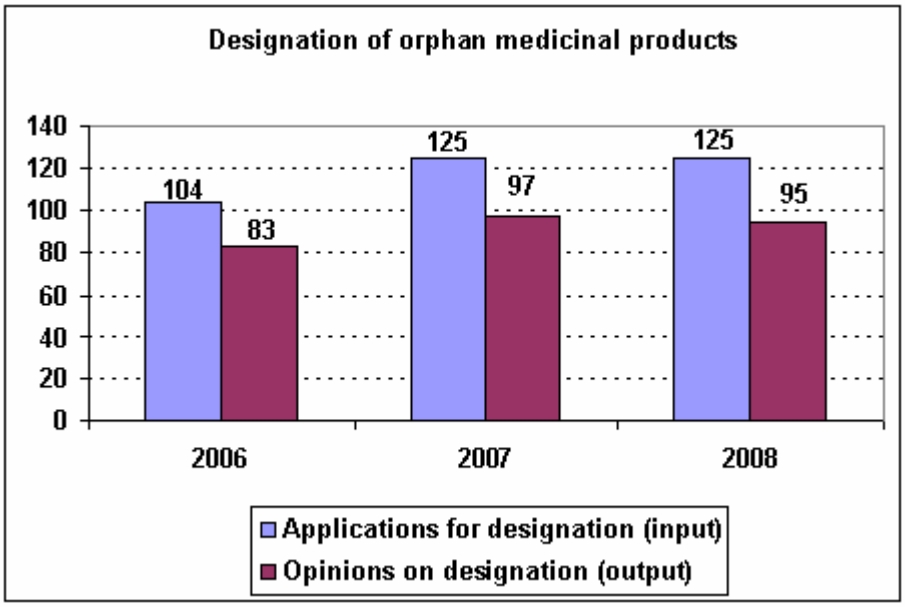
2.1 Orphan medicinal products

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, through the implementation of the orphan medicinal products policy, to the creation of an environment that stimulates innovation and research and improves the availability of medicines to treat rare diseases. As part of this work the Agency provides financial incentives during the development, initial marketing authorisation and, in the case of micro, small and medium-sized companies, post-authorisation phases. Protocol assistance remains a priority area for such incentives.

Trends and new issues

- The Agency will be responsible for the review of the profitability of orphan medicinal products after 5 years of marketing. This will impact strongly on the work of the EMEA due to the complexity of the issue and significance of Agency opinions.
- Applicants with innovative products will require specific advice on issues related to orphan designation.



In addition to core activities relating to the evaluation of applications for designation and development of related guidelines, the Agency will target the following Objectives

- Implement the process for parallel designation (EMEA-US FDA) of orphan medicinal products.
- Streamline the implementation of legislative requirements regarding the review of profitability of orphan medicinal products (Art. 8(2) of Regulation (EC) No 141/2000) in light of the new Commission guideline.
- Prepare for the introduction of electronic-only submissions of orphan designation applications on the basis of initial experience gained from marketing authorisation application submission.

Performance indicators

Performance indicator	Target
Percentage of applications evaluated within the 90-day timeline	100% of applications
Percentage of summaries of COMP opinions published within 1 month of the European Commission's decision on designation	70% of summaries of opinion

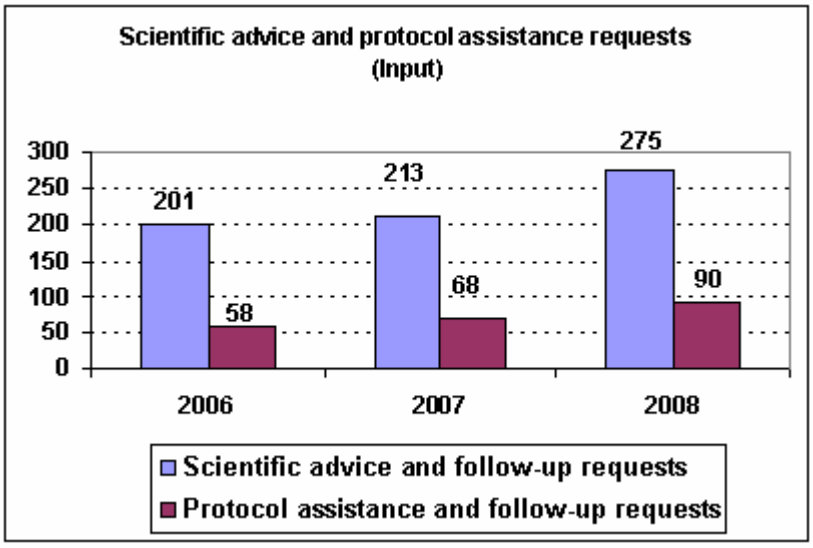
2.2 Scientific advice and protocol assistance

The Agency provides scientific advice and protocol assistance to sponsors during the research and development phase 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.

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

- Quantitative increase and qualitative change in the type and scope of applications. This will include requests on similar biological products, generic medicinal products, alternative clinical trials design, biomarkers, paediatric medicines, products within the extended scope of the centralised procedure, programmes supporting conditional marketing authorisation and authorisation under exceptional circumstances, and programmes for products intended for non-EU markets.
- EMEA's responsibility for SMEs will have a further impact on the nature and volume of scientific advice for innovative products.
- Anticipated significant impact on EMEA and Member State resources because of increased complexity and volume of work in the scientific committees and related working parties.



In addition to core activities relating to the provision of quality scientific advice to applicants, the following objectives will be targeted:

- Improve the scientific advice procedure and assure high quality of the work performed, utilising the expertise of other working parties when required.
- Initiate a feasibility study on exchange of information on advice given by national authorities.

Main initiatives

- Continue conducting peer review prior to finalisation of advice.
- Prepare for electronic-only submissions of scientific advice applications.
- Implement changes in scientific advice procedure, taking into account feedback received from stakeholders.
- Plan for the expansion of the scientific advice database to include national scientific advice, and promote exchange of information on national advice (Road Map initiative).
- Set up a new procedure for advice on biomarkers (Road Map and Think-tank Report initiatives).

Performance indicators

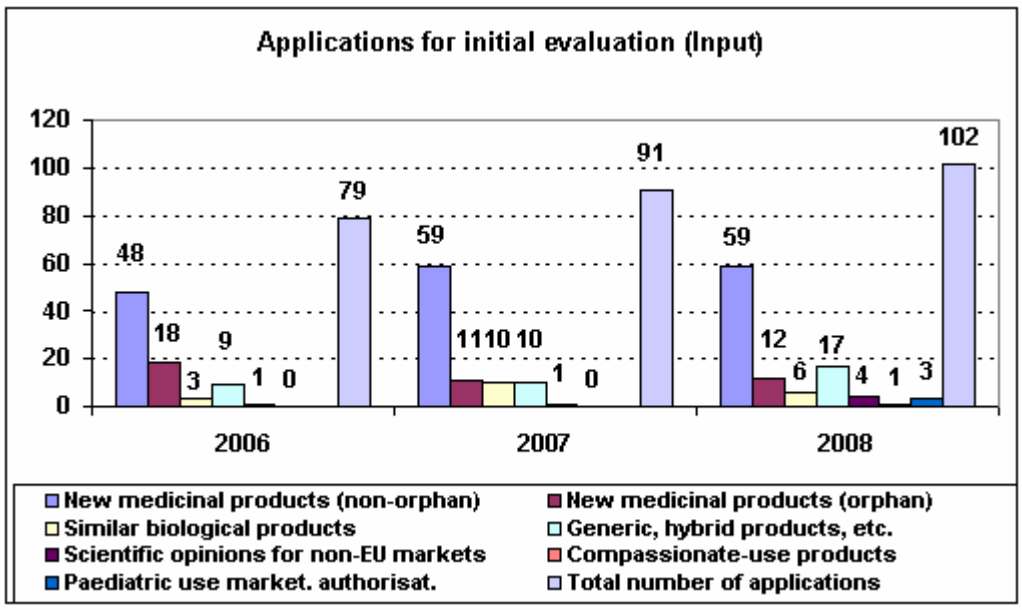
Performance indicator	**Target**
Scientific advice and protocol assistance requests evaluated within the procedural timelines	100% of requests
External experts involved in procedures	50% of scientific advice and protocol assistance requests
Percentage of marketing authorisation applications for new technology products having received scientific advice/protocol assistance	50% of applications

2.3 Initial evaluation

Initial evaluation covers activities relating to the processing of applications for medicinal products (orphan, non-orphan, similar biological (biosimilar), and generic) from pre-submission discussion with future applicants, through evaluation by the CHMP, to the granting of a marketing authorisation by the European Commission. The Agency also provides scientific opinions in collaboration with the WHO for products intended for use exclusively in markets outside the EU. These activities culminate in the production of the European public assessment report (EPAR). Applications for certification of compliance with Community legislation of plasma master files (PMFs) are processed in a similar manner but without the production of an EPAR. Opinions are also provided on ancillary medicinal substances and blood derivatives used in medical devices. The Agency provides regulatory advice to industry during pre-submission meetings.

Trends and new issues

- The number of applications for authorisation of new orphan and non-orphan medicinal products will remain stable compared to 2007. The new areas of generic and biosimilar submissions have grown in 2007. The carry-over of a peak in biosimilar submissions in 2007 and an increase in generic submissions in 2008 will impact on the number of ongoing procedures.
- Shift in therapy areas due to new compounds will have a tangible impact when new therapeutic groups and product types come under the mandatory scope for centralised submissions (anti-virals and medicines for autoimmune diseases and immune dysfunctions).



In addition to the core activity of evaluating applications for marketing authorisation, the following objectives will be targeted:

- Implement the mandatory scope for centralised submissions in the areas of anti-virals, autoimmune diseases and immune dysfunctions.
- Implement a procedure on interaction with the Paediatric Committee during validation of applications.
- Ensure that appropriate pharmacovigilance activities and risk minimisation measures are put in place prior to the marketing authorisation.
- Reinforce pre-submission activities aimed at providing applicants with an integrated view of the procedure in the year preceding actual submission.
- Improve the content and presentation of information in the CHMP assessment report and EPARs in the light of stakeholders' expectations.
- Reinforce assessment procedures for similar medicinal products in the context of orphan products.

Main initiatives

- Finalise guidance on the application of the new mandatory therapeutic areas in the centralised procedure.
- Conduct the peer review of (co-)rapporteurs' assessment reports, including the assessment of RMPs, and ensure consistency across therapeutic classes and product types (Road Map initiative).
- Ensure due care of ethical standards in clinical trials performed in non-EU countries as part of initial marketing authorisations and their subsequent presentation in EPARs.
- Implement as a pilot phase a new assessment-report template that addresses benefit and risk assessment (Road Map initiative).
- Extend validation procedure to include Paediatric Committee compliance check of marketing authorisation applications with paediatric investigation plans, where applicable.
- Review the procedure for assessment of product similarity and clinical superiority during initial evaluation and prior to granting of a marketing authorisation in the light of the upcoming Commission guideline.
- Implement electronic-only submission of marketing authorisation applications as a transitional period to submissions in eCTD format from January 2009.

Performance indicators

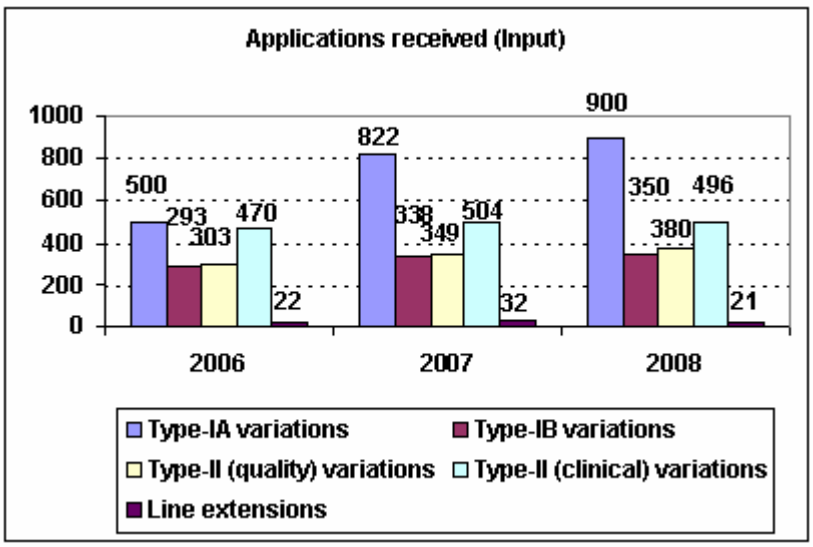
Performance indicator	Target
Percentage of applications evaluated within the regulatory timeline: ▪ Marketing authorisation applications ▪ Accelerated assessment applications ▪ Plasma master file applications	 ▪ 100% of applications ▪ 100% of applications ▪ 100% of applications
Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days	100% of applications
Percentage of marketing authorisation applications including risk-management plans (RMPs) peer reviewed by the EMEA as part of the assessment of the initial marketing authorisation application	80% of applications that include an RMP

2.4 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-IA or IB) or major (type-II) changes. These variations concern quality and (non-)clinical related aspects, including extensions of indications.

Trends and new issues

- The overall number of clinical Type II variations is expected to remain stable in 2008. However, the proportion of variations submitted as a consequence of the implementation of the EU Paediatric Regulation is expected to increase, although the exact impact of the new regulation in 2008 is difficult to predict.
- The increase in quality variations (Types IA, IB and II) is expected to be maintained.
- EMEA will be required to handle the implementation of changes to the product information of generic and similar biological medicinal products subsequent to changes to the reference product, hence ensuring consistency with the Product Information of the reference product.



In addition to the core activity of handling post-authorisation activities, the following objectives will be targeted:

- Ensure regulatory and scientific consistency of CHMP opinions and assessment reports, including those relating to generic and similar biological medicinal products.
- Review the Agency's variation processes to further improve their quality and, where possible, increase the efficiency of their management, for instance by simplifying the processes.
- Review and update guidance to pharmaceutical industry in order to improve the quality of submissions.
- Increase the transparency and the provision of information in relation to post-authorisation activities.

Main initiatives

- Explore, in close collaboration with the CHMP, how the management of post-authorisation activities by the Committee, (Co-)Rapporteurs and the EMEA Secretariat can be facilitated, alongside initiatives to strengthen the quality assurance of the scientific assessment process (Road Map initiative).
- Ensure due care of ethical standards in clinical trials performed in non-EU countries as part of post-authorisation applications.
- Implement the outcome of the EMEA process improvement exercise performed in the area of variation procedures (Road Map initiative) and continue to provide input to the European Commission review of the Variations Regulation.
- Set up a new procedure for the handling of variations for generic and similar biological medicinal products, develop internal/external guidance and SOPs, and train staff. Identify common application difficulties encountered by the pharmaceutical industry and provide feedback to the industry via the EMEA website and guidance documents.

Performance indicators

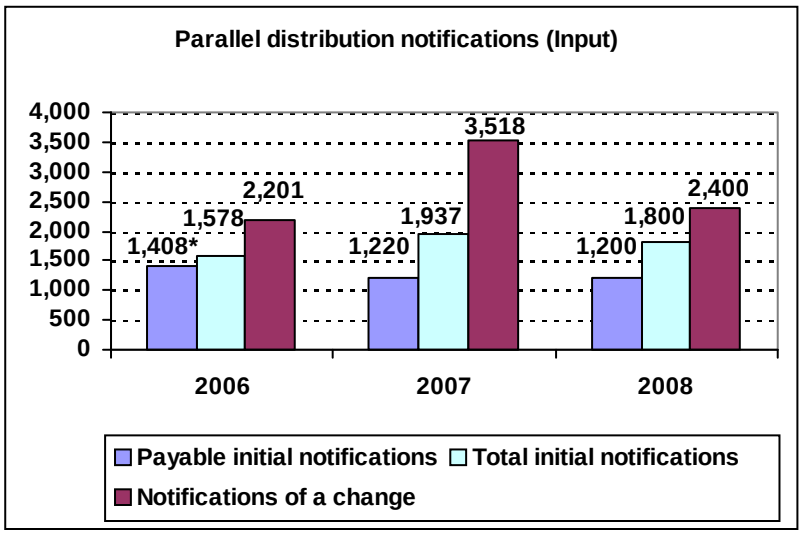
▪ Performance indicator	▪ Target
▪ Percentage of applications for post-authorisation procedures evaluated within the regulatory timelines	▪ 100% of variation applications and 95% of extension applications
▪ Percentage of applications meeting the regulatory timeline of 27 days for the linguistic post-opinion check	▪ 90% of applications

Parallel distribution

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

Trends and new issues

- The number of initial notifications received in 2008 is expected to be comparable to that for 2007. The major parallel distributors already have a wide range of products and extend their portfolio mainly with recently authorised products and with additional pack sizes of products already notified in the past. Smaller and new parallel distributors tend to focus on recently authorised products and on a limited number of pack sizes.



*The figure on payable initial notifications in 2006 includes 350 parallel distribution notifications transferred from 2005 to 2006

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 to providing guidance and information on parallel distribution activities, the following objectives will be targeted:

- Explore what additional improvements can be introduced in the process of handling parallel distribution notifications.
- Ensure compliance of the parallel distributors with the mandatory notification procedure and with the notices issued by the EMEA.

Main initiatives

- Explore the possibility of developing a system for electronic submission and handling of parallel distribution notifications.
- In collaboration with the NCAs, verify compliance with the mandatory notification procedure by parallel distributors.
- Check parallel distributed products on the market for compliance with the Notices and the latest version of the Annexes.

Performance indicators

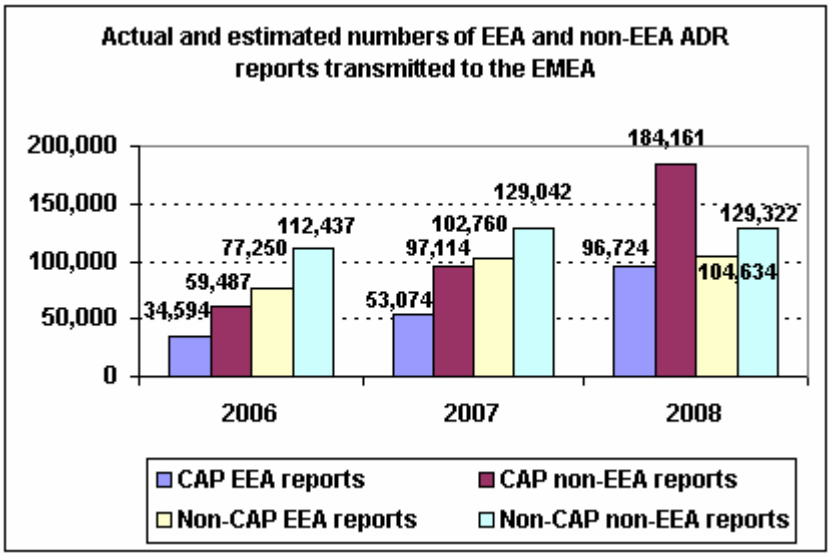
Performance indicator	Target
Percentage of notifications checked for compliance within the regulatory timeline of 35 working days (validation and regulatory check)	70% of applications checked within 35 working days

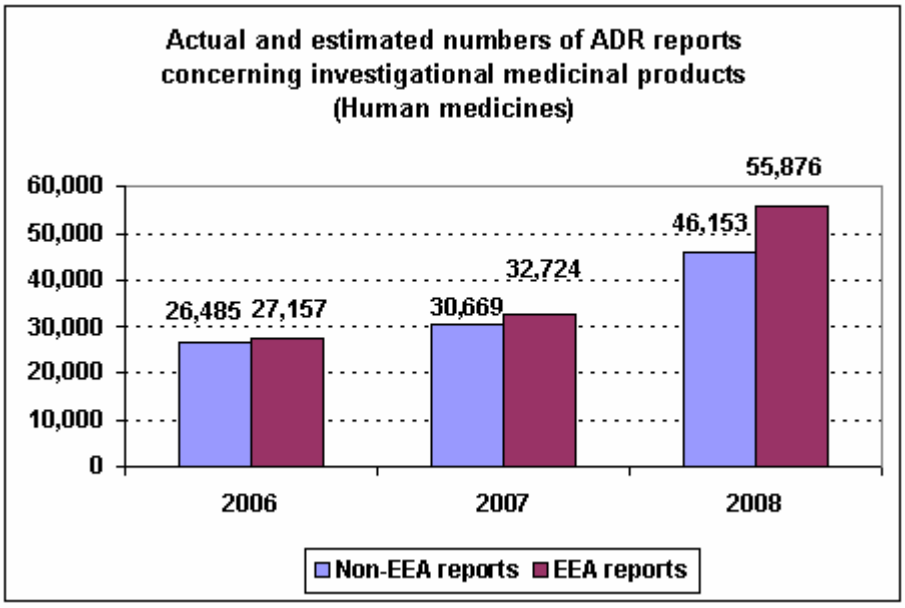
2.5 Pharmacovigilance and maintenance activities

Pharmacovigilance activities include the management of suspected adverse drug reactions in the pre- and post-authorisation phases (individual case safety reports (ICSRs)), periodic safety-update reports (PSURs) and risk-management plans (RMPs). Maintenance activities relate to post-authorisation commitments (specific obligations, follow-up measures), renewal applications and annual reassessments.

