European Medicines Agency

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Work programme for the European Medicines Agency 2007

Adopted by the Management Board on 19 December 2006

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Introduction by the Executive Director

Thomas Lönngren

The year 2007 will be the thirteenth year of operation of the EMEA and of its contribution towards the promotion and protection of public and animal health. The Agency welcomes the national competent authorities of the two new Member States, Bulgaria and Romania, as valued partners in the European medicines network. We look forward to fruitful cooperation with scientific experts from these countries to bring effective and safe medicines to all European citizens.

This EMEA work programme for 2007 has been shaped by a number of factors in the rapidly developing medicines regulation environment, most notably the entry into force of the legislation on paediatric medicines. This is an important new mandate for the EMEA, giving the Agency a significant role in stimulating the availability of safe and effective medicines for children. I wish to point out that this new area of responsibility will affect the existing core activities of the Agency — for example scientific advice, an area in which the Agency expects to receive 30% more requests than in 2006.

The Agency is facing a steady intensification of activities relating to the evaluation and supervision of medicinal products. In some areas, growth during 2006 was substantial, with an increased workload expected again in 2007. This intensification must be supported by improved cost-effectiveness of the Agency's operations and further improvement of its quality-assurance systems. If the Agency is to continue to deliver on its commitment to high-quality results in all core areas, it must also be supported by a corresponding increase in finances, human resources and allocated national experts.

Promoting the safety of medicines has been an important area for the Agency over many years, and will remain a priority in 2007. Medicines agencies have traditionally relied on spontaneous reporting of adverse reactions, and the EMEA EudraVigilance database remains a key tool for this. However, we want to take this a step forward. In addition to the new tools we have already implemented, we want to work with Member State authorities and academic centres on establishing networks of experts to run intensive drug-monitoring programmes that will actively study the safety of targeted medicines.

The EMEA supports the objectives of the Lisbon agenda. Innovation and research are the primary driving forces for new medicines, and, consequently, motors for improved public and animal health. The Agency's efforts to support these objectives in 2007 will focus on: providing scientific advice; providing special support for small and medium-sized enterprises; conducting research into the consistency of the Agency's decision-making; and contributing to pan-European initiatives for facilitating innovative research.

The Agency considers the availability of the same, high-quality information about medicines in all official EU languages to be essential for their optimal use in all Member States. We will work closely with Member States and their experts to ensure that the information we provide is of the highest quality in all languages. We will also strive to improve our communications more generally, covering both our scientific and non-scientific activities. As part of this, we will further promote the participation of patients and healthcare professionals in our activities.

I would like to emphasise that these activities are only possible through the harmonious functioning of the European medicines network, with the EMEA and the national competent authorities working side by side. Fostering this spirit of cooperation and seeking practical solutions to present and future challenges brought by developments in our field will be my final, but nonetheless important, priority for 2007.

Priorities and key objectives for 2007

The Agency will conduct its core activities in the areas of authorisation and supervision of medicines for human and veterinary use to the highest quality standards. It will continuously assess the prioritisation of projects and activities to accommodate a considerably increased volume of activity, and effect improvements where necessary to ensure that high standards are maintained.

Specific priorities in 2007 will include:

Implementation of legislation on medicines for children

- Implement the new regulation on medicinal products for paediatric use, including the establishment of a new Paediatric Committee, delivering opinions and decisions on paediatric investigation plans and waivers, and providing information on paediatric clinical trials.

Safety of medicines for human and veterinary use

- Continue to apply a proactive approach to safety of medicines by initiating early assessment of the safety prior to authorisation, by monitoring implementation of Risk Management Plans after marketing authorisation, and by supervising the updating of such plans throughout the lifecycle of the product.
- Progress the implementation of the European Risk-Management Strategy (ERMS), in close collaboration with the national competent authorities, leading to a more efficient system for supervising the safety of medicinal products.
- Further develop EudraVigilance, one of the main pillars of the ERMS, by implementing and starting the operation of quantitative signal-detection methods, by providing the Agency's stakeholders access to EudraVigilance information, and by setting up and implementing a network of academic centres for the intensive monitoring of targeted medicines.
- Fulfil the Agency's obligations with regard to coordinating the supervision of veterinary medicines once authorised, through effective implementation of pharmacovigilance as well as through the dissemination of information on adverse drug reactions.

Stimulation of innovation

- Further maintain and improve measures for facilitating innovation and research, and thus increasing availability of medicines, in particular through: continuous support for the orphan medicinal products policy; the provision of scientific advice; support for micro, small and medium-sized enterprises; research into the impact and consistency of the Agency's decision making.
- Continue supporting the European Commission through the stages leading to the new regulation on advanced therapies; participate in the work of the Innovative Medicines Initiative for human medicines, the European Technology Platform for Global Animal Health for veterinary medicines, and in other international initiatives to improve drug development.

Earlier and improved availability of medicines

- Operate and increase the effectiveness of marketing-authorisation procedures for facilitating availability of medicines, while maintaining the highest quality standards. These procedures include accelerated assessment, conditional marketing authorisation, and compassionate use.
- Provide opinions on medicinal products intended for non-EU markets.
- Support further initiatives, once identified, to facilitate greater availability of veterinary medicines, particularly through measures to assist companies submitting applications for veterinary medicines which have limited markets or which are intended for diseases with regional distribution.

Transparency, communication and provision of information

- Further implement the EMEA transparency measures and increase the openness of the Agency's activities to underpin its corporate governance.
- Further improve the Agency's contribution towards the provision of high-quality and timely information on medicines in all official EU languages to patients and healthcare professionals; Contribute to the work of the Pharmaceutical Forum, particularly in the area of provision of information to patients.
- Promote the participation of patients and healthcare professionals in the work of the Agency.

The European medicines network

- Strengthen cooperation on pharmacovigilance, EU telematics, scientific advice, support to SMEs and communication.
- Further stimulate complementarities in the network and develop adequate work-sharing and resource-planning activities across the network.
- In light of the increasing tasks at the EU level and the arrival of novel therapies and technologies, work to ensure availability for the network of the highest-quality expertise at EU level for the evaluation of medicines and for monitoring and assessing their safety.

1. EMEA IN THE EUROPEAN SYSTEM

1.1 Management Board

The Management Board will maintain its focus in 2007 in three main areas:

- Monitoring of the Agency's performance, to help it carry out the tasks outlined in the legislation and achieve the aspirations outlined in its long-term strategy (the Road Map).
- Corporate governance and operation of the integrated quality-management system, to increase the effectiveness and operational efficiency of the Agency.
- Certain aspects of the Agency's transparency and communication initiatives, building on the achievements of previous years and expectations for transparency and communication. The Board will discuss a new framework on the interaction between the EMEA and healthcare professional organisations.

The Board will also carry out its statutory obligations. To this end, the Board will:

- Adopt the Agency's work programme, budget and establishment plan for the year 2008, which will take into account priorities and objectives of the long-term strategy.
- Conduct analysis of the Executive Director's annual activity report.
- Provide its opinion on the Agency's final accounts.
- Adopt the Agency's annual report for 2006.

A renomination of the majority of the Management Board members following the completion of the three-year term will be undertaken in May 2007. The Agency will work to ensure timely and smooth transition to the new Management Board.

1.2 European medicines network

The Agency looks forward to welcoming representatives of Bulgaria and Romania as full members of the European medicines network and active participants in the work of the Agency. The EMEA will pay special attention to providing support to Bulgaria and Romania, where needed, in order to ensure that the new Member States are well equipped to participate in the work of the Agency and of the network.

The network of the EMEA and over 40 national competent authorities will operate in the context of: the EU enlargement; work on the strengthening of the network of excellence; the need for careful planning of workload and available resources; better work sharing; and competence development. Appropriate coordination will be needed to successfully implement initiatives outlined in the long-term strategies prepared by the EMEA and the Heads of Medicines Agencies.

In order to address the issue of scarce resources and to avoid potential duplication of work, the Agency, in cooperation with its partners, will work to develop a planning process in the network that would lead to the improved use of resources, and better efficiency. In this context, activities related to meetings and distribution of tasks to committee/working-party members need to be analysed and reviewed.

In light of the growing complexity of evaluation procedures, and the advent of emerging therapies and new technologies, work needs to be continued on securing the long-term availability of expertise in this area. To achieve this, missing expertise will be identified and subsequently complemented, unmet training needs in critical areas will be addressed, and principles and processes established for advanced educational exchanges among regulatory authorities, academia and, where appropriate, industry. An educational programme for regulatory scientists will be developed in conjunction with academia and the national competent authorities.

It is also important to strengthen and improve the complementarity in the network. To this end, an exchange programme has to be established between regulatory agencies, including the EMEA.

1.3 Transparency and communication

The Agency will complete the development of the communication and transparency strategy and begin its implementation during 2007. In addition, a new task will be the implementation of transparency and communication provisions stemming from the legislation on medicines for paediatric use particularly regarding the transparency of paediatric clinical trials. The EMEA will also undertake work to integrate all its tools developed for the provision of information in order to communicate in a more coherent way and to facilitate access to information by its stakeholders.

Steps will be taken to improve EMEA transparency on non-product related issues. The Agency will prepare to publish meeting summaries on non-product related issues of scientific committees and their working parties.

The Agency will complete the implementation of the legislation on access to documents. The electronic register of documents will be published on the Agency's website and the documents will become more easily accessible to the public. The Agency will undertake work to review and improve web-based dissemination of other information.

1.4 Support for innovation and access to medicines

The Agency will remain focused on the objectives of the Lisbon agenda. It will continue implementation of the policy on micro, small and medium-sized enterprises (SMEs), which are often innovative companies working in the field of new technologies and emerging therapies. The Agency will develop guidance and provide specific training to these companies, taking into account issues identified during the course of 2006. The EMEA will work to consolidate the support it provides to SMEs in the area of product information and translations. The Agency will further facilitate electronic reporting of adverse drug data by SMEs through the EudraVigilance system (EudraVigilance web-based system) and will provide associated training.

Other activities relating to stimulation of innovation will encompass the provision of scientific advice to companies developing medicinal products, continued support to the orphan medicinal products policy, and participation in the Innovative Medicines Initiative, which aims to address bottlenecks in development of medicines. The task-force on innovation will continue its work and the EMEA/CHMP think-tank on innovation will finalise its report in the beginning of the year.

The EMEA will continue its initiatives aimed at improving the availability of veterinary medicines. This will be done through the application of principles agreed and implemented, as defined in the Committee for Medicinal Products for Veterinary Use position paper on the availability of products for minor uses and minor species. The EMEA will participate in providing input and advice to the Heads of Veterinary Medicines Agencies Task Force on availability, and to the European Technology Platform for Global Animal Health, which aims to accelerate the development of novel animal health products, for both major and minor markets, within the context of the 7th Framework Programme. As required by the revised legislation, the Agency shall assist companies intending to submit applications through the centralised procedure for products that have limited markets or that are intended for diseases of a regional nature.

1.5 European public-health activities

Important areas of interaction with the European Commission on public-health issues will include: work associated with the legislation and initiatives relating to advanced therapies; support on the updating and further development of the Notice to Applicants; and work within the framework of the public-private partnership aimed at providing quality information to patients. The Agency plans to complete the development of a database on biological warfare agents and treatment/preventive options, and to initiate its rollout.

The Agency will continue its work in respect of, and maintain readiness for, a potential influenza pandemic. As part of this activity, the EMEA will organise training and a simulation exercises to test its state of readiness for an influenza pandemic. A key measure to reduce the likelihood of a pandemic in man is to control the disease effectively in birds. To further this objective the Agency will continue to adopt measures to promote the authorisation through the centralised procedure of safe and effective vaccines for control of avian influenza in birds.

Activities relating to zoonosis (any disease that can be transmitted to humans from animals) will be developed through the establishment of effective procedures for the sharing of information on the subject between the scientific committees.

The Agency will further contribute to the work of the European Commission's Pharmaceutical Forum, in particular in the area of provision of information to patients, and will participate in the discussions on added therapeutic value.

The Agency's scientific committees will continue to participate in activities in support of the EU programme to reduce animal testing and develop other modern approaches to safety assessment of medicines.

The Agency will continue to work through its scientific committees to review and provide advice regarding the use of antimicrobial medicines in humans and animals in order to minimise the occurrence of antimicrobial resistance in the Community, as well as providing expertise and input into global activities on limiting the development of antimicrobial resistance.

The Agency will work to provide adequate guidance to Member States and marketing-authorisation holders on issues relating to environmental risk-assessment for both human and veterinary medicinal products.

Cooperation will continue with the European Centre for Disease Prevention and Control (ECDC), European Food Safety Authority (EFSA), European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the European Directorate for the Quality of Medicines (EDQM).

1.6 Preparations for future enlargement

A multi-beneficiary programme dedicated to supporting the participation of Croatia and Turkey in certain Community agencies will require involvement of the EMEA in the field of medicinal products. The funds allocated for this project amount to €500,000 in 2007 (€200,000 in 2006). The aim of this project is to build contacts and relationships between Croatia and Turkey and the EMEA for future collaboration in the EMEA's activities and its relationships with Member States. This programme will allow the two countries to prepare themselves for participation in the activities of the EMEA and to develop the confidence of the existing Members States in the systems in place in the two candidate countries. The project will also ensure appropriate involvement of Croatia and Turkey in the EU Telematics initiatives (i.e. EudraNet, EudraVigilance, EudraPharm and the European review system), will foster compliance with legislative requirements, and will enable the countries to become part of the electronic network upon accession.

1.7 International cooperation

These activities cover cooperation at international level, namely: coordination of EU experts' participation in the International Conference/Cooperation on Harmonisation (ICH and VICH) and the 7th ICH Conference; and work with the World Health Organization, including on medicinal products for use in developing countries, the Codex Alimentarius, the World Organisation for Animal Health (OIE), the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA).

Ongoing activities within the ICH forum are likely to be extended to cover new topics of common interest. New standards and guidelines originating from the ICH work will have to be implemented. The Agency will also play an active part in implementing the new phase-II strategy for VICH 2006-2010, concentrating on maintaining existing guidelines and developing new guidance.

The Agency will continue its successful and useful cooperation with the FDA and will introduce measures to deepen this cooperation in accordance with the revised EU/FDA Confidentiality Arrangements Implementation Plan. The Agency plans to consolidate procedures for parallel scientific advice and for joint genomic data submissions with the FDA. Cooperation on safety-related issues, especially as regards risk-management plans, and on inspection-related issues will be strengthened. The Agency will liaise with the Center for Veterinary Medicine (CVM) of the FDA and with the USDA to exchange relevant information on veterinary medicines, particularly with regard to scientific advice, product assessments and pharmacovigilance information.

The EMEA, together with the European Commission, plans to continue preliminary discussions with the Japanese medicines agency (MHWL/PMDA) in order to explore the possibility of setting up confidentiality arrangements similar to those concluded with the FDA. The Agency will also provide scientific support to the Commission on EU cooperation with India, in particular in the area of traditional herbal medicinal products.

The Agency will continue to promote the effective operation of mutual-recognition agreements (MRAs) with Australia, New Zealand, Switzerland, Canada and Japan, and work will be carried out to update these agreements to reflect the addition of new Member States and consider the impact of new concepts in quality-risk management.

1.8 Integrated management at the Agency

The Agency's highlight for this year will include the completion of the two-year process-improvement exercise. The objective of the exercise is to optimise key processes of the Agency, improve cost-effectiveness of the Agency's operations, improve performance, and achieve higher satisfaction of its customers and stakeholders. Some outcomes of these initiatives will benefit the European medicines network and will contribute to the ongoing discussion on planning of activities at the level of the European medicines network.

As in previous years, the Agency will carry out self-assessment activities and planned internal audits, and will review the level of implementation of standards for internal control, as well as reviewing the overall effectiveness of its IQM system. A 360-degree evaluation system of management will be introduced. The Agency will conduct staff and stakeholder surveys at planned intervals.

The Agency has introduced an environmental policy for its internal and external operations. The EMEA will endeavour to conduct procurements giving priority, where possible, to environment-friendly products, and will encourage its staff to introduce various environment-friendly practices and habits into their daily work.

2. MEDICINES FOR HUMAN USE

Priorities for medicines for human use in 2007:

- Manage a substantial increase in workload for core activities relating to the authorisation (including scientific advice) and supervision of human medicines (those initiated in 2006 and those begun in 2007), whilst maintaining high quality standards.
- Continue to identify and implement gains in efficiency of operation in all activities, thereby further contributing to improvements in cost-effectiveness.
- Review the first year of full implementation of Regulation (EC) No 726/2004 in all areas of activity, discuss the outcome of the analysis with the Agency's stakeholders and propose any improvements where necessary.
- Implement and strengthen, in close collaboration with the national competent authorities (NCAs), the European Risk Management Strategy (ERMS) project contributing to an intensive drug monitoring system, characterised by a more proactive conduct of pharmacovigilance.
- Develop the Agency's contribution towards the provision of high-quality and timely information on medicines in all official EU languages targeted at patients and healthcare professionals.
- Implement the new regulation on medicinal products for paediatric use, including the establishment of the new Paediatric Committee, provision of opinions and decisions on paediatric investigation plans and waivers, and transparency regarding paediatric clinical trials; prepare for a paediatric research network.
- Stimulate innovation and earlier availability of medicines through measures aimed at facilitating research into medicines and supporting small and medium-sized enterprises (for more information please refer to Chapter 1).
- Develop interaction with the NCAs in the EU regulatory system to strengthen the network of excellence, thereby further increasing the Agency's leading status in the international arena.
- Support the European Commission in new legislative initiatives, including the new regulation on advanced therapies and any other developing activities.

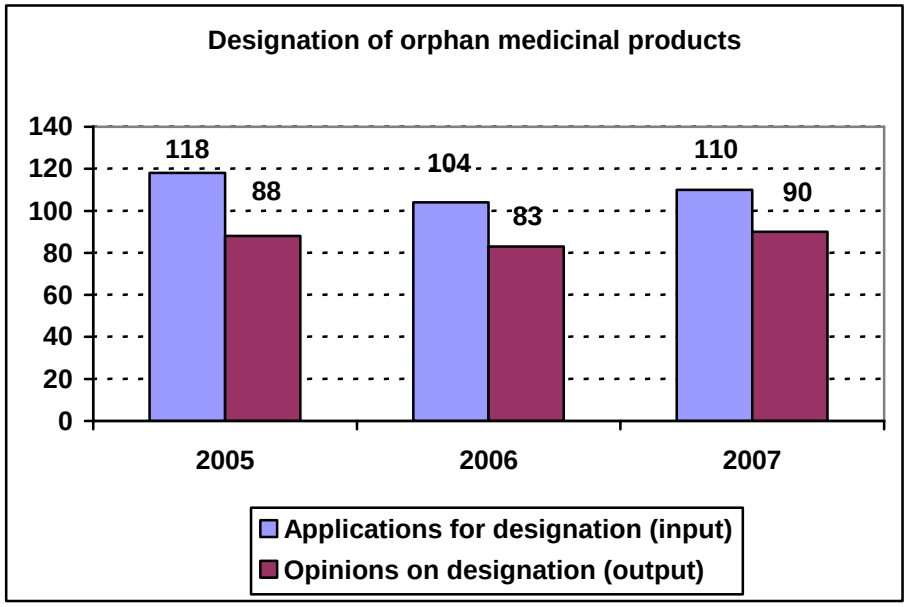
2.1 Orphan medicinal products

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 strives to meet the expectations of patients' organisations and sponsors, and the requirements of the legislation, and to create an environment for innovation and research through the orphan medicinal products policy. Taking this and the level of the orphan medicinal product fund into account, as well as recommendations of the Committee on Orphan Medicinal Products (COMP), the Agency will continue to propose fee reductions, which will provide maximum possible incentives during the development and initial marketing authorisation phases. Protocol assistance will remain a priority area for such incentives.

Trends and new issues

- It is expected that emerging therapies and technologies will have an impact in the field of orphan medicinal products — as it will on many scientific activities of the Agency. This will require close monitoring.



In addition to core activities relating to the evaluation of applications for designation and development of related guidelines, the Agency will work to integrate global development for orphan medicinal products in collaboration with international partners, particularly through increased parallel advice for protocol assistance with the US Food and Drug Administration (FDA).

