European Medicines Agency

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Annual report of the

European Medicines Agency

2007

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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MISSION STATEMENT

The mission of the European Medicines Agency is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.

Legal role

The European Medicines Agency is the European Union body responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products.

The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

Principal activities

Working with the Member States and the European Commission as partners in a European medicines network, the European Medicines Agency:

- provides independent, science-based recommendations on the quality, safety and efficacy of medicines, and on more general issues relevant to public and animal health that involve medicines;
- applies efficient and transparent evaluation procedures to help bring new medicines to the market by means of a single, EU-wide marketing authorisation granted by the European Commission;
- implements measures for continuously supervising the quality, safety and efficacy of authorised medicines to ensure that their benefits outweigh their risks;
- provides scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;
- recommends safe limits for residues of veterinary medicines used in food-producing animals, for the establishment of maximum residue limits by the European Commission;
- involves representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- publishes impartial and comprehensible information about medicines and their use;
- develops best practice for medicines evaluation and supervision in Europe, and contributes alongside the Member States and the European Commission to the harmonisation of regulatory standards at the international level.

Guiding principles

- We are strongly committed to public and animal health.
- We make independent recommendations based on scientific evidence, using state-of-the-art knowledge and expertise in our field.
- We support research and innovation to stimulate the development of better medicines.
- We value the contribution of our partners and stakeholders to our work.
- We assure continual improvement of our processes and procedures, in accordance with recognised quality standards.
- We adhere to high standards of professional and personal integrity.
- We communicate in an open, transparent manner with all of our partners, stakeholders and colleagues.
- We promote the well-being, motivation and ongoing professional development of every member of the Agency.

FOREWORD BY THE CHAIR OF THE MANAGEMENT BOARD

Pat O'Mahony

I am very pleased to introduce the EMEA annual report for 2007. The summaries of activities presented here reflect the excellent performance of all EMEA staff and national competent authority experts.

My role as Chair of the Management Board commenced in June, following my election by the members. It is a great honour to be appointed to this post and I look forward to working with the members and all partners to advance the important work we undertake on behalf of citizens. I succeeded Professor Hannes Wahlroos, who had so successfully chaired the Management Board for the previous three years. I would like to express my deep gratitude, and that of the entire network, to Hannes for his important contribution, which is greatly appreciated.

The mission of the EMEA is to foster scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health, and all that we do collectively is focused to that end.

Throughout 2007, the EMEA worked in close cooperation with others in the European medicines network, in particular in the area of risk-management, which is so fundamental to our consumer-protection role. Other areas of cooperation included the development of telematics and discussion on common resource and competence planning.

The EMEA experienced yet another year of increases in all of its areas of activity. The new paediatric legislation was successfully implemented, and a new scientific committee was established to oversee the performance of new tasks for the Agency and for the network.

The Agency made a substantial contribution in the area of research and development through the work of the EMEA/CHMP think-tank on innovative drug development and through the support given to the Innovative Medicines Initiative.

The Agency also contributed to the availability of a number of new medicines on the market, including new chemical entities and similar biological and generic medicines.

I would like to express my gratitude to the Executive Director and all EMEA staff for their commitment and excellent contribution during the year. I would like to thank the members of all the scientific committees and working parties for their hard work, and also to thank the staff of the European Commission for their ongoing support.

I look forward to continued progress and success in 2008.

INTRODUCTION BY THE EXECUTIVE DIRECTOR

Thomas Lönngren

I am pleased to report that the European Medicines Agency once again made a strong contribution to EU-wide efforts in support of making high-quality, safe and effective medicines available for use in human and animal populations.

In this, the thirteenth year of its operation, the EMEA delivered a strong performance in its core activity areas relating to the evaluation and supervision of medicines, while also pursuing with good results its broader mandate to stimulate innovation within the EU and contribute to European and global cooperation on scientific and regulatory practices in the field of medicines.

An important indicator of the EMEA's activity during any year is the number of applications it receives and processes for the initial marketing authorisation of medicinal products. In 2007, the Agency received 90 such applications relating to medicines for human use and 15 for veterinary medicines. The number for human medicines is higher than in any previous year, and the number of opinions adopted by the Agency's Committee for Medicinal Products for Human Use (CHMP), at 65, was also the highest ever recorded.

The public-health benefit behind these figures is that many new medicines to treat a range of diseases and conditions – from cancers to cardiovascular and neurological disorders – are now available for the treatment of Europe's patients. Similarly, new veterinary prevention and treatment options are now available for Europe's food-producing and companion animals. Notably, given recent attention paid in the media to the risk of a bird-flu pandemic, two vaccines against avian influenza were made available for use in poultry.

Perhaps the most tangible and significant achievement of 2007 was the Agency's successful introduction of new procedures and creation of a new scientific committee dedicated to implementing the EU's Paediatric Regulation, which came into force on 26 January. With the foundation of this new legislative framework and the EMEA's operation of it, children across Europe will begin to benefit from medicines that are developed with their specific needs and best interests at heart.

The Paediatric Committee – the Agency's fifth scientific committee – was launched with great enthusiasm in July of this year, and immediately began to elaborate scientific and procedural arrangements for the assessment of paediatric investigation plans and related regulatory instruments.

This year also saw Bulgaria and Romania welcomed into the EU family of nations, and they were quickly integrated into the work of the EMEA as full members of the European medicines network, while preparatory work to integrate Croatia and Turkey was also conducted in advance of these countries' possible accession to the EU.

Within the existing network, the EMEA worked closely with Member State national competent authorities on activities intended to improve the efficiency of the use of available resources and to secure the long-term availability of appropriate scientific expertise. This latter is particularly necessary given the increasing complexity of evaluation procedures and the advent of advanced therapies and other new technologies in the medical domain.

Activities in the area of supporting innovation and improving access to medicines yielded some very positive results in 2007. The initial success of the EMEA's SME Office seen in 2006 was reconfirmed this year, with Europe's smaller innovative companies demonstrating a keen interest in the dedicated support on offer to them from the EMEA. Interest in the Agency's provision of scientific advice and protocol assistance also continued to be high, with demand increasing for the third year in a row.

Further support for increased availability of medicines was also generated through the Agency's high output in relation to medicines for rare diseases – with more positive opinions being adopted in favour of orphan designation than in any previous year – and through the continuing work of the Agency's Innovation Task Force and Think-tank on innovative drug development, as well as through its support for the European Commission's Pharmaceutical Forum and Innovative Medicines Initiative. Likewise,

innovation and availability remained high priorities in the veterinary area, with input being given from the Agency to the Heads of Medicines Agencies (HMA) action plan to promote the availability of veterinary medicines and to the European Technology Platform for Global Animal Health, as well as to the further development of measures to assist companies seeking to authorise products for limited markets. The EMEA also supported the Commission in its work to develop the new Regulation on Advanced Therapies, which was published in December and which will usher in further new responsibilities for the Agency in 2008.

The EMEA's cooperation with global partner organisations continued apace in 2007, with the Agency playing an active role in the International Conferences on Harmonisation (ICH and VICH); working closely with the World Health Organization, in particular on issues relating to medicines for developing countries; consolidating its information-exchange programme with the US Food and Drug Administration in relation to human and veterinary medicines; and signing confidentiality arrangements to allow closer cooperation between the EMEA, the European Commission and the Japanese authorities on regulatory issues concerning medicines.

Cooperation among EU Agencies was intensive too, with the EMEA engaging in activities with the European Centre for Disease Prevention and Control, in particular in relation to pandemic-influenza preparedness and advanced therapies; with the European Food Safety Authority; with the European Monitoring Centre for Drugs and Drug Addiction; and with the European Directorate for the Quality of Medicines and HealthCare.

On an organisational level, the EMEA conducted elections of chairs and vice-chairs for four of its scientific committees, including the new Paediatric Committee, and of a new chair for its Management Board. The Agency also progressed well with its development and maintenance of information-technology services, as well as with its programme to enhance the participation of patients and healthcare professionals in EMEA activities.

In summary, 2007 was a very productive year with intense activity in many areas, as you will note when you read the detail of this annual report. For their hard work and dedication throughout the year, I express my deep gratitude to all members of the EMEA staff, as well as to all the experts and colleagues of the Member State national competent authorities and our partners at the European Commission and European Parliament who have contributed greatly to another successful year for the EMEA.

1. EMEA IN THE EUROPEAN SYSTEM

1.1 Management Board

In 2007, the EMEA Management Board:

- Adopted the Agency's work programme, budget and establishment plan for the year 2008
- Conducted an analysis of the Executive Director's annual activity report
- Provided an opinion on the Agency's final accounts
- Adopted the Agency's annual report for 2006.
- Re-nominated the majority of Board members in May 2007, following expiry of the three-year mandate. At its June 2007 meeting, the Board elected Pat O'Mahony as Chair and Lisette Tiddens-Engwirda as Vice-chair.

1.2 European medicines network

The European medicines network, a partnership of more than 40 medicines regulatory authorities in the European Union (EU), is the basis of the EMEA's success. The network gives the EMEA access to a pool of more than 4,000 experts, allowing the Agency to source the best-available scientific expertise for the regulation of medicines in the EU. Experts participate in the work of the EMEA as members of the scientific committees, working parties, scientific advisory groups and related groups.

- Bulgaria and Romania joined the EU on 1 January 2007. The transition from observer status to full participation in the European medicines network and in the work of the Agency was facilitated as a result of careful preparations.
- In view of the possible accession of Croatia and Turkey to the EU, the Agency organised a conference in each of these countries to prepare the groundwork for their potential future integration into the European medicines network.
- Resources in the network are scarce and work began to develop planning processes leading to improved use and better efficiency of the available resources.
  - EMEA participated in the planning process at the level of the Heads of Medicines Agencies (HMA).
  - The EMEA started an exercise to improve the organisation of working parties, aimed at achieving more efficient meetings and a better distribution of tasks to the members of the scientific committees and their working parties.
  - Vitero-based audioconferencing was introduced for some meetings, reducing the need for experts to travel to the EMEA.
- In light of the growing complexity of evaluation procedures, and the advent of emerging therapies and new technologies, the EMEA continued to extend the involvement of scientific experts and stakeholders in its work.
  - The Agency held a number of workshops and conferences to address critical scientific areas, involving academia, regulatory authorities and, where appropriate, pharmaceutical industry. Topics covered included: first-in-man clinical trials, biosimilars, immunogenicity of therapeutic proteins, adaptive design in confirmatory clinical trials, process analytical technology for biological medicinal products, and cell- and tissue-engineered products.