Trends and new issues

- Further initiatives will be deployed in the context of the European Risk Management Strategy (ERMS) in accordance with the 2008-2009 Work Programme as adopted by the HMA, with primary focus on the development of a more intensive drug-monitoring system.
- The implementation of the European Paediatric Regulation will be resource intensive in terms of responsibilities for pharmacovigilance and risk management activities.
- The implementation of the Advanced Therapies Regulation will require intensive preparatory work in relation to pharmacovigilance and risk management activities.
- The review of marketing authorisations under conditional approval was a new task in 2007. However, since the experience gained in 2007 was limited, relevant procedural guidance will have to be developed in 2008.





In addition to the Agency's core activities in relation to pharmacovigilance, including signal detection for centrally authorised products, and maintenance activities (periodic safety update reports, follow-up measures, specific obligations), the following objectives will be targeted:

- Implement the ERMS in collaboration with the NCAs, taking into account the second rolling 2-year work plan agreed at HMA level.
- Contribute to the European Commission legislative proposals as a follow-up to the European Commission assessment of the EU system of pharmacovigilance.
- Maintain and further strengthen the EudraVigilance system to support proactive pharmacovigilance.
- Support the risk management and pharmacovigilance activities introduced by the EU Paediatric Regulation.
- Prepare for adequate implementation of the advanced therapies legislation in the fields of pharmacovigilance and safety monitoring of such novel technologies.

Main initiatives

- Prepare for the implementation of ENCePP[8], with a primary focus on the development of general principles, standards, quality assurance and transparency-related aspects to be applied across the network (Road Map initiative).
- Facilitate further implementation of electronic reporting through EudraVigilance by progressing the EudraVigilance Action Plan, which elaborates on various initiatives to address difficulties encountered as regards the quality of the submitted data (Road Map initiative).
- Further develop EudraVigilance through the introduction of additional functionalities, including integration of other health databases in the EudraVigilance system (Road Map initiative).
- Finalise the EudraVigilance Access Policy and subsequently prepare for the implementation of this policy (Road Map initiative).
- Support risk management activities in the context of (pre-)pandemic preparedness (Road Map initiative).
- Extend the existing peer review of RMPs to the field of paediatrics and continue to monitor the impact of RMPs according to practical experience gained.

[8] European Network of Centres for Pharmacovigilance and Pharmacoepidemiology.

- Develop guidance in the fields of post-authorisation follow-up of efficacy, adverse reactions and risk management of advanced therapy medicinal products (ATMPs) (Think-tank Report initiative).

Performance indicators

Performance indicator	Target
Percentage of RMPs that are peer reviewed by the EMEA as part of the assessment of variations and line extensions that result in a significant change to a marketing authorisation	80% of RMPs
Submission of outcome reports for post-authorisation commitments (PACs) to applicants/MAHs within 2 weeks of the CHMP meeting	100% of reports
Review of post-authorisation commitments (PACs) within the agreed timeframe	80% of PACs

2.6 Arbitration, Community referrals and opinions on scientific matters

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 or decentralised procedures.

Article 30 referrals (Directive 2001/83/EC, as amended) are mainly initiated in order to obtain harmonisation of authorisations for medicinal products authorised in the Community by the Member States.

Article 31, 36 and 37 referral procedures (Directive 2001/83/EC, as amended) are mainly initiated in case of Community interest and generally for safety-related issues.

Article 16(1) and 16(4) referrals (Directive 2001/83/EC, as amended) are initiated by Member States regarding herbal medicinal products with a traditional use longer or shorter than 15 years respectively.

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

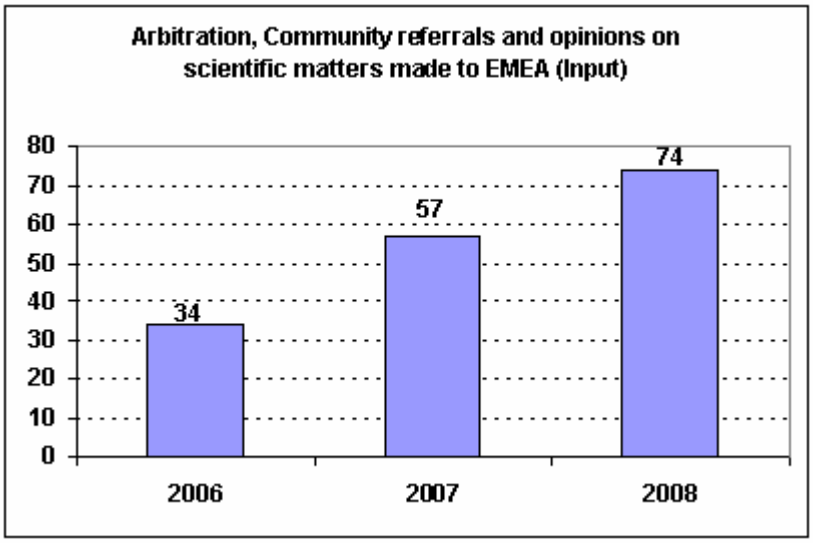
Article 5(3) procedures (Regulation (EC) No 726/2004) require a CHMP opinion on any scientific matter raised by the EMEA, the European Commission or a Member State.

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

- Forecasting of arbitration and referral activities remains difficult. New legal tools have become available, with which more experience is required in order to improve forecasting.
- The number of Article 29 referrals for products having a significant impact on public health is likely to be similar to that in 2007.
- The yearly identification of medicinal products for which a harmonised summary of product characteristics (SPC) should be drawn up will continue to impact on the number of Article 30 referrals to the CHMP. It is expected that marketing authorisation holders will make more voluntary use of this procedure to streamline the harmonisation of the product information and optimise the post-approval maintenance of their products across the EU.
- Based on initial experience during 2007, there is a clear trend for an increase in Article 107 procedures in 2008, and this will have to be closely monitored.

- Referrals concerning new indications, new pharmaceutical forms or new routes of administration relating to paediatric use is a new legislative tool, and the experience with this procedure in 2007 is very limited. The number of procedures is difficult to predict and the impact on the workload for the CHMP and EMEA secretariat will be carefully monitored.



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

- Ensure regulatory and scientific consistency of CHMP opinions and assessment reports.
- Increase the transparency and the provision of information on arbitration and referral procedures.
- Review existing and develop new guidance based on the 2007 experience of the operation of the CMD(h) pre-referral procedure, the SPC harmonisation group and Article 107 referral procedures.
- Explore the possibility of publishing CHMP assessment reports for all safety-related referrals.

Performance indicators

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

2.7 Medicines for paediatric use

This covers EMEA activities relating to the assessment, agreement and verification of compliance with paediatric investigation plans and waivers by the Paediatric Committee (PDCO) 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 and authorised medicinal products, and in a paediatric-use marketing authorisation for off-patent products. Activities also include implementation of the strategy for the establishment of the European network of paediatric research, provision of information on clinical trials performed in children, and agreement on compliance check with Member States.

Trends and new issues

- Following receipt of the first applications during 2007 — the first year of implementation of the Regulation — the number of paediatric investigation plan (PIP) and paediatric waiver applications is expected to be maintained during 2008. A PIP application may cover several clinical

indications, each of which would require a separate assessment. It is expected that around 400 such assessments would be carried out.

- Further implementation of the Paediatric Regulation provisions relating to the paediatric research network, off-label paediatric use, and access to paediatric clinical trials.
- Expectations of industry, patients/families and the public in general regarding the success of the implementation of the regulation on paediatrics are high.

In addition to the Agency's core activities in relation to paediatric medicines (assessment of paediatric investigation plans, applications for waivers), the following objectives will be targeted:

- Streamline assessment of paediatric investigation plans, including the establishment of PDCO specialist subgroups.
- Implement the network of paediatric research in accordance with the strategy adopted by the Management Board.
- Implement public access to paediatric clinical trials.
- Further to the principles on interaction agreed in June 2007 between European Commission, EMEA and US FDA, implement working practice with the FDA Paediatrics Office for the assessment of PIPs.
- Provide pharmacovigilance support in the context of the implementation of the Paediatric Regulation and the new Paediatric Committee.

Main initiatives

- Implement procedure for checking of compliance with PIPs at the request of applicants or EU competent authorities for national marketing authorisations (Road Map initiative).
- Agree on the standards of quality for the paediatric research network (Road Map initiative).
- Constitute the Coordinating Group for the network of existing networks, and organise meetings of paediatric research networks (Road Map initiative).
- Develop expertise on new sources and methods for the intensive monitoring of paediatric use of medicines (Road Map initiative).
- Progress parallel review of development of paediatric medicinal products with the US FDA.
- Implement the paediatric pharmacovigilance guideline and evaluate the practical aspects.
- Follow up on collection of information on off-label paediatric use of medicines by Member States (Road Map initiative).
- Implement a strategy for the exchange of paediatric information with Member States.

Performance indicators

Performance indicator	**Target**
Number of paediatric investigation plan or waiver opinions within legal timelines	100% of opinions
Number of paediatric investigation plan or waiver decisions within legal timelines	100% of decisions
Review of risk-minimisation activities by specialised paediatric/risk-management experts	80% of applications

2.8 Herbal medicinal products

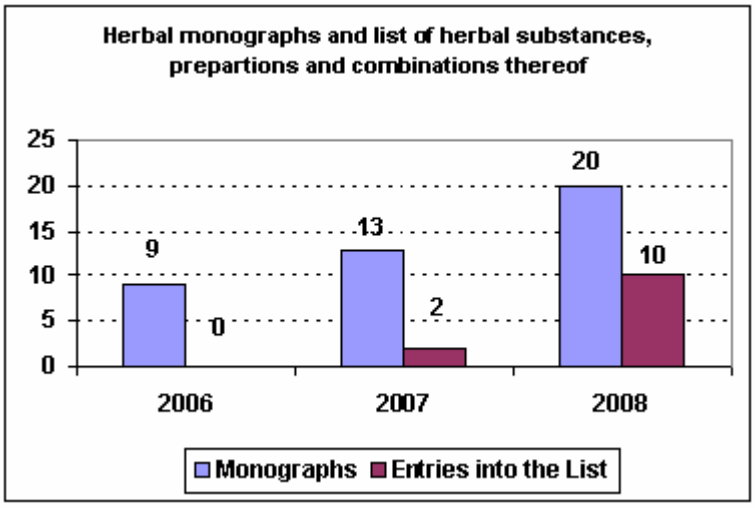
The Agency's activities in the area of herbal medicines include: support to the provision by the Committee on Herbal Medicinal Products of scientific opinions on questions relating to herbal medicines; the establishment of Community herbal monographs for traditional and well-established herbal medicinal 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 evaluations for referral and arbitration procedures concerning traditional herbal medicinal products.

Trends and new issues

- The European Commission published in 2007 a status report on the implementation of the provisions of Chapter 2a of Directive 2001/83/EC as amended by Directive 2004/24/EC as regards traditional herbal medicinal products. This will require adequate follow-up in 2008.

In addition to core activities relating to herbal medicines, the following objectives will be targeted and initiatives implemented:

- Follow up, in close collaboration with the European Commission, on the status report on the implementation of the legislative provisions as regards traditional herbal medicinal products (Road Map initiative).
- Review and improve the process for producing Community herbal monographs and entries to the list of herbal substances, preparations and combinations thereof by exploring the possibility of involving academia alongside the resources made available by the EU medicines network (Road Map initiative).
- Develop a procedure for the revision of established Community herbal monographs and entries to the list of herbal substances, preparations and combinations thereof (Road Map initiative).
- Develop a procedure for handling referrals relating to herbal medicines.
- Update interested parties regarding the operations of the HMPC.



Performance indicators

Performance indicator	Target
Number of Community herbal monographs established	20 Community herbal monographs
Number of entries to the list of herbal substances, preparations and combinations thereof	10 entries to the list

2.9 Advanced therapies and other emerging therapies and new technologies

This area of activity relates to advanced therapy medicinal products (gene therapy, somatic cell therapy or human tissue engineered products) that fall within the scope of Regulation (EC) 1394/2007. The main task of the Committee for Advanced Therapies, established by the Regulation, is to provide specific expertise and advise scientifically on any data related to advanced therapy medicinal products, working in close cooperation with and supporting the CHMP. 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

- Entry into force of the new EU regulation on advanced therapy medicinal products towards the end of 2008.
- A significant increase in interest by major companies is observed with either acquisition or outsourcing of product development in the field of gene and cell therapy. In addition to the observed emerging approaches (gene therapy, cell therapy, human tissue engineered products, new delivery and targeting methods – e.g. monoclonal antibodies) there is a growing interest in new manufacturing processes, new biologicals and nanomedicines. In particular, the increasing uptake of nanotechnologies in the development of medicinal products will require monitoring of the adequacy of current quality, preclinical and clinical scientific standards.
- EMEA will continue to receive marketing authorisation applications for products developed utilising new technologies, most likely from SME companies.
- Non-competitive sharing of data in the field of pharmacogenomics, especially for toxicology and disease-related biomarker qualification and validation, is expected to produce a new wave of scientific advice seeking to incorporate such genomic markers in pharmaceutical R&D and for guiding clinical use.

Objectives

- Implement the new regulation on advanced therapy medicinal products.
- Identify and incorporate additional experts to strengthen the network in the fields of emerging therapies and new technologies.

Main initiatives

- Establish the Committee for Advanced Therapies, its mandate and rules of procedure, and its interaction with the CHMP for the evaluation of marketing authorisation applications and with other Committees, as necessary (Road Map initiative).
- Implement new procedures for the assessment of advanced therapy medicinal products (Road Map initiative).
- Implement procedures for eligibility of medicinal products as advanced therapy products and the early evaluation of quality and non-clinical safety data for advanced therapy products under development (Road Map initiative).
- Identify gaps in the EMEA's scientific secretariat, scientific committees and working parties and seek complementary expertise/experience in close collaboration with Member States (Road Map initiative).
- Plan adequate training for the EMEA's scientific secretariat in the areas of advanced therapy medicinal products and technologies to support the scientific committees (Road Map and Think-tank Report initiatives).

- Maintain and further strengthen dialogue with all stakeholders through joint workshops with the European Commission on both the regulatory and scientific aspects of advanced therapy medicinal products.
- Develop guidance documents in consultation with interested parties on advanced therapy medicinal products and new technologies, including the links between specific therapies, e.g. gene, cell-therapy and tissue-engineered products, and nanomedicines (Road Map and Think-tank Report initiatives).

Performance indicators

Performance indicator	**Target**
Innovation Task Force briefing meetings organised within 60 days from receipt of a request	80% of meetings
Regulatory advice on new-technology, emerging-therapy and borderline medicinal products given within 60 days	80% of requests

2.10 Provision of information to and interaction with patients and healthcare professionals

The Agency has implemented processes and procedures aimed at the provision of targeted, understandable and accessible information for patients and healthcare professionals. In addition to all the transparency measures put in place as a consequence of the 2004 revised legislation (e.g. summaries of opinions, European public assessment reports, information on arbitrations and referrals, information on withdrawals of applications by applicants prior to opinion and on negative decisions, and summaries of EPARs written in a manner more understandable to the public), the Agency will extend the scope of publication of information to paediatric medicinal products.

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

Trends and new issues

- The Pharmaceutical Forum should deliver its outcome in relation to the public-private partnership project on the provision of information to patients.
- The outcome of the European Commission report to the European Parliament and the Council on the current practice with regard to information provision (Article 88a of Directive 2001/83/EC, as amended) is expected to result in legislative changes.
- There is a need to more adequately address the steadily increasing expectations of the EMEA stakeholders for provision of timely and targeted information using the available communication tools in a more efficient manner. This should allow for a better implementation of the Agency's legal responsibilities.
- Publications relating to paediatric investigation plans and paediatric use marketing authorisation applications will increase in 2008.

In addition to the core activities on provision of information and review of quality of product information, the following objectives will be targeted:

- Adapt current information practices and develop new ones addressing the challenges the Agency is facing in a coherent way.
- Incorporate the various tools with which the different types of information are provided into a coherent communication platform.

- Support the European Commission initiatives in relation to provision of information.
- Strengthen the involvement of the Agency's stakeholders (healthcare professionals, patients and consumers) in various EMEA activities, including the involvement of patient representatives in the review of documents developed for patients and the general public.
- Increase quality and consistency of 'user consultation' at European level.

Main initiatives

- Review the current EMEA communication tools and begin implementation of revised tools better adapted to provide high-quality, targeted and timely information (Road Map initiative).
- Develop a coherent communication platform at the EMEA, combining all communication tools, with primary focus on the revision of the Agency's website (Road Map initiative).
- Start preparatory work for the development of a communication structure for dissemination of information by making best use of the EU Regulatory System network (Road Map initiative).
- Analyse and monitor the degree of satisfaction of patients and consumers (based on performance indicators put in place in 2006) (Road Map initiative).
- Finalise the recommendations of the EMEA/CHMP Working Group with HCPs and start to implement them (Road Map initiative).
- Implement the conclusions of the analysis of the EMEA framework for translation-checks, taking into account the 2007 experience, and introduce any additional improvements where relevant.
- Revise the QRD mandate to include additional activities in relation to a further improvement of the quality of product information.

Performance indicators

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	90% of marketing authorisations granted
Percentage of EPARs for extensions of indication published within 2 weeks of the Commission decision	80% of EPARs updated
Percentage of EPAR summaries in a language understandable to the public, published together with the EPAR	90% of EPARs
Percentage of assessment reports published within 2 months of withdrawal of a marketing authorisation application	70% of assessment reports
Percentage of refusal assessment reports published within 2 weeks of the Commission decision	70% of assessment reports
Publication of 'question and answer' documents for Community-interest referrals and Article 107(2) procedures at the time of CHMP opinion	90% of 'question and answer' documents

2.11 Scientific committees, working parties and scientific advisory groups

Scientific committees

Four scientific committees of the EMEA are responsible for various aspects in relation to medicinal products for human use.

- The Committee for Medicinal Products for Human Use (CHMP) is responsible for: scientific evaluation of medicinal products; provision of scientific opinions for the authorisation and maintenance of products; opinions on arbitration and referral procedures; opinions on products intended for use outside the European Union; opinions on any scientific matter at the request of the European Commission or the Executive Director of the Agency; scientific advice and protocol assistance; harmonisation of technical requirements for pharmaceutical regulation; pharmacovigilance; and public health threats.
- The Committee for Orphan Medicinal Products (COMP) is responsible for: recommendations on the designation of orphan medicinal products; advising the European Commission on the development of an orphan medicinal product policy; and providing assistance on liaison with international partners and patients' organisations.
- The Committee on Herbal Medicinal Products (HMPC) is responsible for: the provision 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; the evaluation for referral and arbitration procedures concerning traditional herbal medicinal products; and the harmonisation of procedures and provisions concerning traditional herbal medicinal products laid down in the Member States.
- The Paediatric Committee (PDCO) is responsible for: conducting assessment of, agreement of and verification of compliance with paediatric investigation plans; establishing lists of waivers of specific medicines or classes of medicines that are not suitable or necessary for the treatment of children; and advising the EMEA on the development of a European network for paediatric research.

A fifth committee, the Committee for Advanced Therapies, to be established towards the end of 2008, shall be responsible for: formulating draft opinions on advanced therapy medicinal products for final approval by the CHMP; advising the CHMP on data generated in the development of such products; advising on product classification; contributing to scientific advice; and providing scientific expertise and advice on advanced therapy medicinal products and innovative medicines and therapies.