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
Number of COMP guidelines released or revised on topics as planned	80%

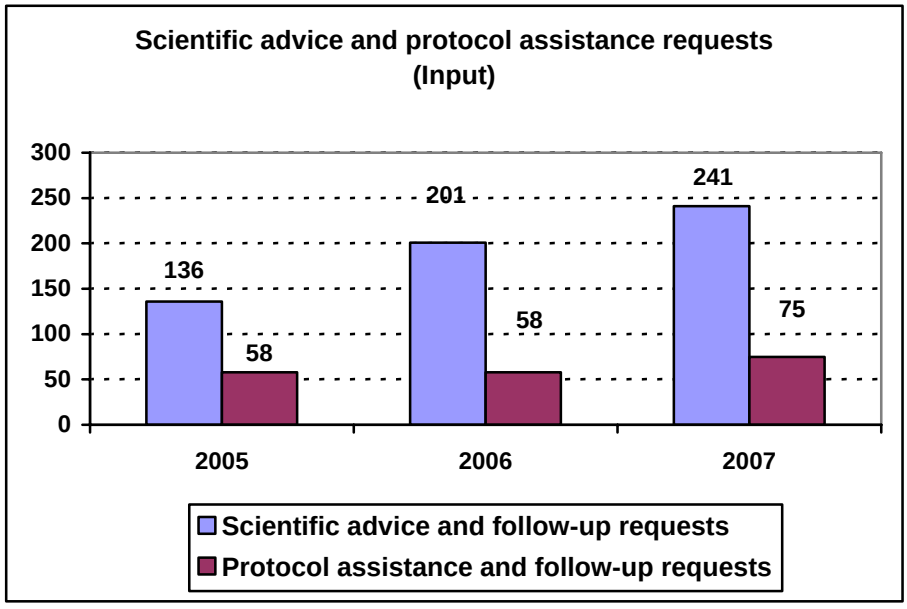
2.2 Scientific advice and protocol assistance

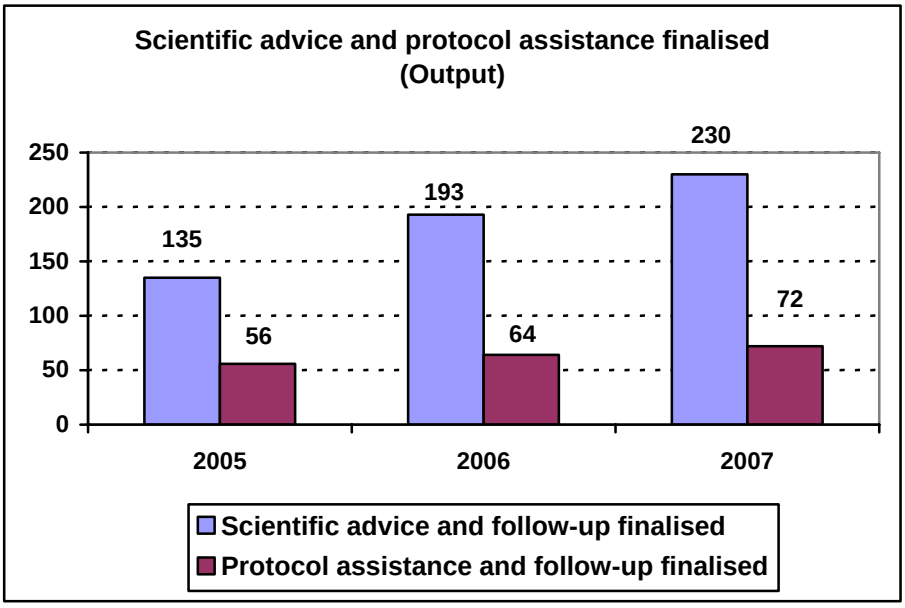
The Agency provides scientific advice and protocol assistance to sponsors during the phase of research and development of medicinal products. Scientific advice is provided on any aspect of research and development relating to quality, safety or efficacy of medicinal products. In addition, the Agency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

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 promote innovation and research.

Trends and new issues

- Following a steep increase in scientific advice and protocol assistance over the last few years, a further increase in the number of requests is expected, with greater contribution by CHMP Working Parties.
- The Agency will further develop scientific advice and protocol assistance for emerging therapies and technologies such as gene therapy, cell therapy and nanotechnology, as well as for pandemic influenza.
- A wider range of internal and external competences for new therapies, bioequivalence, risk management, bio-similarity and comparability will be required.
- The new regulation on medicinal products for paediatric use is expected to generate about 50 requests for scientific advice in the context of marketing authorisation applications and paediatric investigation plans.





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

Objectives

- Fully implement and monitor the revised scientific-advice and protocol-assistance procedures.
- Foster innovation through improved scientific-advice and protocol-assistance procedures.
- Develop risk-management plans at the time of scientific advice/protocol assistance.

Key initiatives to meet the objectives

- Conduct analysis of feedback from scientific advice/protocol assistance users about the new procedure; review procedure and implement changes identified to improve the system further.
- Introduce appropriate changes in the procedure to prepare for risk-management plans.
- Set up procedure to ensure effective co-operation between the Scientific Advice Working Party and the new Paediatric Committee.

Performance indicators

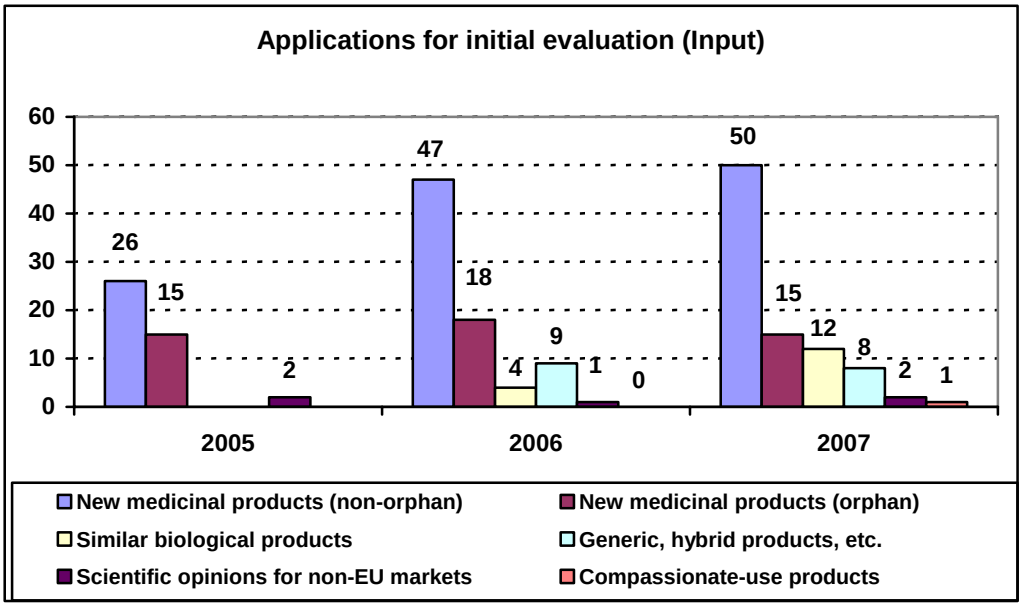
Performance indicator	**Target**
Scientific advice and protocol assistance requests evaluated within the procedural timelines	100% of requests
Percentage of pre-submission meetings for orphan and non-orphan products	60% and 80% of protocol assistance and scientific advice respectively
External experts involved in procedures	at least 70% 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. 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 (PMF) 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 workload in the initial evaluation area is growing substantially. Mainly, this is due to the new legislation expanding the mandatory and non-mandatory scope of the centralised procedure, the introduction of scientific opinions on medicines intended for non-EU markets, and the implementation of compassionate-use procedures. The large number of applications received in 2006 will have a significant impact on the workload in 2007 since procedures run over several months.
- The number of marketing authorisation applications for medicinal products containing new active substances (orphan and non-orphan) is expected to be around 65 in 2007. There will be a qualitative change with more products derived from new therapies and technologies, which will increase the complexity of applications, and products of high public-health interest such as influenza vaccines.
- Marketing authorisation applications for similar biological and generic medicinal products are expected to increase as products come off patent. Trends in the area of self-medication products are more difficult to predict.
- The Agency expects that scientific opinions on medicinal products (including vaccines) for non-EU markets will further develop in the coming years, increasing the requirement for new expertise to deal with diseases not encountered in the Western world, as well as the requirement for reinforced contacts with specialised academic centres, the World Health Organization (WHO), the Directorate-General for Health and Consumer Protection, and non-governmental organisations.



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

Objectives

- Review the outcome of the first year from implementation of new procedures contributing to availability of medicines and their safe use (including procedures reducing regulatory times and those dealing with Risk Management Plans).
- Re-engineer processes for the pre-authorisation phase of marketing authorisation and PMF certification, and reinforce the scientific secretariat input from pre-filing to opinion (Road Map action).
- Develop and improve the peer-review process further, in the context of the integrated quality-management system.

Key initiatives to meet the objectives

- Assess the effectiveness and amend as needed new procedures such as pre-authorisation procedure for risk-management plans, conditional marketing authorisation, accelerated assessment, procedures for generic and similar biological products, and those for compassionate use and products intended for non-EU markets. The Agency will continue to monitor implementation of other aspects of the new legislation and coordinate the updating of processes and procedures.
- Assess the current procedure for pre-filing, pre-submission and evaluation, and plan improvements.
- Take actions to reinforce the link between the scientific advice and marketing authorisation application phases.
- Set up process for rolling review of defined packages of responses to lists of questions (*Road Map action*).
- Assess the peer-review procedures and, if necessary, introduce improvements.

Performance indicators

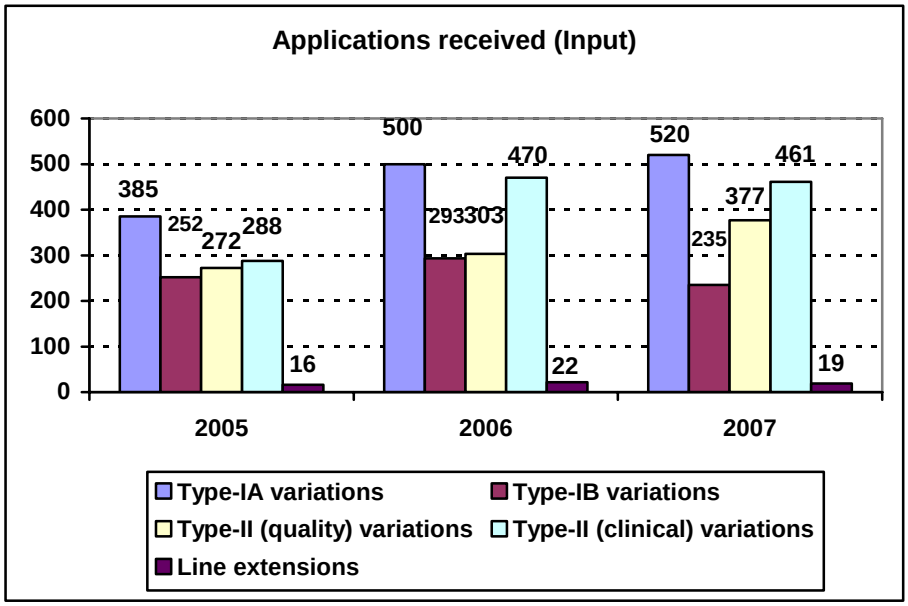
Performance indicator	**Target**
Percentage of applications or accelerated assessment applications evaluated within the regulatory timeline of 210 days or 150 days respectively	100% of applications
Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days	100% of 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
Percentage of opinions for compassionate use given by procedural deadline	80% of applications
Percentage of plasma master file applications evaluated within the regulatory timeline	100% of applications

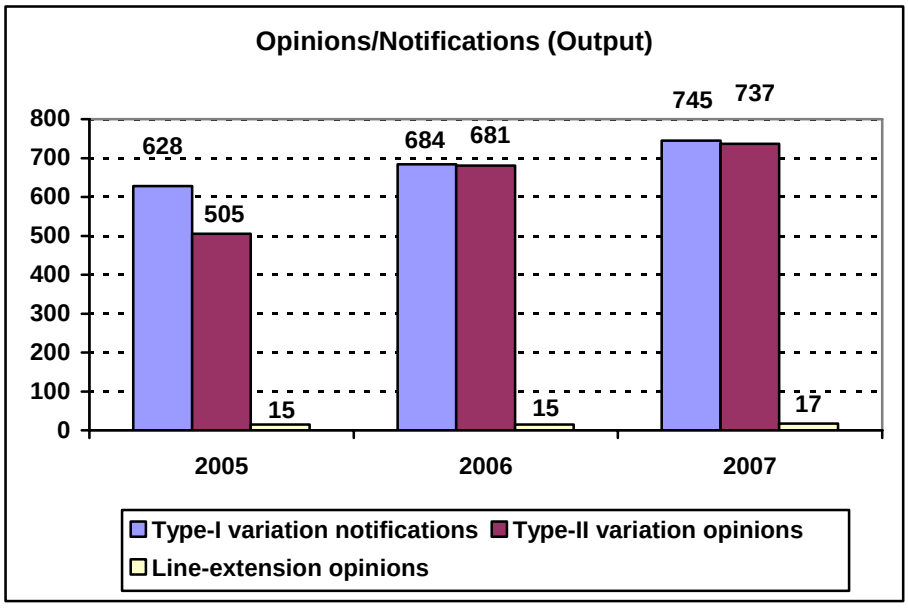
2.4 Post-authorisation activities

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

- A further increase in the number of type-I and II variations is expected, in line with the growing number of centrally authorised products following the expansion of the mandatory and optional scope of the centralised procedure.
- The first variations for similar biological products are expected in 2007, as are the first updates to Article 58 opinions.





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

Objectives and key initiatives

- Review activities related to the processing of type-I and II variations in the context of the EMEA process-improvement exercise with a view to identifying possible complementary process improvements and to further increasing efficiency.
- Strengthen the quality and the regulatory and scientific consistency of CHMP opinions and assessment reports in the post-authorisation phase, building on the operational improvements introduced in 2006. Scientific, regulatory and procedural training will be provided to staff in order to reinforce the scientific secretariat input and support to the CHMP and the (Co)-Rapporteurs in the scientific evaluation process.
- Reinforce the input of specialist advice (e.g. PhVWP co-opted expertise).
- Improve the provision to the public of targeted information in relation to post-authorisation activities.
- Support the European Commission in its review of the current legislative provisions on variations to marketing authorisations.

Performance indicators

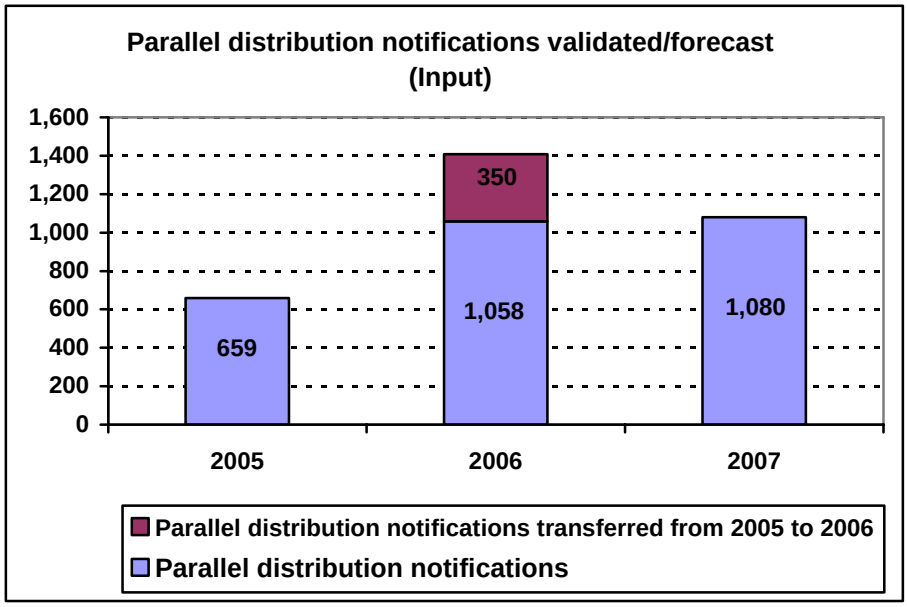
Performance indicator	**Target**
Percentage of applications for post-authorisation procedures evaluated within the regulatory timelines	100% of applications
Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications

Parallel distribution

A Community marketing authorisation is valid throughout the EU and a centrally authorised medicinal product is by definition identical in all Member States. Products placed on the market in one Member State can be marketed in any other part of the Community by a 'parallel distributor' independent of the marketing-authorisation holder. Typically, this is done to benefit from price differentials. The EMEA checks compliance of such products distributed in parallel with the appropriate terms of the Community marketing authorisation.

Trends and new issues

- It is forecast that the number of notifications for 2007 is expected to stabilise at approximately 1,000. Parallel distributors will continue to enlarge their range of medicinal products as a number of recently authorised products are likely to be parallel distributed, and compliance with the mandatory notification procedure by parallel distributors is likely to increase.



In addition to the core activity of checking that the conditions laid down in the Community marketing authorisations are observed, the following objectives will be targeted:

Objectives

- Provide guidance and information on parallel distribution activities.
- Increase parallel distributors' compliance with the checking process.

Key initiatives

- Review and update the EMEA guidance on parallel distribution, taking into account the experience gained.
- Implement initiatives aimed at improving efficiency of parallel distribution notification processes.
- Make the notices for parallel distribution issued by the EMEA publicly available on the Agency's website.

Performance indicators

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

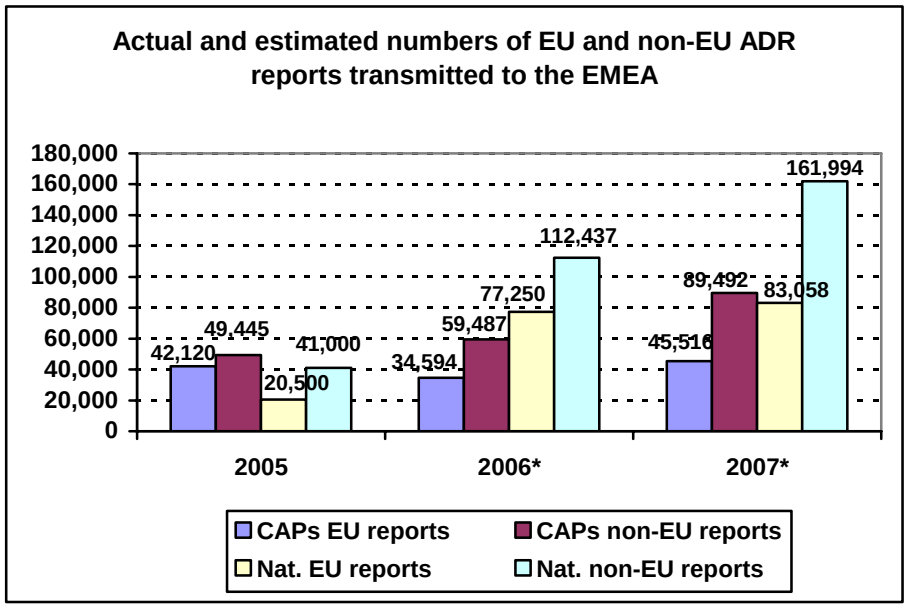
2.5 Pharmacovigilance and maintenance activities

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

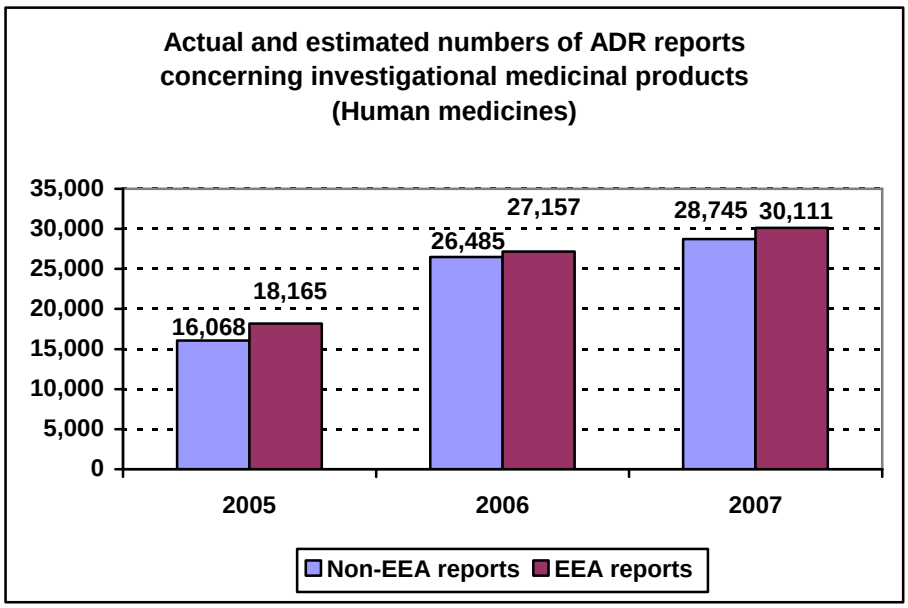
Safety of medicines is a priority area for the EMEA and the Agency will continue to strengthen its efforts in order to ensure the safe use of medicinal products authorised in accordance with the centralised procedure.

Trends and new issues

- Further work will be undertaken by the EMEA and NCAs in the context of the European Risk Management Strategy (ERMS), both in terms of additional activities to be developed and implementation of already agreed initiatives.
- A major increase in the electronic reporting of ICSRs has been observed over the past two years since the implementation of EudraVigilance. However, a number of stakeholders still do not comply with the electronic reporting requirements for EudraVigilance. Aspects relating to the data quality of the ICSRs reported to EudraVigilance and stakeholders' compliance with the expedited reporting timelines will be adequately addressed.
- The signal detection activities will be reinforced with the availability of the EudraVigilance Data Warehouse and Analysis System. This system will facilitate the detection, evaluation and tracking of potential safety issues through the use of quantitative methods of signal detection. It will also facilitate proactive monitoring of the potential safety issues identified in RMPs introduced by marketing authorisation holders.
- Additional functionality will be developed within EudraVigilance, including appropriate access to adverse-drug-reaction data. The level of access will take into account the requirement to guarantee personal data protection, as well as the commercially confidential nature of some of the data stored in EudraVigilance.