  - The Agency also organised a number of training sessions for assessors from the national competent authorities. Topics covered included: gene therapy products, diagnostics, oncology development, new approaches to quality assessment, and influenza pandemic.
  - Principles and processes for advanced education exchanges between regulatory authorities, academia and, where appropriate, industry were established. As a result of this, the Agency held regular contacts with relevant learned societies, in particular in the areas of cardiology, diabetes, central nervous system and oncology.
  - With a view to participating in educational programmes for regulatory scientists, in conjunction with academia and the national competent authorities, the EMEA contributed to the initiative started by Italy for a European school for regulatory assessment of medicines.
- Experts from academia and university hospitals on secondment to the EMEA contributed to the work of the European medicines network, ensuring the availability of complementary expertise.
- The Agency successfully organised a conference with a wide range of stakeholders to examine the operation of the Clinical Trials Directive after three years of operation, and published a report on the outcome.

1.3 Transparency and communication

In 2007, the Agency's activities in relation to transparency and communication concentrated on the consolidation of its existing activities.

- Good progress was made with the implementation of the Agency's rules on access to documents. A functioning internal system is now in place to handle the increasing demand for access to documents. More information about activities in relation to access to documents can be found in section 6.4.
- Further improvements were made in relation to the provision of information on medicines. Some highlights include: the systematic publication of assessment reports for withdrawn or refused marketing-authorisation applications; the publication of press releases and question-and-answer documents to provide better information in cases where there were safety concerns with medicines; the provision of product-related information in all EU languages. More information about activities in relation to the provision of information about medicines can be found in section 2.10.
- Representatives of patients' organisations and healthcare professionals were actively involved in and made valuable contributions to a number of EMEA activities. More information about the work of the EMEA with patients' organisations and healthcare professionals can be found in section 2.10.

1.4 Support for innovation and access to medicines

The Agency remained committed to the objectives of the Lisbon agenda.

Recognising that micro, small and medium-sized enterprises (SMEs) are often a motor for innovation, in particular in the field of new technologies and emerging therapies, the EMEA's SME Office continued to implement the policy to support SMEs.

- The number of companies requesting SME status in 2007 was 212, exceeding the forecast by more than 50%.
- The number of companies assigned SME status was 172, bringing the total number of companies with assigned SME status up to 246 at the end of 2007. Of the assigned companies, the majority are developing medicinal products for human use, 9 are veterinary companies, 8 are developing medicinal products for human and veterinary use, and 19 are regulatory consultants.
- A total of 81 applications for fee reduction or deferrals were received – 70% over forecast.
- A total of 66 fee-reduction or deferral requests were granted.

- A total of 47 requests for administrative assistance were received – over three times more than the initial forecast.
- Two SMEs benefited from translation support for the product information of their medicines.
- The EMEA provided guidance and training for SMEs.
  - The SME User Guide was updated in 2007 to reflect the experience gained during the course of 2006.
  - A news bulletin for SMEs was initiated in 2007.
  - The first SME workshop was held on 2 February 2007.
- The Agency further facilitated electronic reporting of adverse drug data by SMEs through the EudraVigilance system (EudraVigilance web-based system). This was achieved by providing training for SMEs at the EMEA and by providing free access to the system, thus allowing SMEs to fulfil their pharmacovigilance reporting obligations. Twelve training courses took place during the course of 2007.
  - The first workshop on analysis of data in the Eudravigilance Veterinary datawarehouse was held.
- In addition to the other EMEA core activities relating to stimulation of innovation – such as the provision of scientific advice to companies developing medicinal products, support to the orphan medicinal products policy, and the activities of the EMEA Innovation Task Force (ITF) – the Agency participated in the Innovative Medicines Initiative, which aims to address bottlenecks in the development of medicines.
- In the context of the 7th Framework Programme, the EMEA worked with the Directorate-General (DG) Research of the European Commission to define project objectives in the field of rare diseases and collaborated on calls in the field of medicines for children.
- The final report from the EMEA/CHMP think-tank group on innovative drug development, titled 'Innovative Drug Development Approaches', was published in 2007. The work of the think-tank focused on identifying scientific bottlenecks and emerging science in the development of medicines – both in industry's R&D and in the academic environment – and on generating recommendations for future EMEA actions.
- The EMEA and its Committee for Medicinal Products for Veterinary Use (CVMP) maintained priority measures aimed at improving the availability of veterinary medicines, which are detailed in section 3.2.2.
- The EMEA was a member of the Steering Committee of 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. The Agency participated in the preparation of the Action Plan that was released in August 2007 to implement the Strategic Research Agenda.

1.5 European public-health activities

- The EMEA worked closely with the European Commission and other EU bodies on the preparation of the new legislation on advanced therapy medicinal products. The final text of Regulation (EC) No 1394/2007 was adopted on 13 November 2007.
- Patients' and consumers' organisations became involved in the review of Package Leaflets at the time of renewal of a medicinal product and in the preparation of the EPAR summaries aiming at providing quality information to patients.
- The development of a database on biological warfare agents and treatment/prevention options was completed in 2007. The database is expected to be rolled out during the first half of 2008.

- The Agency continued its activities to maintain readiness for a potential influenza pandemic. As part of this, the Agency organised trainings for assessors and staff on the assessment procedures for pandemic-influenza vaccines.
- Availability of effective vaccines for control of avian influenza in birds is a key measure to reduce the likelihood of a pandemic in man. The Agency adopted positive opinions for two vaccines against avian influenza in birds.
- The Agency developed a procedure for sharing of information between the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Medicinal Products for Veterinary Use (CVMP) in relation to initiatives for complementary activities in the field of zoonosis (any disease that can be transmitted to humans from animals). In this context, a revision of the joint CHMP/CVMP 'Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products' is ongoing.
- The EMEA continued its contribution to the work of the European Commission's Pharmaceutical Forum, particularly in the working group on added therapeutic value and on information for patients.
- The Agency continued to participate in activities in support of the EU programme to reduce the use of animals in testing of medicines and develop other modern approaches to safety-assessment of medicines.
  - The Agency participated in the European Partnership for Alternative Approaches to Animal Testing, a joint Commission/industry initiative which has the intention to promote the development of new '3R' methods (refine, reduce, replace) as modern alternative approaches to safety-testing.
  - The CVMP completed a review by its working parties of the use of animals in regulatory testing of veterinary medicinal products and will reflect on the scope for further application of the '3Rs' during 2008.
- The CVMP maintained as a high priority its work to minimise the risk of development of antimicrobial resistance through the use of antibiotics in animals, developing guidance on post-authorisation monitoring and the use of fluoroquinolones.
- The CVMP produced guidance on how applicants should meet the technical requirements of VICH guidelines on environmental risk-assessment (ERA) and assisted the Commission with the production of guidance on meeting the legal requirements of Directive 2001/82/EC with respect to ERA.
- Cooperation continued with the European Centre for Disease Prevention and Control (ECDC), in particular in relation to pandemic-influenza preparedness, advanced therapies and biological warfare agents.
- The EMEA and the European Centre for Disease Control and Prevention (ECDC) made preparations for the establishment of a joint working group to produce a technical report setting out the medical needs in the area of antimicrobial resistance – an initiative arising from the EMEA-CHMP think-tank report.
- Further cooperation continued with the European Food Safety Authority (EFSA), in particular on genetically modified organisms, with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), and with the European Directorate for the Quality of Medicines and HealthCare (EDQM).

1.6 Preparations for future enlargement

- The Agency organised conferences in Croatia and Turkey to prepare the groundwork for the possible accession of these two countries to the European Union. The conferences were held in the context of a multi-beneficiary programme dedicated to supporting the participation of Croatia and Turkey in certain Community agencies.

1.7 International cooperation

These activities cover cooperation at international level, namely: coordination of EU experts' participation in the International Conference on Harmonisation (ICH and VICH); 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); and work with the US Food and Drug Administration (FDA), the US Department of Agriculture (USDA) and Health Level 7 (HL7).

- Within the ICH framework, the EMEA was rapporteur for ICH M5 EWG (Data elements and Standards for Drug Dictionaries) and EU Topic Leader for ICH E2B (Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports). The EMEA also provided input on behalf of the Eudravigilance Expert Working Group (EV-EWG) to the topic ICH-M1 (Medical Dictionary for Drug Regulatory Activities (MedDRA)) and contributed as editor to the ICH Rapporteur for ISO Task Force 215, Work Group 6 (Pharmacy and medication). In addition, the EMEA participated in the working groups of the Council for International Organizations of Medical Sciences (CIOMS) on signal detection, vaccines and Standardised MedDRA Queries (SMQ).
- Confidentiality arrangements were signed between the European Commission, the EMEA, the Japanese Ministry of Health, Labour and Welfare (MHLW) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) at a bilateral meeting in Tokyo held in February 2007.
- Confidentiality arrangements were also signed between the European Commission, the EMEA and the Health Products and Food Branch of Health Canada at a bilateral meeting in Brussels held in December 2007.
- The Agency's cooperation with the US Food and Drug Administration (FDA) was strengthened in accordance with the revised EU/FDA Confidentiality Arrangements Implementation Plan.
- The Agency also provided scientific support to the Commission on EU cooperation with India, in particular in the area of traditional herbal medicinal products. Representatives from the Commission and the EMEA, including from the Agency's Committee on Herbal Medicinal Products (HMPC), participated in a fact-finding mission to India with a view to explore technical issues concerning the potential application of the EU legal framework for traditional herbal medicinal products to Ayurvedic products.
- The Agency continued to promote the effective operation of mutual-recognition agreements (MRAs) with Australia, New Zealand, Switzerland, Canada and Japan.