Standing and temporary working parties and scientific advisory groups

The working parties of the EMEA scientific committees will continue to develop and revise guidelines, and, where required, provide recommendations and advice on medicinal products for which applications are made. They contribute to marketing authorisation, traditional-use registration, post-authorisation and post-registration activities, according to the specific area of responsibility of each group. This includes providing advice and recommendations on general public health issues relating to medicinal products. In addition, they assist in the provision of training for the EU network, and progressively provide fora for discussion with stakeholders on development methods for emerging technologies and innovative medicines.

Scientific advisory groups will continue their work to evaluate and advise on specific types of medicinal products or treatments.

Trends

- The nature and the number of activities arising from new legislation that involve the scientific committees are increasing significantly, together with a corresponding increase in the complexity of procedures.

Main initiatives

- Review the functioning of the CHMP in order to improve its efficiency of operation, including the input from specialist expertise, and to increase quality assurance (Road Map and Think-tank Report initiatives).
- Review the operation of the CHMP and its working parties in line with plans for the integration of the Paediatric Committee and the Committee for Advanced Therapies to assure effective internal coordination and to avoid divergence of assessment standards.
- Evaluate and find ways how to use the available expertise as efficiently as possible from the point of view of the Member States, the EMEA and the European medicines network.
- Produce a report on the first 3 years of coordination between the various EMEA scientific committees.
- Operate the EMEA Policy on Access to Documents in relation to the activities of the EMEA scientific committees. Particular attention will be paid to the status and availability of the agendas and minutes of meetings (Road Map initiative).
- Implement and operate the electronic system for management of meeting documents in all scientific committees' meetings. Operational consequences from the experience with the CHMP meetings will be assessed and the most efficient meeting processes will be implemented in all other meetings.
- Continue to implement process improvements in the operation of working parties. Review the way the scientific committee working parties operate and are established in order to see if the use of resources of the national competent authorities can be rationalised.
- Coordinate procedures with other external bodies and agencies in the framework of Article 59 of Regulation (EC) No 726/2004, e.g. with ECDC regarding pandemic influenza and avian influenza, and with EFSA regarding herbal medicinal products.

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 addition to the activities undertaken in 2006 and 2007, the following initiatives will be carried out:

- Streamline the meetings of the satellite groups (CTS Working group, SPC harmonisation subgroup, CMD(h) – PhVWP Working group) and their interaction with the CMD(h).
- Further improve the coordination of the referral procedure to the CMD(h), with particular attention to the liaison with the Pharmacodynamics – Pharmacokinetics subgroup of the CHMP Efficacy Working Party.
- Monitor the implementation of the CMD(h) referral procedure and assess the impact of the implementation of the 2007 SPC harmonisation list.
- Develop and maintain the CMD(h) memory of regulatory and scientific agreements and of the outcome of discussions regarding mutual recognition and decentralised procedures.
- Support the CMD(h) in the activities arising from the implementation of the Paediatric Regulation (e.g. worksharing for the assessment of paediatric studies submitted according to Articles 45 and 46 of Regulation (EC) No 1901/2006).

2.13 Regulatory and organisational support activities

The Agency provides regulatory and procedural advice to the pharmaceutical industry during the lifecycle of medicinal products, from scientific advice and pre-submission meetings with applicants through to post-authorisation and annual meetings with marketing-authorisation holders.

The Agency also works to continuously address regulatory and procedural issues affecting the EMEA committees, standing and temporary working parties, and associated groups. The Agency also provides support to the receipt and handling of applications and the financial transactions related to applications.

In addition to the Agency's core activities regarding the provision of regulatory and procedural advice, the following objectives will be targeted and initiatives implemented:

- Seek feedback from the Agency's stakeholders on experience obtained from the implementation of the new legislative provisions, in particular the new paediatric legislation, and take remedial action, where necessary (Road Map initiative).
- Update existing and develop new guidance documents with regard to generic medicines and non-prescription medicines.
- Implement the Financial Penalties Regulation.
- Continue updating guidance documents focusing on the key steps of the centralised procedure.
- Develop the guideline on regulatory guidelines.
- Prepare for the implementation of the electronic submission procedure (e-CTD).
- Contribute to efforts to simplify the contractual arrangements between EMEA and the National Competent Authorities for services provided to by the National Competent Authorities.

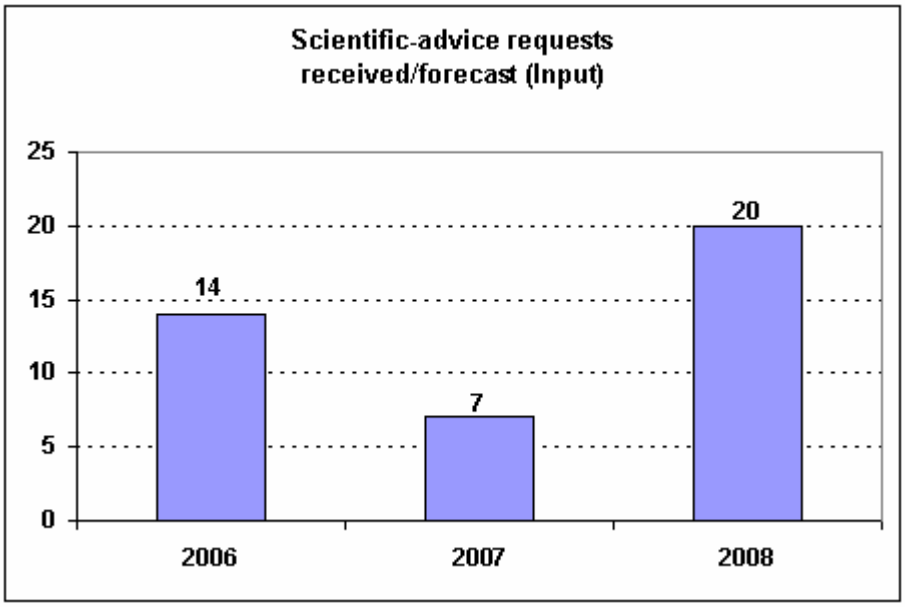
3. VETERINARY MEDICINES

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 EMEA 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

- It is anticipated that as the improvements to the scientific advice procedure continue to be recognised and appreciated by potential applicants the number of submissions made will continue to increase to around 20 per year.
- A number of the applications could be from SMEs in view of the incentives put in place by the SME Regulation and due to increased awareness resulting from the finalisation of the SME User Guide.
- There are likely to be applications for assessment of dossier requirements in relation to products for limited markets now that the guidelines on data requirements are finalised. The number of such applications is likely to increase once measures are implemented by the Agency to assist applicants in line with Article 79 of Regulation (EC) No 726/2004.



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 and initiatives implemented:

- Gain experience of operating the implementation plan of the EC/FDA confidentiality agreement with respect to providing linked or joint scientific advice with the FDA/USDA (Road Map initiative).
- Implement the results and action points resulting from the analysis of the questionnaire on satisfaction with scientific advice by applicants in 2007.

Performance indicators

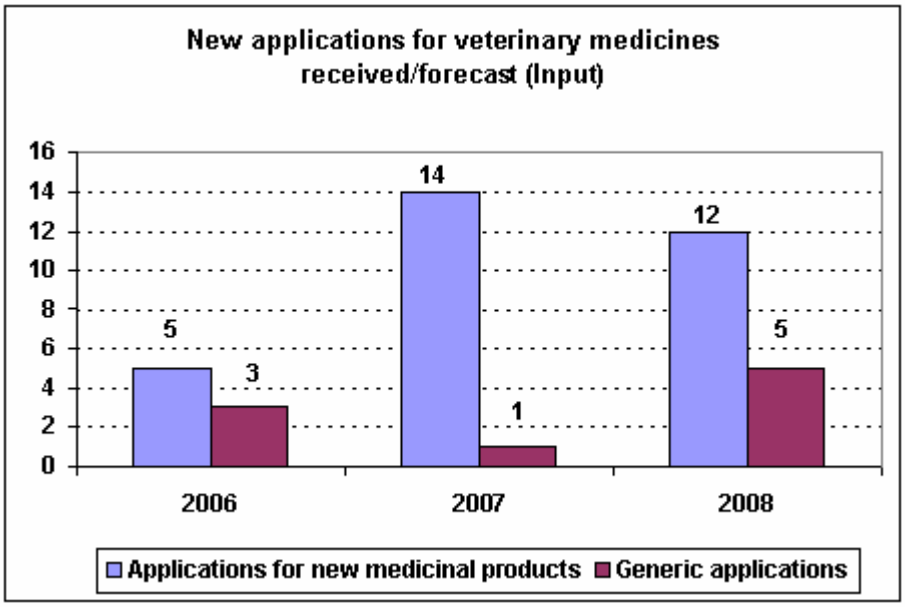
Performance indicator	Target
Scientific advice requests evaluated within the procedural timelines	90% of applications

3.2 Initial evaluation

The initial evaluation phase covers a number of EMEA 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 EMEA 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. A total of 17 applications are currently predicted in 2008. In addition, the Agency will be seeking to provide support to companies considering applications for limited markets and/or for regional diseases, which may increase the number of applications for such products. 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.



In addition to the core activity of evaluating applications for marketing authorisation, the following objectives will be targeted and initiatives implemented:

- Strengthen the quality assurance system in respect of CVMP procedures and establish systems for peer review of the quality and consistency of scientific assessments (Road Map initiative).
- Review the pilot phase for a new process to streamline preparation of the CVMP Assessment Report and EPAR and implement for all initial applications and extensions (Road Map initiative).
- Restart the survey of procedures with IFAH-Europe to assist in reacting to the IFAH Benchmarking survey conducted in 2006, using an updated questionnaire targeted at companies rather than individual products.
- Provide appropriate and timely regulatory and procedural advice and guidance documents to the pharmaceutical industry to optimise use of the centralised procedure.

Performance indicators

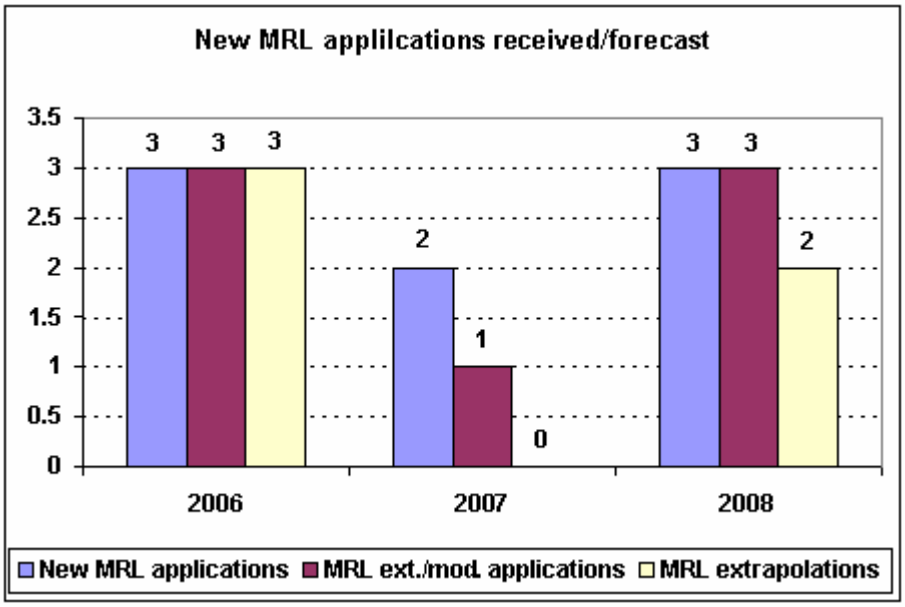
Performance indicator	Target
Percentage of products evaluated within the regulatory timeline of 210 days	100% of applications

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, to provide for the safe use of foodstuffs of animal origin, including meat, fish, milk, eggs and honey.

Trends and new issues

- Within the animal health industry, priorities are expected to remain directed predominantly to the small animal and biological sectors of the market, meaning that the number of new veterinary medicines for food-producing animals is expected to remain at a low level.
- The number of extensions has not increased over the last years, despite the initiatives taken by the CVMP to facilitate the authorisation of products for minor uses and minor species. This situation is expected to continue for 2008.
- Whilst the offer of the EMEA 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 taken up in 2007, a small number of such requests for extrapolations are expected in 2008.
- 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.



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

- Further strengthen the CVMP review process, including MRL assessments.
- Assist the Commission with finalisation of the revised MRL regulation and then implement changes introduced in the revised legislation, including revision of CVMP guidelines and procedures.
- Conduct outcomes investigations in relation to setting MRLs for injectable products for food-producing species.

Performance indicators

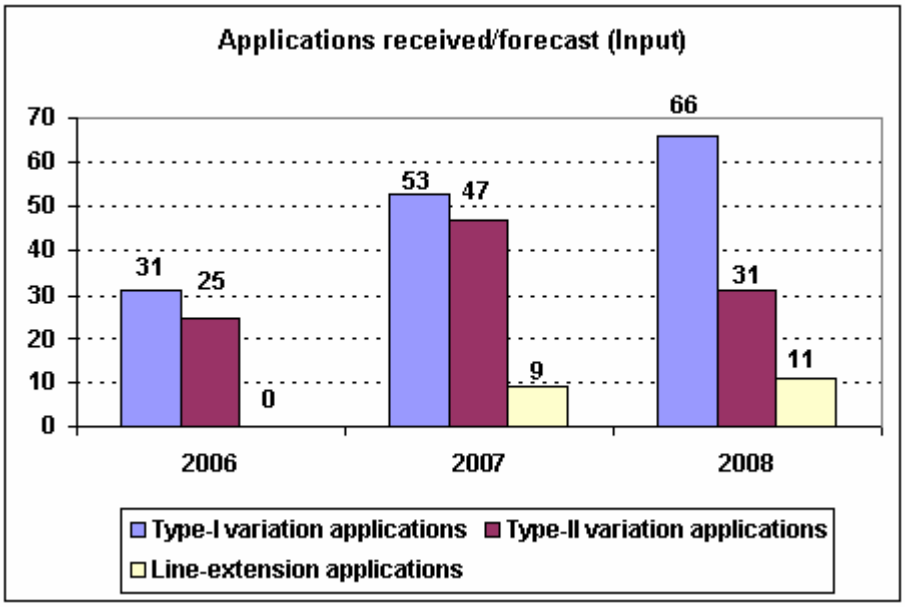
Performance indicator	Target
Percentage of applications evaluated within the 120-day timeline	100% of applications

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

- The amount of work on post-authorisation activities, such as variations and line extensions, will continue to show a long term increase in accordance with the total number of marketing authorisations and correspondingly increased number of products on the market. In terms of actual numbers a slight decrease in the number of procedures is predicted on the 2007 figures due to the short term surge in activity during last year.



In addition to the Agency's core post-authorisation activities, the following objectives will be targeted and initiatives implemented:

- Strengthen the quality and consistency of assessment of post-authorisation applications and, in particular, extensions, via implementation of the new process to streamline preparation of the CVMP Assessment Report and updates to the EPAR (Road Map initiative).
- Implement the changes introduced in the review of the variations regulations (assuming legislation amended according to proposed timescale).

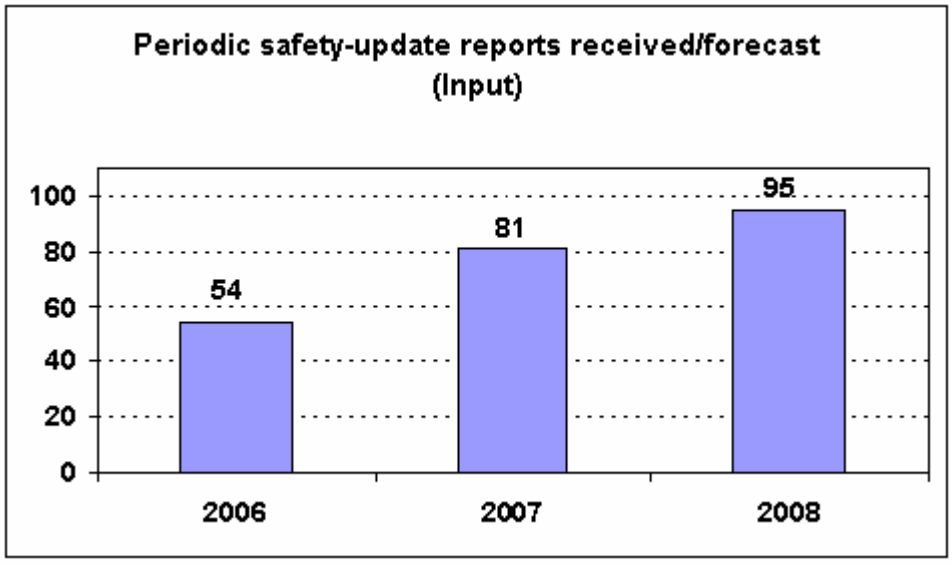
Performance indicators

Performance indicator	Target
Percentage of applications for type-I and II variations and line extensions evaluated within the regulatory timelines	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 2008, 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 2008, as in 2007 over 2006, the number of reports submitted may reach over 2,000, including approximately 95 PSURs.
- The full implementation and development of EudraVigilance Veterinary in line with the EudraVigilance Veterinary Action Plan will allow the Agency, the Member States and the veterinary pharmaceutical industry to improve and streamline the electronic exchange of pharmacovigilance information and, therefore, increase ready access to essential post-authorisation information for safeguarding public and animal health.
- The coordinating role of the Agency in processing pharmacovigilance information will be further rationalised when the EudraVigilance Veterinary Data Warehouse becomes available to all partners in 2008.

In addition to the Agency's core activities in relation to pharmacovigilance and maintenance, the following objectives will be targeted and initiatives implemented:

- Collaborate fully with the Member States to optimise efficiency in the EU regulatory network for veterinary pharmacovigilance for all medicinal products authorised in the Community, through assisting with implementation of the European Surveillance Strategy (ESS) and ensuring the effective functioning of the dual mandate of the CVMP Pharmacovigilance Working Party.
- Finalise and implement the EudraVigilance Veterinary Data Warehouse to improve processing of pharmacovigilance information in accordance with the EudraVigilance Veterinary action plan. Continue to elaborate signal-detection tools and procedures to establish the Agency's surveillance role within the EU (Road Map initiative).
- Further develop and adapt the concept of risk management plans for veterinary medicines, to support targeted pharmacovigilance (Road Map initiative).
- Finalise a review of the Rules Governing Medicinal Products of the European Union – Pharmacovigilance for Veterinary Medicinal Products, and present the outcome to the Commission for review and publishing (Road Map initiative).
- Further strengthen active communication to the professional community as well as access to data for the general public (Road Map initiative).
- Continue initiatives with interested parties, in particular the Federation of Veterinarians of Europe, to train and advise practising veterinarians in the area of pharmacovigilance (Road Map initiative).

Performance indicators

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

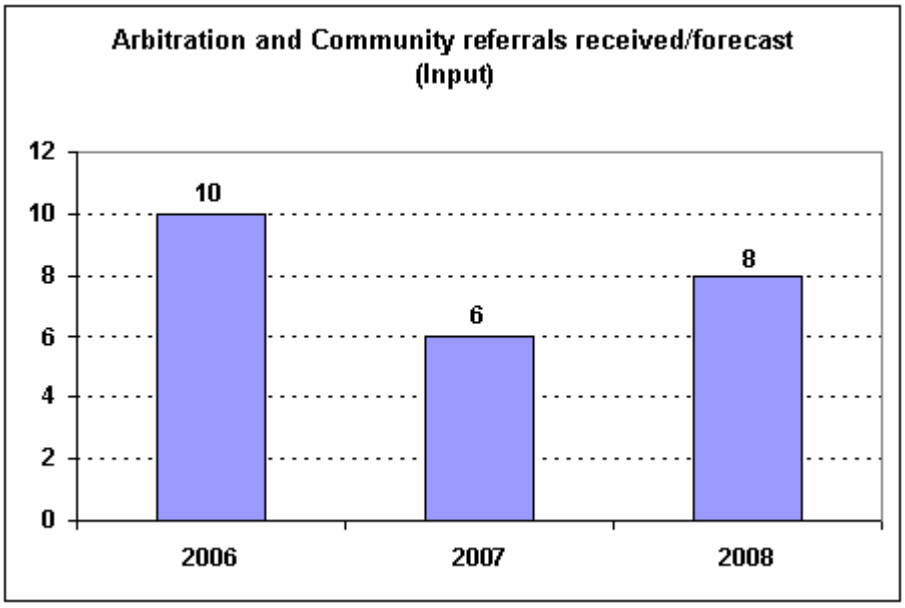
3.6 Arbitration and Community referrals

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

- Following the trend of the second half of 2007, the Agency expects to receive 2 more arbitrations and referrals than in 2007. Considering all referrals received under the new legislation, the majority relate to arbitrations (Article 33). However, more recently the EMEA received an increasing number of referrals related to public health and Community interest. Consequently, the Agency expects one Article 34 and three Article 35 referrals.
- A significant proportion of referrals relate to authorisation of generic products. Authorisation of generics is more complex for veterinary medicines than for human medicines, due to a number of additional factors that need to be considered, including consumer protection and use of the same product in different species.