* With the implementation of the mandatory electronic reporting of ICSRs and the EudraVigilance Data Warehouse and Analysis System, a new method has been developed to present the number of ICSRs received/expected over time. This new method has been used for the numbers as of 2006.



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

Objectives

- Implement the ERMS in collaboration with the national competent authorities of the Member States, taking into account the rolling two-year work plan (2007–2009), with particular emphasis on the establishment of an intensive drug-monitoring system.
- Maintain and strengthen EudraVigilance to support proactive pharmacovigilance.
- The EMEA will take further initiatives to speed up the implementation of the electronic reporting of ICSRs as well as the retrospective population of EudraVigilance.
- Monitor compliance with the submission of post-authorisation commitments and PSURs by applicants and marketing authorisation holders, and take remedial action when relevant.

Key initiatives to meet the objectives

- Prepare a new rolling two-year work plan for the ERMS implementation.
- Implement the ENCePP (European Network of Centres for Pharmacovigilance and Pharmacoepidemiology) project by setting up a network of academic centres for the intensive monitoring of targeted medicines.
- Involve specialised expertise in the scientific evaluation process to support risk minimisation.
- Implement all new legal tools in the field of pharmacovigilance and maintenance, monitor the implementation and take remedial action, where necessary.
- Perform a quality review of RMPs, in the context of the Review and Learning project, and provide regular feedback to stakeholders.
- Speed up the implementation of the electronic reporting of ICSRs by all stakeholders, as well as the retrospective population of EudraVigilance, and address identified problems regarding the quality of the data and compliance with the reporting timelines.
- Roll out the EudraVigilance Data Warehouse and Analysis System; provide training and support to all stakeholders.
- Improve the EudraVigilance Data Warehouse, web-reporting and alerting tools, and develop and implement additional signal-detection methods.

- Develop the EudraVigilance data-processing network and database taking into account the need for the implementation of ICH step 4 guidelines and standards in the area of clinical-data management and multidisciplinary topics (E2B(R), M5 MedDRA and applicable international technical specifications).
- Integrate other healthcare databases, prescription and exposure data.
- Finalise and implement the access policy for EudraVigilance in line with Community legislation.
- Aggregate adverse reaction data collected in EudraVigilance, make them accessible to the stakeholders and provide guidance on the overall interpretation of the aggregated data.

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	70% of RMPs
Percentage of ICSRs reported electronically for CAPs	100% of ICSRs
Review of post-authorisation commitments (PACs) within the agreed timeframe	80% of PACs
Submission of outcome reports for PACs to applicants/MAHs within 2 weeks of the CHMP meeting	100% of reports

2.6 Arbitration and Community referrals

Arbitration procedures (either under Article 29 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 are mainly initiated in order to obtain harmonisation of authorisations for medicinal products authorised in the Community by the Member States.

Article 31 and 36 referral procedures are mainly initiated in case of Community interest and generally for safety-related issues.

Article 16(1) and 16(4) referrals are initiated by Member States regarding herbal medicinal products with a traditional use longer or shorter than 15 years respectively.

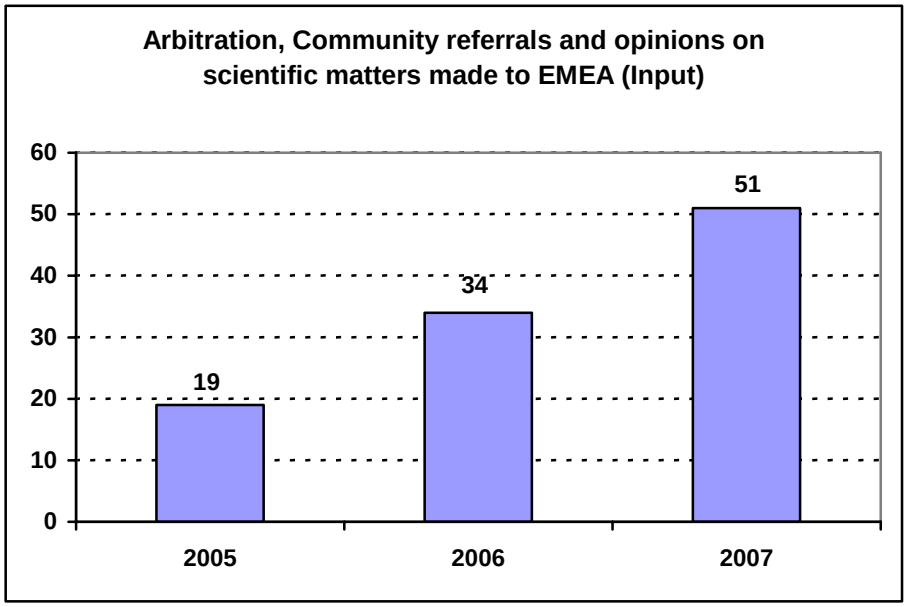
Article 107 procedures under Directive 2001/83/EC, as amended, are initiated to obtain a CHMP opinion further to the suspension or revocation of the marketing authorisation of a medicinal product in a Member State as a result of pharmacovigilance data.

Article 5(3) procedures require a CHMP opinion on any scientific matter raised by the EMEA, the European Commission or a Member State.

Trends and new issues

- The number of Article 29 and 30 opinions is expected to increase substantially in 2007. This is due to automatic referral of Article 29 arbitrations and, in the case of Article 30 referrals, to the legislative requirement for the Coordination Group for Mutual-Recognition and Decentralised Procedures–Human (CMD(h)) to prepare the list of medicinal products for which harmonised product information should be drawn up. In addition, the effectiveness of the pre-referral CMD(h) procedure will become evident.

- The uncertainty as regards the forecast for Article 31 and 36 referral procedures will remain in 2007. Since limited experience is available at this stage regarding the Article 16(1) and 16(4) referrals, it is difficult to make reliable forecasts regarding these types of referrals for 2007.
- Article 5(3) and Article 107(2) procedures are new legislative tools and the experience in 2006 with these procedures has been very limited. As a result, the expected workload for 2007 is difficult to predict. The implementation of these new legal provisions with a potentially high impact on the work undertaken by the CHMP and the EMEA Secretariat will be carefully monitored.



Objectives and key initiatives

- Focus on the effective management of referral and arbitration procedures and work to further strengthen the quality and the regulatory and scientific consistency of CHMP opinions and assessment reports. With this in view, appropriate guidance based on the 2006 experience of the operation of the CMD(h) pre-referral procedure, the SPC harmonisation group and herbal medicinal product related referrals will be developed.
- Finalise and make available general procedural guidance in relation to arbitration and referral procedures, and provide appropriate training to staff in order for the EMEA secretariat to strengthen its support to the CHMP and the (co-)rapporteur.
- Ensure transparency of arbitration and referral procedures by publishing relevant material, including Q&A documents, the latter at the time of adoption of the CHMP opinion.

Performance indicators

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

2.7 Medicines for children

This covers EMEA activities relating to the assessment of, agreement of and verification of compliance with paediatric investigation plans and waivers by the Paediatric Committee of the EMEA. An agreed paediatric investigation plan may lead to information on the paediatric use of medicines being included in a centralised or a national marketing authorisation for new medicinal products and in a paediatric-use marketing authorisation for off-patent products. This includes agreement on the strategy for the establishment of the European network of paediatric research and the provision of information on clinical trials performed in children.

Trends and new issues

- The Agency will receive entirely new responsibilities in the field of paediatric medicines. This will result in the establishment of a new scientific committee (the Paediatric Committee), establishment of procedures for the committee, processes for assessment of paediatric investigation plans and waivers and decisions on such plans or waivers, gradual establishment of a European network of paediatric research, and implementation of requirements related to the transparency of paediatric clinical trials.
- The Agency estimates around 400 requests or applications related to paediatric activities (such as paediatric investigation plans, waivers and scientific advice) will be received in the first year of activity.
- The work on paediatric investigation plans has an impact on activities within the scientific advice, quality and post-authorisation areas, as well as on risk-management plans.

Objectives

- Implement the regulation on medicinal products for paediatric use, establish the Paediatric Committee and provide opinions and decisions on paediatric investigation plans or waivers.
- Provide support for paediatric pharmacovigilance in the context of the new legislation and the new Committee.

Key initiatives to implement the objectives

- Set up the Paediatric Committee and its scientific and administrative support.
- Put in place procedures and guidance for the Paediatric Committee and the issuance of timely decisions.
- Finalise related framework documents, such as format and content of paediatric investigation plans, in liaison with the European Commission.
- Draw up a list of waivers for the consideration of the Paediatric Committee.
- Prepare scientific summaries for the Committee on applications for paediatric investigation plans or waivers.
- Prepare a proposal to the Management Board on the European network of paediatric research.
- Develop, with the Commission and Member States, guidelines for transparency of the EudraCT database in respect of paediatric clinical trials.
- Implement guidelines on paediatric pharmacovigilance; establish expert fora for the investigation of new sources and methods for the intensive monitoring of paediatric use of medicines.

Performance indicators

Performance indicator	Target
Number of paediatric investigation plan or waiver opinions and decisions within legal timelines	100% of opinions/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: the provision by the Committee on Herbal Medicinal Products of scientific opinions on questions relating to herbal medicines; the establishment of Community herbal monographs for traditional and well-established herbal medicinal products; the establishment of a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products; the provision of opinions on herbal substances at the request of the CHMP; and the evaluation for referral and arbitration procedures concerning traditional herbal medicinal products.

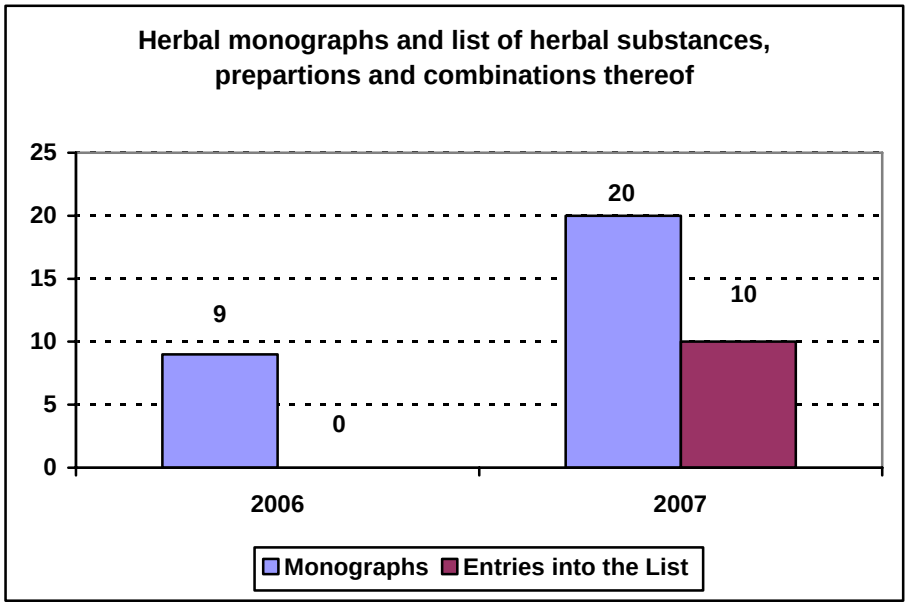
Trends and new issues

- The development of monographs and list entries are critically dependent on the availability of adequate bibliographic compilations provided by interested parties and resources made available at NCA level to support their review. Such availability or lack thereof will have a direct impact on the productivity of the Committee on Herbal Medicinal Products (HMPC) in 2007 and beyond.
- Traditional registration applications are expected to increase in 2007, and the first referrals to the HMPC in support of such applications are expected.

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

Objectives and key initiatives

- Review and improve the process for producing Community herbal monographs and entries to the list of herbal substances.
- Review the operation of the HMPC working parties and drafting groups in order to further improve cooperation with the CHMP working parties.
- Update the interested parties on the operations of the HMPC, with particular emphasis on prioritisation of herbal substances identified for list entry/monograph development.



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 Emerging therapies and new technologies

This area of activity relates to advanced therapy medicinal products, including gene therapy, somatic cell therapy or human tissue engineered products, and to other emerging therapies and new technologies that are not within the scope of the proposed regulation on advanced therapies.

Trends and new issues

- Upcoming legislation on advanced therapies.
- Need for expertise to address scientific issues such as materials science, nanotechnologies and new nuclear medicine applications, amongst others.
- The Agency expects there to be an impact from research and development in relation to targeted and personalised therapies, linking, for example, to the more recent development in pharmacogenomics and in nanotechnology. In addition, a new emerging trend, requiring further pooling of EU expertise, is the increase in development and marketing authorisation applications for "health product" resulting from the combination of products currently regulated by diverse legislative frameworks (e.g. medical devices and advanced therapies in combination).

Objectives and key initiatives

- Promote early dialogue with sponsors of potential applications for advanced therapies and emerging products and technologies. The Agency will organise meetings to address scientific and regulatory matters arising from new products and approaches.
- Extend the dialogue with academia and society at large to identify expertise, expectations and bottlenecks related to the area of new treatment solutions.
- Following discussion with experts from national authorities of Member States, academia, learned societies and pharmaceutical industry on challenges related to new technologies, work will begin on establishing a 'Strategic plan for new technologies' (*Road Map action*).

Performance indicators

Performance indicator	Target
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 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 summaries of opinions, European public assessment reports (EPARs), and information on arbitrations and referrals, the Agency provides a wider range of information. This includes information on withdrawals of applications prior to Commission Decision and on negative decisions, for both new applications and extensions to existing indications, as well as EPAR summaries for the public.

In addition to the core activities outlined above, the following objectives will be targeted:

Objectives

- Provide up-to-date and understandable information targeted at patients and the general public on all products subject to scientific review by the Agency thus promoting the appropriate use of medicines and further contributing to patient safety.
- Develop and reinforce the interaction with and participation of the Agency's stakeholders (healthcare professionals, patients and consumers).

Key initiatives to meet the objectives

- Investigate how best to integrate all available EMEA tools developed for the provision of information with the objective of communicating in a coherent way and facilitating access to information by healthcare professionals, patients and the public.
- Develop the EudraPharm database as outlined in Chapter 5.
- Analyse 2006 experience in relation to publication of EPAR summaries for the public and documents on withdrawals, referrals and safety-related information, and identify areas for improvement.
- Improve the process for the publication of EPARs and their updates, looking at both the internal authoring processes and the publication workflow.
- Monitor and analyse results of the consultation on package leaflets with targeted patient groups, and their evaluation by the CHMP; prepare guidance for industry and the CHMP.
- Analyse the experience gained in the context of the 2005 EMEA framework on the handling of translations of product-related information and introduce amendments, if necessary. Review the mandate of the Quality Review of Documents (QRD) group, with the aim of integrating the group's activities into the provision of updated and targeted information to patients and the general public.
- Integrate Bulgaria and Romania in the translation framework.
- Integrate Malta in the translation framework, given that the derogation for the Maltese language will come to an end in May 2007, and organise a linguistic review process in order to anticipate the smooth phasing-in of the Maltese language version.
- Continue implementation of the recommendations from the EMEA/CHMP Working Group with Patients' and Consumers' Organisations.

- Analyse and monitor the degree of satisfaction of patients and consumers (based on performance indicators agreed by patients' and consumers' organisations put in place in 2006).
- Prepare a framework for interaction with healthcare professionals' organisations.
- Develop recommendations of the EMEA/CHMP Working Group with healthcare professionals.
- Create a forum where healthcare professionals, patients and consumers can discuss issues of common interest.

Performance indicators

Performance indicator	**Target**
Percentage of initial EPARs or updated EPARs (when product information is affected) published within 2 weeks of the Commission decision	80% of marketing authorisations granted or EPARs updated
Percentage of EPAR summaries in a language understandable to the public, published together with the EPAR	80% 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	100% of 'question and answer' documents

2.11 Scientific committees, working parties and scientific advisory groups

The Committee for Medicinal Products for Human Use

The Committee for Medicinal Products for Human Use (CHMP) is responsible for the scientific evaluation and provision of scientific opinions to the European Commission for the authorisation and maintenance of medicinal products. The Committee provides scientific advice and protocol assistance to pharmaceutical enterprises during the process of medicines development. The Committee also provides scientific opinions on medicinal products involved in arbitration and referral procedures, on medicinal products intended for use outside the European Union, and on any matter relating to the evaluation of medicinal products at the request of the European Commission or the Executive Director of the Agency. Furthermore, work is undertaken in the fields of harmonisation of technical requirements for pharmaceutical regulation, pharmacovigilance and public health threats.

A renomination of the majority of the CHMP members following the completion of the three-year term will be undertaken in May 2007, and the Agency will work to ensure timely and smooth transition from the former Committee.

The CHMP will meet 11 times in 2007, with each meeting lasting four days.

The Committee on Orphan Medicinal Products

The Committee on Orphan Medicinal Products (COMP) is responsible for making recommendations to the European Commission for the designation of orphan medicinal products for rare diseases. The COMP is also responsible for advising the European Commission on the development of an orphan medicinal product policy, and for providing assistance on liaison with international partners and patients' organisations on this issue.

The COMP will meet 11 times in 2007, with each meeting lasting up to two days.

The Committee on Herbal Medicinal Products

In addition to the tasks described in Section 2.8, the Committee on Herbal Medicinal Products (HMPC) will help to harmonise procedures and provisions concerning traditional herbal medicinal products laid down in the Member States, and help to further integrate herbal medicinal products in the European regulatory framework.

The renomination of the majority of the HMPC members following the completion of the three-year term will take place in 2007, and the Agency will work to ensure timely and smooth transition from the former Committee.

The HMPC will meet 6 times in 2007, with each meeting lasting one and a half days.

The Paediatric Committee

The Paediatric Committee (PDCO) will conduct assessment of, agreement of and verification of compliance with paediatric investigation plans. The Committee will also establish lists of waivers of specific or classes of medicinal products that are not suitable or necessary for the treatment of children. The Committee will advise the EMEA on the development of a European network of paediatric research. For more information, refer to Section 2.7.

The PDCO will meet every month from its establishment in 2007, with each meeting lasting up to three days.

Standing and temporary working parties and scientific advisory groups

The working parties of the EMEA scientific committees responsible for medicinal products for human use are involved in the development and revision of guidelines, and the provision of recommendations and advice on medicinal products for which applications are made. In addition, 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.

Scientific advisory groups are established by the CHMP to evaluate and advise on specific types of medicinal products or treatments. They are composed of experts from academia and university hospitals, representing various schools of thought and medical practices in the EU.

The Agency will discuss with the Member States' competent authorities and the CHMP the mandate of the Pharmacovigilance Working Party, and will introduce any necessary changes.

The Agency will monitor the effectiveness of the implementation of the procedure for EU pharmaceutical guidelines, and will assess the impact of the first full year of activity of scientific advisory groups established by the CHMP. Greater use of this scientific expertise is expected.

The EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) replaces the EMEA/CHMP Working Group with Patients' and Consumers' Organisations. Its mandate relates to the activities of the three scientific committees (CHMP, COMP and HMPC). It will also continue to implement the recommendations of the previous working group.

Further to a workshop with healthcare professionals' organisations held in 2006, an EMEA/CHMP Working Group with Healthcare Professionals' Organisations will be established in 2007.

Work will continue on improving the cost-effectiveness of the arrangements for working parties, including review of their mandates, distribution of work, and support provided by the secretariat. Expertise needed in the working parties will be addressed together with the Heads of Medicines Agencies.

An increase in the number of meeting days of the Scientific Advice Working Party is expected because of additional requests for advice, particularly those arising from implementation of the legislation on medicines for paediatric use. This new legislation will also see the phasing out of the Paediatric Working Party to be replaced by the Paediatric Committee. Activities of the Cell-based

Products Working Party are expected to increase in view of preparations for a new regulation on advanced therapies.

2.12 Coordination group

The Agency provides secretarial support to the Coordination Group for Mutual-Recognition and Decentralised Procedures–Human (CMD)(h) and its sub-groups/working groups, in accordance with the approved rules of procedure. In 2007, the Agency will consolidate its activities, based on a review of the experience gained during the first year of operation of the CMD(h). The main tasks of the Agency, in addition to the provision of secretarial support, will be:

- Prepare agreements and monthly and yearly statistics, and provide a list of positions taken.
- Facilitate liaison with other scientific forums (e.g. the Pharmacovigilance Working Party) and with interested parties.
- Prepare the list of medicinal products for which a harmonised summary of product characteristics should be drawn up.
- Maintain a CMD(h) memory of all regulatory and scientific agreements.

The CMD(h) will meet 11 times in 2007, with each meeting lasting two to three days.