1.8 Integrated management at the Agency

- The Agency continued the process-improvement exercise it begun in 2006. 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 stakeholders. Improvement actions that were identified have started to be implemented and the process is expected to continue into 2008.
- A programme of 11 internal audits was carried out in 2007, looking at key processes such as procurement, information technology, outsourcing of infrastructure services, the functioning of orphan product designation and of the Committee on Orphan Medicinal Products (COMP), Quality Review of Documents, management and running of the Veterinary Unit, and processing of access-to-documents requests.
- The level of implementation of standards for internal control, as well as the overall effectiveness of the Agency's IQM system, was reviewed. A number of improvement actions were proposed and implementation of some of them started in 2007.
- The Agency introduced an environmental policy for its internal and external operations. As part of the policy, the EMEA endeavours to conduct procurements giving priority, where possible, to environment-friendly products, and is introducing various environment-friendly practices across the Agency.

2. MEDICINES FOR HUMAN USE

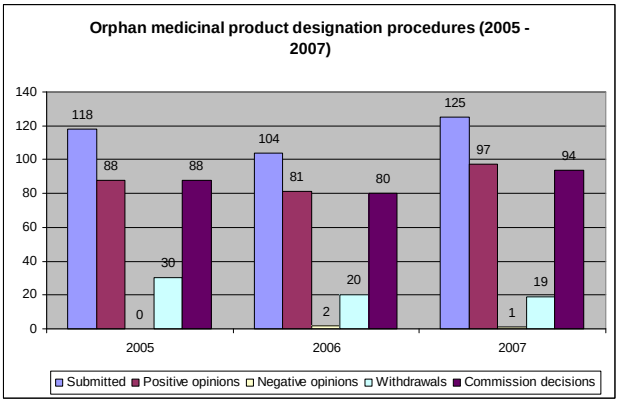
2.1 Orphan medicinal products

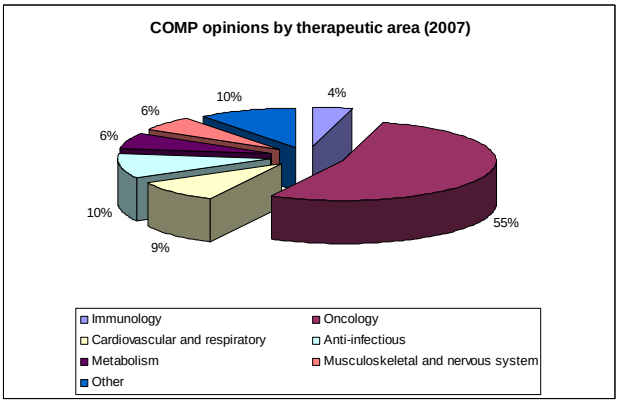
Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union, or where for economic reasons such medicines would not be developed without incentives.

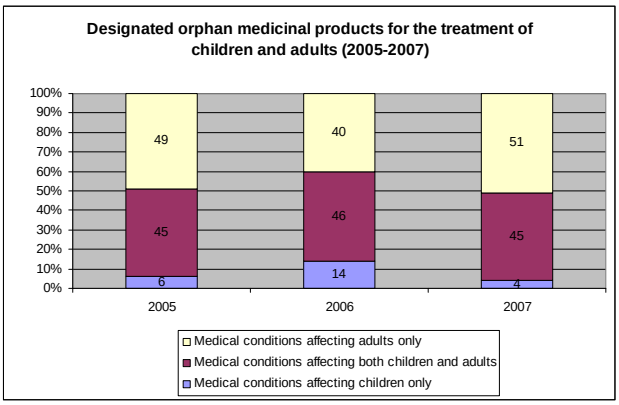
2.1.1 Core activities

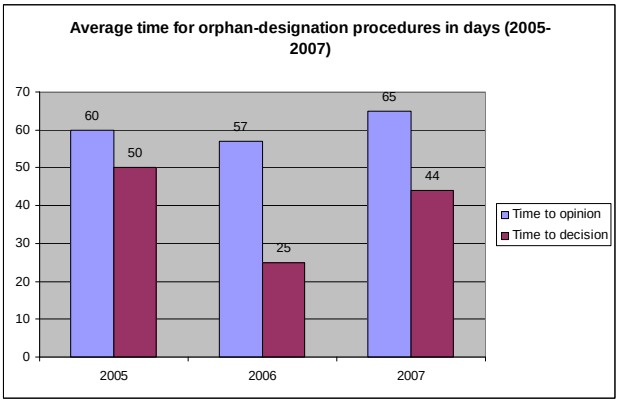
Orphan designation

- For the fourth consecutive year, more than one hundred applications were received for the designation of orphan medicinal products: a total of 125 applications were submitted.
- The number of withdrawn applications (19) was the lowest in the past seven years.
- The Committee for Orphan Medicinal Products (COMP) adopted 97 positive opinions – the highest number ever – and one negative opinion.
- As in previous years, cancer treatment was the most-represented therapeutic area for which the COMP adopted positive orphan-designation opinions.
- Almost half of the positive opinions for orphan designation were for conditions affecting children.
- The average time taken by the COMP to evaluate applications was 65 days, slightly higher than in the previous two years.







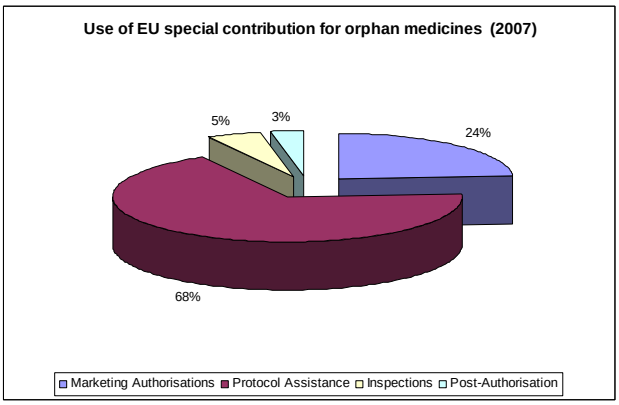


Performance indicators

Performance indicator	Target	Outcome 2007
Percentage of applications evaluated within the 90-day timeline	100% of applications	98%
Percentage of summaries of COMP opinions published within 1 month of the European Commission's decision on designation	70% of summaries of opinion	27%. This was because effort focused on clearing the backlog from 2006 which was created due to staff shortages
Number of COMP guidelines released or revised on topics as planned	80%	100%. All COMP guidelines were released or revised as planned

EU special contribution for orphan medicines

- A total of €4.89 million from the EU special contribution was used to grant fee reductions for orphan medicines in 2007.
- The Agency amended its policy on fee reductions for orphan medicines in 2007 to continue to focus on incentives to support protocol assistance, marketing-authorisation applications and other pre-authorisation activities, and to support SMEs in the first year after granting of a marketing authorisation.



2.1.2 Specific objectives in 2007

- Work to integrate global development for orphan medicinal products in collaboration with the US Food and Drug Administration (FDA) is ongoing.
  - The European Commission, EMEA and FDA adopted a common application form for sponsors seeking orphan designation of medicines in the EU and USA in December 2007. This initiative aims at simplifying the process of obtaining orphan status for medicines intended for rare diseases in both jurisdictions.
  - No requests for parallel advice for protocol assistance with the FDA were received in 2007.

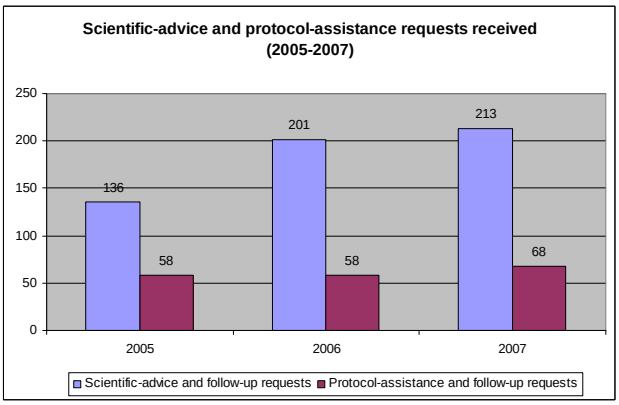
2.2 Scientific advice and protocol assistance

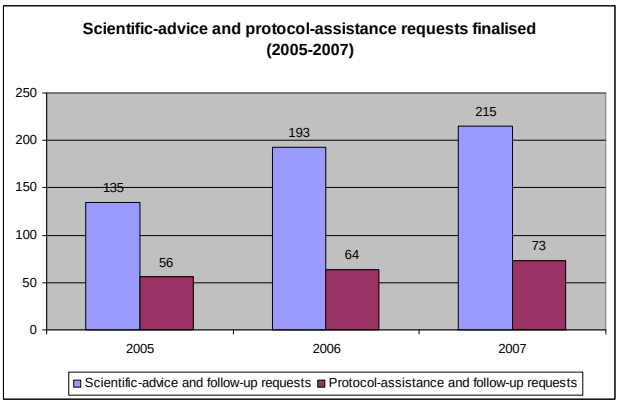
The Agency provides scientific advice and protocol assistance to sponsors during the phase of research and development of medicinal products. Scientific advice is provided on any aspect of research and development relating to quality, safety or efficacy of medicinal products. In addition, the Agency 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.