In addition to the Agency's core activities in relation to provision of high-quality opinions arising from arbitration and referral procedures, the following objectives will be targeted and initiatives implemented:

- Continue to implement measures in agreement with both CVMP and CMD(v) to reduce the number of avoidable referrals.
- Update and complete guidance to Member States and marketing authorisation holders on referrals and arbitration procedures, in relation to both innovator and generic products.

Performance indicators

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

3.7 Scientific committee

The Committee for Medicinal 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.

Objectives and main initiatives

- Review, together with the CVMP and the veterinary Coordination group on mutual recognition and decentralised procedures (CMD(v)), the cooperation between these two groups, in order to ensure harmonised and consistent scientific and regulatory approaches, avoiding duplication of efforts and ensuring that arbitrations referred to the CVMP relate to scientific rather than regulatory or procedural issues.
- Promote authorisation through the centralised procedure of vaccines against epizootic diseases such as foot-and-mouth disease, bluetongue and avian influenza, by considering requests, where appropriate, for accelerated assessment or authorisation under exceptional circumstances, and by further development and implementation of the 'multistrain dossier' approach.

- Continue the work of the Committee in the priority areas of minimising the potential for the development of antimicrobial resistance through the use of veterinary medicines, by implementing the CVMP Strategy on Antimicrobials 2006-2010 and in close cooperation with international organisations active in this area, such as OIE, FAO, CODEX and WHO.
- Continue the CVMP review of the approach to consider residues at the injection site, in liaison with the European Commission and Member States, with the aim of providing a constructive contribution to the debate of the issue at international level.
- Continue the CVMP's work in promoting the availability of veterinary medicines, through playing its part in implementing the action plan arising from the HMA Taskforce on Availability and through facilitating, where possible, the authorisation of products for limited markets.
- Strengthen liaison with other scientific committees, in particular the EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed, to ensure consistency of scientific opinions for veterinary medicines and feed additives.
- Liaise with the Animal Health and Welfare Panel of the European Food Standards Agency to consider the use of veterinary medicines in the control of diseases of importance to animal health at the Community level.
- Continue the development of guidance in relation to environmental risk assessments for veterinary medicinal products.

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 enquiries from companies being considered by both the CVMP and the Coordination Group.

3.8 Coordination group

The Agency provides secretarial support to the Coordination group for mutual recognition and decentralised procedures (veterinary products) (CMD(v)) and its sub-groups/working groups.

Trend

- In general, the Agency expects that the number of decentralised procedures will be greater than in 2007, when this procedure was first introduced, and that the number of mutual recognition procedures will be maintained. However, a shift to more generics is expected, as a policy change for generics is under discussion.

Objectives and main initiatives

- Assist the chair of the CMD(v) in identifying issues that affect the efficient working of the European Regulatory Network at the level of the CMD(v), and promote the resolution of these issues through active liaison with the Heads of Medicines Agencies.
- Assist the CMD(v) to review its effectiveness in terms of mutual recognition and decentralised procedures and general operation.
- Discuss the requirements and objectives of the proposal to create a database for all regulatory and scientific decisions.

4. INSPECTIONS

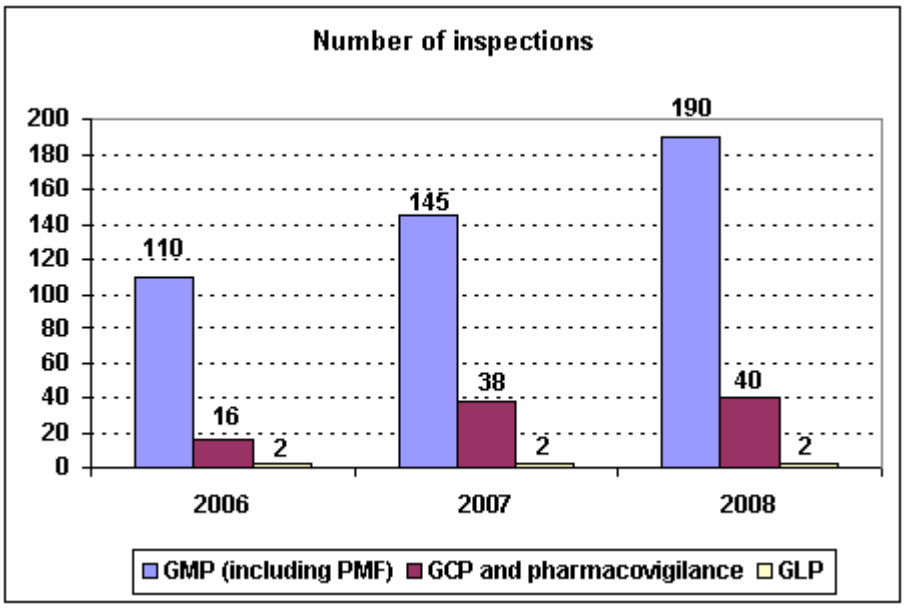
4.1 Inspections

The EMEA 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 European 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 EMEA 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 EMEA.

Trends and new issues

- GMP inspection numbers are expected to rise significantly showing an increase of over 30% compared to 2007. This takes into account the increasing number of authorised products requiring re-inspection, increasing numbers of variations, the impact of generic applications, and new requirements for GMP for active substances in accordance with the new GMP requirements. In addition, a number of inspections to support plasma-file certification are planned, contributing to about 15% of the total number.
- GCP and pharmacovigilance inspections are expected to rise relative to previous years, taking into account the GCP policy on increasing numbers of routine inspections and increasing pharmacovigilance activity, as well as the need for greater supervision of the conduct and ethical standards of clinical trials performed outside the EU.
- Increasing demand for international collaboration on worksharing of all types of inspections.
- Impact of the ICH guideline on Pharmaceutical Quality Systems.



In addition to core activities relating to effective coordination of inspections and management of quality defects, the following objectives will be targeted and initiatives implemented:

- Finalise all outstanding work arising from the 2004 legislative review.
- Develop and strengthen policies and procedures in the area of pharmacovigilance inspections (Road Map initiative).
- Improve cooperation within the European medicines network (bilateral discussions, meetings of pharmacovigilance inspectors).
- Further develop the Community database on manufacturing authorisations and GMP certificates (EudraGMP) and initial phase of the corporate GXP database.
- Assess the impact of the advanced therapy legislation on GMP, GCP and pharmacovigilance activities and review procedures in the light of experience.
- Contribute to international discussions on worksharing and cooperation on all types of inspections with FDA and WHO (initiate discussions with Health Canada) (Road Map initiative).

Performance indicators

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

Meetings of GMDP, GCP, GLP inspectors working groups and Joint CHMP/CVMP Quality Working Party

Main initiatives

- Organise training activities on GCP and quality.
- Continue developing cooperation between inspection and assessment functions, particularly through the work of the Process Analytical Technology team and joint sessions with GMP inspectors and quality assessors as well as GCP inspectors and clinical assessors.
- Develop guidelines and Community procedures on GXP-related aspects of advanced therapy legislation.
- Contribute to Community and international work on anti-counterfeiting and parallel distribution, with particular focus on improving the distribution network (Road Map initiative).
- Clarify GLP requirements in the context of bioequivalence studies.
- Develop a coordinated approach to taking action in the event of serious GMP non-compliance.
- Progress the topic of dealing with minor deviations from the marketing authorisation in the context of wider developments at Community level.
- Continue the introduction of risk management into the Compilation of Community Procedures.

4.2 Mutual-recognition agreements

Mutual-recognition agreements (MRAs) between the European Community 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 EMEA 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.

Trends and new issues

- Discussion on role and capability of EudraGMP to exchange GMP certificates.
- Impact of implementation of ICH Pharmaceutical Quality Systems in EU GMP on the activities under the MRAs.

In addition to the core activities relating to the implementation of MRAs, the following objectives will be targeted:

- Complete the remaining evaluation work (Bulgaria and Romania) and follow-up with new Member States in the context of the European Commission-Canada MRA.
- Review the impact of EudraGMP on operation of exchange of information with MRA partners.
- Review the impact of implementation of ICH Pharmaceutical Quality Systems in EU GMP on the equivalency with MRA partners.
- Implement an expanded scope of the GMP Annex with European Commission-Japan MRA and Maintenance Arrangements.
- Reinforce operational activities with Australia and New Zealand.

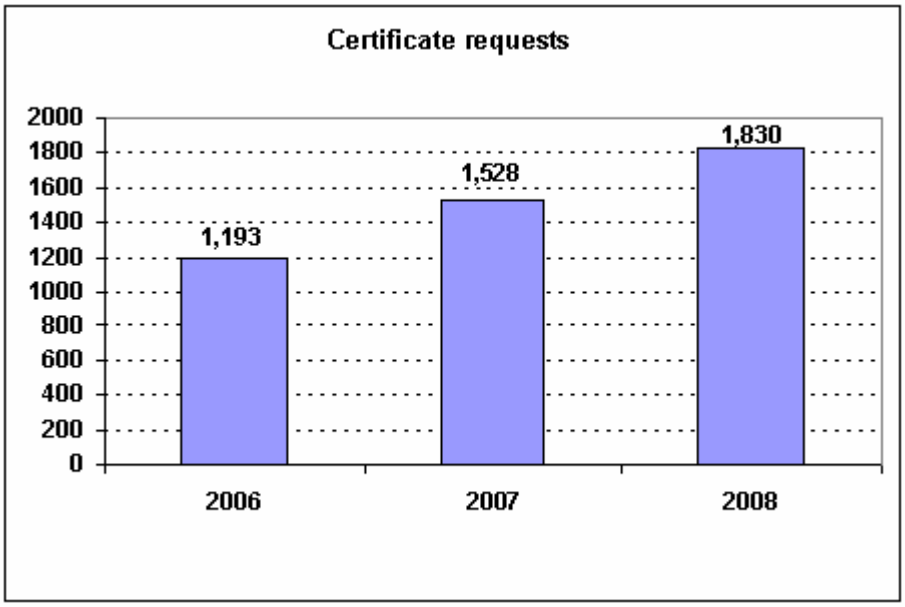
Main initiatives

- Review protocols for sharing of inspection-related information to reflect the use of EudraGMP with MRA partners. Stepwise implementation with all MRA partners.
- Intensify the dialogue with Japan on best ways to include outstanding product groups within the scope.

4.3 Certificates of medicinal products

The purpose of the EMEA scheme for certificates of medicinal products is to support the work of health authorities outside the European Union, in particular in developing countries. EMEA 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 EMEA. 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 number of certificate requests is expected to increase by 20%, due to the increased number of approved marketing authorisations. Certificates within the framework of cooperation with the WHO and certificates resulting from requests by SMEs are also expected to increase in 2008.



In addition to the core activities in the certification scheme, the following objectives will be targeted:

- Implementation of a web-based application with a view towards rationalisation and automation of the certification process.

Performance indicators

Performance indicator	Target
Percentage of certificates issued to requesting parties within the timeline	90% compliance
Implementation of web-based application	Q2 2008

4.4 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 European Directorate for the Quality of Medicines and HealthCare (EDQM). A selection of centrally authorised products is included in each annual programme.

In addition to core activities relating to the sampling and testing of centrally authorised products, the following objectives will be targeted and initiatives implemented:

- Progress the risk-based approach to the selection of products and parameters for testing, taking account of generic applications and advances in technology (process analytical technology).
- Review the received generic applications for possible impact on testing parameters and adapt the procedures for selection of products as necessary.

Performance indicators

Performance indicator	Target
Percentage of planned products (42) actually tested	95% of planned products

4.5 Implementation of the Clinical Trials Directive

Objectives and main initiatives

- Support the implementation of the Clinical Trials Directive (2001/20/EC) and the GCP Directive (2005/28/EC) for human medicines, and of the next phase of the EudraCT database incorporating aspects of the Paediatric Regulation.
- Further develop GCP-inspection-related procedures and guidelines, to enable greater harmonisation of procedures and practices (Road Map initiative).
- Provide assistance in the area of competence development.
- Cooperate with Member State competent authorities and the Commission on issues relating to the Clinical Trials Directive.
- Follow up on the 2007 conference on clinical trials (Road Map initiative).
- Upgrade functionality of the EudraCT database.

5. EU TELEMATICS STRATEGY

The EU telematics strategy for pharmaceuticals is agreed between Member States, the EMEA and the European Commission. In order to implement European pharmaceutical policy and legislation, the various initiatives aim to increase efficiency and enhance transparency, and to 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, clinical trials and good manufacturing practice. In addition, the Telematics Steering Committee has endorsed a set of horizontal services that are necessary to support the implementation of the systems mentioned.

EU telematics remains an important area in 2008, which will be the sixth year of implementation by the Agency, with national competent authorities, of the programme of projects described in the Telematics Implementation Plan. The primary responsibility for implementation lies with the Agency, under the auspices of the telematics management structure.

Trends and new issues

- External expectations for the Eudra systems (across all the stakeholder communities) continue to be very high, particularly as regards the availability of information on medicines, and the uses to which such information might be put.
- In the context of eCTD, there is a need to build appropriate interfaces to enable the integrated 'case management' tools to operate in conjunction with the Telematics systems.
- The technical details for information to be used across the European medicines regulatory network, as well as across the telematics systems, are being clarified.

Development milestones of the telematics systems in 2008

System or process	2008 milestones
EudraCT-Paediatrics Database	Extension of EudraCT to comply with the Paediatrics Regulation with regard to the submission of information.
EudraVigilance	Speed up development of EudraVigilance to deliver requested functionality and resolve known defects (iterations); complete validation of the EudraVigilance data-analysis system.
Eudra Data Warehouse	Continue development of the Eudra Data Warehouse. Provide access to the veterinarian data warehouse and data-analysis system to national competent authorities and to other stakeholders.
EU Telematics Controlled Terms	Finalisation of system development. Implementation of majority of controlled-terms lists. Maintenance.
eCTD (common technical document)	Complete development of the electronic Application Form, eAF, and maintenance of the standards. Maintenance of the eAF system for the centralised procedure; implement common electronic repository for the centralised procedure.
EudraPharm	Complete EudraPharm to Tandem Group specifications (final iteration, multilingual navigation and content, advanced search and provision for structured product information, automatic import and export facilities for NCAs (NCA version only).
EudraCT	Development and implementation of six additional areas of functionality identified by the Clinical Trials Facilitation Group.
EudraGMP	Development and implementation of module dealing with negative inspection outcome.

European Review System	Maintenance.
PIM (Product Information Management)	Centrally authorised products: ▪ Final version of PIM for centrally authorised products: Maintenance of the system and the Data Exchange Standard. Decentralised and mutual recognition products: ▪ Formal business and functional analysis to define the PIM system for extension to decentralised and mutual recognition procedures (specifications).
EudraNet	Maintenance; no further development.

The strategy, priorities, implementation plans, budget assumptions and expenditure for EU telematics are described in detail in the EU telematics master plan 2007-2013, which was submitted to the Management Board for approval at its meeting in October 2007. The Master Plan will be updated to reflect the changes introduced as a result of the second amending budget 2007 and will be submitted to the Management Board for approval at its second meeting in 2008.

Operations

Operational support has been put into place to complement the investment in systems and infrastructure over the past years. The Eudra Service Desk will continue to provide assistance to users, and may be accessed by e-mail or telephone. Appropriate structures will be maintained to provide support in accordance with the stated service levels, elements of which are set out below in the performance indicators.

Performance indicators

Performance indicator	**Target**
Project management in EU telematics	
Project delivery in accordance with stated timelines	All projects
Project delivery in line with the anticipated budget	All projects
Project deliverables perceived as being in line with expectations	All projects
Provision of service in EU telematics	
Availability of services (excluding planned maintenance downtime) (during EMEA office hours)	98%
Response time to 80% of EU telematics IT helpdesk requests	4 hours[9]
Response time to 15% of EU telematics IT helpdesk requests	2 days[9]
EudraNet availability of services (excluding local NCA downtime)	99%
Response time to 80% of EudraNet and EudraLink IT helpdesk requests	3 hours[9]
Response time to 15% of EudraNet and EudraLink IT helpdesk requests	1.5 days[9]

[9] These targets reflect the time required to fix the problem.

6. SUPPORT ACTIVITIES

6.1 Administration

Administration tasks include: managing revenue, expenditure and accounts according to existing rules and regulations; recruiting, managing and administering staff and seconded personnel; and providing and running the necessary infrastructure services for an effective functioning of the Agency. To achieve this, close cooperation is required with the European Parliament and the Council (Budgetary Authority) as well as with the Commission and the Court of Auditors on matters relating to administration, the budget, personnel and rules and regulations on finances, audit, and accounting.

Particular challenges in the area of administration in 2008

- Replacing the finance and accounting system SI2 with a new integrated system (Enterprise Resource Planning System).
- The commencement of the first-floor lease and planning of refurbishment work.
- Improving and consolidating core business areas on the basis of proposed actions and improvement plans following audits from the internal audit function, the Commission's Internal Audit Service, the Court of Auditors and BEMA.

Personnel and budget

The principal activities in the personnel and budget area include: the development and timely and accurate management of EMEA's human and financial resources, including budget estimates and management; overall financial coordination; recruitment procedures; personnel administration; and professional training, as well as the provision of information to staff and other concerned persons on these matters.

Trends and new issues

- Observed difficulty to recruit specialised contract agents for replacements and staff with high level of scientific and other qualifications due to competition from the industry and living costs in London.
- Expanded internal business-oriented and enhanced scientific training as a response to the changing role of the Agency necessitating an increased scientific input. Staff will be offered training to build on existing knowledge and to develop broad understanding of the medical/veterinary, pharmaceutical, biological and biometric body of scientific knowledge as applied to drug regulation.

In addition to core activities relating to the management of personnel and budget described above, the following objectives will be targeted and initiatives implemented:

- Continue implementation of staff regulations and management of implementing rules.
- Maintain the ex-posts control system in accordance with the EMEA standards for internal control.
- Develop and provide tailored training for financial actors.
- Prepare an outline for a 'Basic Scientific Training Programme' for EMEA staff.
- Draft a detailed syllabus based on scientific training needs for EMEA staff, i.e. a gap analysis of existing expertise within the EMEA Secretariat (Road Map initiative) and start a pilot phase for this training.

Accounts

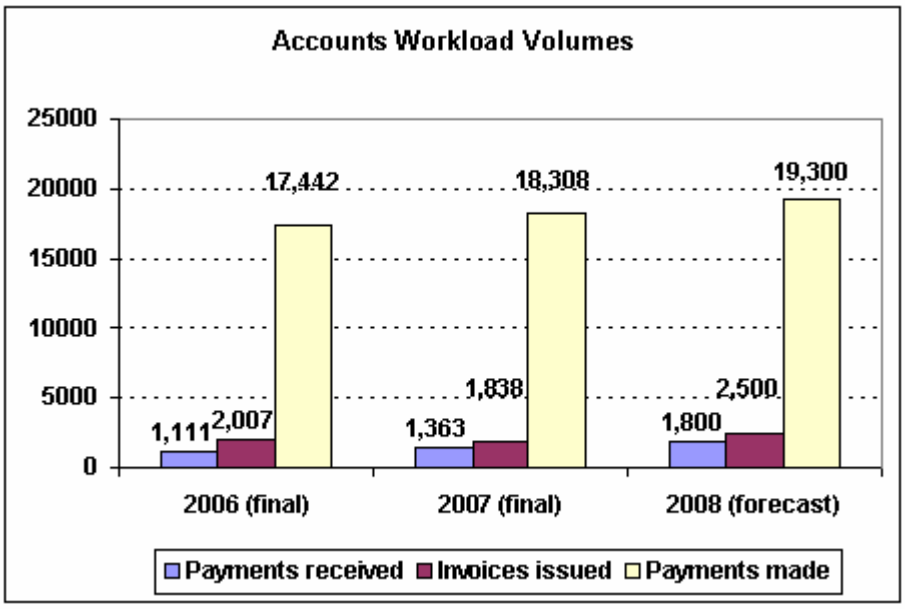
The principal activities in the accounts area include: maintaining financial and budgetary accounts; making payments and collecting revenue in accordance with the procedures laid down in the Financial Regulation; management of supplier and customer accounts; efficiently managing the cash resources of the Agency and the relationship with the Agency's banks; and providing accurate and timely financial information to management.