2.13 Regulatory 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. It will continue to update and develop guidance documents focusing on the key steps of the centralised procedure, as well as on issues of quality, safety and efficacy of medicinal products, to facilitate use of the centralised procedure and support the submission of applications of the required quality.

The Agency also works to continuously address regulatory and procedural issues affecting the EMEA committees, standing and temporary working parties, and associated groups. Emphasis will be put in 2007 on a close monitoring of the implementation of the new legal provisions for the authorisation and supervision of human medicines, and remedial action will be taken if required. Feedback from the Agency's stakeholders will be sought on experience obtained from the implementation of the new legislative provisions. In addition, regulatory and procedural support will be provided on the implementation of new Community legislation in relation to paediatric medicines.

3. VETERINARY MEDICINES

Priorities for medicines for veterinary use in 2007:

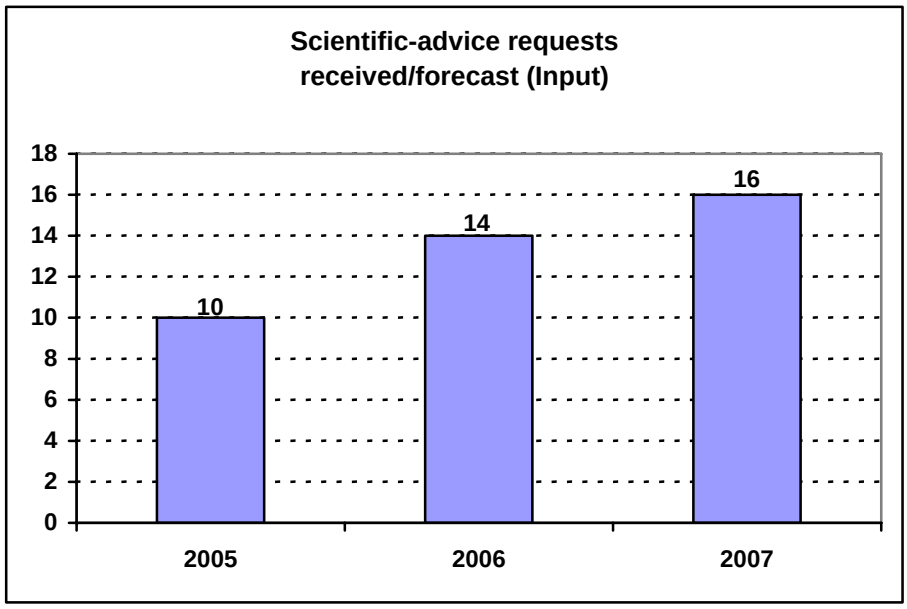
- Meet the Agency's targets in relation to authorisation and supervision of centrally authorised veterinary medicinal products.
- Promote the supervision of veterinary medicines once authorised, through effective pharmacovigilance, further development of the EudraVigilance Veterinary database and support for the European Surveillance Strategy (ESS).
- Within the working parties of the Committee for Medicinal Products for Veterinary Use (CVMP), give priority to the further elaboration of guidance on the following topics; measures to reduce the development of antimicrobial resistance; environmental risk assessment; authorisation of vaccines against epizootic disease of animals, particularly avian influenza in birds; and, support of the EU programme to reduce animal testing.
- Promote innovation through continued involvement in the European Technology Platform for Global Animal Health (for additional information on the Agency's initiatives aimed at promoting availability and innovation in the animal sector, please refer to Chapter 1).
- Promote greater availability of medicines through measures to assist SMEs and companies seeking to authorise products for minor species and/or limited markets, and through implementing recommendations arising from the Heads of Medicines Agency Taskforce on Availability.
- Promote close cooperation between the CVMP and the Coordination Group for Mutual-Recognition and Decentralised Procedures–Veterinary (CMD(v)) to promote efficient functioning of the European medicines network.

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 expected that, as the improvements to the scientific advice procedure continue to be recognised and appreciated by potential applicants, and as industry gains confidence through experience with the procedure, the number of submissions made will continue to increase, reaching 16 in 2007.



Objectives and key initiatives

- Work to provide quality scientific advice to applicants and support the Scientific Advice Working Party, taking account of the further experience gained with the new procedure, the updated web guidance document and the mandate.
- Measure the level of satisfaction with the new procedure, as indicated in the questionnaires to applicants, and make necessary improvements.
- Initiate development of a database for tracking applications for veterinary scientific advice, further to the internal audit conducted in 2006.

Performance indicators

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

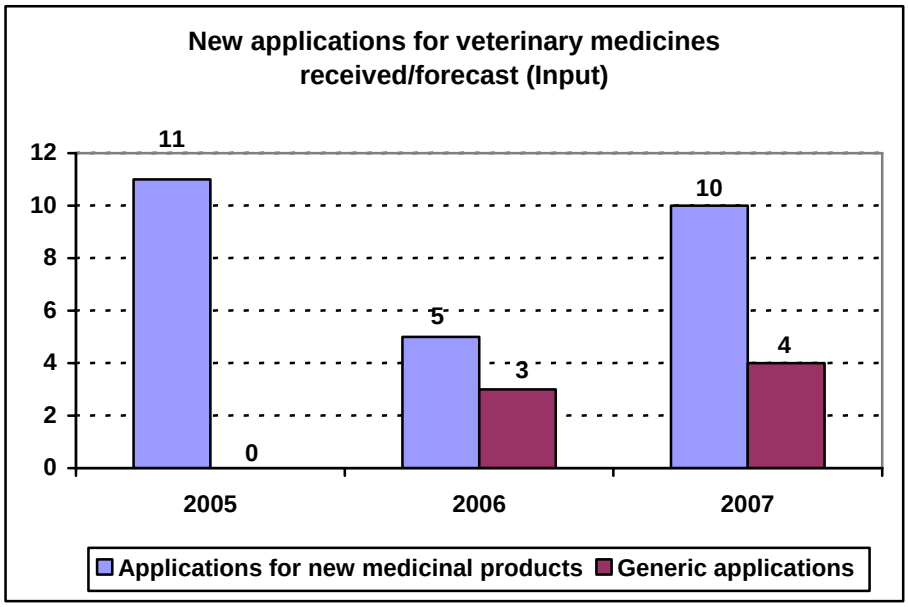
3.2 Initial evaluation

The initial evaluation phase covers a number of 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 overall number of initial-evaluation applications is forecast to remain constant at a total of 14. This forecast takes into account the following considerations: the increased scope of the procedure in the revised legislation; the guidance and possible support available to companies considering applications for limited markets and/or for regional diseases; the continued submission of applications for immunological products for diseases where there is a Community interest; and the expected increase in generic applications for centralised products as more patents expire for existing centralised products.



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

Objective

- Maintain and improve, where possible, the quality of the processing and evaluation of marketing authorisation applications and opinions.

Key initiatives to meet the objective

- Develop and maintain the scientific memory database to assist in ensuring the quality and scientific and regulatory consistency of scientific assessments.
- Strengthen the quality assurance system in respect of CVMP procedures.
- Hold pre-submission meetings with the involvement of both the rapporteur and co-rapporteur and any experts required, to ensure that scientific issues are fully discussed prior to submission, with the principal objective of avoiding premature applications. In this context, the use of videoconferencing will be evaluated as a way of reducing cost and facilitating input from experts in national competent authorities.

Performance indicators

Performance indicator	**Target**
Percentage of products evaluated within the regulatory timeline of 210 days	100% of applications
Percentage of opinions sent to the European Commission within the	100% of applications

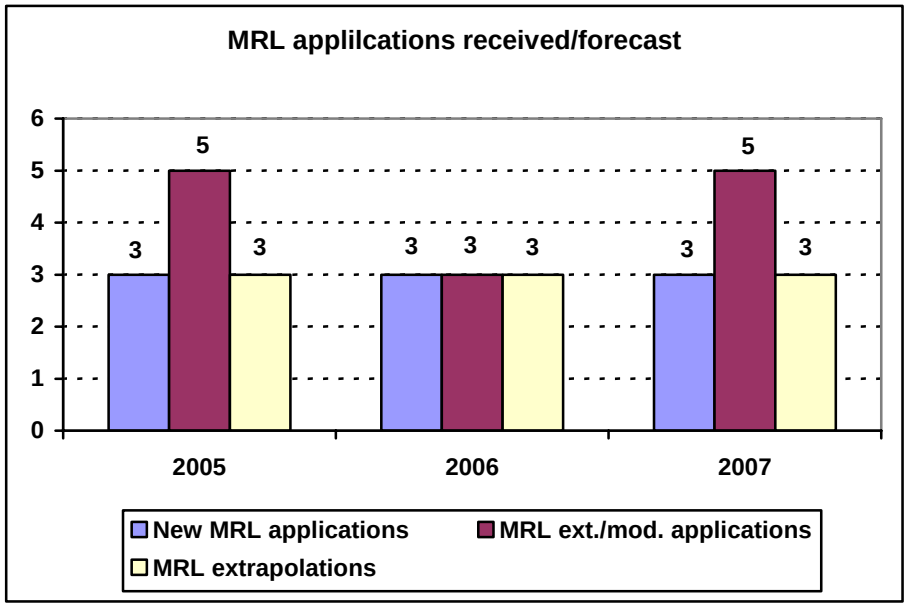
regulatory timeline of 15 days	

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 focused within 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 relatively stable. The number of new MRL applications is therefore predicted to remain constant, with 3 applications forecast for new MRLs.
- The number of extensions and modifications has remained constant 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 in 2007, with 5 applications being expected.
- Three requests for extrapolation of MRLs to minor species are expected in 2007.



Objectives and key initiatives

- Continue to ensure high-quality assessment of MRL applications through a strengthened review process by the CVMP.
- In order to facilitate marketing authorisation for veterinary medicines for minor species and minor uses, continue to extrapolate MRLs to minor species upon request by companies in accordance with the CVMP policy on availability.
- Assist the Commission with the review of Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin.

Performance indicators

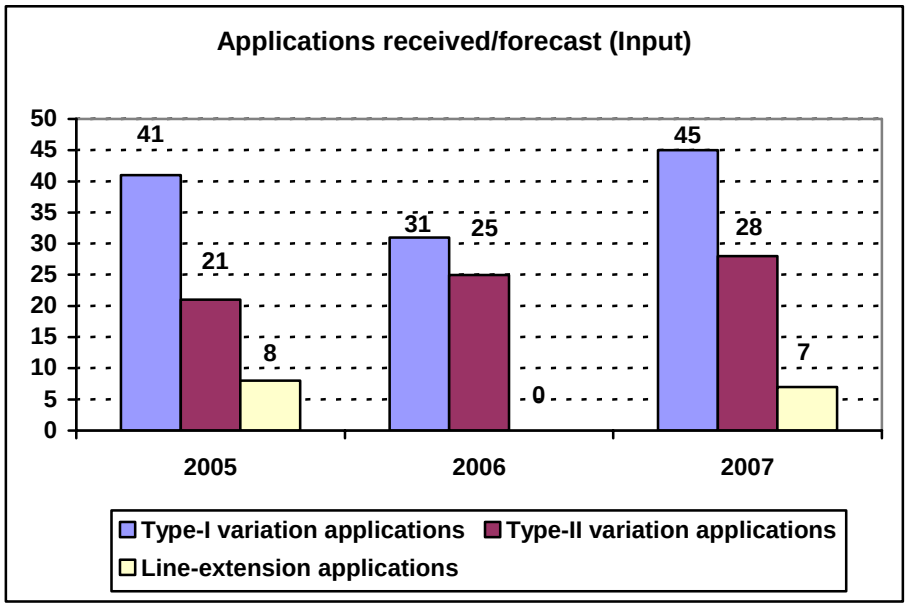
Performance indicator	**Target**
Percentage of applications evaluated within the 120-day timeline	100% of applications

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 change in accordance with the total number of marketing authorisations and the increased number of products that will be on the market. The number of type-I applications forecast is 45, while for type-II variations the number forecast is 28, taking account of the number of applications predicted for 2006. The Agency forecasts 7 applications for extensions.



Objectives and key initiatives

- Ensure high-quality assessment of post-authorisation applications.

- Prepare EPAR summary updates for line extensions that lead to major changes in the indications or conditions of use.
- Assist the Commission with revision of the regulations governing variations to marketing authorisations (Regulations (EC) No 1084/2003 and 1085/2003).
- Implement procedures for monitoring the actual placing on the market of authorised products with respect to the requirements of the revised legislation.

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
Percentage of applications meeting the legal timeline of 15 days for the linguistic post-opinion checking procedure	100% of applications

3.5 Pharmacovigilance and maintenance activities

This activity relates to pharmacovigilance information, including adverse-drug-reaction reports (ADRs) and periodic safety-update reports (PSURs). Pharmacovigilance remains a high priority of the Agency for 2007, to ensure that effective risk-management is continuously applied to post-authorisation monitoring of veterinary medicines throughout the EU.

Trends and new issues

- The continuing emphasis on the safety of veterinary medicines in the post-authorisation phase and the need to implement and further improve a risk-management approach to this important issue will continue to feature highly on the list of priority activities again in 2007.
- It is expected that over 70 centralised products will be marketed by 2007. The Agency forecasts the number of serious adverse reaction reports will rise to over 800, with 64 PSURs to be submitted (54 were submitted in 2006).
- With the need to meet the Agency's obligations on pharmacovigilance reporting and communication as stated in the legislation, a considerable increase in data analysis within EudraVigilance Veterinary (EVV) and subsequent reporting and greater transparency is expected.
- The impact of the new legal provisions for ‘automatic referrals’ to the CVMP of urgent measures by Member States due to pharmacovigilance issues under Article 78 of Directive 2001/82/EC, as amended, is difficult to predict at present. However, discussions with Member States indicate a significant workload may arise from these provisions.

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

Objectives and key initiatives

- Collaborate fully and work with Member States in the European Surveillance Strategy (ESS) to foster a joint approach to optimising the efficiency of EU veterinary pharmacovigilance for all medicinal products authorised in the Community.
- Provide assistance to Member States on the import of product-related data into EVV and on the analysis of pharmacovigilance data within the EVV Data Warehouse to identify any signals.
- Develop the analytical and reporting functions of the EVV Data Warehouse in line with the project plan agreed with stakeholders in Member States and industry.

- Following the full switch to electronic reporting for all Member States and marketing authorisation holders, undertake activities relating to further training and the provision of assistance to Member States and industry.
- Continue to improve on EMEA communication to the public, and encourage a reporting culture through collaborative efforts with interested parties and the Member States.

Performance indicators

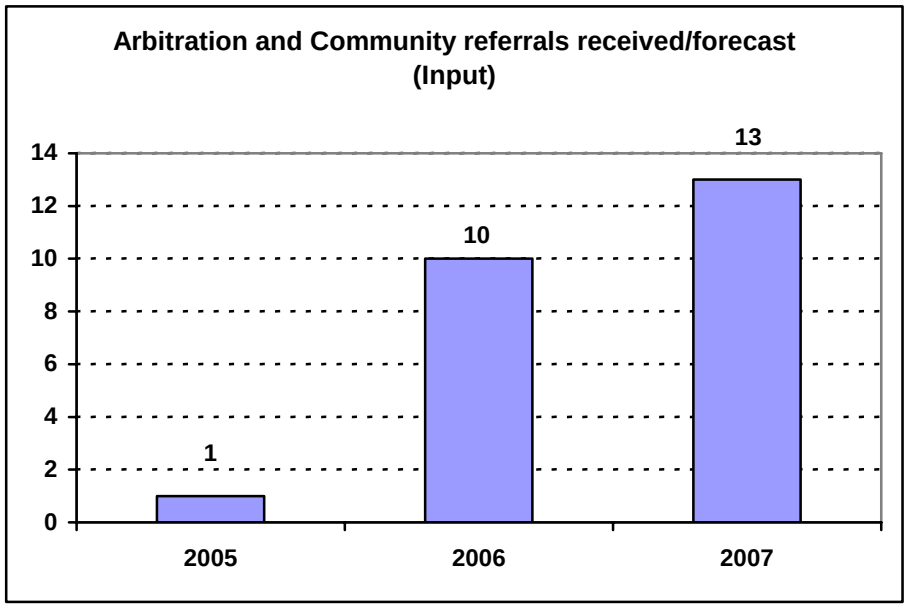
Performance indicator	Target
Percentage of PSURs evaluated within the established timeline of 60 days	80% of PSURs

3.6 Arbitration and Community referrals

Arbitration procedures are initiated because of disagreement between Member States within the framework of the mutual-recognition 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

- Referrals to the CVMP following mutual-recognition and decentralised procedures are expected to continue in 2007. The number of such referrals is difficult to predict. Twelve referrals are estimated at this stage — a slight increase in comparison to 2006.
- The number of referrals triggered by safety concerns where there is a Community interest remains low, and only 1 is predicted for 2007.
- In total, 13 arbitrations/referrals are expected to be submitted to the CVMP in 2007, representing a 30% increase on the 2006 number.



The Agency will focus on ensuring provision of quality opinions arising from arbitration and referral procedures, and will work to adhere to regulatory timelines. The Agency will ensure optimal

coordination between the CMD(v), the CVMP and the working parties to minimise 'unnecessary' referrals.

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) will need to continuously reflect on its performance in meeting its obligations under the new legislation, and in particular to ensure compliance with the requirements of the EMEA Road Map for the strengthening of the quality of assessments and improvement of information to the public.

The Committee will also need to review, together with the Coordination Group for Mutual-Recognition and Decentralised Procedures–Veterinary (CMD(v)), the cooperation between them 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.

Following the revision of Annex I to Directive 2001/82/EC, as amended, the CVMP, with the support of its working parties, will update all relevant guidelines.

Following the end of the current three-year term for the majority of CVMP members that were nominated after the entry into force of Title IV of the new Regulation in May 2007, the Agency will work to ensure timely and smooth transition for the Committee.

Additional work will be required to train and accommodate representatives of Bulgaria and Romania as from January 2007. Training activities will be extended to include these new Member States, as well as Turkey and Croatia, in preparation for their possible accession in the future.

Working parties and scientific advisory group

The CVMP working parties and scientific advisory group will be renewed in 2007 following the end of the first three-year period of the majority of Committee members under the new regulation. Having reviewed the mandate and operation of its standing and temporary working parties in 2006, the CVMP will draw up lists of specialised European experts who are ready to support the CVMP and its working parties on specific scientific subjects, if the need for their expertise arises.

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 relating to applications under consideration by the CVMP or the Coordination Group, and on enquiries from companies relating to the interpretation of guidelines.

The CVMP and its working parties will have as priority areas for 2007:

- Advice and guidance regarding antimicrobial resistance.
- Elaboration of regional guidance on environmental risk assessment.
- Technical requirements to support the 'multistrain dossier' approach to promote authorisation of vaccines against antigenically variable viruses such as avian influenza, bluetongue and foot-and-mouth disease.
- Support for the EU programme to reduce animal testing and develop other modern approaches to safety assessment of medicines.

3.8 Coordination group

The secretariat of the Coordination Group for Mutual-Recognition and Decentralised Procedures–Veterinary (CMD(v)) is now fully established. A significant increase in workload is expected for the new coordination group, particularly in relation to referrals. There will also be greater reliance on the formal secretariat provided by EMEA staff in 2007.

The Agency's support for the CMD(v) will include:

- Preparing agreements and monthly statistics, and provide a list of positions taken.
- Facilitating liaison with the CVMP, other scientific working groups and with interested parties.
- Maintaining a CMD(v) memory of all regulatory and scientific agreements.
- Where appropriate, facilitating resolution of issues arising during mutual-recognition and decentralised procedures through effective communication and coordination at both scientific and procedural levels.

The CMD(v) will meet 11 times in 2007, with each meeting lasting two days.

4. INSPECTIONS

Priorities for inspections in 2007:

- Further implement the new pharmaceutical legislation on GMP requirements for active substances and certain excipients.
- Implement new ICH quality guidelines and integrate principles into relevant GMP and quality-related guidance documents.
- Conduct preliminary work on adaptation of certain quality, GMP, GCP and pharmacovigilance inspection requirements in view of forthcoming regulations on advanced therapies and paediatric medicines.
- Continue to provide support for the clinical trials and GCP directives for human medicines, in particular the implementation of activities relating to GCP inspections and GMP requirements, as well as the transparency requirements in Regulation (EC) No 726/2004 and the proposed Paediatric Regulation.
- Strengthen cooperation between Member States on GMP, GCP and GLP inspection performance and outcomes, including consideration of specific needs identified by Bulgaria and Romania.
- Facilitate innovation and continuous improvement in the context of manufacturing and control methods, through the work of the Process Analytical Technology (PAT) team and international cooperation.