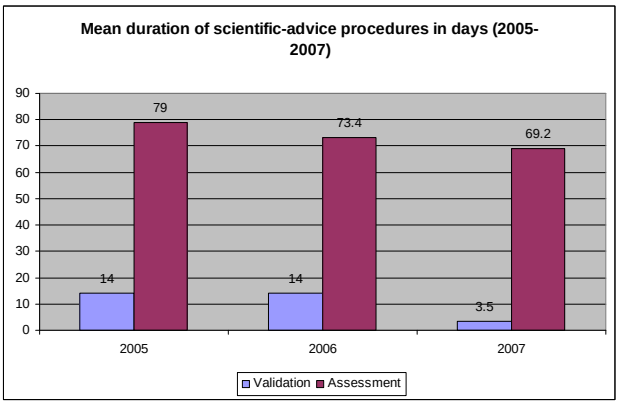
Scientific advice and protocol assistance are key areas of activity for the Agency, in particular with respect to fostering new innovative technologies and therapies. The Agency considers scientific advice as a means to facilitate and improve earlier availability of medicinal products to patients and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

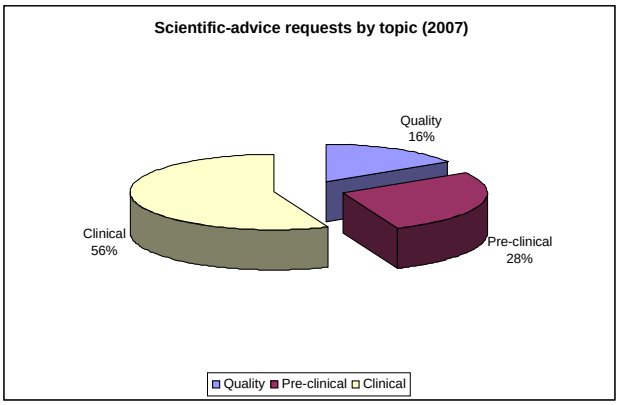
2.2.1 Core activities

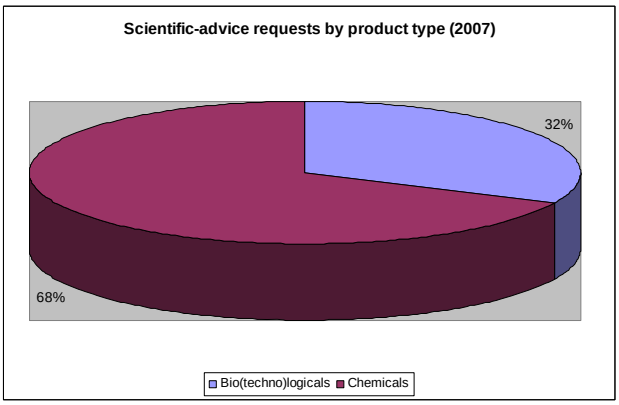
- Interest in scientific advice and protocol assistance from the EMEA remains high. 213 requests for scientific advice were received in 2007.
- A marked increase in the number of requests for protocol assistance was registered in 2007, with 17% more requests received than in 2006.
- As in previous years, the Agency and the Scientific Advice Working Party (SAWP) have yet again shortened the timelines for the delivery of scientific advice.

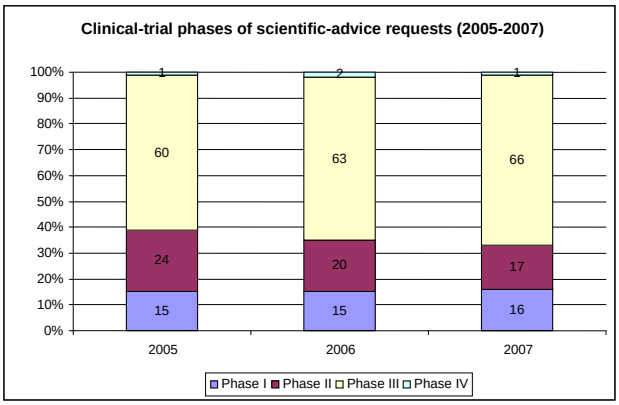

Scientific-advice and protocol-assistance requests received (2005-2007)
250
200
150
100
50
0
136
58
201
58
213
68
2005
2006
2007
Scientific-advice and follow-up requests
Protocol-assistance and follow-up requests

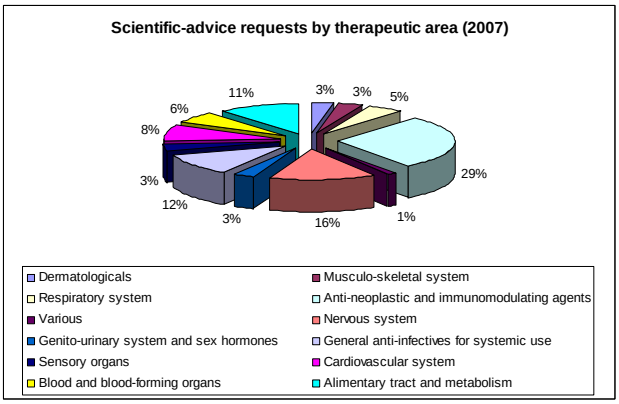

Scientific-advice and protocol-assistance requests finalised (2005-2007)
250
200
150
100
50
0
135
56
193
64
215
73
2005
2006
2007
Scientific-advice and follow-up requests
Protocol-assistance and follow-up requests


Mean duration of scientific-advice procedures in days (2005-2007)
90
80
70
60
50
40
30
20
10
0
14
79
14
73.4
3.5
69.2
2005
2006
2007
Validation
Assessment


Scientific-advice requests by topic (2007)
Quality 16%
Clinical 56%
Pre-clinical 28%
Quality
Pre-clinical
Clinical







2.2.2 Specific objectives in 2007

- Review of scientific-advice and protocol-assistance procedures with a view to improving them for the benefit of fostering innovation in all procedures is ongoing.
  - A questionnaire, developed together with EFPIA, was distributed to users of scientific-advice and protocol-assistance procedures.
  - A procedure was set up to ensure effective coordination between the Scientific Advice Working Party (SAWP) and the Paediatric Committee (PDCO).
- In the context of the European Risk Management Strategy, the EMEA considers the risk-management plans early on in a medicine's lifecycle. Changes were introduced to the scientific-advice/protocol-assistance procedure to prepare for risk-management plans.

Performance indicators

Performance indicator	Target	Outcome 2007
Scientific-advice and protocol-assistance requests evaluated within the procedural timelines	100% of requests	99.7%
Percentage of pre-submission meetings for orphan and non-orphan products	60% of protocol assistance and 80% of scientific advice respectively	41% of protocol assistance and 33% of scientific advice
External experts involved in procedures	at least 70% of scientific-advice and protocol-assistance requests	53%
Percentage of marketing-authorisation applications for new technology products having received scientific advice/protocol assistance	50% of applications	50%

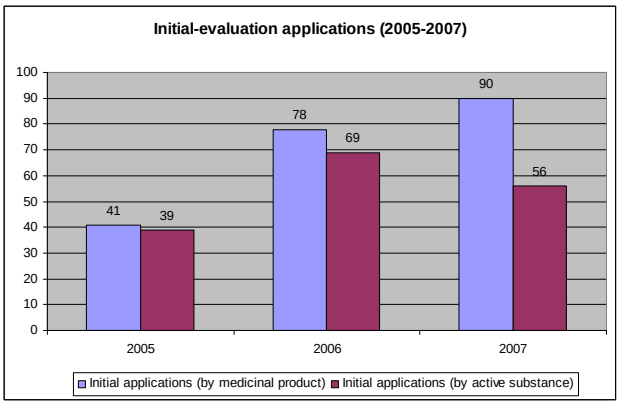
2.3 Initial evaluation

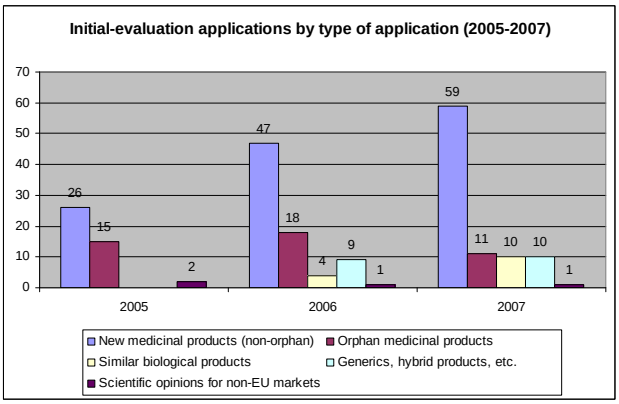
Initial evaluation covers activities relating to the processing of applications for medicinal products (orphan, non-orphan, similar biological (biosimilar), generic, etc.) from pre-submission discussion with future applicants, through evaluation by the CHMP, to the granting of a marketing authorisation 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.

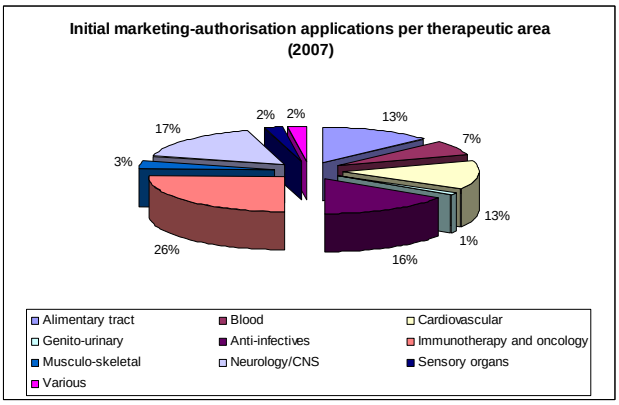
2.3.1 Core activities

New applications

- The total number of new applications was higher than in any other year. However, the number of initial applications by active substance, i.e. without double applications, was 19% lower than in 2006.
- Applications for new products for use in the treatment of cancer once again represented the highest proportion by therapeutic area in 2007. Neurology and the central nervous system followed by anti-infectives were the next most-represented therapeutic groups.
- The number of marketing-authorisation applications for orphan designated medicines was lower than in 2006 but close to the 7-year average since the introduction of orphan legislation.
- With the legal and regulatory framework for similar biological medicines now firmly established, 10 applications for these were received in 2007.
- One application was received for a scientific opinion on medicinal products intended for non-EU markets.