Trends and new issues

- Steady rise in the number of transactions year-on-year (estimated 10% increase compared to 2007).
- Recently changed invoicing system and the new fee regulation increased complexity of customer accounting and credit control activities.
- Replacement of the current EMEA finance and accounting system SI2.

In addition to the core activities in the accounts area described above, the following new objective will be targeted in 2008:

- Selection, development and testing of an integrated Enterprise Resource Planning System replacing the Agency's financial IT system SI2.

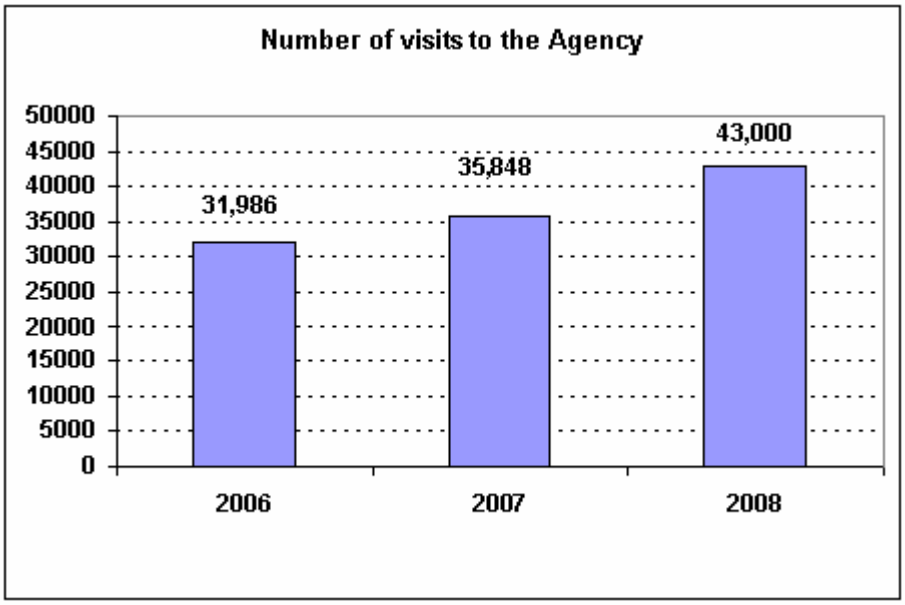


Infrastructure services at the EMEA

The Agency's main aim in the area of infrastructure services is to ensure a safe and efficient work environment for staff, delegates and visitors. The area covers a wide range of services, including office-accommodation planning and acquisition, environmental management system, contracts and procurement, security, telecommunications, reception, switchboard, archiving, mail, reprographics, technical assistance to meeting rooms, management of confidential waste, health & safety, fire and emergency planning, business continuity planning, inventory, office equipment and supplies, maintenance, refurbishment and fitting out, and management of the catering facilities.

Trends and new issues

- Responding to needs arising through increase in the number of meetings and staff. This affects accommodation planning, management of office environment, meeting room facilities and the restaurant.



In addition to the core activities of the infrastructure area described above, the following objectives will be targeted and initiatives implemented in 2008:

- Continue cooperation with other agencies and the European Commission regarding best procurement practices and the introduction of tools and methods for e-procurement.
- Start the lease for the first floor and plan the refurbishment to include a new reception area, a number of small meeting rooms and delegate offices.
- Prepare plans for the partial refurbishment of the fourth floor to reconfigure the reception area, a meeting room and the security office to provide additional office accommodation.
- Implement the environmental policy and the achievement of an environmental management system.
- Enhance the ex-post control system in accordance with the EMEA standards for internal control.
- Review business continuity and disaster recovery measures to ensure that the business continuity facilities and the back-up to essential services are tested for their appropriateness and ability to respond to any unforeseen event that may occur.

Verification Service

The Agency's verifying officer is responsible for the mandatory ex-ante verification of each operation having a financial impact. The verifying officer cannot modify the operation that has been initiated, but he verifies (the 'four eyes' principle) whether the operation is legal, regular and compliant with the principle of sound financial management. He also ensures that all tasks are carried out correctly in conformity with the requirements of the Financial Regulation, the Fees and/or the Staff regulations and their implementing rules, the VO Charter and other working instructions in force.

Main trends and new issues

- Decentralisation of verification function and further implementation of new ex-post verification functions.

In addition to the core activities of the verification service described above, the following objectives will be targeted in 2008:

- Finalise the implementation and the coordination of the decentralised ex-ante verification, including new reporting tools.
- Implement new type of ex-post controls.
- Provide training on ex-ante and ex-post verification for financial actors based on checklists tailor-made for different services and actors.
- Review the checklists of the decentralised verification.

6.2 Implementation and operation of corporate IT

Information Technology (IT) has progressed from being a facility and a service provider to being a business enabler through collaboration with the Agency's senior management. IT will continue to extend this principle in 2008 through working in direct partnership with the business in order to develop and implement a range of critical applications. The principle of partnership also applies directly to the operational support of all existing applications whereby IT must work with the business to define the levels of service and the necessary prioritisation of Agency systems support in both routine and business continuity scenarios.

The deployment of best practice support processes based on the IT Infrastructure Library (ITIL) service management, which engages EMEA users to work in partnership with IT to the benefit of all concerned, will be progressed in 2008. This will ensure the provision of reliable and robust IT services to its staff, delegates and all users of pan-European systems. Improvements will be made to the support and Service Desk functions and also to the archiving and back-up of data, while maintaining a high level of security and confidentiality for all data held on EMEA systems. In addition, new services and improvements to the infrastructure as required from business and users alike are constantly introduced, taking into account prevailing technological trends to ensure that infrastructure and facilities are continually improved.

The maintenance and operational support of both corporate and EU telematics applications, and the development of the new EU telematics projects, must be fully aligned to the EMEA's long-term business strategy as set out in the Road Map.

Trends and new issues

- The requirement to provide and maintain a paperless meeting-room environment that is both effective and secure will be a major undertaking in 2008, based around the consolidation of

MMD. The extended implementation of MMD across the whole Agency will lead to modified and harmonised working methods and procedures.

- Guarantee of higher overall service availability to the business in both normal and abnormal circumstances whereby business continuity has to be invoked. The overall trend in 2008 is for IT to provide high levels of service availability and good IT quality of service utilising appropriate ITIL business processes.
- Significant impact on the size and capacity of IT facilities and EMEA processes results from: a large number of external users of EMEA IT facilities (delegates and staff accessing EMEA systems remotely), increased connectivity and complexity of both telematics and corporate IT systems, and migration to all-electronic workflow for product lifecycle.

In addition to the core activities in the areas of corporate IT operation, maintenance and development, the following projects will be advanced:

- The critical project for IT is the implementation of Phase 4 of the business-continuity IT solution to support a range of disaster recovery scenarios. This will include deployment of a new back-up and storage system as part of one overall integrated business-continuity solution. A key component of the solution includes location-independent working, which will be supported by additional Citrix facilities.
- Development of unified telecommunications environment based around telephony, videoconferencing and integration with current IT systems. It also includes extending virtual meetings solutions in line with specific meeting requirements.
- Enhancement of the electronic document management system (Managing Meeting Documents, e-Collaboration and setting up workflows).
- Enhancement of the electronic records management system.
- Complete elaboration phase of the development of the Enterprise Resource Planning System (SI2 replacement system).
- Development of other EMEA core applications such as paediatrics, SIAMED II and further enhancements to the scientific advice database, which will be extended for use by the veterinary database, the corporate GXP-inspections database and a number of other specific medicinal applications and administrative databases.

Performance indicators

Performance indicator	**Target**
Percentage of systems 'downtime'	0.01%
Percentage of user satisfaction	95%
Delivery of IT projects against plan and budget	95%
Effective transition to production/operation	95%
Corporate availability of services (excluding planned maintenance downtime)	99.5%
Response time to 80% of corporate IT ServiceDesk requests	2 hours[10]
Response time to 15% of corporate IT ServiceDesk requests	1 day[10]

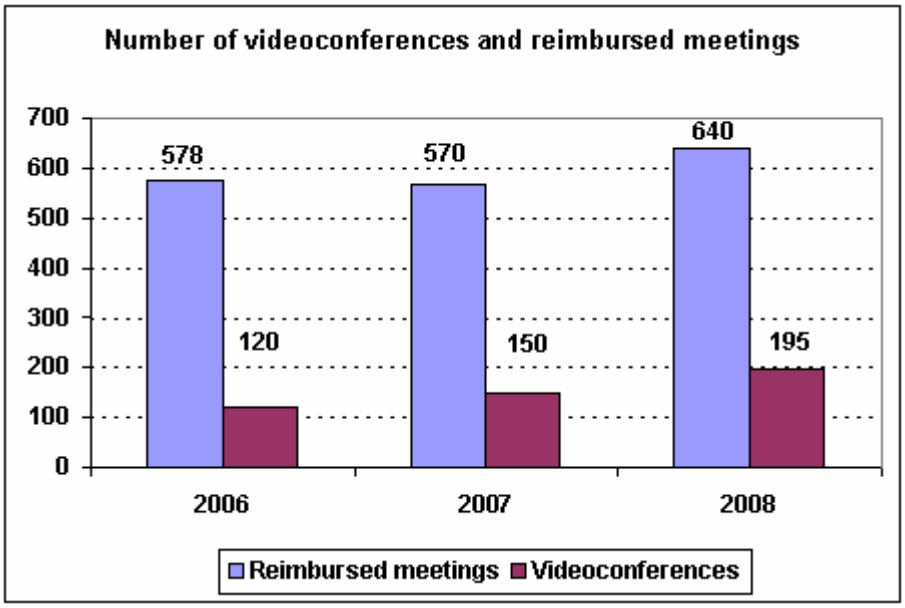
[10] These targets reflect the time required to fix the problem.

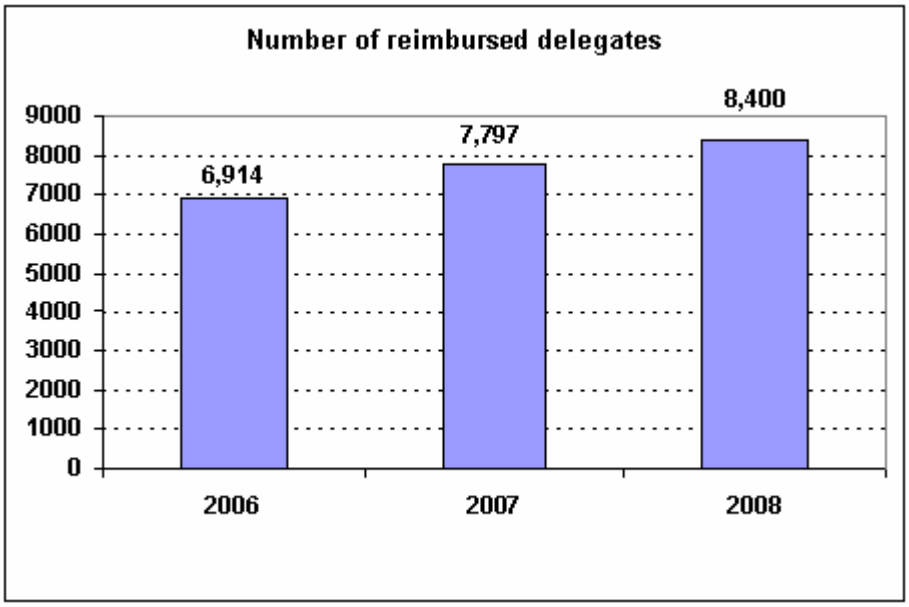
6.3 Meetings and conferences at the EMEA

The EMEA ensures efficient support for meetings organised by the Agency, provides facilities and services, and constantly improves the resources available. The Agency assists delegates with logistics and practical arrangements. This includes organisation of meetings, organisation of travel and hotel arrangements for delegates and hosts, reception of visitors, reimbursement of delegates' expenses, and payment of suppliers' invoices, as well as preparation and follow-up of meeting-room facilities.

Trends and new issues

- The environmental factors affecting the number of meetings are: the establishment of the Paediatric Committee (the Committee will hold more meetings than in 2007 since this will be its first full year of operation), the future Committee for Advanced Therapies and the increased number of applications leading to additional meetings with applicants. The number of meetings is forecast to increase by 12% and the number of reimbursed delegates by 8%.
- The Agency will maintain its readiness to organise emergency meetings in case of flu pandemic or any business continuity requirement.
- Strong pressure for alternatives to conventional meetings.





In addition to the core activities in the area of meetings management, the following objectives will be targeted:

- Implement the new reimbursement rules for meeting expenses
- Improve videoconferencing facilities and communication tools, e.g. meeting web-broadcasting and net meetings. These facilities will be developed mainly for use by national competent authorities and EMEA experts in order to facilitate communication and ultimately to reduce the number of reimbursed meetings.
- Investigate alternative strategies to accommodate delegates in London during busy periods.
- Launch the electronic Meeting Management System (MMS-E) enabling web-based management of hotel and flight bookings by delegates.
- Provide monthly payment information to national competent authorities in order to monitor the efficiency of the use of the budget.

Performance indicators

Performance indicator	**Target**
Satisfaction of interested parties (delegates, national authorities, suppliers)	95%
The percentage of delegates using MMS-E system by the end of 2008	80%

6.4 EMEA document management and publishing

The Agency ensures full compliance with all regulatory and quality requirements in the areas of document and records management. This includes: ensuring best practice in document and records management; ensuring best practice in the areas of access to information and documents; providing staff with the most effective access to internal and external information needed to perform their professional duties; verifying the accuracy of translations (excluding medical product information); and organising and supporting the Agency's exhibitions.

Trends and new issues

- The number of requests for information has been growing steadily over the years and the nature of questions has become increasingly complex. The Agency estimates requests for access to information will increase by 29% (to 4,500 requests).
- There may be a 68% increase in requests for access to documents (to 155 requests including appeals, where a single request may encompass hundreds of documents).
- The number of translation jobs is estimated to increase by 38% and the number of translated pages by 43%.

In addition to core activities in the areas of document management and publishing, records management, and revision of quality of translations, the following initiatives are foreseen:

- Start a programme for the upgrading of information management practices at the Agency.
- Review policies and budget in relation to access to documents and information.
- Review policies in relation to translation services.
- Review terminology database and translation memory.

Performance indicators

Performance indicator	**Target**
Percentage of requests for information processed within established timelines	95%
Percentage of requests for documents processed within established timelines	95%
Percentage of translations processed within established timelines	100%

ANNEXES

Annex 1 EMEA establishment plan 2006-2008

Function group & Grade	Occupied as per 31.12.06		Authorised for 2007		Requested for 2008[11]	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	1	-	1	-	1
AD 15	-	3	-	3	-	3
AD 14	-	3	-	4	-	4
AD 13	-	4	-	4	-	5
AD 12	-	33	-	34	-	34
AD 11	-	33	-	33	-	33
AD 10	-	33	-	34	-	33
AD 9	-	11	-	13	-	20
AD 8	-	32	-	36	-	41
AD 7	-	38	-	43	-	43
AD 6	-	8	-	12	-	22
AD 5	-	-	-	10	-	9
Total grade AD	*0*	*199*	*0*	*227*	*0*	*248*
AST 11	-	-	-	-	-	-
AST 10	-	6	-	6	-	6
AST 9	-	2	-	2	-	2
AST 8	-	10	-	10	-	11
AST 7	-	12	-	14	-	14
AST 6	-	30	-	30	-	33
AST 5	-	29	-	32	-	34
AST 4	-	50	-	54	-	56
AST 3	-	20	-	24	-	26
AST 2	-	9	-	10	-	19
AST 1	-	28	-	32	-	26
Total grade AST	*0*	*196*	*0*	*214*	*0*	*227*
Grand Total	**0**	**395**	**0**	**441**	**0**	**475**

[11] Excluding the six additional posts for paediatrics legislation as per decision of the Management Board (EMEA/MB/244582/2007).

Annex 2 Revenue and expenditure overview 2006–2008

		2006[12]		2007[13]		2008 DB[14]	
		€ '000	%	€ '000	%	€ '000	%
Revenue							
Fees		94,556	*67.03*	108,570	*66.56*	126,318	*72.89*
General EU contribution		22,107	*15.67*	20,174	*12.37*	14,589	*8.42*
EU contribution for SME policy		1,826	*1.29*	3,015	*1.85*	3,695	*2.13*
EU contribution for paediatrics policy		0	*0.00*	2,647	*1.62*	4,944	*2.85*
EU contribution for IT Telematics strategy		8,000	*5.67*	13,808	*8.47*	8,772	*5.06*
Special EU contribution for orphan medicinal products		6,633	*4.70*	6,000	*3.68*	6,000	*3.46*
Contribution from EEA		618	*0.44*	904	*0.55*	765	*0.44*
Community programmes		498	*0.35*	706	*0.43*	600	*0.35*
Other		6,820	*4.84*	7,289	*4.47*	7,624	*4.40*
TOTAL REVENUE		**141,059**	*100.00*	**163,113**	*100.00*	**173,307**	*100.00*
Expenditure							
Staff							
11	Staff in active employment	40,544	*29.78*	47,259	*28.97*	54,411	*31.40*
13	Mission expenses	525	*0.39*	660	*0.40*	639	*0.37*
14	Socio-medical infrastructure	399	*0.29*	459	*0.28*	603	*0.35*
15	Exchange of civil servants and experts	1,002	*0.74*	1,205	*0.74*	2,437	*1.41*
16	Social welfare	3	*0.00*	55	*0.03*	55	*0.03*
17	Entertainment and representation expenses	30	*0.02*	37	*0.02*	38	*0.02*
18	Staff insurances	1,205	*0.89*	1,457	*0.89*	1,657	*0.96*
	Total Title 1	*43,709*	*32.10*	*51,132*	*31.35*	*59,840*	*34.53*
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	17,159	*12.60*	16,740	*10.26*	15,618	*9.01*
21	Expenditure on data processing	14,490	*10.64*	25,460	*15.61*	20,502	*11.83*
22	Movable property and associated costs	1,011	*0.74*	3,148	*1.93*	1,617	*0.93*
23	Other administrative expenditure	632	*0.46*	792	*0.49*	861	*0.50*
24	Postage and communications	661	*0.49*	983	*0.60*	1,048	*0.60*
25	Expenditure on formal and other meetings	54	*0.04*	75	*0.05*	79	*0.05*
	Total Title 2	*34,007*	*24.98*	*47,198*	*28.94*	*39,725*	*22.92*
Operational expenditure							
300	Meetings	6,093	*4.48*	7,144	*4.38*	8,156	*4.71*
301	Evaluations	49,431	*36.31*	53,632	*32.88*	60,406	*34.85*
302	Translation	2,110	*1.55*	3,183	*1.95*	4,001	*2.31*
303	Studies and consultants	150	*0.11*	100	*0.06*	80	*0.05*
304	Publications	114	*0.08*	74	*0.05*	499	*0.29*
305	Community programmes	534	*0.39*	650	*0.40*	600	*0.35*
	Total Title 3	*58,431*	*42.92*	*64,783*	*39.72*	*73,742*	*42.55*
TOTAL EXPENDITURE		**136,147**	*100.00*	**163,113**	*100.00*	**173,307**	*100.00*

[12] Appropriation/Budget 2006 as per final accounts.
[13] Appropriation/Budget 2007 as of 31 December 2007.
[14] Appropriation/Draft Budget 2008 as adopted by the Management Board on 13 December 2007.