4.1 Inspections

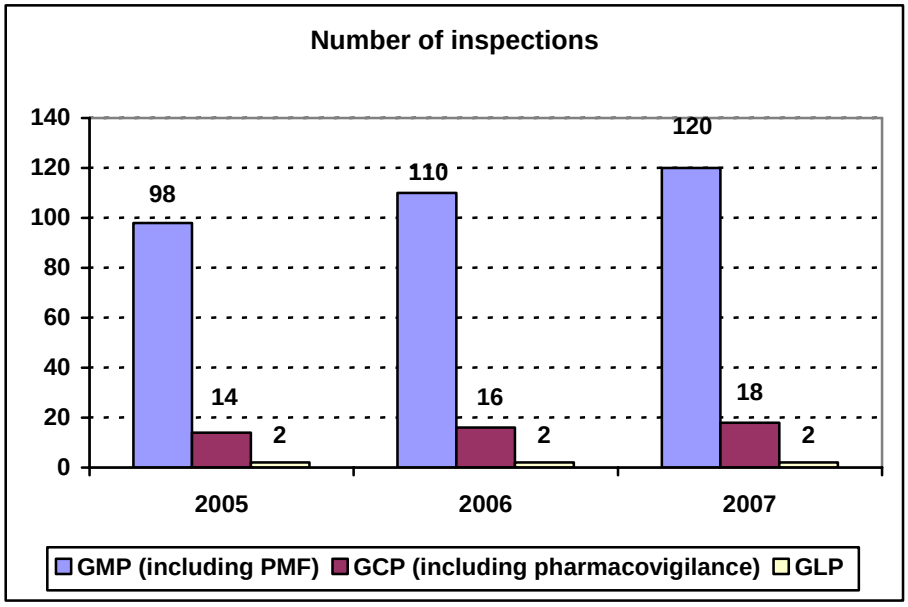
The EMEA coordinates the verification of compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP) and good laboratory practice (GLP), and with certain aspects of the supervision of authorised medicinal products in use in the European Community. It does this through 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.

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

- Both GMP and PMF inspections numbers are expected to rise relative to 2006. 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.
- Numbers of GCP and pharmacovigilance inspections are also expected to rise.
- The impact of inspections in the context of the proposed paediatric and tissue-engineering regulations will have to be reviewed, depending on the progress of these legislative initiatives.
- Increase in post-authorisation follow-up and coordination of actions aimed at dealing with quality defects of centralised products, including coordination of actions with national enforcement officers and the European Directorate for the Quality of medicines, as necessary, in the case of suspected counterfeits.

- Further development of policy and procedures on pharmacovigilance inspections, including inspection triggers and timing.



In addition to core activities relating to inspection coordination, the following objectives will be targeted:

Objectives and key initiatives

- Assess the impact of procedural requirements in the area of GMP for active substances and certain excipients, and review procedures and guidance documents as appropriate.
- Coordinate activities and optimise the joint audit programme for GMP inspectorates.
- Implement and integrate ICH concepts of quality-risk management, design space and pharmaceutical quality systems in assessment and inspection areas.
- Assess the impact of new legislation on GCP and pharmacovigilance activities, and review procedures in the light of experience.
- Strengthen the approach to inspections of bioequivalence studies in the context of generic applications.
- Analyse findings on GMP and PMF deficiencies during inspections conducted in 2007. Compare with report prepared in 2006.
- Review and analyse all quality defects handled during 2007, and publish the report on the website.
- Improve cooperation within the European medicines network through specific bilateral discussions on coordination of good practice inspections, and the organisation of dedicated meetings of pharmacovigilance inspectors.

Performance indicators

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

Ad hoc meetings of GMP, GCP, GLP inspection services and Joint CHMP/CVMP Quality Working party

The GMP and GCP inspectors' meetings and Quality Working Party will each meet four times in 2007. A meeting of GLP inspectors is also expected to be scheduled. Related training activities on GCP and quality/GMP will also be organised. Cooperation between inspection and assessment functions will continue to be developed, particularly through the work of the Process Analytical Technology team and joint sessions with GMP inspectors/quality assessors and GCP inspectors/clinical assessors (Road Map action). Terms of reference for Ad Hoc GMP and GCP Inspection Services will be agreed in 2007. The GMP and quality groups will contribute to the Commission's initiatives on revision of the variations, anti-counterfeiting and parallel trade projects.

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

- The internal evaluations of new Member States will continue with Bulgaria and Romania in the context of the mutual-recognition agreements.
- This will also extend the external evaluations by MRA partners well into 2007 and possibly beyond.
- The increasing number of regulatory authorities participating in the operational aspects of the MRAs requires intensified harmonisation of procedures.
- As EudraGMP progresses, improvements in exchange of information with MRA and other international partners should be possible.

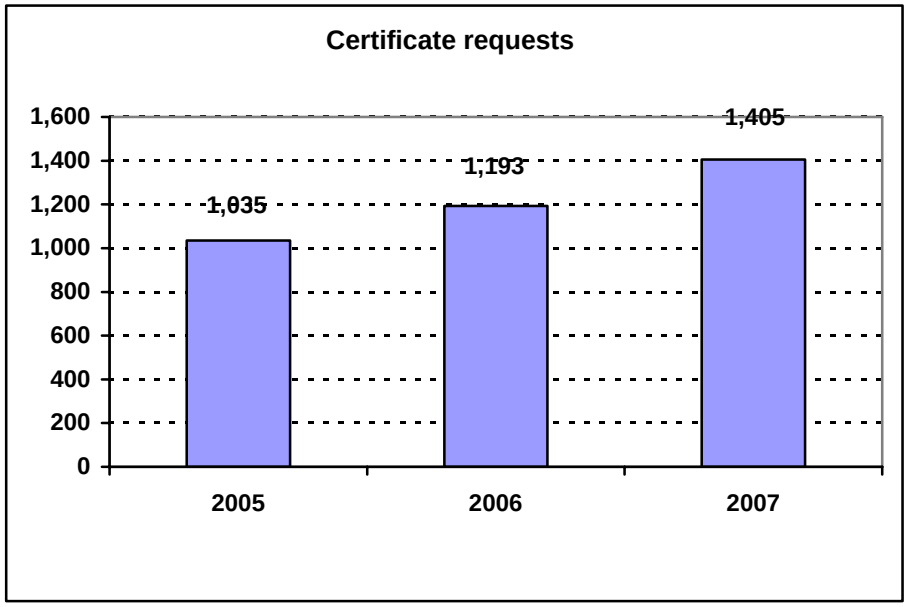
Objectives and key initiatives

- Harmonise operational aspects of the respective mutual-recognition agreements (MRAs).
- Complete the remaining internal evaluation work and follow-up with new Member States in the context of the EC-Canada MRA, with inclusion of Bulgaria and Romania in the internal evaluation work.
- Complete external evaluations in the context of the MRA with Canada.
- Contribute to confidence-building between MRA partners and new Member States.
- Complete the implementation of the full scope of the GMP Annex with EC-Japan MRA and maintenance arrangements.
- Analyse the changes to GMP in view of the implementation of quality-risk-management discussions with MRA partners.

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 of 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.

The number of certificate requests is expected to increase by 18%, due to the ever-increasing number of approved marketing authorisations. Certificates within the framework of cooperation with the WHO and certificates for SMEs are also expected to increase in 2007.



The Agency will continue to work on rationalisation of the process, including staff allocation and IT developments.

Performance indicators

Performance indicator	Target
Percentage of certificates issued to requesting parties within the timeline	95% compliance

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

The sampling and testing programme for centrally authorised products will continue in 2007 and will enable the quality of medicinal products on the market in the EEA to be monitored, using the expertise

of the EEA network of official medicines-control laboratories. Close collaboration between the EMEA, the EDQM and the national authorities in the programme continues to prove invaluable in assuring effective and continued post-marketing surveillance of the quality of medicines.

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

Objectives and key initiatives

- Progress a risk-based approach to the selection of products and parameters for testing in view of generic applications and advances in technology (Process Analytical Technology).
- Review the one-laboratory testing scheme and assess its possible introduction for biological products.
- Consider further the need to adapt strategy and /or testing requirements in view of the inclusion of authorised generic products.

Performance indicators

Performance indicator	Target
Percentage of planned products (40) actually tested	95% of planned products

4.5 Implementation of the clinical trials directives

The Agency will provide continuing support for the implementation of Directive 2001/20/EC and Directive 2005/28/EC, which will involve:

- Further developing GCP-inspection-related procedures and guidelines, to enable greater harmonisation of procedures and practices.
- Organising training sessions for GCP inspectors, joint sessions with assessors and joint sessions with GMP inspectors.
- Continuing the dialogue on interpretation of GMP in the context of investigational medicinal products, with a view towards publication of question-and-answer documents.
- Coordinating with Member State competent authorities and the Commission on issues relating to clinical trials directive.
- Support for ongoing activities in the context of the EudraCT database.

4.6 GMP harmonisation

Work will continue on the preparation of guidelines and Community procedures associated with implementation of GMP-related aspects of the new legislation, which will include finalisation of the revisions of GMP Annexes 2, 3, 6 and 7. Guideline topics will include: practical implementation of GMP for dedicated manufacturing facilities for certain product types; revision of the requirements for sterile manufacture; preparation for discussions on GMP issues arising from the regulation on advanced therapies; and contribution to the European Commission's work on good practice guidelines for manufacture of blood products and subsequent revision of Annex 14 to the GMP Guide. The work in this area will be carried out in the context of international discussions on quality systems, implementation of quality-risk-management principles and involvement of Bulgaria and Romania.

The review of the published reflection paper on compliance with the requirements of the marketing authorisation will continue, with input from other working parties, taking into account feedback from external stakeholders.

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 telematics 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. The projects that have been agreed are EudraNet, EudraVigilance, EudraPharm, electronic submissions, and the clinical-trials and good-manufacturing-practice databases. In addition, the Telematics Steering Committee has endorsed a set of horizontal services that are necessary to support the implementation of the systems mentioned.

EU telematics remains an important area in 2007, which will be the fifth 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.

The majority of EU telematics systems will be in use at the beginning of 2007. These systems are evolving in line with communicated requirements. The table below provides an overview of the expected development of systems in 2007.

System or process ***(Status in 2006)***	**2007 milestones**
EudraNet *(In production)*	Bringing inspections agencies into service over EudraNet where these are not part of the national medicines regulator. Implementation of advanced network management and performance services. Provision of additional EudraNet back-up systems.
EudraPharm *(In production)*	In line with the legislation, development will focus on products authorised using the centralised procedure in this first phase. Quarterly releases are anticipated, implementing increases in functionality in the areas of search, use by specific audiences, data entry, interaction with other systems, and use of controlled vocabularies.
EudraVigilance *(In production)*	Up to three releases are planned, implementing increases in functionality in the product dictionary, the first part of signal tracking, and access by specific audiences.
Eudra Data Warehouse *(In pre-production)*	Regular releases throughout the year are foreseen, putting into place reporting against the requested pre-defined queries for pharmacovigilance (in respect of both human and veterinary products).
EudraCT *(In production)*	Work will include background upgrading of the underlying infrastructure, followed by the delivery of improved systems for importing and exporting sets of data. This will result from routine maintenance activities.
EudraCT-Paediatrics Database *(At inception)*	This database is in the first stages of the design process. During 2007, it is anticipated that the high-level design will be completed, that the system will be prototyped, and that work on the first production version will be initiated.
EudraGMP *(In final testing)*	The first version of this will be delivered early in 2007. Work on the next version will be postponed to 2009.
European Review System *(Pre-installation)*	Following the tender procedure in 2006, it is anticipated that over the year, the system will be installed in agencies across the

	European Economic Area that require it.
PIM (Product Information Management) *(In pilot production)*	Subject to successful conclusion of pilot activities for both new marketing-authorisation applications and post-authorisation activities, the system will go into full production during the year. One or two new releases of both the review and light-authoring systems are anticipated. Except for specification, work on extending the system to mutual-recognition and decentralised procedures has been postponed to 2008-2009.
EU Telematics Controlled Terms *(2nd proof of concept concluded)*	This system is intended to act as a central repository for controlled terms for the European medicines network. A production system is anticipated which will be in a position to make available sets of controlled terms, subject to the establishment of a formal process for the control of such terms.

Operations

Operational support has been put into place to complement the investment in systems and infrastructure over the past four years. The Eudra Service Desk will 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 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[1]
Response-time to 15% of EU telematics IT helpdesk requests	2 days[1]
EudraNet availability of services (excluding local NCA downtime)	99%
Response-time to 80% of EudraNet and EudraLink IT helpdesk requests	3 hours[1]
Response-time to 15% of EudraNet and EudraLink IT helpdesk requests	1.5 days[1]

[1] 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 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 2007 will be:

- To assure continued functioning of the Agency against the background of expanded legal requirements.
- The expansion and provision of EMEA working facilities.
- The selection and development of a new budget and accounting system / SI2 replacement.

Personnel and budget

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

In addition to the core activities mentioned above, the following initiatives will be undertaken in 2007:

- Review of Activity Based Budget (ABB).
- Conduct of a tender procedure for insurance provider.
- Implementation of missions online system.
- Further progressing of business process/enhanced scientific training.
- Development of a 360-degree performance-evaluation system for managers.

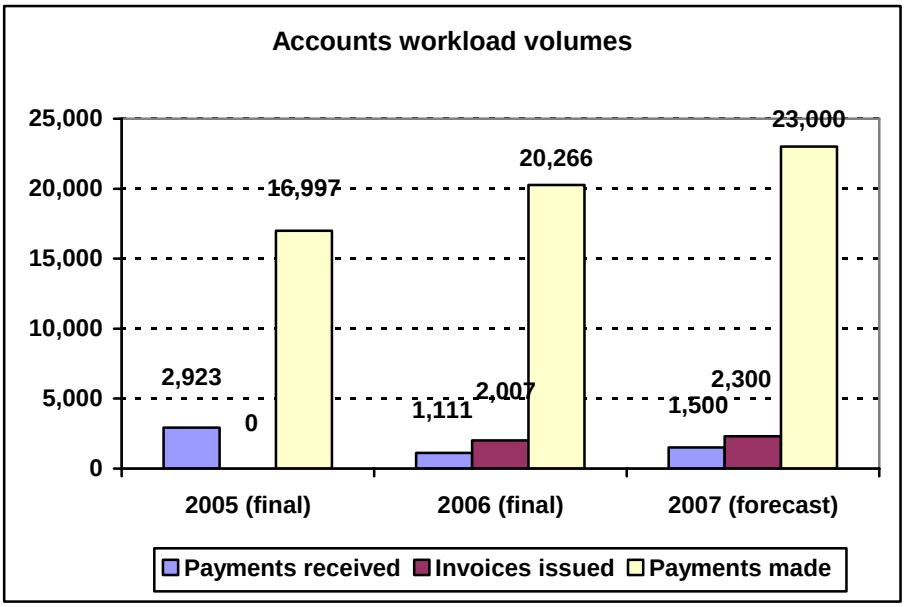
	2005 (final)	**2006 (final)**	**2007 projected**
Workload			
Total staff	372[2] + 44[3]	435[2] + 62[3]	452[2] + 70[3]
EMEA budget	€ 111,835,000	€ 138,676,000	€154,538,000
Selection procedures	39	32	32
Mission claims	1,186	1,059	1,300
Salary payments	4,613	5,000	5,500
Staff mobility	318	350	350

[2] Establishment plan minus vacancy rate plus Contract Agents.
[3] Estimated number of interims, Trainees, Auxiliary agents and National Experts.

Accounts

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

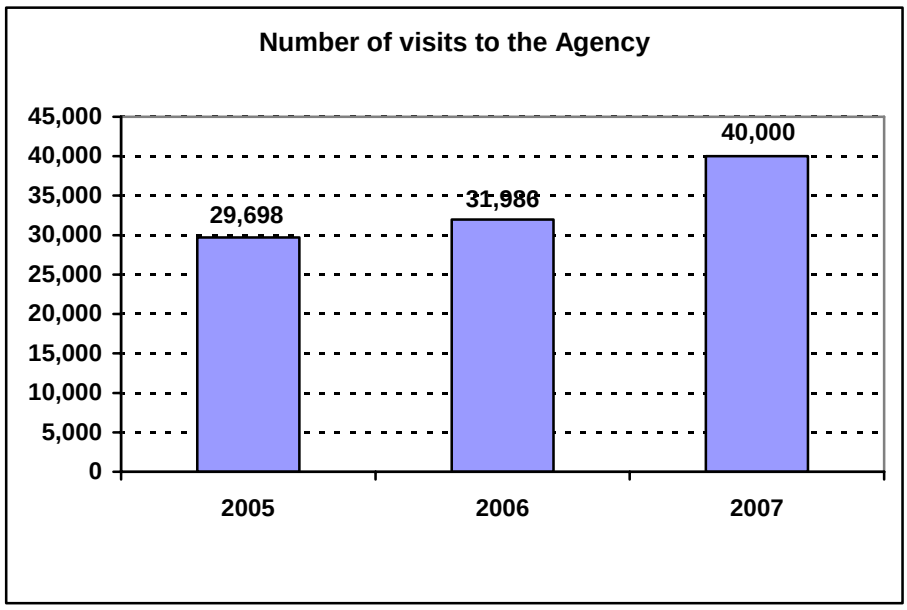
In addition to the core activities in the accounts area, the Agency will start the inception phase of the new integrated accounting system, which will replace the current EMEA financial system SI2, taking into account that the European Commission is phasing out the IT support to the present system by the end of 2008. The outcome of a tender procedure for banking services will also be implemented.



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, contracts and procurement, security, telecommunications, reception, switchboard, archiving, mail, reprographics, technical assistance to meeting rooms, management of confidential waste, health & safety, fire and emergency plans, business-continuity planning, inventory, office equipment and supplies, maintenance, refurbishment and fitting-out, management of the catering facilities and the financial management of 30 budget lines.

The Agency currently manages the following outsourced contracts: switchboard/reception (4-person team); audiovisual technicians (2-person team); security guarding (2-person team); catering (16-person team). These contracts may be supplemented during 2007 by the outsourcing of reprographics and ancillary services.



In addition to the core activities mentioned above, the following initiatives will be undertaken in 2007:

- Integration of building-services helpdesk and computer-aided facilities-management system.
- Design and plan for first floor of 7 Westferry Circus, refit of fourth floor and ground-floor reception desk.
- Refurbishment of sixth floor of 1 Westferry Circus.
- Refurbishment of restaurant servery.
- Termination of refurbishment of the second floor (which commenced in 2006).
- Exercising of business-continuity plans.
- Introduction of e-procurement tools, systems and procedures.
- Introduction of health & safety awareness campaigns.

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. 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 have been carried out correctly in conformity with the requirements of the financial, fees and/or staff regulations and their implementing rules, the VO Charter and other working instructions in force.

In addition to the core activities mentioned above, the following initiatives will be undertaken in 2007:

- Decentralisation of the verification function as requested in the operational units.
- The development of an integrated system to replace SI2.
- Audit, coordination and harmonisation of the decentralised verification bodies.

Workload

	2005 (final)	2006 (final)	2007 (proj.)
Transactions number*	30,300	34,092	38,850
Financial transactions	24,500	27,114	31,500
Operational transactions			
– Staff recruitment documents	300	446	350
– Staff-related transactions	900	1,300	1,500
– Salaries	4,600	5,232	5,500
VO reports	-	2	4

* Corresponds to a number of operational and financial transactions to be checked.

6.2 Information technology

In the past three years, information technology (IT) has progressed from being a facility and a service to being a business enabler. This principle will continue to be extended in 2007 through direct partnering with business units in order to develop and implement a range of critical applications.

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 2007.
- The overall trend in 2007 is for IT to provide high levels of service availability and good IT quality of service, utilising appropriate ITIL (IT infrastructure library) business processes.
- It is important to guarantee higher overall service availability to business units in both normal and extraordinary circumstances in which business-continuity has to be invoked.

Main activities and projects for 2007

- Progressing the deployment of best-practice support processes based on the ITIL service management, which engages EMEA users to work in partnership with IT for the benefit of all concerned. This will ensure the provision of reliable and robust IT services to staff, delegates and all users of pan-European systems. Improvements will be made to the support and helpdesk services and to the archiving and back-up of data, while maintaining a high level of security and confidentiality for all data held on EMEA systems.
- The critical project for IT is the implementation of Phase 3 of the business-continuity IT solution to support a range of disaster-recovery scenarios. This will include major improvements to back-up and storage systems in order to be 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 integrated videoconferencing and other virtual-meetings solutions will be progressed in line with specific meeting requirements.

- Development of several EMEA core applications, such as: the application and product-tracking database, SIAMED II; the scientific advice database, which will be extended for use in relation to veterinary medicines and to support the new paediatrics legislation; the corporate GMP inspections database; and the replacement of SI2. An enhanced recruitment database with electronic-applications workflow and MMS (Meetings Management System) IV will also be progressed.
- Further development and operational support of corporate IT programmes, including EDMS support, applications support, servers, Oracle, SAN and LAN; applying patches and bug fixes to the OS; operating, support and maintenance of all existing hardware and software of the Agency; ensuring virus protection; and data-centre management services.
- IT infrastructure will also be provided for the new second floor and sixth floor extension at the EMEA.
- Enhancement of the electronic document management system (Managing Meeting Documents, e-Collaboration and setting up workflows). This will be supported in the new second-floor meeting-room area by the implementation of a comprehensive and secure wireless LAN infrastructure.