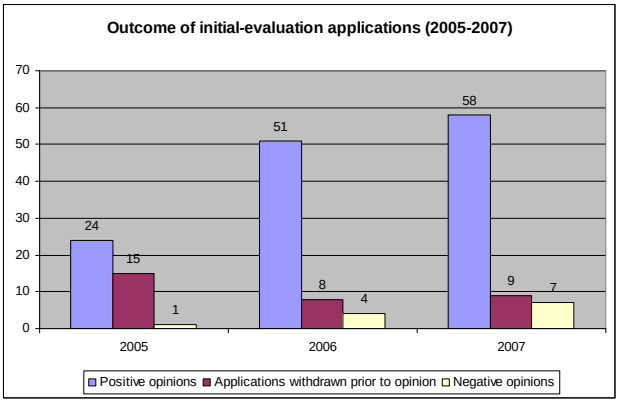


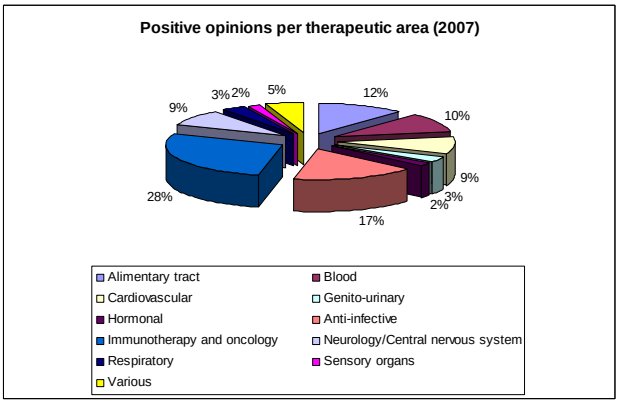


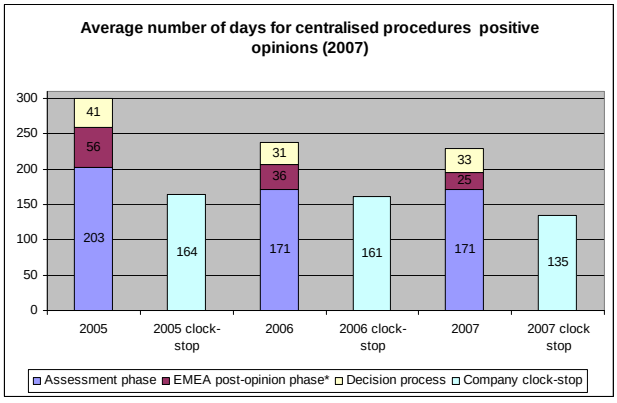
Opinions

- In 2007, the EMEA's Committee for Medicinal Products for Human Use (CHMP) adopted 58 positive opinions on initial-evaluation applications, the highest number ever.
- Seven out of the total number of 65 opinions adopted were negative, recommending that the marketing authorisation for these medicines be refused. 9 applications were withdrawn.
- The highest number of positive opinions adopted was for cancer products, followed by anti-infectives and alimentary-tract products.
- Two positive opinions were adopted for medicines that were reviewed under accelerated assessment.
- Three opinions were adopted recommending granting of a conditional marketing authorisation.
- Four opinions were adopted recommending granting of a marketing authorisation under exceptional circumstances.

- The first 'live' marketing-authorisation application using the PIM (product information management) system was successfully finalised with the adoption of a positive CHMP opinion in July 2007. PIM increases the efficiency of the management and exchange of product information by all parties involved in the evaluation process, using electronic means. In addition, it helps improve the quality and consistency of the published product information.







* The EMEA post-opinion phase accounts for the Agency's processing time as well as the time required by applicants and Member States to carry out their post-opinion translations and checks.

Public-health benefits of medicines recommended for authorisation in 2007

Medicines of notable public-health interest that received a positive opinion from the CHMP in 2007 included:

- A designated orphan medicinal product intended to reduce haemolysis (destruction of red blood cells) in patients with paroxysmal nocturnal haemoglobinuria (PNH), a rare blood disorder in which the red blood cells are destroyed more rapidly than normal, causing the urine to turn dark. This was the first medicine for which an accelerated assessment procedure was concluded successfully. It was also the first medicine submitted by a company benefiting from incentives for SMEs.
- A second vaccine for prophylaxis against high-grade cervical intraepithelial neoplasia (CIN grades 2 and 3) and cervical cancer causally related to human papilloma virus (HPV) types 16 and 18.
- A medicine belonging to a new class of antiretrovirals (CCR5 inhibitors) that reduce the amount of HIV in plasma (viral load) and increase the number of T cells (specifically CD4 cells) in heavily experienced patients with CCR5-tropic HIV-1, when used in combination with other anti-retroviral medicines.
- Two mock-up pandemic-influenza vaccines intended for the prevention of influenza during an officially declared pandemic situation. Marketing authorisations under exceptional circumstances were granted subject to certain specific obligations to be reviewed annually. (A mock-up pandemic vaccine is not intended for stockpiling, but can be used to speed up the availability of a final vaccine in the event of a pandemic, once the pandemic strain has been identified.)
- A medicine with a chemical structure resembling that of thalidomide. It is approved in multiple myeloma, where it works by blocking the development of tumour cells and by stimulating some of the specialised cells of the immune system to attack the cancerous cells.
- The first two dipeptidyl peptidase 4 (DPP-IV) inhibitors, both indicated for type II diabetes. They work by blocking the breakdown of incretin hormones in the body, thereby stimulating the pancreas to produce insulin when blood-glucose level is high, and also decreasing the levels of the hormone glucagon. They bring about a reduction in blood-glucose levels and help to control type II diabetes.
- The first renin inhibitor indicated for treatment of hypertension. It blocks the activity of renin, an enzyme which is involved in the production of angiotensin I that is subsequently converted into the hormone angiotensin II, a powerful vasoconstrictor (it narrows blood vessels and consequently raises the blood pressure). By blocking the production of angiotensin I, levels of both angiotensin I and angiotensin II fall.
- A medicinal product for the treatment of metastatic carcinoma of the colon or rectum after failure of oxaliplatin- and/or irinotecan-containing chemotherapy regimens.
- A medicinal product for the treatment of patients with advanced soft-tissue sarcoma (namely liposarcoma and leiomyosarcoma), after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents.
- An antidote medicinal product used for treating cyanide poisoning.

2.3.2 Specific objectives for 2007

- Review of 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) was completed.
  - Preparations for a monitoring system were made.
  - An assessment of procedures for early access to medicines was completed.

- Re-engineering exercise of the processes for the pre-authorisation phase of marketing authorisation and PMF certification, and reinforcement of scientific-secretariat input from pre-filing to opinion, are ongoing.
  - Following review of its processes from the pre-filing stage through to the adoption of the opinion, EMEA prepared improvement plans which are currently under discussion.
  - A system was piloted for reviewing scientific-advice requests in order to strengthen the link between scientific advice and the initial-evaluation phase.
  - A process for the rolling review of defined packages of applicants' responses to lists of questions will be developed as part of the EMEA-CHMP think-tank plan.
- Development and improvement of the peer-review process advanced well.
  - A pilot peer-review was successful: all new marketing-authorisation applications, including similar biological medicinal products, generics and influenza vaccines, were peer reviewed in 2007. The pilot phase was extended to 2008.
  - The Biologics Working Party peer-reviewed quality aspects of marketing-authorisation applications for biologics.
- There was further extension of the use of the European medicines network in the areas of advanced therapies through the establishment of specialised contact points in national competent authorities.

Performance indicators

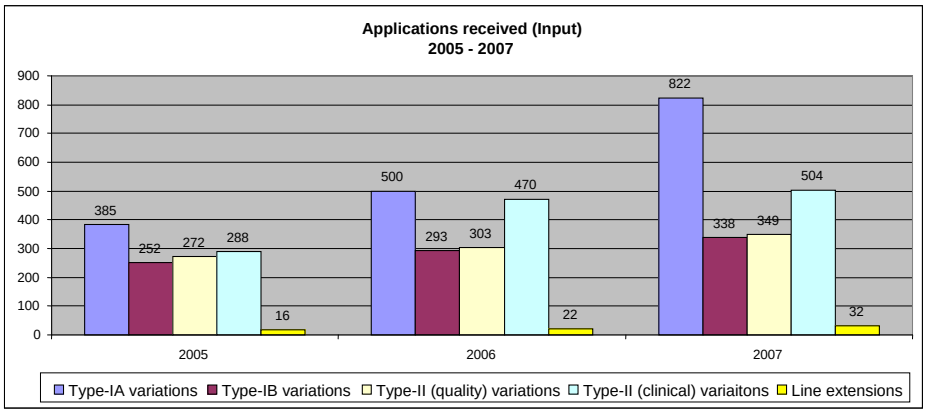
Performance indicator	Target	Outcome at end of 2007
Percentage of applications evaluated within regulatory timeline of 210 days	100% compliance	100%
Percentage of accelerated-assessment applications evaluated within regulatory timeline of 150 days	90% compliance	100%
Percentage of marketing-authorisation applications including risk-management plans (RMP) peer reviewed by the EMEA as part of the assessment of the initial marketing-authorisation application	80% of applications that include an RMP	92%
Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days	95% compliance	98%
Number of opinions for compassionate use given by procedural deadline	80% compliance	None received in 2007
Percentage of plasma-master-file applications evaluated within the regulatory timeline	100% of applications	100%

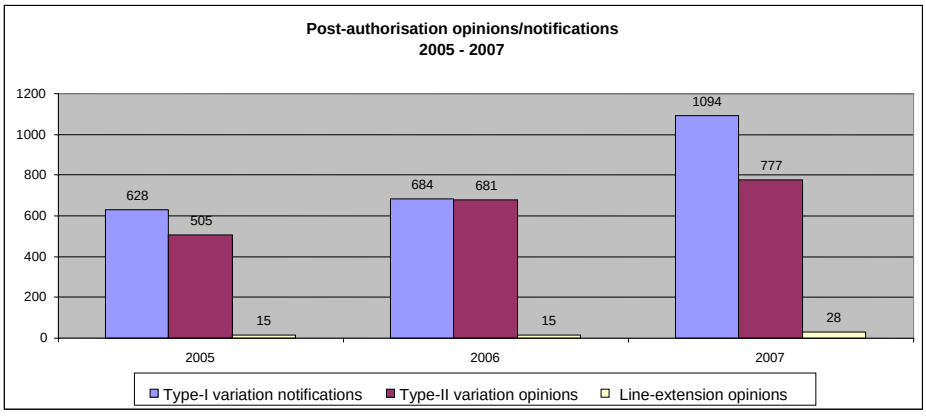
2.4 Post-authorisation activities

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.