Annex 3 Meeting dates of the EMEA Management Board, scientific committees and Coordination Groups for Mutual-Recognition and Decentralised Procedures

Management Board meetings in 2008	
5-6 March	2 October
12 June	11 December

CHMP meetings in 2008	
21-24 January	21-24 July
18-21 February	No meeting in August
17-19 March	22-25 September
21-24 April	20-23 October
27-29 May	17-20 November
23-26 June	15-18 December

CVMP meetings in 2008	
15-17 January	15-17 July
12-14 February	No meeting in August
11-13 March	16-18 September
15-17 April	14-16 October
13-15 May	11-13 November
17-19 June	9-11 December

COMP meetings in 2008	
9-10 January	8-9 July
5-6 February	No meeting in August
4-5 March	9-10 September
8-9 April	7-8 October
13-14 May	4-5 November
10-11 June	9-10 December

HMPC meetings in 2008	
9-10 January	2-3 July
5-6 March	3-4 September
7-8 May	5-6 November

PDCO meetings in 2008	
16-18 January	2-4 July
13-15 February	27-29 August
12-14 March	17-19 September
9-11 April	15-17 October
6-8 May	12-14 November
2-4 June	10-12 Decmber

CMD(h) meetings in 2008	
21-23 January	21-23 July
18-20 February	No meeting in August
17-19 March	22-24 September
21-23 April	20-22 October
27-28 May	17-19 November
23-25 June	15-17 December

CMD(v) meetings in 2008	
17-18 January	17-18 July
14-15 February	No meeting in August
13-14 March	18-19 September
17-18 April	16-17 October
15-16 May	13-14 November
19-20 June	11-12 December

Annex 4 EMEA standing and temporary working parties and scientific advisory groups

CHMP standing and temporary working parties	*Number of plenary meetings in 2008*
Biologics Working Party	11
Blood Products Working Party	2
Efficacy Working Party	4
Gene Therapy Working Party	4
Joint CHMP/CVMP Quality Working Party	4
Pharmacogenetics Working Party	5
Pharmacovigilance Working Party	11
Safety Working Party	4
Scientific Advice Working Party	11
Vaccine Working Party	6
Working Party on Cell-Based Products	6
Working Party on Similar Biological Medicinal Products	1
EMEA/CHMP Working Group with Healthcare Professionals' Organisations	3

CHMP scientific advisory groups (SAGs)	*Number of meetings in 2008*
SAGs on anti-infectives, cardiovascular system, central nervous system, diabetes/endocrinology, diagnostics, HIV/viral diseases, oncology and medicinal products intended for non-EU markets (Article 58)	18

CHMP-associated groups	*Number of meetings in 2008*
(Invented) Name Review Group	11
Working Group on Quality Review of Documents	4
Quality Review of Documents Subgroup	11

CVMP standing and temporary working parties, and scientific advisory groups	*Number of meetings in 2008*
Efficacy Working Party	4
Environmental Risk-assessment Working Party	3
Immunologicals Working Party	3
Pharmacovigilance Working Party	6
Joint CHMP/CVMP Quality Working Party	4
Safety Working Party	4
Scientific Advice Working Party	11
Scientific Advisory Group on Antimicrobials	4

COMP focus groups	*Number of meetings in 2008*
Focus groups	2

HMPC working parties and associated groups	*Number of meetings in 2008*
Working Party on Community Monographs and Community List	6
Drafting Group on Quality	6
Drafting Group on Organisational Matters	6

Working party associated to the CHMP, COMP and HMPC	*Number of meetings in 2008*
EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	3

CMD(h) working parties	*Number of meetings in 2008*
CTS Working group	8
SPC Harmonisation Sub-group	8
Joint Pharmacovigilance WP/CMD(h) Working group	6
CMD(h)-EMEA Sub-group on Paediatric Regulation	6

GMP, GCP, GLP inspectors, PAT Team and PhV Inspectors	*Number of meetings in 2008*
GMDP inspectors working group	4
GCP inspectors working group	4
Ad hoc group of GLP inspectors	1
PAT Team Meeting	4
Ad hoc group PhV - Inspectors (Humans)	4
Ad hoc group PhV - Inspectors (Vets)	2

Annex 5 Committee Working Parties' guidelines and working documents

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

CHMP Biologics Working Party

Reference Number	Document Title	Status
CHMP/BWP/398498/05	Virus Safety Evaluation of Biotechnological Investigational Medicinal Products	Finalisation of guideline in 2008
	Concept Paper on Quality aspects of Biotechnological investigational medicinal products	Development of concept paper for external consultation
EMEA/410/01	Revision of the TSE Note for Guidance	Draft guideline for external consultation
CPMP/BWP/269/95 REV 3	Revision of the note for guidance on plasma-derived medicinal products	Ongoing discussion
CPMP/BWP/2879/02	CHMP Position Statement on Creutzfeldt-Jakob Disease and plasma-derived and urine-derived medicinal products	Revision of position statement in 2008; publication of report of 2005 and 2007 workshops
	The need for guidance on replacement of pyrogen testing by LAL testing for blood products	Development of guideline for external consultation
CHMP/BWP/99698/2007	Guideline on fast track procedure for community human influenza vaccines	Finalisation of guideline in 2008
	EU recommendations for the seasonal Influenza Vaccine Composition for the Season 2008/2009	Ongoing discussion
CPMP/BWP/214/96	Guideline on harmonisation of requirements for influenza vaccines	Discussion to be initiated in conjunction with VWP
	Guideline on stability data for cumulative storage periods for vaccines/intermediates	Discussion to be initiated
CPMP/BWP/2758/02	Note for Guidance on pharmaceutical aspects of the product literature for human vaccines	Need for revision to be discussed
	Guideline on the quality, preclinical and clinical aspects of medicinal products containing genetically modified cells.	Development of guideline for external consultation
	Guideline for DNA vaccines	Development of guideline for external consultation

	Guideline on live recombinant vector vaccines	Development of guideline for external consultation
CHMP/BWP/378448/2006	Revision of the Note for Guidance on the Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products	Discussion on possible revision
CHMP/165085/2007	Guideline on xenogeneic cell based medicinal products	Development of guideline for external consultation
CHMP/BWP/271475/2006	Guidance document for potency testing of cell based immunotherapy medicinal products for the treatment of cancer	Finalisation of guideline in 2008
CHMP/410869/2006	Guideline on Cell-based medicinal products	Finalisation in 2Q 2008
	Development of technical requirements for advanced therapy medicinal products	Input to amendment of annex I to directive 2001/83/EC, as required
CHMP/BWP/157653/2007	Revision of the guideline on Production and quality control of monoclonal antibodies and related substances	Finalisation of revision of guideline in 2008
CPMP/BWP/243/96 CHMP/BWP/304831/2007 (production and quality issues)	Revision of Guideline on allergen products	Finalisation of guideline in 2008
3AB7A	Note for Guidance on the Use of transgenic animals in the manufacture of biological medicinal products for human use	Development of a concept paper
CHMP/BWP/48316/2006	Guideline on the quality of biological active substances produced by stable transgene expression in higher plants	Finalisation of guideline in 2008
CHMP/BWP/81118/2007	Reflection Paper on proposed solution for dealing with minor deviations from the detail described in the Marketing Authorisation for Human and Veterinary Medicinal products (including biological products).	Ongoing discussion; BWP input for biological products
	Production and Quality Control of Medicinal Products Derived by Recombinant DNA Technology	Development of reflection papers
CPMP/BWP/1793/01	Note for Guidance on the use of bovine serum used in the manufacture of human biological medicinal products	Need for revision to be discussed

CHMP Blood Products Working Party

Reference Number	Document Title	Status
CPMP/BPWG/388/95 rev 1	Note for guidance on the Clinical investigation of Human normal immunoglobulin for intravenous administration (IVIg)	Revision of guideline expected to be finalised in 2008
CPMP/BPWG/1561/99	Note for guidance on the Clinical investigation of recombinant Factor VIII and IX products	Revision of guideline released for consultation in 2007 and expected to be finalised in 2008
CPMP/BPWG/198/95 rev. 1	Note for guidance on the Clinical investigation of human plasma derived Factor VIII and IX products	Revision of guideline released for consultation in 2007 and expected to be finalised in 2008.
CPMP/BPWG/283/00	Note for guidance on the Clinical investigation of Human normal immunoglobulin for subcutaneous and intramuscular use	Concept paper in 2008. Revision expected to be released for consultation in 2008.
	Guideline on the Clinical investigation of alpha1-proteinase inhibitor (alpha1 antitrypsin)	Concept paper in 2008
	Guideline on non-clinical testing for blood products	Consideration of whether guideline is needed. If needed, concept paper in 2008.
	Guideline on the Clinical investigation of recombinant Factor VIIa (eptacog)	Concept paper in 2008.
	Guideline on the Clinical investigation of human C1 inhibitor	If guideline needed, concept paper in 2008
CHMP/BPWP/122007/2005	Core SPC for Human plasma derived fibrinogen products	Released for consultation in 2007; to be finalised in 2008
CPMP/BPWG/859/95 rev 2	Core SPC for Human normal immunoglobulin for intravenous administration (IVIg)	Revision expected to be finalised in 2008
CPMP/BPWG/1619/99	Core SPC for Human plasma derived and recombinant coagulation Factor VIII products	Revision released for consultation in 2007; expected to be finalised in 2008
CPMP/BPWG/1625/99	Core SPC for Human plasma derived and recombinant coagulation Factor IX products	Revision released for consultation in 2007; expected to be finalised in 2008
CPMP/BPWG/282/00	Core SPC for Human normal immunoglobulin for subcutaneous and intramuscular use	Concept paper in 2008; revision expected to be released for consultation in 2008
	Warning on transmissible agents for SPCs and patient leaflets	To provide guidance during 2008 as needed
CPMP/PhVWP/BPWG/2231/99 /Rev. 2	Core SPC for Human albumin solution	To be kept under review
	Guideline on the Core SPC for alpha1-proteinase inhibitor (alpha1 antitrypsin)	Concept paper in 2008

	Guideline on the Core SPC for recombinant Factor VIIa (eptacog)	Concept paper in 2008
	Guideline on the Core SPC for human C1 inhibitor	If guideline needed, concept paper in 2008

CHMP Efficacy Working Party

Reference Number	Document Title	Status
CPMP/EWP/633/02	Revision of Guideline on the Clinical Development of Medicinal Products for Treatment of HIV Infection	Finalisation expected in 4Q 2008/1Q 2009.
CHMP/EWP/18463/06	Guideline on Clinical Investigation of Medicinal Products for the Treatment of Ulcerative Colitis	Finalisation expected in 4Q 2007/1Q 2008
CPMP/EWP/2284/99	Revision of Points to Consider on Clinical Investigation of Medicinal Products for the Management of Crohn's Disease	Finalisation expected in 1Q/2Q 2008
CHMP/EWP/122355/07	Concept paper on the need for a Guideline on the clinical development of medicinal products for Tuberculosis	Draft guideline expected to be released for consultation in 1Q/2Q 2008
CHMP/EWP/156308/07	Concept paper on the need for a Guideline on the clinical development of medicinal products for Hepatitis C	Draft guideline expected to be released for consultation in 1Q/2Q 2008
CPMP/EWP/1343/01	Revision of the Points to Consider on the Clinical Evaluation of New Agents for Invasive Fungal Infections	Concept paper expected in 1Q 2008
CPMP/EWP/205/95 Rev. 3	Annex to the Guideline on the evaluation of Anticancer Medicinal Products in Man on Haematology Malignancies	Concept paper expected 1Q 2008
CPMP/EWP/205/95 Rev. 3	Appendix to the Guideline on the evaluation of Anticancer Medicinal Products in Man	Finalisation expected in 1Q 2008
CHMP/EWP/498145/06	Reflection Paper on Gender Effects in Cardiovascular Medicinal Products	Reflection paper expected to be finalised in 4Q 2007/1Q 2008
CHMP/EWP/327726/2005	Guideline on the evaluation of the Medicinal Substances Contained in Drug-Eluting (Medicinal Substance-Eluting) Coronary Stents within the Framework of a Consultation Procedure for Combination Products	Finalisation expected in 1Q/2Q 2008
CHMP/EWP/311890/07	Guideline on Clinical investigation of medicinal products for Secondary Prevention of Cardiovascular Events	Finalisation expected in 2Q/3Q 2008

Reference Number	Document Title	Status
CPMP/EWP/237/95	Revision of Guideline on Antiarrhythmics	Draft revised guideline to be released for consultation in 1Q 2008
CPMP/EWP/1080/00	Revision of Guideline on Clinical Investigation of Medicinal Products in the Treatment of Diabetes Mellitus	Revision to be reconsidered in 1Q 2008
CPMP/EWP/1119/98	Revision of Guideline on the Evaluation of Diagnostic Agents	Draft guideline expected to be released for consultation in 1Q/2Q 2008
CPMP/EWP/4891/03	Guideline on clinical investigation of medicinal products for treatment of ankylosing spondylitis	Finalisation expected in 4Q 2007/1Q 2008
CPMP/EWP/784/97	Points to Consider on Clinical Investigation of Medicinal Products used in the Treatment of Osteoarthritis	Revision to be considered in 2008
CHMP/EWP/356538/2005	Guideline on the development of new products for the treatment of Nicotine Dependence	Finalisation expected in 2Q/3Q 2008
CHMP/EWP/358650/2006	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Post-Traumatic Stress Disorder	Finalisation expected in 2Q/3Q 2008
CHMP/EWP/310566/07	Recommendation for Revision of the Guideline on Clinical Investigation of Hypnotic Medicinal Products	Draft guideline expected to be released for consultation in 1Q/2Q 2008
CHMP/EWP//	Guideline on the development of new products for the treatment of Alcohol Dependence	Draft guideline expected to be released for consultation in 2Q/3Q 2008
CPMP/EWP/565/98	Points to Consider on Clinical Investigation of Medicinal Products for the Treatment of Amyotrophic Lateral Sclerosis	Revision to be considered in 2008
CPMP/EWP/566/98	Note of Guidance on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders	Draft guideline expected to be released for consultation in 2Q/3Q 2008
CPMP/EWP/553/95	Revision of Guideline on Medicinal Products in the Treatment of Alzheimer's Disease	Finalisation expected in 2Q/3Q 2008
CPMP/EWP/563/95	Revision of Guideline on Clinical Investigation of Medicinal Products in the Treatment of Parkinson's Disease	Finalisation expected in 2Q/3Q 2008

Reference Number	Document Title	Status
	Annex to the Guideline on Methodological Issues Relating to the Provision of Clinical Data on Efficacy and Safety for Conditional Marketing Authorisations	Draft expected in 1Q/2Q 2008
CPMP/EWP/1776/99	Points to Consider on Missing Data	Release for public consultation expected in 2Q/3Q 2008
CHMP/EWP/213035/07	Concept Paper on Biowaivers	Draft guideline expected to be released for consultation in 4Q 2007/1Q 2008
CPMP/EWP/QWP/1401/98	Need for revision of the Note for Guidance on the Investigation of Bioavailability and Bioequivalence	Draft guideline expected to be released for consultation in 4Q 2007/1Q 2008.
	Concept paper on the need for a Guideline on the clinical development of medicinal products for Cystic Fibrosis	Draft guideline expected to be released for consultation in 1Q 2008
CPMP/EWP/4151/00	Q&A on the Guideline on the requirements for clinical documentation for Orally inhaled products (OIP)	Draft guideline expected to be released for consultation in 4Q 2007/1Q 2008
CHMP/EWP/15263/2006	Guideline on the clinical development of products for specific immunotherapy for the treatment of Allergic Diseases	Draft released for consultation in May 2007; finalisation expected in 2Q 2008
CHMP/EWP/263148/2006	Guideline on clinical investigation of medicinal products in the Solid Organ Transplantation	Finalisation expected in 2Q/3Q 2008
CHMP/EWP/7799/2007	Guideline on Extrapolation Results in Clinical Studies to the EU-Population	Draft guideline expected to be released for consultation in 1Q/2Q 2008
CPMP/EWP/707/98	Revision of the Guideline on Clinical Investigation of Medicinal Products for Prophylaxis of Intra- and Post-operative Venous Thromboembolic Risk	Draft guideline released for consultation in November 2006; finalisation expected in 4Q 2007/1Q 2008
	Guideline on Fixed Combination Medicinal Products	Revision to be considered in 2008

CHMP Gene Therapy Working Party

Reference Number	Document Title	Status
CPMP/BWP/3088/99	Note for guidance on quality, preclinical and clinical aspects of gene transfer medicinal products	Ongoing survey of current relevant issues; possible revision of the guideline
EMEA/GTWP/158090	Reflection paper on scientific criteria for qualification as gene therapy medicinal products	Finalisation in 1Q 2008

EMEA/58311/2007	Guideline on the quality, preclinical and clinical aspects of medicinal products containing genetically modified cells	Draft guideline expected to be released for consultation in 1Q/2Q 2008.
EMEA/CHMP/GTWP/125459/ 2006	Guideline on non-clinical studies required before first clinical use of gene therapy medicinal products	Finalisation expected in 1Q/2Q 2008
EMEA/GTWP/60436/2007	Guideline on clinical monitoring and follow-up of patients exposed to gene therapy/gene transfer medicinal products	Draft guideline expected to be released for consultation in 1Q/2Q 2008
EMEA/CHMP/GTWP/125491/ 2006	Guideline on scientific requirements for the environmental risk assessment of gene therapy medicinal products	Finalisation expected in 4Q 2007/1Q 2008
EMEA/GTWP/405677/2006	Guideline on live recombinant vectored vaccines	Draft guideline expected to be released for consultation in 4Q 2008

CHMP Pharmacogenetics Working Party

Reference Number	Document Title	Status
	Reflection Paper on the use of Pharmacogenetics in the Pharmacokinetic evaluation of medicinal products	Discussion on the need to revise the current reflection paper 3Q 2008
	Reflection Paper PG testing in drug development in EU	Draft expected to be released for consultation in 4Q 2008
	Reflection Paper: Pharmacogenomics EMEA Experience in oncology	Finalisation in 2Q 2008
	SPC Guideline	Finalisation of contribution on genomics information in 3Q 2008

CHMP Pharmacovigilance Working Party

Reference Number	Document Title	Status
Volume 9A Chapter II.2.A	Conduct of Pharmacovigilance for Centrally Authorised Products	In 2008: 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 2008: Revision taking into account revised CHMP/PhVWP procedures and EU Incident Management Plan, for public consultation
	Conduct of Pharmacovigilance for Vaccines for Pre- and Post-Exposure Prophylaxis Against Infectious Diseases	In 2008: Finalisation of draft Guideline following public consultation in 2008

	Guidelines in relation to public communication of pharmaco-vigilance information	In 2008: Continued development of Concept Papers and Guidelines in the context of overall EMEA communication and transparency strategy, which is currently under development in order to implement the revised Legislation. Issues previously raised by the PhVWP in relation to the transmission of PhVWP reports for nationally authorised products to marketing authorisation holders will be taken into account
	Criteria for recall and repackaging following urgent safety restriction and variation procedures	In 2008: Development of criteria for discussion by CHMP as contribution to appropriate Guideline
CPMP/PhVWP/135/00	Standard Operating Procedure for the Review of CPMP Scientific Advice by the CPMP Pharmacovigilance Working Party	In 2008: Revision with view to Risk Management Plans, if considered necessary in the light of experience gained

CHMP Safety Working Party

Reference Number	Document Title	Status
EMEA/CHMP/SWP/169215/2005	Guideline on the Need for Non-clinical Testing in Juvenile Animals on Human Pharmaceuticals for Paediatric Indications	Guideline expected to be finalised in 2Q 2008
EMEA/CHMP/SWP/150115/2006	Guideline on Detection of Early Signals of Drug-Induced Hepatotoxicity in Non-Clinical Studies	Guideline/reflection paper expected to be re-released for consultation in 2Q 2008 and finalised in 2008-2009
CPMP/SWP/QWP/4446/00	Guideline on Specification Limits for Residues of Metal Catalysts in Medicinal Products	Guideline expected to be finalised in 4Q 2008
EMEA/CHMP/SWP/203927/2005	Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling	Guideline expected to be finalised in 4Q 2007/1Q 2008
	Reflection Paper on the In-Vitro Investigation of Mitochondrial Toxicity of Anti-HIV Nucleoside Reverse Transcriptase Inhibitors	Reflection paper expected to be finalised in 1Q 2008
	Guideline on the Development of a CHMP Guideline on the Non-Clinical Requirements to Support Early Phase I Clinical Trials with Pharmaceutical Compounds	Draft guideline expected to be released for consultation in 4Q 2008