Enhancement of the electronic records-management system, including implementation of mail registration and electronic archiving solutions.

Performance indicators

Performance indicator	**Target**
Corporate availability of services (excluding planned maintenance downtime)	99.35%
Response-time to 80% of corporate IT helpdesk requests	2 hours[4]
Response-time to 15% of corporate IT helpdesk requests	1 day[4]

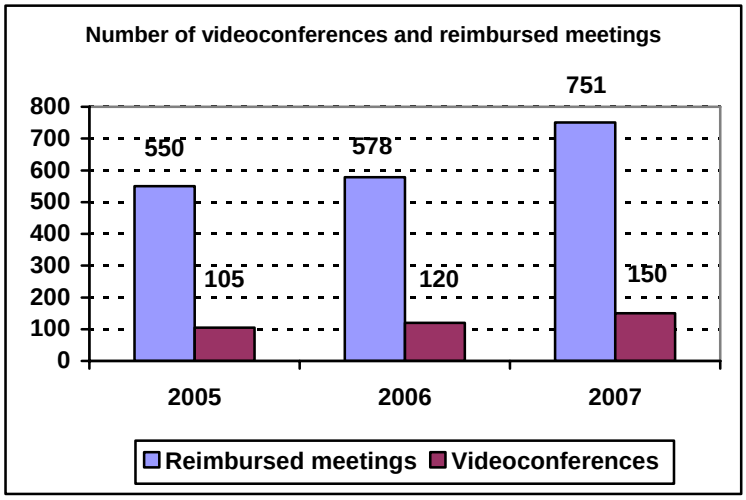
6.3 Meetings and conferences at the EMEA

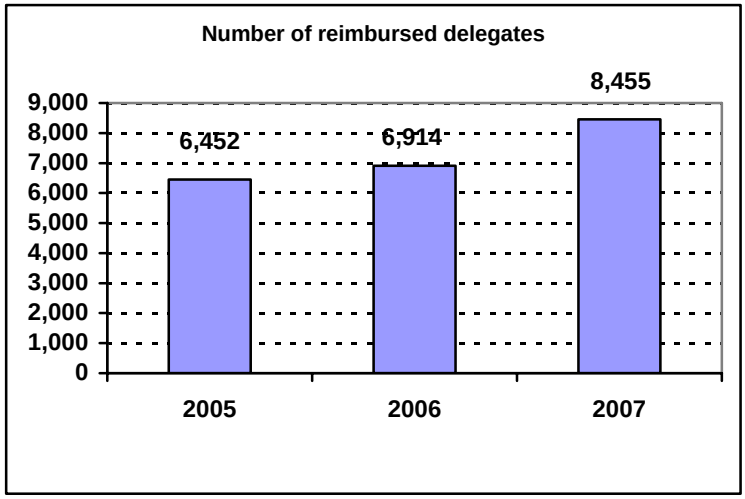
The EMEA ensures efficient support for meetings organised by the Agency, provides facilities and services, and constantly improves the resources available. The Agency assists delegates with logistics and practical arrangements. This includes organisation of meetings, organisation of travel and hotel 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. The Meeting Management and Conference sector coordinates enlargement activities for new Member States and candidate countries.

Trends and new issues

- The factors influencing the number of meetings to be held at the Agency in 2007 include: the increasing responsibilities of the Agency (paediatric legislation); a growing interest in the centralised procedure (leading to more meetings with applicants); activities in the field of innovation; and intensified cooperation in the network (including training activities). The increase also takes into account activities postponed from 2006, as well as the participation of representatives of candidate countries in meetings, training courses and conferences.
- Availability of conference facilities will be an important issue for the Agency.
- The number of reimbursed meetings is forecast to grow by 30%, and reimbursed meeting days by 33%.
- The number of reimbursed delegates might increase by a maximum of 25% in 2007.

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





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

Objectives

- Provide the best-possible support to delegates attending meetings and to EMEA staff members, with the same high level of satisfaction expressed by the delegates.
- Improve the meetings-organisation workflow and procedures (Meeting Management System).
- Develop videoconferencing and meeting broadcasting for national competent authorities and EMEA experts in order to facilitate communication and, ultimately, to reduce the number of physical meetings or at least the number of delegates required to travel to attend them.

Key initiatives to meet the objectives

- Develop methods to improve efficiency of reimbursement procedures, where appropriate, and revise the reimbursement rules in order to streamline the reimbursement process.
- Maintain and develop negotiations with hotels. Carry out a delegate survey in order to evaluate if their requirements are met.
- Meeting Management System (MMS) will be developed to set up a tracking system for hotel and travel details, the availability of online booking facilities for delegates on the EMEA MMS website, a further MMS module pertaining to the financial area, expediting the reimbursement process, and allowing the provision of clearer information to delegates and national competent authorities.

- Maintain and test the ability to organise meetings in 24 hours, including outside working hours and during weekends (in case of emergency situations such as pandemic influenza).
- Room-based videoconferencing using a dedicated facility with special equipment will be developed; if justified, develop desktop videoconferencing and implement pilot web-broadcasts of scientific meetings.

Performance indicators

Performance indicator	**Target**
Proportion of virtual meetings compared to all meetings	20% of all meetings
Delegates' satisfaction regarding travel and accommodation bookings	95%

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; verifying the quality of all published documents (excluding content); providing Agency staff with the most effective access to internal and external information needed to perform their professional duties; verifying the accuracy of translations (excluding product information); and organising and supporting the Agency's exhibitions.

Trends and new issues

- The new financial regulation and pressures from interested parties will increase the need for an improved records-management policy and implementation, and for extensive electronic archiving of all records, including electronic mail.
- Any further enlargement of the EU will result in an increase in multilingual communication activities, i.e. provision of more translated documents and a multilingual website.
- The Agency forecasts a 12% increase in number of requests for access to information in 2007 (to 3,200 requests) and an 82% increase in number of requests for access to documents (where a single request may encompass hundreds of documents) (to 100 requests).
- The volume of translations is expected to increase by 97% compared to 2006 (to 40,950 pages).

In addition to core activities in the area of document-management and publishing, the Agency plans to target the following objectives and initiatives:

Objectives and key initiatives

- Enhance the electronic document-management system (EDMS), which is important for effective publishing of core business information to the web interface, together with the necessary development of document-management, records-management (including retention policies) and mail-registration capabilities.
- Develop and implement an electronic records-management system.
- Continue revisiting and enhancing the implementation of the policy on access to information and documents.
- In light of the revision of European copyright laws, re-visit copyright issues such as the copyright-licensing policy.
- Re-examine the Agency's translation policies to take into account the increase in multilingual communication activities following EU enlargement and the growing volume of translations.
- Develop and implement the terminology and translation-memory databases in order to maintain and improve the quality of translations of non-product information documents.

Performance indicators

Performance indicator	**Target**
Percentage of requests for information processed within 48 hours	95%
Percentage of requests for documents processed within established timelines	95%
Percentage of requests for copyrights processed within 48 hours	100%
Percentage of translations processed within established timelines	100%

ANNEXES

Annex 1 EMEA establishment plan 2005–2007

Function group & grade	**TEMPORARY POSTS**		
	Occupied as per 31.12.05	Authorised for 2006	Authorised for 2007
AD 16	-	1	1
AD 15	1	3	3
AD 14	6	4	4
AD 13	4	4	4
AD 12	33	34	34
AD 11	32	33	33
AD 10	34	34	34
AD 9	10	13	13
AD 8	31	32	36
AD 7	37	43	43
AD 6	-	12	12
AD 5	-	-	10
Total function group AD	*188*	*213*	*227*
AST 11	-	-	-
AST 10	6	6	6
AST 9	-	2	2
AST 8	9	10	10
AST 7	12	14	14
AST 6	27	30	30
AST 5	29	32	32
AST 4	46.5	54	54
AST 3	14	23	24
AST 2	2	10	10
AST 1	4	30	32
Total function group AST	*149.5*	*211*	*214*
Total staff	**337.5**	**424**	**441**

Annex 2 Revenue and expenditure overview 2005–2007

		2005[5]		2006[6]		2007[7]	
		€ '000	%	€ '000	%	€ '000	%
Revenue							
Fees		71,895	*65.72*	92,580	*66.76*	105,870	*68.51*
General EU contribution		19,588	*17.91*	20,174	*14.55*	20,174	*13.05*
EU contribution for SME policy		0	*0.00*	1,826	*1.32*	3,015	*1.95*
EU contribution for paediatrics policy		0	*0.00*	n/a	*0.00*	2,647	*1.71*
EU contribution for IT telematics strategy		7,500	*6.86*	8,000	*5.77*	9,164	*5.93*
Special EU contribution for orphan medicinal products		6,110	*5.59*	7,400	*5.34*	6,000	*3.88*
Contribution from EEA		535.94	*0.49*	650	*0.47*	798	*0.52*
Community programmes		0	*0.00*	760	*0.55*	490	*0.32*
Other		3,767	*3.44*	7,286	*5.25*	6,380	*4.13*
TOTAL REVENUE		**109,396**	*100.00*	**138,676**	*100.00*	**154,538**	*100.00*
Expenditure							
Staff							
11	Staff in active employment	36,463	*33.98*	41,376	*29.84*	47,708	*30.87*
13	Mission expenses	560	*0.52*	586	*0.42*	610	*0.39*
14	Socio-medical infrastructure	436	*0.41*	440	*0.32*	499	*0.32*
15	Exchange of civil servants and experts	726	*0.68*	1,119	*0.81*	1,375	*0.89*
16	Social welfare	6	*0.01*	155	*0.11*	240	*0.16*
17	Entertainment and representation expenses	52	*0.05*	31	*0.02*	24	*0.02*
18	Staff insurances	1,065	*0.99*	1,214	*0.88*	1,457	*0.94*
	Total title 1	*39,307*	*36.63*	*44,921*	*32.39*	*51,913*	*33.59*
Building/equipment							
20	Investment in immovable property, renting of building and asset costs	12,475	*11.62*	17,260	*12.45*	16,606	*10.75*
21	Expenditure on data processing	10,889	*10.15*	14,623	*10.54*	18,223	*11.79*
22	Movable property and asset costs	1,482	*1.38*	1,057	*0.76*	3,148	*2.04*
23	Other administrative expenditure	540	*0.50*	756	*0.55*	792	*0.51*
24	Postage and communications	624	*0.58*	684	*0.49*	983	*0.64*
25	Expenditure on formal and other meetings	4	*0.00*	74	*0.05*	75	*0.05*
	Total title 2	*26,015*	*24.24*	*34,454*	*24.84*	*39,827*	*25.77*
Operational expenditure							
300	Meetings	5,825	*5.43*	6,355	*4.58*	7,298	*4.72*
301	Evaluations	34,727	*32.36*	49,827	*35.93*	51,089	*33.06*
302	Translations	1,043	*0.97*	2,215	*1.60*	3,593	*2.32*
303	Studies and consultants	150	*0.14*	170	*0.12*	150	*0.10*
304	Publications	122	*0.11*	124	*0.09*	178	*0.12*
305	Community programmes	132	*0.12*	610	*0.44*	490	*0.32*
	Total title 3	*42,000*	*39.13*	*59,301*	*42.76*	*62,798*	*40.64*
TOTAL EXPENDITURE		**107,322**	*100.00*	**138,676**	*100.00*	**154,538**	*100.00*

[5] Final accounts 2005.
[6] Appropriation/Budget 2006 as of 31 December 2006.
[7] Appropriation/Budget 2007 as adopted by the Management Board on 19 December 2006.

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

Management Board meetings in 2007	
7-8 March	4 October
7 June	13 December

CHMP meetings in 2007	
22-25 January	16-19 July
19-22 February	No meeting in August
19-22 March	17-20 September
23-26 April	15-18 October
21-24 May	12-15 November
18-21 June	10-13 December

CVMP meetings in 2007	
16-18 January	10-12 July
13-15 February	No meeting in August
13-15 March	11-13 September
17-19 April	9-11 October
15-16 May	6-8 November
12-14 June	11-13 December

COMP meetings in 2007	
9-10 January	24-25 July
6-7 February	No meeting in August
7-8 March	11-12 September
11-12 April	9-10 October
30-31 May	7-8 November
26-27 June	5-6 December

HMPC meetings in 2007	
10-11 January	4-5 July

7-8 March	5-6 September
8 May	30-31 October

Planned PDCO meetings in 2007	
5-7 June	2-4 October
2-4 July	29-31 October
29-31 August	27-29 November

CMD(h) meetings in 2007	
22-24 January	16-18 July
19-21 February	No meeting in August
19-21 March	17-19 September
23-25 April	15-17 October
21-23 May	12-15 November
18-20 June	10-12 December

CMD(v) meetings in 2007	
18-19 January	12-13 July
15-16 February	No meeting in August
15-16 March	13-14 September
19-20 April	11-12 October
10-11 May	8-9 November
14-15 June	13-14 December

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

CHMP standing and temporary working parties	**Number of plenary meetings in 2007**
Biologics Working Party	11
Blood Products Working Party	2
Efficacy Working Party	4
Gene Therapy Working Party	5
Joint CHMP/CVMP Quality Working Party	4
Paediatric Working Party	3
Pharmacogenetics Working Party	4
Pharmacovigilance Working Party	11
Safety Working Party	4
Scientific Advice Working Party	11
Vaccine Working Party	6
Working Party on Cell-Based Products	5
Working Party on Similar Biological Medicinal Products	3
EMEA/CHMP Working Group with Healthcare Professionals' Organisations	2

CHMP scientific advisory groups (SAGs)	**Number of meetings in 2007**
SAGs on anti-infectives, autoimmune diseases and immune dysfunctions, cardiovascular system, central nervous system, diabetes/endocrinology, diagnostics, HIV/viral diseases, and oncology	21

CHMP-associated groups	**Number of meetings in 2007**
(Invented) Name Review Group	11
Working Group on Quality Review of Documents	5
Quality Review of Documents Subgroup	11

CVMP standing and temporary working parties, and scientific advisory groups	Number of meetings
Efficacy Working Party	4
Environmental Risk-assessment Working Party	3
Immunologicals Working Party	3
Pharmacovigilance Working Party	10
Joint CHMP/CVMP Quality Working Party	4
Safety Working Party	4
Scientific Advice Working Party	11
Scientific Advisory Group on Antimicrobials	4

COMP working groups	Number of meetings in 2007
Working Group with Interested Parties	4
Working Group on Prevalence	1

HMPC working parties and associated groups	Number of meetings in 2007
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 2007
EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	3

CMD(h) working parties in 2007	Number of meetings
CTS/Eudratrack Subgroup	8
SPC Harmonisation Working Group	8
Joint Pharmacovigilance WP/CMD(h) WG	6

Ad hoc groups of GMP, GCP and GLP inspectors	Number of meetings
Ad hoc group of GMP inspectors	4
Ad hoc group of GCP inspectors	4
Ad hoc group of GLP inspectors	1

Annex 5 Guidelines and working documents in 2007

CHMP Biologics Working Party

Reference Number	Document Title	Status
EMEA/410/01	Revision of Note for guidance on minimising the risks of TSE transmission via medicinal products	A draft revision will be developed for discussion in BWP and CVMP
CPMP/BWP/269/95	Note for guidance on Plasma-derived medicinal products	Concept paper on revision in 2007
CPMP/BWP/3794/03	Guideline on the scientific data requirements for a plasma master file (PMF)	Development of templates for evaluation report
CPMP/BWP/125/04	Guideline on epidemiological data on blood transmissible infections	Implementation of the guideline to be monitored in 2007-2008 in relation to PMF dossiers
CHMP/BWP/188268/05	Guideline on validation of immunoassay for the detection of antibody to human immunodeficiency virus (Anti-HIV) in plasma pools	Maintenance of guideline
CHMP/BWP/188270/05	Guideline on validation of immunoassay for the detection of Hepatitis B virus surface antigen (HBsAg) in plasma pools	Maintenance of guideline
CPMP/BPWG/BWP/561/03	Note for Guidance on the Warning on transmissible agents in Summary of Product Characteristics (SPCs) and Package Leaflets for Plasma-derived medicinal products	Possible revision in 2007
	Information for the public on how safety with respect to transmissible agents is evaluated for plasma-derived medicinal products	To be initiated in 2007
EMEA/CPMP/BWP/2879/02	CHMP Position Statement on Creutzfeldt-Jakob Disease and plasma derived and urine-derived medicinal products	Revision of position statement in 2007 and publication of report of 2005 Workshop.
EMEA/CPMP/BWP/3752/03	CPMP Position Statement on West Nile Virus and plasma-derived medicinal products	If update needed, revision to be initiated in 2007.
Ref. 3AB1A, Dec 2994	Production and Quality Control of Medicinal Products Derived by Recombinant DNA Technology	Maintenance of guideline; update in the light of scientific developments e.g. reflection paper on peptide mapping test, particulate matter (in line with guideline on monoclonal antibodies)
EMEA/CPMP/BWP/268/95	Guideline on virus validation studies: The design, contribution and interpretation of studies validating the inactivation and removal of viruses	Clarification concerning GLP/GMP to be added in 2007
EMEA/CHMP/BWP/49348/2005	Guideline on similar biological medicinal products containing biotechnology derived proteins as active substances: Quality issues	Maintenance of guideline and contribution to meetings of the BMWP dealing with clinical and pre-clinical issues of comparability

Reference Number	Document Title	Status
	Guideline on immunogenicity of biotechnological medicinal products	Contribution to development of guideline for quality aspects of guideline
EMEA/CPMP/BWP/243/96	Guideline on allergen products	Revision of guideline expected to be released for consultation in Q2 2007. Scope of guideline to be extended to recombinant allergens
Ref. 3AB4A/Rev. Dec 1994	Revision of the Guideline on Production and Quality Control of Monoclonal Antibodies	Draft guideline expected to be released for consultation in Q1 2007
	Interferons and neutralising antibodies in multiple sclerosis. Development of a common assay methodology	Scientific input into co-ordinator's meetings
	Concept paper on development of assays for neutralising antibodies for biotech medicinal products	Discussion on need for development of concept paper
	ICH guideline on manufacturing process development and validation for biological / biotechnological substances	Discussion on development of guideline in conjunction with ICH Quality Guidelines
	Process Analytical Technology (PAT)	Organisation of workshop in 2007 with interested parties
EMEA/CHMP/BWP/388681/2005	Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products	Review of comments following public consultation and finalisation of the guideline
	Guideline on biological quality aspects of biological medicinal products to be used in Clinical Trials	Development of concept papers and guidance for specific topics
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 in BWP
EMEA/CHMP/BWP/271475/2006	Guideline on potency testing of cell based immunotherapy medicinal products for human use	Review of comments and finalisation of guideline in 2007
3AB7A	Note for guidance on the Use of transgenic animals in the manufacture of biological medicinal products for human use	Discussion on need to develop a concept paper on possible revision of guideline
EMEA/CHMP/BWP/48316/2006	Guideline on quality aspects of medicinal products containing active substances produced by stable transgene expression in higher plants	Review of comments following public consultation. Possible need for a workshop with stakeholders. Preparation of final draft
	Guideline on Dossier Requirements and content of Applications for Pandemic Influenza Vaccines	Discussion on need to review quality aspects, in conjunction with VWP
	Guideline on Dossier structure and content of marketing authorisation applications for influenza strains with a pandemic potential and intended for use before the pandemic is declared	Development of quality aspects, in conjunction with VWP
CPMP/BWP/214/96	Guideline on harmonisation of requirements for influenza vaccines	Discussion to be initiated in conjunction with VWP

Reference Number	Document Title	Status
	Guideline on stability data for cumulative storage periods for vaccines/intermediates	Discussion to be initiated
EMEA/CPMP/BWP/2758/02	Note for guidance on pharmaceutical aspects of the product literature for human vaccines	Discussion on whether guideline needs to be updated
EMEA/CHMP/BWP/3088/99	Note for guidance on Quality, Preclinical and Clinical aspects of gene transfer medicinal products	Preparation of a concept paper and possibly initiation of revision of the guideline.
CPMP/BWP/1700/01	Points to Consider on xenogeneic cell therapy products	Review in 2007, following finalisation of Guideline on human cell-based products
	ICH M5 proposed structure and mapping of active ingredients in vaccines	Development of mapping structure
CPMP/BWP/41450/98	The Manufacture and Quality Control of Human Somatic Cell Therapy Medicinal Products	Finalisation of quality part of the Guideline on cell-based products. Draft guideline expected to be released for consultation in 1Q 2007
EMEA/CHMP/GTWP/125491/2006	Scientific requirements for the environmental risk assessment for gene therapy medical products	Finalisation of draft guideline jointly by GTWP, BWP and SWP. Release for public consultation
EMEA/CHMP/135148/04	Environmental Risk Assessments for Medicinal products containing, or consisting of, Genetically Modified Organisms (GMOs) (Module 1.6.2)	Finalisation of guideline by CHMP in 1Q 2007
	Commission consultation on the need for a community legal framework on advanced therapies	Initiation depending on the status of discussion of the draft Regulation on advanced therapies