2.4.1 Core activities

- The number of applications for variations and line extensions of marketing authorisations continues to rise. A total of 2,045 applications were received in 2007 – an increase of almost 30% compared to the previous year.
- For adopted post-authorisation opinions or notifications, the increase was even more pronounced. The number rose by 37% over the previous year. The Agency was able to cope with the increased workload partly due to process improvements for the handling of variation applications that led to efficiency gains in the handling of certain types of variations.
- CHMP adopted 41 opinions for new indications, providing additional treatment options for patients.
- The CHMP adopted two negative opinions, recommending the refusal of two applications for an extension of indication. The CHMP also restricted the indication for a number of products for efficacy or safety reasons.
- The CHMP recommended new contra-indications or the removal of contra-indications for a number of products, as well as concluded more than 100 type-II variations pertaining to warnings and precautions for use.





Public-health impact of the EMEA's post-authorisation activities in 2007

Positive opinions for new indications

The CHMP adopted 41 opinions on new indications, providing additional treatment options for patients.

- Most of the new indications related to medicinal products approved for the treatment of various forms of cancer, such as hepatocellular carcinoma, locally advanced squamous cell carcinoma, metastatic breast cancer, advanced gastric cancer, advanced or metastatic renal cell cancer, metastatic colorectal cancer, non-small cell lung cancer, relapsed multiple myeloma and B-cell chronic lymphocytic leukaemia, and follicular non-Hodgkin's lymphoma.
- Several extensions of indication were also granted for the treatment of diabetes (providing more options for the combined use of oral antidiabetics and insulins).
- New indications were also approved in the fields of cardiovascular, infectious, rheumatoid and inflammatory-bowel diseases and central nervous system disorders.
- Six medicinal products had their use extended to include the treatment of children and adolescents having Crohn's disease, anaemia associated with chronic renal failure, or HIV, or to include immunisation against additional infections caused by streptococcus pneumoniae.

Negative opinions for new indications

The CHMP adopted two negative opinions, recommending the refusal of two applications for an extension of indication:

- one for NutropinAq (recombinant somatropin) to add the long-term treatment of children with severe idiopathic short stature, due to the lack of evidence that the benefits of NutropinAq in the long-term treatment of children with severe idiopathic short stature did not outweigh its possible risks;
- one for Zavesca (miglustat) to add the treatment of the 'neurological' symptoms of Niemann Pick type C disease. Although the CHMP acknowledged that there are no alternative treatments for Niemann Pick type C disease, it was concerned that a benefit of Zavesca in the proposed indication had not been sufficiently demonstrated.

Restriction or deletion of indications

The CHMP also recommended the restriction or the deletion of the indications of some centrally authorised medicines.

- Visudyne (verteporfin): the indication in patients with age-related macular degeneration with occult subfoveal choroidal neovascularisation with evidence of recent or ongoing disease progression was deleted, as the results of a confirmatory study failed to support the efficacy of the use of Visudyne in these patients. The benefit/risk balance of Visudyne in the other approved indications remained positive.
- Ketek (telithromycin): three of the four approved indications were restricted. For the treatment of bronchitis, sinusitis and tonsillitis/pharyngitis, Ketek should only be used for infections caused by bacterial strains that are suspected or proven to be resistant to, or cannot be treated with, macrolide or beta-lactam antibiotics. No such restrictions were recommended for the remaining indication, the treatment of community-acquired pneumonia.
- The safety of epoetins – both centrally authorised (Aranesp, Nespo, Dynepo, Mircera, NeoRecormon, Binokrit, Epoetin Alfa Hexal, Abseamed) and nationally authorised (Eprex) – was reviewed because data from recent clinical trials showed a consistent unexplained excess mortality in patients with anaemia associated with cancer who have been treated with epoetins. The CHMP concluded that the benefits of these products continue to outweigh their risks in the approved indications. However, the indication in the treatment of anaemia was restricted to anaemia associated with symptoms.

Contra-indications, warnings and precautions for use

The CHMP recommended new contra-indications for 20 centrally authorised medicinal products, and in some instances for the entire classes of centrally authorised medicinal products (class labelling), including:

- Viracept (nelfinavir mesilate): co-administration with omeprazole;
- Acomplia (rimonabant): ongoing major depressive illness and/or ongoing antidepressive treatment;
- Agenerase, Aptivus, Crixivan, Invirase, Kaletra, Norvir, Prezista, Reyataz, Telzir, Viracept (protease inhibitors): concomitant use with oral midazolam (while further directions concerning co-administration with parenteral midazolam are provided in the SPC) (class labelling);
- Pegintron (peginterferon alpha 2b), Viraferonpeg (peginterferon alpha 2b) and Rebetol (ribavirin): initiation of treatment of hepatitis C in patients with hepatitis C and HIV co-infection who have cirrhosis and a Child-Pugh score of 6 or higher.

The CHMP recommended the deletion of contra-indications for 12 centrally authorised medicinal products, and in some instances for the entire class of centrally authorised medicinal products (class labelling), including:

- Pioglitazone- (Actos, Glustin, Competact, Tandemact) and rosiglitazone- (Avandia, Avandamet, Avaglim) containing medicinal products: deletion of the contra-indication for their combined use with insulins (class labelling);
- Stocrin and Sustiva (efavirenz): deletion of the contra-indication for their co-administration with voriconazole.

The CHMP concluded more than 100 type-II variations relating to special warnings and precautions for use, including:

- a new safety warning for Tamiflu (oseltamivir phosphate) and the risk of neuro-psychiatric adverse events;
- a new warning for recombinant factor VIII medicinal products regarding the possible recurrence of inhibitors after switching from one recombinant factor VIII product to another in previously treated patients with more than 100 exposure days who have a history of inhibitor development (class labelling);
- a new warning for pioglitazone- and rosiglitazone-containing medicinal products regarding the increase of bone fractures in women; and for rosiglitazone-containing medicinal products only regarding a possible risk of ischaemic heart disease;
- a new warning with an urgent safety procedure (USR) concerning the rare but serious risk of drug rash with eosinophilia and systemic symptoms (a severe type of allergic reaction) with strontium-ranelate-containing medicinal products (used to treat osteoporosis in women who have been through menopause).

Safety review of Viracept

- The CHMP conducted a review of Viracept (nelfinavir) further to contamination during the manufacturing process of several batches of the active substance with ethyl mesilate, a known genotoxic substance. The CHMP first recommended the suspension of the marketing authorisation and the recall of Viracept from the market. Following the assessment of the corrective and preventive measures put in place by the marketing-authorisation holder and the inspection of the manufacturing site – which provided reassurance that the cause of the contamination had been eliminated and that future production of Viracept would meet the required quality standards – the CHMP subsequently recommended the lifting of the suspension of the marketing authorisation and the re-introduction of the medicine onto the market in the European Union.

2.4.2 Specific objectives in 2007

- The EMEA continued its process process-improvement-exercise activities related to the processing of type-I and II variations.
  - Reports on process improvement for type-I and II variations were finalised. Implementation of the improvement actions was begun.
- The EMEA supported the European Commission's review of the Variations Regulation (Regulation (EC) No 1085/2003).
- Building on the operational improvements introduced in 2006, the EMEA continued its exercise to strengthen the quality and the regulatory and scientific consistency of CHMP opinions and assessment reports.
  - Staff received scientific, regulatory and procedural training in order to reinforce the EMEA's role as scientific secretariat.
  - The input of specialist advice was further strengthened in 2007, building on the work already undertaken in 2006, through a re-enforcement of the participation of the Pharmacovigilance Working Party (PhVWP) co-opted members in safety safety-related issues.

Performance indicators

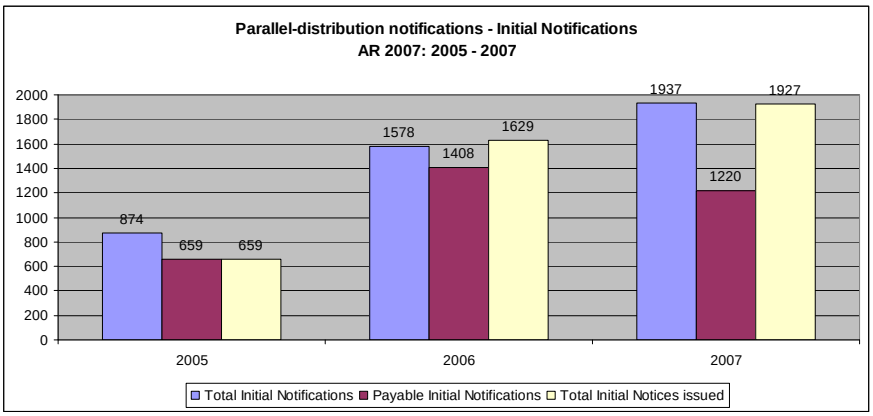
Performance indicator	Target	Outcome
Percentage of applications for post-authorisation procedures evaluated within the regulatory timelines	100% of applications	100%
Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications	41% between January and June. 45% between July and November

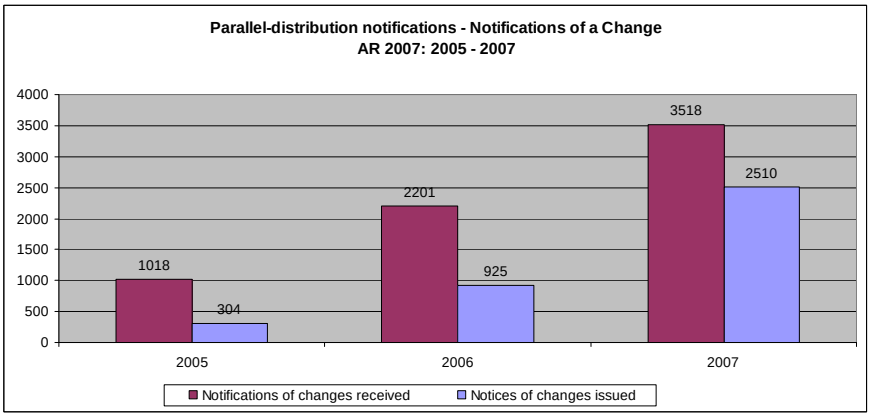
2.5 Parallel distribution

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.