	Genotoxic Impurities: Q & A document	To be considered for revision in 2008
CPMP/SWP/104/99	Note for Guidance on Repeated Dose Toxicity	Under revision; expected to be finalised in 2008
Eudralex vol. 3B3BS1A	Note for Guidance on Single Dose Toxicity	Possible revision depending on ICH M3
CPMP/372/01	Points to Consider on the Non-Clinical Assessment of the Carcinogenic Potential of Insulin Analogues	Possible revision depending on ICH S6
CPMP/SWP/398/01	Note for Guidance on Photosafety Testing	To be considered for revision in 2008

CHMP Scientific Advice Working Party

Reference Number	Document Title	Status
	EMEA-FDA parallel scientific advice pilot programme: general principles	To be revised in agreement with FDA; finalisation 4Q 2008/1Q 2009

CHMP Similar Biological (Biosimilar) Medicinal Products Working Party

Reference Number	Document Title	Status
EMEA/CHMP/BMWP/102046/2006	Guideline on similar medicinal products containing recombinant α-Interferons Guideline	End of external consultation 1Q 2008; finalisation of guideline expected in 2Q 2008
CHMP/BMWP/496286/06	Guideline on similar biological medicinal products containing low molecular weight heparins	End of external consultation 1Q 2008; finalisation of guideline expected in 3Q/4Q 2008

CHMP Vaccine Working Party

Reference Number	Document Title	Status
	Guideline on live recombinant vector vaccines	Concept paper released for consultation in July 2007; guideline to be released for consultation in 4Q 2008
	Guidance for DNA vaccines	Concept paper released for consultation in July 2007; guideline to be drafted in 2008
	Guidance on conjugate vaccines	Concept paper to be released for consultation in 2Q 2008
	Reflection paper on seasonal influenza vaccines – clinical data for annual strain update	To be released for consultation in 4Q 2008
EMEA/CPMP/VEG/4717/03	Guideline on Dossier Structure and Content for Pandemic Influenza Vaccine Marketing Authorisation Application	Draft guideline (EMEA/CHMP/166042/2007) expected to be released for consultation in 1Q 2008
CHMP/VEG/193031/04	Core SPC for Pandemic Influenza Vaccines	Revision as required. In conjunction with revision of (EMEA/CHMP/166042/2007)

CHMP Working Party on Cell-based Products

Reference Number	Document Title	Status
EMEA/CHMP/410869/2006	Guideline on Cell-based medicinal products	Finalisation in 1Q/2Q 2008
	Guideline on xenogeneic cell-based medicinal product (revision of the Point to Consider on xenogeneic cell therapy medicinal products)	Draft guideline to be released for consultation in 1Q/2Q 2008
	Concept paper on a Guideline on Post-Marketing Surveillance of cell-based medicinal products	Concept paper to be released for consultation in 1Q/2Q 2008
	Refection paper on stem cell products	Draft reflection paper to be released for consultation
	Development of technical requirements for advance therapy medicinal products	Input to amendment of annex I to directive 2001/83/EC, as required

CHMP Working Group with Health-Care Professionals' Organisations

Reference Number	Document Title	Status
EMEA/149379/2007	Recommendations and proposals for action	Draft document under preparation
EMEA/384343/2007	Framework on interaction between EMEA and HCPs' organisations	Draft document under preparation
EMEA/42240/2007	Criteria to be fulfilled by HCPs' organisations involved in EMEA activities	Draft document agreed by working group
EMEA/421182/2006	Mandate and Rules of Procedure	Expected revision
EMEA/161660/2005	Rules of Involvement of Members of Patients' and/or Consumers' Organisations in Committees Related Activities	Expected revision to include HCPs' organisations
	Workplan 2008	Document adopted by the group

CHMP Invented Name Review Group

Reference Number	Document Title	Status
EMEA/CPMP/328/98 Rev 5	Guidelines on the acceptability of invented names for medicinal products processed through the centralised procedure	Finalisation in Q1 2008
EMEA/CHMP/186988/2007	Mandate and Rules of Procedure	Draft document under preparation

Committee on Herbal Medicinal Products (HMPC)

Reference Number	Document Title	Status
EMEA/HMPC/214869/2006	Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products	For finalisation (expected 1Q 2008)
	Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the labelling	Under preparation (release for consultation expected 1-2Q 2008)
	Reflection paper on proper use of dosage forms specific to (traditional) herbal medicinal products	To be developed (release for consultation expected 1-2Q 2008)
	Reflection paper on marker substances	To be developed (release for consultation expected 1-2Q 2008)
	Questions & Answers document on contaminants in herbal medicinal products and herbal substances/preparations	To be developed (release for consultation expected 3-4Q 2008)
EMEA/HMPC/151144/2005	Overview of Questions and Answers relating to technical/scientific issues	Revision as needed (new technical/scientific issues raised)
EMEA/HMPC/107079/2007	Guideline on the assessment of genotoxic constituents in herbal substances/preparations	Under preparation (release for consultation expected 1-2Q 2008)
	Reflection paper on ethanol as part of the active substance in herbal preparations used in children	To be developed (release for consultation expected 3-4Q 2008).
EMEA/HMPC/326440/2007	Reflection paper on the criteria and timelines for the revision of final Community monographs/list entries	Under preparation (release for consultation expected 1-2Q 2008)
EMEA/HMPC/328575/2007	Procedure on management of proposals submitted by interested parties for Community list entries and Community herbal monographs	For finalisation (expected 2Q 2008)
	Procedure for the adoption and transmission to the European Commission of an opinion of the Committee to vary/suspend/withdraw from the list a herbal substance, preparation or combination	To be developed.
	Procedure, timelines and templates for the adoption of an HMPC opinion on a referral on a traditional herbal medicinal product according to Article 16h(1)(c) of the Community code	To be developed.

	Procedure and templates for the adoption and transmission to the CHMP of an HMPC opinion on the herbal substance contained in a herbal medicinal product subject to a referral according to Article 16h(1)(d) of the Community code.	To be developed.
	Procedure and templates for the submission of requests for scientific support by Member States to the HMPC	To be developed.

HMPC Working Party on Community monographs and Community list

Reference Number	Document Title	Status
EMEA/HMPC/297757/2007	Community List entry on Anisi fructus	For finalisation 1-2 Q
EMEA/HMPC/202966/2007	Community Herbal Monograph on Avenae herba	For finalisation 1-2 Q
EMEA/HMPC/368600/2007	Community Herbal Monograph on Avenae fructus	For finalisation 1-2 Q
EMEA/HMPC/260019/2006	Community Herbal Monograph on Betulae folium	For finalisation 1-2 Q
EMEA/HMPC/179281/2007	Community Herbal Monograph on Calendulae flos	For finalisation 1-2 Q
EMEA/HMPC/179283/2007	Community List entry on Calendulae flos	For finalisation 1-2 Q
EMEA/HMPC/104945/2006	Community Herbal Monograph on Echinaceae purpureae herba	For finalisation 1-2 Q
EMEA/HMPC/189629/2007	Community List entry on Echinaceae purpureae herba	For finalisation 1-2 Q
EMEA/HMPC/244569/2006	Community Herbal Monograph on Eleutherococci radix	For finalisation 1-2 Q
EMEA/HMPC/83756/2007	Community List entry on Eleutherococci radix	For finalisation 1-2 Q
EMEA/HMPC/99116/2007	Reflection paper on the adaptogenic concept	For finalisation 1-2 Q
EMEA/HMPC/394894/2007	Community Herbal Monograph on Equiseti herba	For finalisation 1-2 Q
EMEA/HMPC/513617/2006	Community Herbal Monograph on Lupuli flos	For finalisation 1-2 Q
EMEA/HMPC/193909/2007	Community Herbal Monograph on Menthae piperitae folium	For finalisation 1-2 Q
EMEA/HMPC/354177/2007	Community Herbal Monograph on Meliloti herba	For finalisation 1-2 Q
EMEA/HMPC/295338/2007	Community Herbal Monograph on Salicis cortex	For finalisation 1-2 Q
EMEA/HMPC/283166/2007	Community Herbal Monograph on Sambuci flos	For finalisation 1-2 Q
EMEA/HMPC/285758/2007	Community Herbal Monograph on Solidaginis virgaureae herba	For finalisation 1-2 Q
EMEA/HMPC/261938/2007	Community Herbal Monograph on Rusci aculeati rhizoma	For finalisation 1-2 Q
EMEA/HMPC/170261/2006	Community Herbal Monograph on Urticae herba	For finalisation 1-2 Q

EMEA/HMPC/395213/2007	Community Herbal Monograph on Verbasci flos	For finalisation 1-2 Q
	Community Herbal Monograph /Community List Entry on Absinthii herba	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph /Community List Entry on Althaeae radix	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph/ Community List Entry on Boldo folium	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph/ Community List Entry on Carvi fructus	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph/ Community List Entry on Centaurii herba	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph/ Community List Entry on Cimicifugae rhizoma	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph /Community List Entry on Cynarae folium	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph /Community List Entry on Hamamelis cortex	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph/ Community List Entry on Hamamelis folium	Draft t be released for public consultation 1-2 Q
	Community Herbal Monograph /Community List Entry on Hamamelis folium et cortex, distillate	Draft to be released for public consultation 1-2 Q
EMEA/HMPC/251323/2006	Community Herbal Monograph on Harpagophyti radix	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph/ Community List Entry on Hyperici herba	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph /Community List Entry on Polypodii radix	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph /Community List Entry on Ribis nigri folium	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph/ Community List Entry on Urticae folium	Draft to be released for public consultation 1-2 Q
	Community Herbal Monograph /Community List Entry on Crataegi folium cum flore	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph /Community List Entry on Crataegi fructus	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph/ Community List Entry on Echinaceae angustifolia radix	Draft to be released for public consultation 3-4 Q

	Community Herbal Monograph /Community List Entry on Echinaceae pallidae radix	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph /Community List Entry on Echinaceae purpureae radix	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph /Community List Entry on Hippocastani semen	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph/ Community List Entry on Primula/Thyme	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph /Community List Entry on Rosmarini folium	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph/ Community List Entry on Salviae folium	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph /Community List Entry on Taraxaci radix cum herba	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph/ Community List Entry on Urticae radix	Draft to be released for public consultation 3-4 Q
	Community Herbal Monograph /Community List Entry on Zingiberis rhizoma	Draft to be released for public consultation 3-4 Q

Committee for Orphan Medicinal Products (COMP)

Guideline content to be determined by COMP during 2008.

Paediatric Committee (PDCO)

Guideline content to be determined by PDCO during 2008.

Committee for Advanced Therapy medicinal products (CAT)

Guideline content to be determined by CAT during 2008.

EMEA Human Scientific Committees Working Party with Patients and Consumers' Organisations

Reference Number	Document Title	Status
EMEA/161660/2005	Rules for involvement of members of patients' and/or consumers' organisations in committees related activities.	Expected revision of adopted document to include HCPs' organisations

Other EMEA Scientific Committees and Working Party Guidelines

Reference Number	Document Title	Status
EMEA/382712/2006	EMEA Guidance on pre-submission meetings for initial marketing authorisation applications for human medicinal products in the centralised procedure	Final version to be published Q1 2008
EMEA/509951/2006	Guideline on the scientific application and the practical arrangements necessary to implement Commission Regulation (EC) No. 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004	Final version to be published Q2 2008
EMEA/282954/2005	Guideline on therapeutic areas within the mandatory scope of the centralised procedure for the evaluation for marketing authorisation applications with reference to Article 3 and point 3 of the Annex to Regulation (EC) No 726/2004	Revised version to reflect extension of the mandatory scope, to be published Q1 2008
EMEA/H-38179-1998	EMEA pre-submission guidance for users of the centralised procedure	Updated version to further reflect Review implementation, to be published by Q2 2008.
EMEA/310007/2006	EMEA post-authorisation guidance for users of the centralised procedure	Updated version to further reflect Review implementation, to be published by Q2 2008.
EMEA/CHMP/401993/2005	Guideline on the procedural aspects and dossier requirements for the consultation to the EMEA by a notified body on an ancillary medicinal substance used in a medical device	Final version to be published Q2 2008.
EMEA/CHMP/50745/2006	Guideline on Procedures for re-examination of CHMP opinions	Revision of guideline to be prepared by 4Q 2008
EMEA/124066/2005	CHMP Rapporteur/Co-Rapporteur appointment: Principles, Objective Criteria and Methodology	Revision of document to be prepared by 4Q 2008

	Post-authorisation follow-up of safety and efficacy of Advance Therapy Medicinal products	Draft Guideline to be prepared by Q4 2008

EMEA contribution to European Commission guidelines

Reference Number	Document Title	Status
Notice to Applicants	Guideline on the Packaging Information of medicinal products for human use authorised by the Community – Revision 9	Revision 10 expected in 2008 (to be confirmed).
Notice to Applicants	Application Forms for New Applications & Variations	Revision to reflect new paediatric requirements.
Notice to Applicants	Revision of Variations Regulation	
Notice to Applicants	CTD Module 1	Revision to reflect new paediatric requirements.

CVMP Efficacy Working Party

Reference Number	Document Title	Status
EMEA/CVMP/315262/2006-draft	Dossier requirements for oncology products Multidisciplinary guideline: Involved WPs are EWP, SWP , QWP and ERAWP	New guideline Draft Guideline to be prepared for adoption by CVMP for 6-months public consultation (anticipated for Q1 2008)
EMEA/CVMP/019/00-Rev.2-draft	Conduct of bioequivalence studies for veterinary medicinal products Multidisciplinary guideline: involved WPs are EWP and QWP	Revision of existing guideline Draft Guideline to be prepared for adoption by CVMP for public consultation (Q2-3 2008)
EMEA/CVMP/EWP/362275/2007-CONSULTATION	Veterinary medicinal products controlling Varroa destructor and Acarapis woodi parasitosis in bees	Concept paper for the revision of guideline Adopted by CVMP for public consultation September 2007 (end of consultation: March 2008) Draft Guideline to be prepared for adoption by CVMP for public consultation (anticipated for Q2-3 2009)
EMEA/CVMP/EWP/85954/2007-CONSULTATION	Guideline on Efficacy of veterinary medicinal products for use in farmed aquatic species	Concept paper for the revision of guideline Adopted by CVMP for public consultation October 2007 (end of consultation January 2008) Draft Guideline to be prepared for adoption by CVMP for public consultation (anticipated for Q4 2008/Q1 2009) Focus Group meeting with interested parties scheduled for Q3 2008

Reference Number	Document Title	Status
EMEA/CVMP/VICH/393388/2006	VICH GL43 (Target Animal Safety – Pharmaceuticals)	EU contribution to development of guideline (currently Step 4)

CVMP Environmental Risk Assessment Working Party

Reference Number	Document Title	Status
	Consider the need to provide guidance on environmental risk assessment for veterinary medicines for aquaculture	Considerations to be developed during 2008.
	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)	Considerations to be developed during 2008.

CVMP Immunologicals Working Party

Reference Number	Document Title	Status
EMEA/CVMP/552/02	Guideline on EU requirements for batches with maximum and minimum titre or batch potency for developmental safety and efficacy studies.	Draft Guideline to be released for consultation by IWP/CVMP following the revision of Annex I of Directive 2001/82/EC as amended
	Procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with Bovine Viral Diarrhoea (BVD) virus	Draft Guideline to be released for consultation by IWP/CVMP Q1/2 2008
EMEA/CVMP/IWP/219089/2006	Guideline on requirements for in-use stability claims	Draft Guideline to be released for consultation by IWP/CVMP Q2/3 2008
EMEA/CVMP/IWP/205712/2006	Guideline on preparation of master seeds to replace established master seeds already used in authorised immunological veterinary medicinal products (IVMPs)	Draft Guideline to be released for consultation by IWP/CVMP Q2/3 2008
	Guideline on compliance of veterinary vaccines with veterinary vaccine monographs of the European Pharmacopoeia	Draft Guideline to be released for consultation by IWP/CVMP Q1/2 2008
	Guideline on the need for requiring data to demonstrate the influence of maternally derived antibodies on the vaccination of very young animals	Draft Guideline to be released for consultation by IWP/CVMP Q2/3 2008
	Revised Guideline on requirements for combined veterinary vaccines	Draft Guideline to be released for consultation by IWP/CVMP following the revision of Annex I of Directive 2001/82/EC as amended

Reference Number	Document Title	Status
	VICH Guideline on Target Animal Safety for Veterinary Biological Products.	(EU contribution to development of guideline)
	VICH Guideline on examination of live veterinary vaccines for reversion to virulence	(EU contribution to development of guideline)
	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	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)
	Guideline on the requirements for multistrain dossiers	Draft Guideline to be released for consultation by IWP/CVMP following the revision of Annex I of Directive 2001/82/EC as amended
	Concept paper on the minimum requirements for Bluetongue vaccines	Concept paper (following the reflection paper on the same topic) to be released for consultation by IWP/CVMP Q3/4 2008
	Validation of batch potency tests and establishing pass criteria	Concept paper to be released for consultation by IWP/CVMP Q3/4 2008
	Revision of the guideline on requirements for fish vaccines	Concept paper to be released for consultation by IWP/CVMP Q3/4 2008

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference Number	Document Title	Status
EMEA/CVMP/183/96 Rev.2 – consultation.	Guideline on pharmacovigilance for veterinary medicinal products – procedures for marketing authorisation holders	The guideline is under review by the Commission aiming at publication. Further considerations on additional revision will be undertaken during the development of Volume 9B
EMEA/CVMP/900/03	Guideline on a strategy for triggering pharmacovigilance investigations preceding regulatory actions by EU competent authorities	Considerations on the revision of this guideline will be undertaken within the procedure for developing Volume 9B
EMEA/CVMP/143/99-Rev.1	Note for Guidance: Conduct of pharmacovigilance for veterinary medicinal products authorised through the mutual recognition procedure	Considerations on the revision of this guideline will be undertaken within the procedure for developing Volume 9B

Reference Number	Document Title	Status
EMEA/CVMP/471721/2006	Guideline on the use of data contained in EudraVigilance and EudraVigilance Veterinary (EVvet)	To be developed further to the public consultation of the Concept paper on the same topic, the results on pilot monitoring undertaken by the PhVWP-V subgroup, and considering the final policy on transparency of the data. Following finalisation of the guidance, it is foreseen for inclusion in Volume 9B
EMEA/CVMP/VICH/547/00	VICH GL24 Step 7: Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports	To be implemented within the procedure for developing Volume 9B
EMEA/CVMP/VICH/646/01	VICH GL29 Step 7: Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSURs)	To be implemented within the procedure for finalising EMEA/CVMP/183/96 Rev.2
EMEA/CVMP/VICH/647/01	VICH GL30: Pharmacovigilance of Veterinary Medicinal Products: Controlled list of terms	To be developed in 2008, on basis of the VICH nternal 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 in 2008, on basis of the VICH nternal position paper developed in 2007
EMEA/CVMP/VICH/355996/05	VICH GL42 Step 7: Guideline on pharmacovigilance of veterinary medicinal products: data elements for submission of adverse event reports	To be implemented within the procedure for developing Volume 9B
EMEA/CVMP/4550/2006	Guideline on a Periodic Safety Update Report (PSUR) assessment guideline for veterinary medicinal products	Following the consultation period the guideline will be finalised and published for use in 2008, with the aim to include the guideline in Volume 9B
	Volume 9B of the Rules Governing Medicinal Products in the European Union – Pharmacovigilance of veterinary medicinal products	Finalisation of the draft Volume 9B further to end of public consultation upon request from the European Commission
EMEA/CVMP/413/99 – Rev. 4 EMEA/CVMP/891/04 – Rev. 2 EMEA/CVMP/553/03 – Rev. 2 EMEA/CVMP/PhVWP/195384/2007	Annual review of Standard lists used for reporting suspected adverse reactions	Expected date(s) of drafting/expert group: 24 April 2008
EMEA/CVMP/552/03	Guideline on Harmonising the approach to causality assessment for adverse reactions to veterinary medicinal products	Concept paper to be finalised in 2008 aiming at revision of the guideline