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)	Report of Workshop to be published in 2007. Revision of guideline expected to be released for consultation in 2007
CPMP/BPWG/1561/99	Note for guidance on the Clinical investigation of recombinant Factor VIII and IX products	Report of Workshop to be published in early 2007. Revision of guideline expected to be released for consultation in 2007
CPMP/BPWG/198/95 rev. 1	Note for guidance on the Clinical investigation of human plasma derived Factor VIII and IX products	Report of Workshop to be published in early 2007. Revision of guideline expected to be released for consultation in 2007
CPMP/BPWG/575/99 Rev 1	Note for guidance on the Clinical investigation of human anti-D immunoglobulin for intravenous and/or intramuscular use	To be finalised in 2007
CPMP/BPWG/283/00	Note for guidance on the Clinical investigation of Human normal immunoglobulin for subcutaneous and intramuscular use	Review and possible revision of the guideline after experience with its use. Concept Paper in 2007
	Guideline on the Clinical investigation of alpha1-proteinase inhibitor (alpha1-antitrypsin)	If guideline needed, Concept Paper in 2007

Reference Number	Document Title	Status
CPMP/BPWG/859/95 rev 2	Core SPC for Human normal immunoglobulin for intravenous administration (IVIg)	Report of Workshop to be published in 2007. Revision of core SPC expected to be released for consultation in 2007
CHMP/BPWP/319615/2005	Core SPC for Human anti-D immunoglobulin for intravenous use – revision 1	To be finalised in 2007
CPMP/BPWG/574/99 rev.1	Core SPC for Human anti-D immunoglobulin for intramuscular use	To be finalised in 2007
CPMP/BPWG/1619/99	Core SPC for Human plasma derived and recombinant coagulation Factor VIII products	Revision of core SPCs expected to be released for consultation in 2007
CPMP/BPWG/1625/99	Core SPC for Human plasma derived and recombinant coagulation Factor IX products	Revision of core SPCs expected to be released for consultation in 2007
CPMP/BPWG/282/00	Core SPC for Human normal immunoglobulin for subcutaneous and intramuscular use	Review and possible revision of the core SPC after experience with its use. Concept Paper in 2007.
CHMP/BPWP/122007/2005	Core SPC for Human plasma derived fibrinogen products	Core SPC to be released for consultation in early 2007
CPMP/BPWG/BWP/561/03	Warning on transmissible agents for SPCs and patient leaflets	Discussions to continue in 2007 on whether to make specific reference to vCJD and whether to develop statements for when albumin is used as an excipient
	Guideline on the Core SPC for $alpha_1$-proteinase inhibitor ($alpha_1$ antitrypsin)	If guideline needed, Concept Paper in 2007

CHMP Efficacy Working Party

Reference Number	Document Title	Status
CPMP/EWP/553/95	Revision of the Guideline on Medicinal Products in the Treatment of Alzheimer's Disease	Draft Guideline expected to be released for consultation by 1Q 2007
CPMP/EWP/563/95	Revision of the Guideline on Clinical Investigation of Medicinal Products in the Treatment of Parkinson's Disease	Draft Guideline expected to be released for consultation by 1Q 2007
CPMP/EWP/1080/00	Revision of the Guideline on Clinical Investigation of Medicinal Products in the Treatment of Diabetes Mellitus	Revision to be considered in 4Q 2007
CHMP/EWP/356538/2005	Concept Paper for the development of a Guideline on the development of new products for the Treatment of Tobacco and Alcohol Dependence	Draft Guideline expected to be released for consultation in 1/2Q 2007
CHMP/EWP/56477/2005	Concept Paper on the Development of a CHMP Guideline on the evaluation of non-clinical and clinical data on the medicinal substances contained in drug-eluting (medicinal substance eluting) coronary stents within the framework of a consultation procedure for combination products	Draft Guideline expected to be released for consultation by 1Q 2007

Reference Number	Document Title	Status
CPMP/EWP/237/95	Revision of the Guideline on antiarrhythmics	Revision to be considered in 2007
CHMP/EWP/18463/06	Concept Paper on the Development of new Products for the Treatment of Ulcerative Colitis	Draft Guideline was Released for Consultation in 4Q 2006. Finalisation expected in 3/4Q 2007
CPMP/EWP/281/96	Revision of the Guideline on Clinical Investigation of Drugs used in Weight Control	Draft revised Guideline released for consultation in 2Q 2006. Finalisation expected in 3/4Q 2007
CPMP/EWP/2284/99	Revision of Points to Consider on Clinical Investigation of Medicinal Products for the Management of Crohn's Disease	Draft Guideline expected to be released for consultation in 1/2Q 2007
CPMP/EWP/2459/02	Reflection Paper on Statistical Methods for Flexible Design and Analysis of Confirmatory Clinical Trials	Draft Guideline released for consultation in 1Q 2006. Finalisation expected in 1/2Q 2007
CHMP/EWP/195220/2005	Guideline on Reporting the Results of Population Pharmacokinetics Analyses	Draft Guideline released for consultation in 2/3Q 2006. Finalisation expected in 3/4Q 2007
CHMP/EWP/147231/2006	Concept Paper for an addendum to the Note for Guidance on the investigation of bioavailability and bioequivalence: Evaluation of bioequivalence of highly variable drugs and drug products	Draft expected to be released for consultation in 2/3Q 2007
	Concept Paper on Pharmacogenetics in PK Studies	Concept Paper expected in 1/2Q 2007
CPMP/EWP/707/98	Revision of Points to Consider on Clinical Investigation of Medicinal Products for Prophylaxis of Intra- and Post-Operative Venous Thromboembolic Risk	Draft Guideline released for consultation in 4Q 2006. Finalisation expected in 3/4Q 2007
CPMP/EWP/4151/00	Q/A on the Guideline on Requirements for Clinical Documentation for Orally Inhaled Products (OIP)	For discussion in 1Q 2007
	Concept Paper on Cystic Fibrosis	Concept Paper expected to be adopted in 1/2Q 2007
CPMP/EWP/1776/99	Points to Consider on Missing Data	For discussion in 2007
CPMP/EWP/240/95	Revision of Guideline on fixed combination medicinal products	For discussion in 2007
CPMP/EWP/566/98	Revision of the Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders	For discussion in 2007
CHMP/EWP/4490/2006	Guideline on Post-Traumatic Stress Disorder	Draft guideline expected to be released for consultation in 3/4Q 2007
CHMP/EWP/21441/2006	Q&A on Corticosteroids for Topical Use	Document expected to be adopted in 1/2 Q 2007
	CP on a Guideline in the Transplantation Area	For discussion in 2007
CPMP/EWP/205/95 Rev. 3	Appendix to the Guideline on the evaluation of Anticancer Medicinal Products in Man	Released for consultation in July 2006. Finalisation expected 3Q 2007
CHMP/EWP/277794/2006	Reflection Paper on Gender Effects in Cardiovascular Medicinal Products	Reflection paper expected to be finalised in 1Q 2007

Reference Number	Document Title	Status
CHMP/EWP/1470/04	Guidance on Clinical investigation of medicinal products for Secondary Prevention of Cardiovascular Events	Draft Guideline expected to be released for consultation in 2/3Q 2007
CPMP/EWP/784/97	Points to Consider on Clinical Investigation of Medicinal Products used in the Treatment of Osteoarthritis	Revision to be considered in 2007
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 2007
	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 1/2Q 2007
CHMP/EWP/147231/2006	Guideline on the evaluation of the pharmacokinetics of highly variable medicinal products	Draft Guideline expected to be released for consultation in 2/3Q 2007
CHMP/EWP/18504/2006	Concept Paper on the preparation of a Guideline on the clinical development of products for specific immunotherapy for the treatment of Allergic Diseases	Draft Guideline expected to be released for consultation in 1/2Q 2007
	Concept Paper on the need for a Guideline on Medicinal Products in the Treatment of Actinic Keratosis	For discussion in 2007
(EUDRA/C/91/036 – 3CC27a)	Recommendation on the Need for Revision of Eudralex Guideline on Clinical Investigation of Hypnotic Medicinal Products	For discussion in 2007
CPMP/EWP/1119/98	Points to Consider on the Evaluation of the diagnostic agents (Adopted November 2001)	For re-discussion / update in 2007

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
	Guideline on genetically modified cells as gene therapy medicinal products	Concept paper for release 2Q 2007
	Guideline on gene-therapy vaccines, (for preventive and therapeutic use) including vectors and naked DNA.	Concept paper to be finalised by 3Q 2007
(EMEA/CHMP/GTWP/125459/2006)	Guideline on non-clinical studies prior to clinical use of gene therapy medicinal products	Finalisation expected in 4Q 2007
(EMEA/CHMP/GTWP/125491/2006)	Guideline on scientific requirements for the environmental risk assessment of gene therapy medicinal products.	Finalisation expected in 4Q 2007
	Guideline on clinical monitoring of subjects treated with gene therapy medicinal products	Concept paper for release in 2Q 2007. Draft guideline expected to be released for consultation in 4Q 2007/Q1 2008

Reference Number	Document Title	Status
	Reflection paper on scientific criteria for qualification as gene therapy medicinal products	Draft Reflection Paper to be finalised by 1Q 2008
	ICH Considerations on oncolytic viruses	First draft expected 2Q 2007
	ICH Considerations on virus/vector shedding	For discussion in GTWP during 2007 Possible workshop in 4Q 2007

CHMP Paediatrics Working Party

Reference Number	Document Title	Status
	Draft Guideline on the impact of immaturity when investigating medicinal products intended for neonatal use	Concept papers on organ immaturity released for consultation. Draft guideline expected to be released in 2Q 2007

CHMP Pharmacogenetics Working Party

Reference Number	Document Title	Status
(Reflection Paper-EMEA/201914/2006)	Reflection Paper on pharmacogenetics samples, testing and data handling	Released 4Q 2006. Finalisation in 2Q 2007
(General-EMEA/128517/2006)	Reflection paper on Pharmacogenetics and Pharmacokinetic Studies	Released 2Q 2006. Finalisation in 1Q 2007
(Reflection Paper-EMEA/CHMP/PGxWP/278789/2006)	Reflection paper on the use of genomics in clinical trials to explore between treatment and genomic traits	Released 4Q 2006. Finalisation in 3Q 2007
(Concept Paper-EMEA/CHMP/PGxWP/128435/2006)	Concept Paper: experience on pharmacogenomics in the oncology centralised procedure	Released 4Q 2006. Finalisation in 2Q 2007
CHMP/ICH/437986/2006	ICH Guideline on the Terminology in Pharmacogenetics	Step 2 ICH Guideline released for consultation in 4Q 2006. Finalisation in 2Q 2007

CHMP Pharmacovigilance Working Party

Reference Number	Document Title	Status
Volume 9A Chapter II.2.A	Conduct of Pharmacovigilance for Centrally Authorised Products	In 2007: Revision taking into account revised CHMP procedures, for public consultation
Volume 9A Chapter II.2.B	Crisis Management Plan for Centrally Authorised Products	In 2007: Revision taking into account revised CHMP procedures, for public consultation

Reference Number	Document Title	Status
	Guidelines in relation to public communication of pharmaco-vigilance information	In 2007: 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 2007: Development of criteria for discussion by CHMP as contribution to appropriate Guideline
-	Good Pharmacovigilance Practice (GVP)	In 2007: Finalisation of draft, taking into account the Paper on Pharmacovigilance in Europe: The Way Forward – Views of the CPMP Pharmacovigilance Working Party of 2002 which includes the draft Paper on Principles of Study System for Safety Monitoring developed by the PhVWP drafting group in 2001
CPMP/PhVWP/135/00	Standard Operating Procedure for the Review of CPMP Scientific Advice by the CPMP Pharmacovigilance Working Party	In 2007: Revision with view to Risk Management Plans, if considered necessary in the light of experience to be gained by early 2007
		The Working Party shall contribute to applicable ICH guidelines under development that are identified after adoption of this work plan.

CHMP Safety Working Party

Reference Number	Document Title	Status
EMEA/CHMP/SWP/149188/2004	Guideline on the Need for Pre-clinical Testing of Human Pharmaceuticals in Juvenile Animals	Guideline expected to be finalised in 2Q 2007
EMEA/CHMP/SWP/178958/2004	Guideline on Drug-Induced Hepatotoxicity	For discussion towards finalisation in 2007.
EMEA/CHMP/SWP/258498/2005	Guideline on the Non-Clinical Development of Fixed Combinations of Medicinal Products	Guideline expected to be finalised in 1Q 2007
CPMP/SWP/QWP/4446/00	Guideline on Specification Limits for Residues of Metal Catalysts in Medicinal Products	Guideline expected to be finalised in 1Q 2007
EMEA/CHMP/SWP/203927/2005	Guideline on Risk Assessment of Medicinal Products on Human Reproductive and Development Toxicities: from Data to Labelling	Guideline expected to be finalised in 4Q 2007

Reference Number	Document Title	Status
EMEA/CPMP/SWP/2877/00	Guideline on the Assessment of Carcinogenic and Mutagenic Potential of anti-HIV Medicinal Products	Guideline expected to be finalised in 4Q 2007
EMEA/CHMP/SWP/5382/2003	Note for Guidance on the Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products: Annex on Nonclinical Testing for Inadvertent Germline Transmission of Gene Transfer Vector	Guideline expected to be finalised in 1Q 2007
	Guideline on NRTI-Induced Mitochondrial Toxicity	For discussion towards finalisation in 2007.
	Guideline on A Reduced Toxicology Package to Support Early Clinical Investigative Studies	Draft Guideline expected to be released for consultation in 2Q 2007
CPMP/SWP/104/99	Revision of the Note for Guidance on Repeated Dose Toxicity	Considered for revision in 2007
Eudralex vol. 3B3BS1A	Revision of the Note for Guidance on Single Dose Toxicity	Considered for revision in 2007
CPMP/372/01	Points to Consider on the Non-Clinical Assessment of the Carcinogenic Potential of Insulin Analogues	Considered for revision in 2007

CHMP Similar Biological (Biosimilar) Medicinal Products Working Party

Reference Number	Document Title	Status
(EMEA/CHMP/94526/05)	Annex Guideline biosimilar medicinal products containing biotechnology-derived proteins as active substance – non-clinical and clinical issues: Guideline on similar biological medicinal Products containing recombinant α-Interferons	Guideline to be released for internal consultation 2Q 2007
EMEA/14327/2006	Guideline on Immunogenicity Assessment of Biological/Biotechnology-Derived Proteins	Guideline to be released for consultation 1Q 2007
EMEA/101695/2006	Note for Guidance on Comparability of medicinal products containing biotechnology-derived proteins as active substance after change in manufacturing process – non-clinical and clinical issues	Finalisation 2Q 2007
	Guideline on similar biological medicinal products containing low molecular weight heparins	Guideline to be released for internal consultation 2Q 2007

CHMP Vaccine Working Party

Reference Number	Document Title	Status

Reference Number	Document Title	Status
CPMP/VEG/15/04	Guideline on clinical evaluation of vaccines	Finalisation and publication of guideline
	Guidance on the development of vaccines against emerging or re-emerging diseases, such as SARS, pathogens potentially used for bioterrorism, monovalent polio vaccines to be used in the event of a re-occurrence of polio in the post-eradication period.	Under consideration
CPMP/BWP/2289/01	Points to Consider on the Development of Live Attenuated Influenza Vaccines	Under consideration
CPMP/1100/02	Note for guidance on the development of vaccinia-based vaccines against smallpox	Possible revision in 2007
	Guideline on requirements for evaluation of therapeutic vaccines	Multidisciplinary input required
EMEA/CHMP/VEG/134716/2004	Guideline on adjuvants in vaccines for human use	Possible revision in 2007
	Guideline on dossier structure and content of marketing authorisation applications for influenza vaccines with avian strains with a pandemic potential for use outside of the core dossier context	Possible revision in 2007

CHMP Working Party on Cell-based Products

Reference Number	Document Title	Status
	Guideline on cell-based products	Guideline to be released for external consultation in 1Q 2007. Finalisation in 4Q 2007
CPMP/1199/02	Points to consider on xenogeneic cell therapy medicinal products	Consider for revision in 2007

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

Reference Number	Document Title	Status
EMEA/345483/2006	EMEA Performance Indicators for the Interaction with Patients' and Consumers' Organisations	Finalisation and publication of document on 1Q 2007
	Procedure for Review Of Information on Product by Patients'/Consumers' Organisations	To be published and to come into effect in a step-wise approach from 2Q 2007
	Procedure for providing Patients' and Consumers' Organisations with EMEA tailored information, including safety related	To be finalised by end 2007

CHMP Working Group with Healthcare Professionals' Organisations

Reference Number	Document Title	Status
	To define "Criteria to be fulfilled by Health-Care Professionals Organisations involved in EMEA activities"	Draft to be released for consultation by 3Q 2007
	To define a framework of interaction between EMEA and Health-Care Professionals	Draft to be released for consultation by 3Q 2007
	To develop recommendations and proposals for action in relation to the interaction between EMEA and Health-Care Professionals	Draft to be released for consultation in 2008

CHMP Invented Name Review Group

Reference Number	Document Title	Status
CPMP/328/98 Rev 5	Guidelines on the acceptability of invented names for medicinal products processed through the centralised procedure	Revision finalised in December 2006 and to be adopted in January 2007

CVMP Efficacy Working Party

Reference Number	Document Title	Status
EMEA/CVMP/EWP/117899/2004-CONSULTATION	Guideline on Efficacy and Target Animal Safety Data Requirements for Veterinary Medicinal Products intended for Minor Uses and Minor Species	Consultation ended 31 October 2005 To be finalised Q3 2007
EMEA/CVMP/83804/2005-CONSULTATION	Fixed combinations of veterinary pharmaceutical products Multidisciplinary guideline: Involved WPs are EWP, SWP and ERAWP	Revised guideline to be published December 2006. Coming into effect June 2007.
EMEA/CVMP/EWP/170208/2005-CONSULTATION	Guideline on the SPC for anthelmintics	Consultation ends 31 December 2006 Guideline to be finalised Q2-3 2007
-	Dossier requirements for oncology products Multidisciplinary guideline: Involved WPs are EWP, SWP , QWP and ERAWP	Consultation of concept paper ended 30 September 2005 Draft Guideline to be prepared for adoption by CVMP for public consultation in Q1 2008
EMEA/CVMP/005/00-Rev.1	Testing and evaluation of the efficacy of antiparasitic substances for the treatment of tick and flea infestations in dogs and cats	Revision of existing guideline Draft guideline published for consultation until 30 April 2007 Guideline to be finalised Q4 2007

Reference Number	Document Title	Status
-	Dossier requirements for bibliographic applications Multidisciplinary Guideline: Involved WPs are EWP, SWP and CMDV	Concept paper to be released for public consultation *(tbc)*
EMEA/CVMP/019/00	Conduct of bioequivalence studies for veterinary medicinal products Multidisciplinary guideline: involved WPs are EWP and QWP	Revision of existing guideline: Concept paper to be prepared for public consultation (Q1 2007)
	Veterinary medicinal products controlling Varroa jacobsoni and Acarapis woodi parasitosis in bees	Revision of existing guideline: Concept paper to be prepared for public consultation (Q2-Q3 2007)
	Efficacy of veterinary medicinal products for use in farmed aquatic species Multidisciplinary Guideline: Involved WPs are EWP	Revision of existing guideline: Concept paper to be prepared for public consultation (Q2 2007)
-	VICH Target Animal Safety – Pharmaceuticals	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)

CVMP Environmental Risk Assessment Working Party

Reference Number	Document Title	Status
-	Technical Guidance Document on the environmental impact assessment of veterinary medicinal products (issues where the VICH Phase II document recommends "seek regulatory guidance")	Guideline expected to be finalised by Q2 2007
-	Alternatives to animal testing	WP considerations to be developed by Q2 2007

CVMP Immunologicals Working Party

Reference Number	Document Title	Status
EMEA/CVMP/IWP/123243/2006-CONSULTATION	Reduced requirements for IVMPs intended for minor species or minor indications	Draft Guideline currently published for consultation until 31 January 2007. To be finalised for adoption by CVMP Q1 2007
EMEA/CVMP/54533/2006	User Safety Guideline	Draft Guideline to be finalised for adoption by CVMP Q1 2007

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 prepared for adoption by CVMP (following revision of Annex I of Directive 2001/82/EC)
-	Proposed approach for the consideration of substances other than active ingredients present in veterinary medicinal products.	Draft Guideline to be prepared for adoption by CVMP Q4 2007
	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 prepared for adoption by CVMP Q1 2007
EMEA/CVMP/IWP/219089/2006	Requirements for in-use stability claims	Draft Guideline to be prepared for adoption by CVMP (Q1 2007)
EMEA/CVMP/IWP/205712/2006	Preparation of new master seeds	Draft Guideline to be prepared for adoption by CVMP (Q1 2007)
EMEA/CVMP/378570/2006	Concept Paper on the need for revision of the position paper on compliance of veterinary vaccines with veterinary vaccine monographs of the European Pharmacopoeia	Draft Guideline to be prepared for adoption by CVMP (Q2 2007)
-	The impact of Maternally Derived Antibodies on vaccination	Concept paper to be released for public consultation Q2 2007
-	Requirements for Combined Veterinary Vaccines	Concept paper to be released for public consultation Q2 2007
-	Validation of patch potency tests and establishing pass criteria	Concept paper to be developed (tbc)
-	Revision of the guideline on requirements for fish vaccines	Concept paper to be developed (tbc)
-	VICH Guideline on Target Animal Safety for Veterinary Biological Products.	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)
-	VICH Guideline on examination of live veterinary vaccines for reversion to virulence	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)