2.5.1 Core activities

- The number of initial parallel-distribution notifications and the number of notifications of change have exceeded the expected number. 1,937 initial notifications were received this year, 8% more than forecast. 3,518 notifications of change were received, 45% more than forecast.
- The timelines set out in the procedures were not adhered to due to the high number of notification requests received, a backlog from previous years, and a lack of resources.





2.5.2 Specific Objectives in 2007

- Review and update of the EMEA guidance on parallel distribution was postponed to 2008.
- Efforts were undertaken to increase parallel distributors' compliance with the checking process.
  - An overview of notices for parallel distribution issued by the EMEA has been published monthly since 1 January 2007.
  - A discussion on proposals aimed at improving efficiency of the parallel-distribution-notification process was initiated in 2007.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of notifications checked for compliance within the regulatory timeline of 35 working days (validation and regulatory check)	70% of applications checked within 35 working days	46% of applications were handled in 35 working days. Average handling time was 72 working days.

2.6 Pharmacovigilance and maintenance activities

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

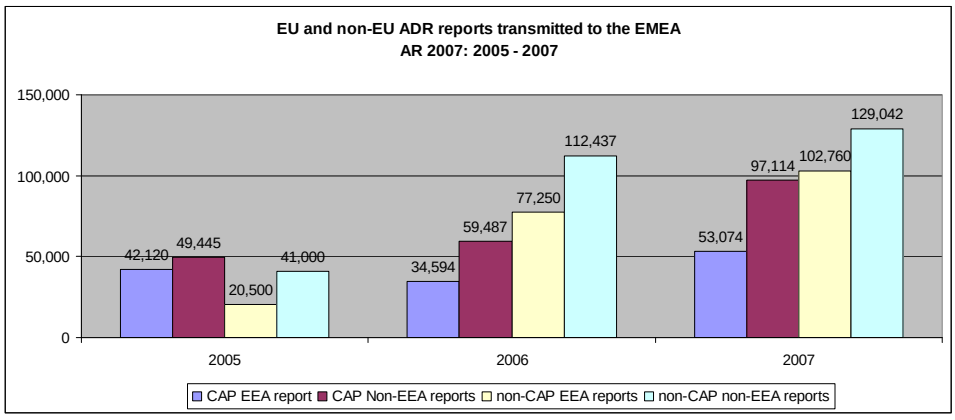
Safety of medicines is a priority area for the EMEA and the Agency will continue to strengthen its efforts in order to ensure the safe use of medicinal products authorised in accordance with the centralised procedure.

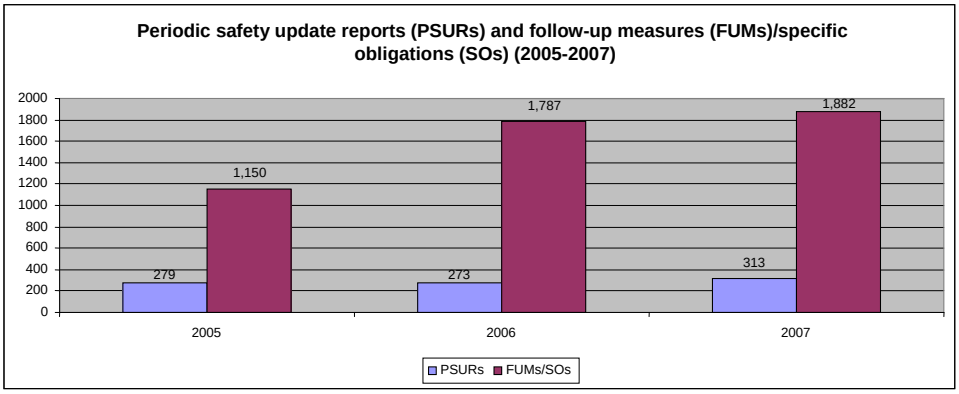
The wide range of activities undertaken in the field of pharmacovigilance and maintenance (and which, to an important extent, come within the scope of the EMEA Road Map and the ERMS), have allowed a more proactive approach to safety of medicines to be taken, hence protecting public health.

2.6.1 Core activities

Pharmacovigilance

- The EMEA received 381,990 adverse-drug-reaction (ADR) reports in 2007 – an increase of more than 25% compared to the previous year. 40% of ADR reports received related to centrally authorised medicinal products.
- The EMEA received 63,393 reports concerning investigational medicines, i.e. adverse drug reactions observed during clinical trials. This is an increase of 18% compared to 2006.
- A total of 762 suspected signals concerning 139 intensively monitored products, and 349 suspected signals concerning 162 routinely monitored products, were identified. Following further investigation, 22% (132) of suspected signals required follow-up for intensively monitored products, including involving the rapporteur for 43 signals. About 10% (33) signals were followed up for routinely monitored products, with involvement of the rapporteur in 21 cases.
- The Agency reviewed 92% of the risk-management plans (RMPs) submitted as part of new applications. This review was undertaken in the context of the peer-review process prior to day 120 and continued up to finalisation of the scientific review by the CHMP.
- The number of periodic safety update reviews conducted during 2007 was 15% higher than in 2006.
- The number of follow-up measures (FUMs) and specific obligations (SOs) submitted increased slightly (5%) in 2007. It should be noted that the high number submitted in 2006 was partly explained by submissions following a reminder to marketing-authorisation holders to submit any data (including paediatric data) that might be available and which had not previously been submitted to the EMEA.





2.6.2 Specific objectives in 2007

- Considerable efforts were made to apply a proactive approach to safety of medicines, with particular emphasis on the establishment of an intensive drug-monitoring system. Activities undertaken come within the scope of the EMEA Road Map and the implementation of the European Risk Management Strategy (ERMS), in collaboration with the national competent authorities of the Member States.
  - A new rolling two-year work programme for 2008-2009 was prepared and adopted by the Heads of Medicines Agency, together with the ERMS status report.
  - A review and learning project for risk-management plans submitted to the EMEA as part of an application is ongoing at the level of the CHMP and the PhVWP.
  - The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) project is progressing very well. The first phase, i.e. the identification of centres across the EU, was concluded, resulting in the establishment of an inventory. A kick-off meeting with academic centres was organised at the end of June. Discussions have started on the development of a structure and model for the future network.
  - The topic 'Relative safety of NSAIDs' was included in the 2007 work programme for the Health theme of the 7th Framework Programme as a result of discussions with the European Commission (DG Research). In addition, a list of the top five public-health issues in drug safety was developed by the CHMP/PhVWP in view of a reply to subsequent calls for proposals in the context of the 7th Framework Programme.

- Activities to strengthen EudraVigilance to support proactive pharmacovigilance continued in 2007, and resulted in the following:
  - the number of national competent authorities and pharmaceutical companies reporting electronically to Eudravigilance has increased. However, 100% compliance has still not been achieved;
  - the EMEA prepared a EudraVigilance action plan, which was subsequently agreed by the Heads of Medicines Agencies and the EMEA Management Board. The plan addresses implementation problems related to the quality of the submitted data and the legal reporting deadlines;
  - the EudraVigilance Datawarehouse and Analysis System (EVDAS) was rolled out to the national competent authorities on 6 July 2007. It is designed to support signal-detection and the assessment of adverse-drug-reaction reports;
  - the EMEA made efforts to improve the efficiency of its operation in the area of signal detection and assessment of adverse drug reactions. Quantitative signal-detection methodologies were included in EVDAS and new functionalities facilitating the review of signals were added to EudraVigilance;

- delays have occurred in the introduction of other additional functionalities, re-coding activities and the implementation of the EudraVigilance access policy, because efforts had to be directed to the roll-out of EVDAS;
- progress was made in the field of international standardisation activities concerning the finalisation of ICH step 4 guidelines and standards in the area of clinical-data management and multidisciplinary topics (i.e. E2B(R), M5);
- with a view to integrate additional healthcare data, the THIN database – a medical research database of anonymised patient records from information entered by general practices – was integrated at the EMEA and a research project initiated.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
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	90% for line-extension applications and 86% for extension-of-indication applications
Percentage of ICSRs reported electronically for centrally authorised products (CAPs)	100% of ICSRs	93% of MAHs are compliant with the electronic reporting of CAPs
Review of post-authorisation commitments (PACs) within the agreed timeframe	80% of PACs	68% of all PACs were reviewed within a 60-day timeframe (80% for quality PACs only and 63% for clinical PACs) Delays have occurred and the extent of these delays will be monitored in 2008
Submission of outcome reports for PACs to applicants/MAHs within 2 weeks of the CHMP meeting	100% of reports	95%

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

2.7.1 Core activities

- The number of referrals submitted to the EMEA continues to rise. A total of 57 referrals were received in 2007, 40% more than in 2006.
- A new referral procedure – the procedure following Article 107(2) of Directive 2001/83/C as amended – was used for the first time in 2007. Altogether, five referrals were carried out under this procedure.
- Nine out of the 36 finalised referral procedures related to safety concerns. In 3 cases the CHMP recommended withdrawal and in 2 cases temporary suspension of the involved marketing authorisations.
- According to revised Community legislation, Member States can initiate referrals regarding herbal medicinal products. Up to December 2007, however, no referrals regarding herbal medicinal products were received.
- The CHMP adopted 2 opinions on scientific matters in the context of Article 5(3) procedures:
  - opinion on the adequacy of guidelines on medicinal products for human use in the context of the elderly;
  - opinion on the potential risk of carcinogens, mutagens and substances toxic to reproduction (CMRs) when used as excipients in medicinal products for human use.