CVMP Safety Working Party

Reference Number	Document Title	Status
	Guideline on the approach on how to prove whether a substance is capable of pharmacological action or not	Guideline to be finalised after consultation (Q3/Q4)
	Guideline on the assessment of pharmacological/pharmacodynamic data to establish a pharmacological ADI	Guideline to be finalised after consultation (Q3/Q4)
	Dossier requirements for oncology products Multidisciplinary guideline: Involved WPs are EWP, SWP, QWP and ERAWP	Draft Guideline to be prepared for adoption by CVMP (Q1 2008)
	Review of alternative reference limits	Reflection paper to be developed during 2008
	Dossier requirements for bibliographic applications Multidisciplinary Guideline: Involved WPs are EWP, SWP and CMDV	Concept paper to be released for public consultation (tbc)
	MRLs and bioavailability of bound residues	Reflection paper to be finalised after consultation (Q2/Q3)
	Possible update of guideline on establishment of withdrawal periods for milk producing animals during the dry period (and relevant parts of SPC guideline)	Depending on outcome of Working Party and CVMP considerations in 2007, possible update required during 2008
	Extrapolation of MRLs and gathering of information allowing to establish a scientific basis from "Absorption, Distribution, Metabolism and Excretion" similarities/differences	Await outcome of Commission funded research project before preparing concept paper
	Conditions for use of faecal binding studies for the establishment of microbiological ADI	Reflection paper to be developed during 2008
	Conduct of bioequivalence studies for veterinary medicinal products (EMEA/CVMP/019/00) Multidisciplinary Guideline: Involved WPs are EWP, QWP and SWP	Revision of existing guideline: Draft Guideline to be prepared for adoption by CVMP (Q2-3 2008)
	(VICH) Guideline on metabolism and residue kinetics: Study to identify the nature and quantity of residues Study requirements to demonstrate residue depletion Validation requirements for analytical methods used in	Support to EU position during 2008

	residue studies Harmonisation of scientific model assumptions Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals	
	(VICH) Guideline on elaboration of Acute Reference Dose for Veterinary Medicinal Products	Support to EU position during 2008

CVMP Scientific Advice Working Party

Reference Number	Document Title	Status
EMEA/CVMP/172329/04-Rev.2	EMEA 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
EMEA/CVMP/SAGAM/374571 /2005	Further guidance on pre-approval information according to VICH GL27	Draft Guideline to be published depending on outcome on WHO/OIE discussions on critically important antibacterial during 2008
	Companion animals and horses- provide updated information to CVMP discussing the increasing problems with antimicrobial resistance in companion animals and horses with special focus on methicillin resistant coagulase positive staphylococci	Considerations to be prepared during 2008
EMEA/CVMP/SAGAM/81730/2 006	Use of 3rd and 4th generation cephalosporins in food-producing animals in the European Union.	Document to be finalised during 2008 following publication of Reflection Paper
	Use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union	Publication of concept paper during 2008

Joint CHMP/CVMP Quality Working Party

Reference number	Document title	Status
CPMP/QWP/3309/01 EMEA/CVMP/961/01	CPMP/CVMP Note for Guidance on the use of near infrared spectroscopy by the Pharmaceutical Industry and the Data to be forwarded in the Part II of the Dossier for a Marketing Authorisation	Finalisation of revision to take account of advances in this area
CPMP/QWP/155/96 & EMEA/CVMP/315/98	CPMP and CVMP Guidelines on Pharmaceutical Development	Discussion on the impact of new technologies and approaches as described in ICH Guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality Systems) on current concepts
CPMP/QWP/3015/99 & EMEA/CVMP/QWP/339588/2005	CPMP and CVMP Guidelines on Parametric Release	
CPMP/ICH/367/96 & 3A Q11a Vol. IIIA	CPMP and CVMP Guidelines on Specifications	
CHMP/QWP/848/96 EMEA/CVMP/598/99	CPMP/CVMP Guideline on Process Validation	
EMEA/CHMP/CVMP/QWP/450653/2006	Assessment of the Quality of Medicinal Products Containing Existing/Known Active Substances (H & V)	Finalisation after end of public consultation on 31 January 2008
	CVMP Guideline on the quality aspects of single-dose veterinary spot-on products	Guideline expected to be released for consultation in late 2007/early 2007. Then finalisation after end of public consultation
	CVMP Guideline on dossier requirements for anticancer medicinal products for dogs and cats	Contribution to draft guideline prior to its release for consultation
EMEA/CVMP/134/02 Rev 2 CPMP/QWP/227/02 Rev 1	CHMP/CVMP Guideline on Active Substance Master File - introduction of an Annex for Herbal Medicinal Products, on referral by the HMPC	Finalisation of the revision (introduction of an Annex for Herbal Medicinal Products)
Eudralex 3AQ20A	Radiopharmaceuticals	Finalisation of revision after end of public consultation on 31 March 2008
EMEA/HMPC/CHMP/CVMP/58222/06	Guideline on Quality of Combination Herbal Medicinal Products/Traditional Herbal Medicinal Products (H & V)	Contribution to finalisation after end of public consultation
EMEA/CHMP/167068/2004-ICH	ICH Guideline on Pharmaceutical Development (Q8)	Contribution to ICH work on implementation of the guideline in the EU
EMEA/INS/GMP/157614/2005-ICH	ICH Guideline on Quality Risk Management (Q9)	Contribution to ICH work on implementation of the guideline in the EU
ICH Q10	Quality Systems (Q10)	Contribution to ICH work on implementation of the guideline in the EU

Reference number	Document title	Status
EMEA/CVMP/016/00	CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products	Contribution to revision of the guideline prior to its release for consultation
	Contribution to the revision of the variations regulations	As requested by the European Commission and EMEA
	Setting Specifications for Antibiotics and Peptides	Adoption of Concept Paper and start of work on a guideline
EMEA/CVMP/QWP/846/99-Rev.1	CVMP Guideline on Stability Testing: Stability Testing of Existing Active Substances and Related Finished Products	Finalisation of revised guideline after end of public consultation on 30 April 2008

CVMP General

Reference Number	Document Title	Status
EMEA/CVMP/248499/2007-CONSULTATION	Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products	Adopted by CVMP for public consultation September 2007 (end of consultation March 2008)

Annex 6 EMEA contact points

Pharmacovigilance and product quality defect reporting

The constant monitoring of the safety of medicines after authorisation ('pharmacovigilance') is an important part of the work of the national competent authorities and EMEA. The EMEA receives safety reports and product quality defect reports from within the EU and outside concerning centrally authorised medicinal products and coordinates action relating to the safety and quality of medicinal products.

For matters relating to pharmacovigilance for medicinal products for human use

Sabine BROSCH
Direct telephone: (44-20) 74 18 85 69
E-mail: pharmacovigilance@emea.europa.eu

For matters relating to pharmacovigilance for medicinal products for veterinary use

Fia WESTERHOLM
Direct telephone: (44-20) 74 18 85 81
E-mail: vet-phv@emea.europa.eu

For product quality defects and recalls see the instructions and contact points provided at: www.emea.europa.eu/inspections/defectinstruction.html

E-mail: qdefect@emea.europa.eu
Direct telephone: (44-20) 75 23 70 75
Fax: (44-20) 74 18 85 90
Out of hours telephone: (44) 78 80 55 06 97

SME Office

The SME office has been set up within the Agency to address the particular needs of smaller companies. The office aims to facilitate communication with SMEs through dedicated personnel within the Agency who will respond to practical or procedural enquiries, monitor applications, and organise workshops and training sessions for SMEs. Any comments on the content of this draft SME User Guide should also be forwarded to the SME office.

SME office contact point:

Melanie CARR
Direct telephone: (44-20) 74 18 85 75/84 63
Fax: (44-20) 75 23 70 40
E-mail: smeoffice@emea.europa.eu

Certificates of a medicinal product

The EMEA issues certificates of a medicinal product in conformity with the arrangements laid down by the World Health Organisation. These certify the marketing authorisation and good manufacturing status of medicinal products in the EU and are intended for use in support of marketing authorisation applications in and export to non-EU countries.

For enquiries concerning certificates for centrally authorised medicines for human or veterinary use	E-mail: certificate@emea.europa.eu Direct telephone: (44-20) 75 23 71 07 Fax: (44-20) 74 18 85 95

PMF/VAMF EMEA certificates

The EMEA issues plasma master file (PMF) and vaccine antigen master file (VAMF) certificates of a medicinal product in conformity with the arrangements laid down by Community legislation. The EMEA PMF/VAMF certification process is an assessment of the PMF/VAMF application dossier. The certificate of compliance is valid throughout the European Community.

For enquiries concerning PMF certificates	Silvia DOMINGO ROIGÉ Direct telephone: (44-20) 74 18 85 52 Fax: (44-20) 74 18 85 45 E-mail: PMF@emea.europa.eu
For enquiries concerning VAMF certificates	Ragini SHIVJI Direct telephone: (44-20) 74 18 8698 Fax: (44-20) 74 18 85 45 E-mail: VAMF@emea.europa.eu

Information service

A wide range of documents are published by the EMEA, including press releases, general information documents, annual reports and work programmes.

These are available:	on the Internet at: www.emea.europa.eu by e-mail request to: info@emea.europa.eu by fax to: (44-20) 7418 8670 by writing to: EMEA Documentation service European Medicines Agency 7 Westferry Circus Canary Wharf London E14 4HB UK

European experts list

The EMEA uses the services of over 4,000 European experts in its scientific evaluation work. The list of names of these European experts is available on the EMEA website at: http://www.emea.europa.eu/htms/aboutus/experts.htm

Details of the areas of expertise, and the declaration of interests, of each expert can be examined at the EMEA office, on request. Requests must be made using the Request form.

Integrated quality management – Internal audit

IQM adviser	Marijke KORTEWEG Direct telephone: (44-20) 74 18 85 56 E-mail: iqmanagement@emea.europa.eu

Press office

Press officer	Martin HARVEY ALLCHURCH Direct telephone: (44-20) 74 18 84 27 E-mail: press@emea.europa.eu

Annex 7 Profiles of EMEA personalities

Management

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. Mr O'Mahony 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 O'Mahony 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 EMEA 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 Organization 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 organizations. 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 has been Executive Director of the EMEA since January 2001.

EMEA 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, a post he continues to hold today. 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 as 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 is a CVMP member since 1997, he was elected vice-chair of CVMP in 2001. He was first elected chairman 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 as Vice-chair of CVMP in October 2006.

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. Associate 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.

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 holds the position of Director and Professor at the Federal Institute for Drugs and Medical Devices. He is currently working within the department for international pharmaceutical affairs at the German Ministry of Health. 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 1990 Lecturer and since 2002 Assoc. Prof. at the University of Athens, School of Pharmacy, Div 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 2005 and has been elected as Vice-chair of the HMPC Working Party on Community Lists and Monographs (MLWP) in January 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 and chapters in scientific books.

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 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.

Unit for the Pre-authorisation evaluation of medicines for human use

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 a French CPMP delegate. He joined the EMEA 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. Further to the restructuring of the Human Medicines Evaluation Unit in 2001, he was appointed Head of Unit for the Pre-authorisation evaluation of medicines for human use in March 2001.

Agnès Saint Raymond, Head of Sector for orphan drugs and scientific advice, 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 EMEA in January 2000 and was appointed Head of Sector for scientific advice and orphan drugs in December 2001, a Sector which includes the EMEA Office for Small and Medium-Sized Enterprises since December 2005. Dr Saint Raymond was acting Head of Sector for safety & efficacy from October 2004 to December 2005. She is also in charge of issues relating to medicines used in children and the implementation of the European regulation on medicinal products for paediatric use.

Spiros Vamvakas, Acting Deputy Head of Sector for orphan drugs and scientific advice, n. German/Greek

Education: Qualified medical doctor from the University of Wuerzburg, Germany. Board certified specialist in Pharmacology and Toxicology (Bavarian Chamber of Physicians). Associate Professor for Pharmacology and Toxicology in the University of Wuerzburg.

Career to date: Since 1984 Prof Vamvakas held positions in the Department of Pharmacology and Toxicology of the University of Wuerzburg and in the Department of Pharmacology in the Medical Centre of the University of Rochester NY, USA. He joined the EMEA in May 1999 and one of his major activities in recent years was the establishment of Orphan Drug designation and Protocol Assistance in the EMEA. He has a continuing teaching appointment for Pharmacology and Toxicology in the University of Wuerzburg. He was appointed acting Deputy Head of Sector for scientific advice and orphan drugs in October 2004 and is more specifically in charge of Scientific Advice.

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 EMEA in August 1996 as Head of Sector for biotechnology and biologicals. He was appointed Head of Sector for quality of medicines in January 2001.

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 EMEA in December 2005 as Head of Sector for safety and efficacy of medicines.

Marisa Papaluca Amati, Deputy Head of Sector for safety and efficacy of medicines,

n. Italian

Education: Qualified as medical doctor in Rome in July 1978. Specialist in internal medicine. Post-graduate studies in cardiology and endocrinology.

Career to date: From 1978 to 1983 research fellow in the State University of Rome in the area of clinical immunology, oncology and cellular immunology. From 1984 to 1994, at the Pharmaceutical Department of the Italian Ministry of Health, she was in charge as medical director of the Operative Centre for Community Procedures and was Italian member of the former Committee for Proprietary Medicinal Products also involved in a number of ICH activities. She joined the EMEA in October 1994. She acted as scientific secretary of the Biotechnology Working Party till December 2000. She was appointed Deputy Head of Sector for safety and efficacy of medicines in January 2001 and since she has also been in charge of EMEA activities in the field of innovation, emerging therapies and technologies and the coordination of scientific training.

Unit for the Post-authorisation evaluation of medicines for human use

Noël Wathion, Head of Unit, n. Belgian

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 the 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 EMEA 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.

Noël Wathion is currently also Acting Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines.

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 EMEA in May 1996 and was appointed Head of Sector for regulatory affairs and operational support in January 2001.

Sabine Brosch, Deputy Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines, n. Austrian

Education: Masters Degree in pharmacy and Doctor of Natural Sciences Degree in pharmacology from the University of Vienna. Post-graduate studies in pharmacology at the University of Melbourne and Auckland.

Career to date: From 1988 to 1992, Dr Brosch worked as an assistant professor at the Department of Pharmacology and Toxicology at the University of Vienna, where she was specialised in electrophysiology. In 1992 she moved to the Pharmacovigilance Department at the Austrian Ministry of Health and completed a 6-month regulatory traineeship in the Pharmaceuticals Unit of the European Commission in 1995. She joined the EMEA in November 1996 and was appointed Deputy Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines in January 2001.

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 EMEA 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. Since September 2005 she has taken up new responsibilities as Head of the Medical Information Sector.

Unit for Veterinary medicines and inspections

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.

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 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.

Jill Ashley-Smith, Head of Sector for veterinary marketing authorisation procedures, n. British

Education: Graduated in pharmacology from Kings College, London University. Qualified as a veterinary surgeon from the Royal Veterinary College, London University. Member of the Royal College of Veterinary Surgeons of the United Kingdom.

Career to date: From 1987 to 1994, Dr Ashley-Smith was employed in the veterinary pharmaceutical industry, first as a technical adviser and subsequently as a registration manager. In 1994, she joined the UK Veterinary Medicines Directorate as senior veterinary assessor in the pharmaceuticals and feed additives team. She participated as UK CVMP member from 1996 until joining the EMEA in July 1997 as Head of Sector.

Melanie Leivers, Deputy Head of Sector for veterinary marketing authorisation procedures, n. British

Education: Graduate in biochemistry and pharmacology from Leeds University. Post-graduate diploma in European Community law from King's College, London.

Career to date: Miss Leivers worked for the Milk Marketing Board for England and Wales (MMB) as a Liaison Chemist for 5 years prior to being appointed Assistant Director of the MMB/Federation of Agricultural Cooperatives office in Brussels, representing all sectors of agricultural cooperation to the

European institutions. Following this she worked for a short-term contract at the European Commission (DG XI) and then in industry at Pfizer (formerly SmithKline Beecham Animal Health) as a regulatory affairs manager. Miss Leivers joined the EMEA in February 1996 and was appointed Deputy Head of Sector in June 2001.

Kornelia Grein, Head of Sector for safety of 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 harmonization 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 EMEA in April 1996 as head of sector.

Emer Cooke, Head of Sector for inspections, n. Irish

Education: Qualified Pharmacist with Masters degree in Pharmaceutical Chemistry and Masters in Business Administration (MBA) from Trinity College Dublin. Member of the Pharmaceutical Society of Ireland.

Career to date: Ms. Cooke worked in a number of positions within the Irish pharmaceutical industry before joining the Irish Medicines Board as a pharmaceutical assessor in 1988. Following graduation with a MBA degree in 1991, she joined EFPIA, the European pharmaceutical industry association as Manager of Scientific and Regulatory Affairs. Her responsibilities there included coordination of regulatory aspects of European procedures and International Conference on Harmonisation (ICH) activities. After a three-year stay in Prague, Czech Republic, where she worked as a consultant on European pharmaceutical matters as well as continuing her work with EFPIA, she joined the Pharmaceuticals Unit of the European Commission in September 1998. Her responsibilities there included coordination of ICH activities, relations with the FDA, pharmaceutical aspects of mutual recognition agreements, GMP and inspection-related matters, orphan medicinal products, preparatory work on a regulation on paediatric medicinal product and issues relating to EU enlargement. She joined the EMEA as Head of the Inspections Sector in July 2002.

Communications and networking Unit

Hans-Georg Wagner, Head of Unit, 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 EMEA on 1 May 2002.

Beatrice Fayl, Head of Sector for document management and publishing, n. Danish

Education: Bachelor of Arts in languages and linguistics at the University of East Anglia and post-graduate degree in librarianship and information science at University of Wales.

Career to date: Ms Fayl held various positions as a documentalist in several European countries, the latest from 1988 to 1995 setting up and running the documentation service in the European Commission Delegation to Norway and Iceland. Ms Fayl joined the EMEA in April 1995.

Sylvie Bénéfice, Head of Sector for meeting management and conferences, n. French

Education: Doctorate of Sciences in Physical Sciences; Doctorate in Physical Organic Chemistry, Qualified in research management; Masters degree in physical organic chemistry; Degree in biochemistry.

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 1st 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 EMEA in September 1997.

Tim Buxton, Head of Sector for project management,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 EMEA. He was appointed Head of Sector on 1 May 2002.

David Drakeford, Head of Sector for information technology, 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 EMEA in February 1997 and has been Head of Sector IT since 2003.

Riccardo Ettore, Deputy Head of Sector for information technology, 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 EMEA in May 1995 and was appointed Deputy Head of Sector in July 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 EMEA in May 2000.

Frances Nuttall, Head of Sector for personnel and budget, 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 EMEA in May 1995.

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 EMEA in November 1994 and was nominated as head of sector in November 2002.

Gerard O'Malley, Head of Sector for accounting, n. Irish

Education: Bachelor of Commerce from University College Dublin. Fellow of the Institute of Chartered Accountants in Ireland. Censor Jurado de Cuentas and Member of the Registro Oficial de Auditores de Cuentas in Spain.

Career to date: From 1971 to 1974, Mr O'Malley completed articles in Dublin. From 1974 to 1985 he was an audit manager in Spain with Ernst and Young and from 1985 to 1995 he was Financial Controller at Johnson Wax Española. He joined the EMEA in April 1995.

Services attached to the Executive Director

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

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

Career to date: Prof. Eichler has been Professor and Chair of Clinical Pharmacology at the Medical University of Vienna, Austria, since 1992. In 2003, he assumed the position of Vice Rector for Research and International Relations. He received his clinical training at the 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 has been

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 Executive Support, 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 EMEA 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 Sector, 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 EMEA as Head of Legal Sector on 16 November 2004. He was appointed as Data Protection Officer in July 2005.

Marijke Korteweg, Integrated Quality Management Adviser, n. Belgian

Education: PhD (Chemistry) and PhD (Biochemistry), University of Ghent, Belgium. Fellow of the Institute of Quality Assurance, UK.

Career to date: After 10 years of fundamental prostaglandin research she joined the pharmaceutical industry in 1981 as a clinical research associate. In 1984 Dr Korteweg created the regulatory compliance/quality assurance audit department for the European Pharmaceutical R&D Division of Bristol-Myers Squibb, later becoming Director of Worldwide Regulatory Compliance (auditing). She was editor for the ICH GCP guideline from February 1992 until its adoption in May 1996.
Dr Korteweg joined the EMEA in August 1997 and has acted as EMEA quality manager since July 1998. She has led the Agency's integrated quality management system and internal audit system since November 1999. She was appointed integrated quality management advisor in January 2004.