Reference Number	Document Title	Status
-	VICH Guideline for the tests on the presence of extraneous viruses in veterinary viral vaccines	Draft Guideline to be prepared for public consultation (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)

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	Further considerations on the need for additional revision needs to be made, followed by appropriate consultation
EMEA/CVMP/413/99-Rev.2	VEDDRA List of clinical terms for reporting adverse reactions in animals to veterinary medicines	To be revised as per PhVWP-V work program for 2007)
EMEA/CVMP/891/04	VEDDRA List of clinical terms for reporting Suspected Adverse Reactions in Human Beings to veterinary medicinal products	To be updated regularly (yearly review)
EMEA/CVMP/553/03	List of species and breeds for electronic reporting of adverse reactions in veterinary pharmacovigilance	To be updated regularly (yearly review)
EMEA/CVMP/900/03	Guideline on a strategy for triggering pharmacovigilance investigations preceding regulatory actions by EU competent authorities	Update required to take into account the to be agreed harmonised approach on the use of EudraVigilance Veterinary data
EMEA/CVMP/143/99-Rev.1	Note for Guidance: Conduct of pharmacovigilance for veterinary medicinal products authorised through the mutual recognition procedure	Update required to take into account the to be agreed harmonised approach on the use of EudraVigilance Veterinary data
EMEA/CVMP/471721/2006	Guideline on the use of data contained in EudraVigilance and EudraVigilance Veterinary (EVvet) [further to the review of the EU pharmaceutical legislation]	To be developed following end of public consultation of the concept paper. Draft to be released for public consultation in 2007.
CVMP/VICH/547/00	VICH GL24: Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports	Guideline expected to be finalised 2007
CVMP/VICH/646/01	VICH GL29: Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSURs)	To be finalised Q1 2007

Reference Number	Document Title	Status
CVMP/VICH/647/01	VICH GL30: Pharmacovigilance of Veterinary Medicinal Products: Controlled list of terms	To be finalised 2007.
	VICH GL35: Pharmacovigilance of Veterinary Medicinal Products: Electronic standards for transfer of data	Guideline expected to be finalised Q4 2007 – Q1 2008.
CVMP/VICH/355996/05	VICH GL42 Step 4: Guideline on pharmacovigilance of veterinary medicinal products: data elements for submission of adverse event reports	Guideline expected to be finalised Q4 2007 – Q1 2008
EMEA/CVMP/PhVWP/145320/2005-CONSULTATION	Guideline on a Periodic Safety Update Report (PSUR) assessment guideline for veterinary medicinal products	Following the consultation period foreseen in 2007 the development of the guideline will be finalised

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	Draft Guideline to be developed Q2 2007
-	Guideline on the assessment of pharmacological/pharmacodynamic data to establish a pharmacological ADI	Draft Guideline to be developed Q1 2007
-	Dossier requirements for oncology products Multidisciplinary guideline: Involved WPs are EWP, SWP, QWP and ERAWP	Draft Guideline to be prepared for adoption by CVMP in 2007
	Review of alternative reference limits	Working Party considerations during Q3-Q4 2006, for further discussion at CVMP during 2007, and if confirmed a concept paper will be prepared
	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	Working Party considerations during 2Q 2007, for further discussion at CVMP during 2007, and if confirmed a concept paper will be prepared.
	Possible update of guideline on establishment of withdrawal periods for milk producing animals during the dry period (and relevant parts of SPC guideline)	Working Party considerations during 2007

-	Extrapolation of MRLs and gathering of information allowing to establish a scientific basis from "Absorption, Distribution, Metabolism and Excretion" similarities/differences	Working Party considerations during 3-4 Q 2006, for further discussion at CVMP during 2007, and if confirmed a concept paper will be prepared.
-	Conditions for use of faecal binding studies for the establishment of microbiological ADI	Working Party considerations during 3-4Q 2006, for further discussion at CVMP during 2007, and if confirmed a concept paper will be prepared.
-	Guideline on metabolism and residue kinetics	Support to EU position in VICH during 2007

CVMP Scientific Advice Working Party

Reference Number	Document Title	Status
EMEA/CVMP/854/02-Rev.1	EMEA guidance for companies requesting scientific advice	Review SOP and Guidance document in 2007 and revise where necessary in view of experience gained with the procedure

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
-	Further guidance on pre-approval information according to VICH GL27	Draft Guideline to be developed by 3-4 Q 2006 and published for consultation during 1Q 2007. Final guideline, following consultation period, to be published during 2007.
-	Revision of SPC antimicrobials guideline	Draft Guideline finalised to be agreed by EWP and CVMP by 2Q 2006. Publication fro consultation during 1-2 Q 2007. Final guideline, following consultation period, to be published during 2007.
-	Support of the EU position on the VICH topic: Standardization of Antimicrobial Susceptibility Testing Methodology and Interpretive Criteria	Support to EU position during 2006 -2007

CVMP General

Reference Number	Document Title	Status
	Guideline on ongoing risk/benefit evaluation	Following the consultation period foreseen in 2007 the development of the guideline will be finalised

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	Revision to take account of advances in this area in progress.
CPMP/QWP/155/96 & EMEA/CVMP/315/98	CPMP and CVMP Guidelines on Pharmaceutical Development	May need to be reviewed in the light of the ICH Guidelines Q8 and Q9 and after the initiative on Q10 has been stabilised at step 2.
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	Quality of Products Containing Existing/Known Active Substances	Reflection Paper adopted at CHMP and CVMP, to be adopted by CMD(h) and CMD(v) and by the European Commission prior to publication for public consultation.
EMEA/CVMP/QWP/434665/2006	CVMP Guideline on Spot-on products	Concept paper on the development of a guideline on spot-on products adopted at December 2006 CVMP. Work on the draft guideline in progress.
	Dossier requirements for Veterinary oncology products	Guideline initiated by EWP (V). Contribution by QWP.
EMEA/CVMP/134/02 Rev 2 CPMP/QWP/227/02 Rev 1	Guideline on Active Substance Master File - introduction of an Annex for Herbal Medicinal Products, on referral by the HMPC	Public consultation period expired. Finalisation of the revision foreseen for 1Q 2007.
CPMP/QWP/419/03	CHMP Guideline on excipients, antioxidants and antimicrobial preservatives	Due to substantial comments received during the first public consultation phase, the revised draft guideline has been re-published for a second 3 months public consultation period. Finalisation of the guideline foreseen for 2Q 2007.
CPMP/SWP/QWP/4446/00	CPMP Guideline on Specification Limits for Residues of Metal Catalysts in Medicinal Products	Guideline expected to be finalised in 1Q 2007
Eudralex 3AQ20A	Radiopharmaceuticals	Revision to take account of advances in this area is in progress.

Reference number	Document title	Status
EMEA/HMPC/CHMP/CVMP/287539/05	Guideline on Declaration of Herbal Substances in Herbal Medicinal Products/Traditional Herbal Medicinal Products in the SPC	QWP contribution on referral from HMPC. Guideline published for public consultation. End of consultation period December 2006.
EMEA/HMPC/CHMP/CVMP/58222/06	Guideline on Quality of Combination Herbal Medicinal Products/Traditional Herbal Medicinal Products	QWP contribution on referral from HMPC. Work on the draft guideline in progress.
EMEA/CHMP/167068/2004-ICH	ICH Guideline on Pharmaceutical Development (Q8)	After the adoption of the ICH Q8 document by the ICH Steering Committee, work is in progress on an annex for specific pharmaceutical forms.
EMEA/INS/GMP/157614/2005-ICH	ICH Guideline on Quality Risk Management (Q9)	After the adoption of the ICH Q9 document by the ICH Steering Committee, work is in progress on impact of it on the assessment of quality in Europe.
ICH Q10	Quality Systems (Q10)	Work in progress to finalise the ICH Q10 document.
EMEA/CVMP/VICH/899/99 Rev 1	Guideline on Stability testing of new veterinary drug substances and medicinal products (GL3(R))	Public consultation period expired. Finalisation of the revision foreseen for 1Q 2007.
CVMP/VICH/837/99 Rev 1 and CVMP/VICH/838/99 Rev 1	Guidelines on Impurities in New Veterinary Drug Substances and Impurities in New Veterinary Medicinal Products (GL10(R) and GL11(R))	Public consultation period expired. Finalisation of the guidelines foreseen for 1Q 2007.
EMEA/CVMP/019/00	Conduct of bioequivalence studies for veterinary medicinal products. It is a multidisciplinary guideline: involved WPs are EWP (Vet) and QWP	Revision led by EWP (Vet): Concept paper for the revision of the existing guideline to be prepared for public consultation (Q1 2007)
	Contribution to the revision of the variations regulations	Expected in 1-2Q 2007.
	Review of validity of existing Veterinary and Human Quality Guidelines	Ongoing.

Committee on Herbal Medicinal Products (HMPC)*

Reference Number	Document Title	Status
EMEA/HMPC/CHMP/CVMP/214869/2006	Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products	Draft expected for release for public consultation in 2Q 2007.
	Contribution to finalisation of the revised Annex 7 to GMP guide – Manufacture of herbal medicinal products	Expected in 1-2Q 2007.
	Contribution to the revision of the	Expected in 1-2Q 2007.

	variations regulations	
	Follow-up to contribution to improvement of the Community system of pharmacovigilance	Expected in 1-2Q 2007.
EMEA/HMPC/418902/2005	Assessment report template for the preparation of Community herbal monographs and for the inclusion of herbal substance(s), preparation(s) or combinations thereof in the Community list	Finalisation expected in 1Q 2007.
EMEA/HMPC/128772/2006	Procedure for the submission of a proposal by interested parties for inclusion of herbal substances, preparations and combinations thereof in the Community list	Draft expected for release for public consultation in 2Q 2007. Finalisation expected in 4Q 2007.
Not yet assigned	Guideline on the assessment of genotoxic constituents in herbal substances/preparations	Draft expected for release for public consultation in 4Q 2007.

* The HMPC does not generate an annual work programme. The documents listed in the overview are the expected finalisations of already ongoing work in the temporary drafting groups on quality and organisational matters.

HMPC Working Party on Community monographs and Community list

Reference Number	Document Title	Status
EMEA/HMPC/137423/2006	Community herbal monograph on Anisi fructus	Finalisation expected in 2Q 2007.
EMEA/HMPC/263273/2006	Community herbal monograph on Anisi aetheroleum	Finalisation expected in 2Q 2007.
EMEA/HMPC/260019/2006	Community herbal monograph on Betulae folium	Draft to be released for public consultation in 3Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Calendulae flos	Draft to be released for public consultation in 3Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Cynarae folium	Draft to be released for public consultation in 4Q 2007.
EMEA/HMPC/104945/2006	Community herbal monograph on Echinaceae purpureae herba	Draft to be released for public consultation in 2Q 2007. Finalisation expected in 4Q 2007.
EMEA/HMPC/244569/2006	Community herbal monograph on Eleutherococci radix	Draft to be released for public consultation in 2Q 2007. Finalisation expected in 4Q 2007.
EMEA/HMPC/137428/2006	Community herbal monograph on Foeniculi amari fructus	Finalisation expected in 2Q 2007.
EMEA/HMPC/263293/2006	Community herbal monograph on Foeniculi dulcis fructus	Finalisation expected in 2Q 2007.
EMEA/HMPC/263292/2006	Community herbal monograph on Foeniculi amari fructus aetheroleum	Finalisation expected in 2Q 2007.
EMEA/HMPC/428817/2006	Community list entry on Foeniculi amari fructus	Finalisation expected in 2Q 2007.
EMEA/HMPC/428963/2006	Community list entry on Foeniculi dulcis fructus	Finalisation expected in 2Q 2007.

Reference Number	Document Title	Status
EMEA/HMPC/251323/2006	Community herbal monograph on Harpagophyti radix	Draft to be released for public consultation in 2Q 2007. Finalisation expected in 4Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Lupuli flos	Draft to be released for public consultation in 4Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Melissae folium	Draft to be released for public consultation in 4Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Menthae piperitae aetheroleum	Draft to be released for public consultation in 3Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Menthae piperitae folium	Draft to be released for public consultation in 3Q 2007.
EMEA/HMPC/230962/2006	Community herbal monograph on Passiflorae herba	Draft to be released for public consultation in 1Q 2007. Finalisation expected 4Q 2007.
EMEA/HMPC/143370/2006	Community herbal monograph on Primulae radix	Draft to be released for public consultation in 1Q 2007. Finalisation expected in 4Q 2007.
Not yet assigned	Community herbal monograph on Primulae flos	Draft to be released for public consultation in 1Q 2007. Finalisation expected in 4Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Rhamni purshiani cortex	Draft to be released for public consultation in 4Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Rhei radix	Draft to be released for public consultation in 4Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Rusci aculeati rhizoma	Draft to be released for public consultation in 4Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Salicis cortex	Draft to be released for public consultation in 4Q 2007.
EMEA/HMPC/234113/2006	Community herbal monograph on Thymi herba	Draft to be released for public consultation in 1Q 2007. Finalisation expected 4Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Urticae folium	Draft to be released for public consultation in 3Q 2007.
EMEA/HMPC/170261/2006 EMEA/HMPC/168377/2006	Community herbal monograph/ Community list entry on Urticae herba	Draft to be released for public consultation in 3Q 2007.
Not yet assigned	Community herbal monograph/ Community list entry on Urticae radix	Draft to be released for public consultation in 3Q 2007.

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 the 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	Panos TSINTIS Direct telephone: (44-20) 75 23 71 08 E-mail: panos.tsintis@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: www.emea.europa.eu/inspections/defectinstruction.html for instructions and contact points

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 75/86 43
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: silvia.domingo@emea.europa.eu

For enquiries concerning VAMF certificates

Peter RICHARDSON

Direct telephone: (44-20) 75 23 7114

Fax: (44-20) 74 18 85 45

E-mail: peter.richardson@emea.europa.eu

Information service

The EMEA publishes a wide range of documents, including press releases, general information documents, annual reports and work programmes.

These and other documents are available:

- on the Internet at: www.emea.europa.eu
- by email request to: info@emea.europa.eu
- by fax to: (44-20) 74 18 86 70
- by writing to: European Medicines Agency, Information service, 7 Westferry Circus, Canary Wharf, London E14 4HB, UK

European experts list

Over 4 000 experts are used by the EMEA in its scientific evaluation work. The list of these European experts is available for examination on request at the EMEA offices.

Requests should be sent in writing to the EMEA

or by e-mail to

E-mail: europeanexperts@emea.europa.eu

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 personnel

Hannes Wahlroos, Chair of the Management Board, n. Finnish

Education: Prof. Wahlroos is a qualified pharmacist (pharmacology) from the University of Helsinki and a Ph.D. (Soc.Pharm.) from the University of Kuopio. Post-graduate studies in management, leadership and administration.

Career to date: From 1973 to 1979, Prof. Wahlroos served as a pharmacist and a researcher in several pharmacies, University of Helsinki and pharmaceutical industry. In 1979, he joined the National Board of Health where he acted as senior pharmaceutical inspector and Head of Pharmaceuticals Department. Prof. Wahlroos was appointed Director General of the National Agency for Medicines (NAM) in 1993. As the first Director General of the NAM, he was responsible to establish the Agency's strategies and working operations. From 1993 to 1994, he acted as the Vice-Chair of the EFTA Expert Group on Pharmaceuticals and from 1994 to 1995 as the Chair of the Nordic Council on Medicines. Prof. Wahlroos had a central role in the pharmaceutical sector in the preparations for the accession of Finland to the EU in 1995. He has been a member of the EMEA Management Board since 1995. He was elected Chair of the Board in May 2004.

Jytte Lyngvig, Vice-Chair of the Management Board, n. Danish

Education: Graduate in chemical engineering from the Technical University of Denmark. Post-graduate studies include a PhD in socio-economic planning.

Career to date: From 1976 to 1980, Dr Lyngvig was research-assistant and lecturer at the Technical University of Denmark. She worked at the Danish Environment Ministry from 1979 to 1985, first as a consultant and later as an official, before moving to the City of Copenhagen Environment Protection Agency until 1988. Dr Lyngvig has 12 years' private sector experience in the transport and consultancy industries and was appointed Chief Executive Office of the Danish Medicines Agency in 2000. She joined the EMEA Management Board in the same year and was elected vice-Chair in 2003.

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.

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 1982 to 1994. He joined the Swedish Medicinal Products Agency in 1990, serving as Director of Operations and later as Deputy Director-General. He is Executive Director of the EMEA since January 2001.

EMEA scientific committees

Daniel Brasseur, Chair of the CHMP, 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 re-elected as Chair in 2004.

Eric Abadie, Vice-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 and returned to industry until 1994. He joined the French medicines agency in 1994 as director of pharmacotherapeutic evaluation, a post he holds today. Dr Abadie has been a consultant in cardiology and diabetology since 1984. He was re-elected as vice-Chair in 2004.

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. He is a CVMP member since 1997, he was elected vice Chair of CVMP in 2001. He was first elected Chair of the CVMP in January 2003 and he was re-elected in 2004.

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: Anja Holm, Vice-Chair of the CVMP, n. Danish.

Education: Career to date: From 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, 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 the 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 to 1996). 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.

Heribert Pittner, Vice-Chair of the HMPC, n. Austrian

Education: Qualified medical doctor from the University of Graz. Post-graduate degree in pharmacology, Associate Professor in pharmacology and toxicology from the University of Vienna.

Career to date: Dr Pittner worked in the pharmaceutical industry from 1972 to 1985 where he discovered the pharmacological properties of the beta 1 - adrenoceptor antagonist celiprolol. In 1986, he joined the Austrian drug regulatory authority; since 2006, he has been Chief Medical Consultant and Head of the Department for Herbal Medicinal Products of AGES PharmMed (Austrian Drug Agency). Dr Pittner joined the Herbal Medicinal Products Working Party (HMPWP) in 1999 and was Vice-Chair of the working party from 2002 to 2004. In January 2006, Dr Pittner has been elected as Chair of the HMPC Working Party on Community Lists and Monographs (MLWP).

Moreover, Dr Pittner has been CPMP delegate from 1995 to 1997 and from 2001 until April 2004; since May 2004 Dr Pittner is CHMP delegate.

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.

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: From 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, including inspector of pharmaceutical manufacture, reviewer of dossiers and manager of the Biotechnology and Biological Unit. He was the UK representative at the Biotechnology Working Party, involved in the

generation of many guidelines relating to 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), and assistant in gastrointestinal and psychosomatic disorders. 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 on projects in the area of clinical immunology, oncology and cellular immunology. From 1984 to 1994, as medical director at the Pharmaceutical Department of the Italian Ministry of Health, she was in charge of the Operative Centre for Community Procedures and was Italian member of the former Committee for Proprietary Medicinal Products also involved in ICH activities. She joined the EMEA in October 1994. She acted as scientific secretary of the Biotechnology Working Party until December 2000. She was appointed Deputy Head of Sector for safety and efficacy of medicines in January 2001 and since then 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.

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.

Panos Tsintis, Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines, n. British and Cypriot

Education: Qualified in medicine from Sheffield University in 1983. Post-graduate qualifications in internal medicine (FRCP) and pharmaceutical medicine (FFPM).

Career to date: Six years of clinical experience in UK hospitals, 5 years as Director of Pharmacovigilance and Regulatory Affairs at Astra Pharmaceuticals in the UK and a total of 7 years at the UK Medicines and Healthcare Products Regulatory Agency (MHRA). Prior to his appointment as Unit Manager in Pharmacovigilance, he held a number of positions in both pre- and post-authorisation areas and was also the UK delegate to the CPMP Pharmacovigilance Working Party. Dr Tsintis joined EMEA as Head of Sector, Pharmacovigilance and post-authorisation safety and efficacy of medicines in March 2002.

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: Qualified chemist and pharmacist from the Free University of Berlin. PhD in organic chemistry 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 coordinated the development of the EU approach on risk assessment for chemicals. She was also involved in international harmonization activities on this subject. In 1995, she returned to Germany to the Ministry for Environment as scientific administrator. She joined the EMEA in April 1996.

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 Science in physical sciences; qualification in research management; PhD in physical organic chemistry; 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.

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 is a member of several medical advisory boards at the Austrian Ministry of Health. Since 2000, 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.

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), Ph.D. in European Law from the European University Institute of Florence (I), *Avvocato*, Chair Professor of International Law.

Career to date: From 1991 to 2004 Mr. 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.

Marijke Korteweg, Integrated quality management advisor, 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.