Procedure Type	2005 Started	2005 Finalised	2006 Started	2006 Finalised	2007 Started	2007 Finalised
Article 6(12) of Commission Regulation (EC) No 1084/2003	3	1	0	2	6	2
Article 6(13) of Commission Regulation (EC) No 1084/2003	4	0	0	4	0	0
Article 29 of Directive 2001/83/EC	7	5	20	12	22	18
Article 30 of Directive 2001/83/EC	3	0	1	4	14	1
Article 31 of Directive 2001/83/EC	2	0	3	1	4	4
Article 36 of Directive 2001/83/EC	0	0	7	7	4	4
Article 5(3) of Regulation (EC) No 726/2004			3	2	2	2
Article 16(1) Herbal			0	0	0	0
Article 16(4) Herbal			0	0	0	0
Article 107(2) of Directive 2001/83/EC			0	0	5	5
Article 29 of Regulation (EC) No 1901/2006					0	0
Totals:	19	6	34	32	57	36

Procedures of high public-health interest finalised in 2007:

- Review of mifepristone-containing medicinal products, following safety and efficacy concerns regarding the use of the approved dose of 600 mg mifepristone, as compared to the use of a 200 mg dose, in the medical termination of developing intra-uterine pregnancy in sequential use with prostaglandin analogue. The CHMP concluded that the available data support the effectiveness of a 600 mg dose of mifepristone, followed by the use of prostaglandin analogues, for the termination of pregnancy up to 63 days of amenorrhoea (absence of menstrual periods). In pregnancies up to 63 days, comparative studies between 200 mg and 600 mg mifepristone in combination with 1 mg gemeprost delivered vaginally suggest that 200 mg mifepristone may be as effective as 600 mg mifepristone. However, in pregnancies up to 49 days, comparative studies between 200 mg and 600 mg mifepristone in combination with 400 µg misoprostol delivered orally cannot exclude a slightly higher risk of continuing pregnancies with the 200 mg dose. Based on the available published data, the benefit/risk profile of mifepristone in combination with oral misoprostol for pregnancy from 50 to up to 63 days is unfavourable due to poor efficacy (Article 31 procedure).
- Review of medicinal products containing bicalutamide 150 mg, triggered by safety concerns, in particular heart problems, when the medicinal product is used in the treatment of early prostate cancer. The CHMP concluded that the benefits of these products outweigh their risks, but only in those patients who are at high risk of their disease getting worse (Article 31 procedure).
- Review of piroxicam-containing medicinal products, triggered by safety concerns over gastrointestinal side effects and serious skin reactions. The CHMP concluded that piroxicam should no longer be used for treatment of short-term painful and inflammatory conditions. Piroxicam can still be prescribed for the symptomatic relief of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. However, it should not be the first choice of non-steroidal anti-inflammatory drug (NSAID) treatment in these conditions (Article 31 procedure).
- Review of veralipride-containing medicinal products following the withdrawal of veralipride form the Spanish market because of reports of serious side effects affecting the nervous system and by a number of regulatory actions in other EU Member States where veralipride was authorised. The CHMP concluded that the risks outweigh the benefits and recommended the withdrawal of the marketing authorisation for all veralipride-containing medicines (Article 31 procedure).
- Review of systemic formulation of nimesulide-containing medicinal products, following the suspension of the marketing authorisation for these medicines in Ireland, due to concerns over serious liver problems. The CHMP concluded that the benefit-risk of nimesulide continues to be positive and recommended the maintenance of the marketing authorisation but that there is a need to restrict its use (Article 107(2) procedure).
- Review of clobutinol-containing medicinal products, following the suspension of the marketing authorisation for these medicines in Germany, due to concerns regarding side-effects affecting the heart. The CHMP concluded that the benefits of these medicines do not outweigh their risks and therefore recommended that the marketing authorisations for clobutinol-containing medicines be withdrawn throughout the EU (Article 107(2) procedure).
- Review of carisoprodol, following the plan to withdraw the marketing authorisation for this medicine in Norway, due to risks of intoxication, psychomotor impairment, addiction and misuse due to off-label prescribing. The CHMP concluded the risks of these medicines outweigh their benefits and recommended the suspension of the marketing authorisations (Article 107(2) procedure).
- Review of lumiracoxib-containing medicinal products, intended for the treatment of osteoarthritis further to the notification by the UK which was considering the suspension of the marketing authorisation due to possible increased risk of hepatotoxic adverse events at the 100 mg dose. The CHMP recommended the withdrawal of the marketing authorisations for all lumiracoxib-containing medicines, because of the risk of serious side effects affecting the liver (Article 107(2) procedure).
- Review of aprotinin-containing medicinal products, used for the prophylactic use to reduce perioperative blood loss and the need for blood transfusion in those patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft (CABG) surgery. This was

further to the decision by Germany to suspend all nationally authorised products containing aprotinin for intravenous use due to an increased risk of mortality in the aprotinin arm of the BART study (Article 107(2) procedure).

- Review of medicinal products containing 30 µg ethinyl estradiol + 2 mg chlormadinone acetate, because of differences among Member States on whether the indication of these two products should be extended to include the treatment of women suffering from moderate acne. The CHMP recommended the refusal of the new indication because the data submitted were considered insufficient to demonstrate efficacy in the applied indication (Article 6(12) procedure).
- Review of generic medicinal products containing cetirizine because of concerns over their bioequivalence. Further to a CHMP review conducted in 2006, the concerned national marketing authorisations were suspended by the European Commission because of concerns regarding good clinical and laboratory practices (GCP/GLP) compliance that impacted on the quality and reliability of bioequivalence studies supporting the marketing authorisations. Due to GCP concerns still identified in a further study, the CHMP recommended the revocation of the marketing authorisations for these generic medicinal products (Article 36 procedure).

Procedures of high public-health interest started but not yet finalised in 2007:

- Review of medicinal products containing ergot-derived dopa agonists, triggered by safety concerns in relation to fibrotic disorders and cardiac valvulopathy (Article 31 procedure).
- Review of methylphenidate-containing medicinal products triggered by safety concerns related to cardiovascular events and cerebrovascular disorders (Article 31 procedure).
- Review of oral formulation of norfloxacin-containing medicinal products to re-assess the balance of benefits and risks of these medicinal products (Article 31 procedure).
- Review of etoricoxib-containing medicinal products triggered by cardiovascular safety concerns when these medicinal products are used in the long-term treatment of ankylosing spondylitis and rheumatoid arthritis: Article 6(12) procedures for Arcoxia (centrally authorised medicinal product) extension of indications and Article 31 procedure for all etoricoxib-containing medicinal products.
- Review of moxifloxacin-containing medicinal products because of differences among Member States on the extension of the therapeutic indication of moxifloxacin to include pelvic inflammatory disease (Article 6(12) procedures).

2.7.2 Specific objectives in 2007

- An external guidance document on referral procedures was published.
- With a view to ensuring transparency and appropriate information for patients and the public, question-and-answer documents were systematically published at the time of the adoption of the CHMP opinions for procedures conducted in accordance with Article 31 and Article 107(2).

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100%

2.8 Medicines for children

This covers EMEA activities relating to the assessment and agreement of, and verification of compliance with, paediatric investigation plans (PIPs) 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. It also 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.

The Agency received entirely new responsibilities with the entry into force of Regulation (EC) No 1901/2006 on medicinal products for paediatric use (the Paediatric Regulation) on 26 January 2007. These activities received a high level of support from the network of Medicines Agencies, in particular for the Paediatric Committee activities.

2.8.1 Core activities

Applications for PIPs and waivers received

- The EMEA received applications for PIPs and waivers relating to 202 indications. These correspond to 85 applications with an average of 2-4 indications per application. The assessment of each indication may extend to several age groups, each of which requires a separate scientific evaluation.
- The applications also include PIPs where a full and/or a partial waiver may be sought for one or more indications in addition to the PIP.
- Seventeen per cent of applications were requests for full waivers, where for every indication a full waiver is sought.
- While the number of applications was lower than announced by pharmaceutical companies, the high number of PIPs for medicines authorised at the level of the Member States and the complexity of the applications due to multiple indications and several age groups per application resulted in a much higher workload than expected. Since applications forecast by companies have been delayed, their submission is now planned for early 2008. A high workload has resulted from these complex applications; the workload was shared between the EMEA secretariat and the Paediatric Committee members.

Opinions and decisions adopted

- The PDCO adopted 10 opinions on PIPs and waivers, covering 15 indications. Eight of the 10 opinions were adopted for full waivers and 2 for PIPs.
- The EMEA had adopted a decision on 4 of the 10 opinions by the end of 2007.
- The number of opinions is lower than the forecast, since in most cases the PDCO adopts opinions at day 120 of the procedure, due to the complexity of applications and the related discussions. Therefore, as a result of the need for full procedural timelines and associated clock-stops requested by applicants, more opinions on applications submitted in 2007 are expected in 2008.

List of class waivers

- Following the opinion of the PDCO, the EMEA issued a decision on a 'list of class waivers' on 3 December 2007. The list includes 17 symptomatic conditions relating to different types of cancer (lung cancer, basal cell carcinoma, breast and ovarian cancer, multiple myeloma, etc.), neurodegenerative conditions (Alzheimer's disease, Parkinson's disease) and other conditions that occur only in the adult population (age-related macular degeneration, menopausal disorders, etc.). These conditions do not affect children and the requirement to submit a paediatric investigation plan

can therefore be waived. Further guidance to applicants who intend to develop a medicinal product for treatment of a condition that appears on the above-mentioned list is under preparation.

2.8.2 Specific objectives in 2007

- The implementation of the regulation on medicinal products for paediatric use, including the establishment of the new Paediatric Committee (PDCO), was one of the EMEA's top priorities in 2007.
  - The PDCO was established within the required legislative timing and held its first meeting on 4-5 July 2007.
  - Committee members nominated by the CHMP and the Member States were identified before the July 2007 deadline. Representatives of patients' and healthcare professionals' organisations had not yet joined the PDCO by year's end. The European Commission launched selection procedure for the appointment of these members.
  - The EMEA established the necessary procedures and guidance to ensure timely decision-making. This included preparation of templates for opinions, decisions and summary reports, as well as practical and procedural guidance for the PDCO and applicants.
  - The PDCO prepared a proposal for an implementing strategy for the European network of paediatric research, which was adopted by the EMEA Management Board during its December 2007 meeting.
  - The new legislation requires that transparency of EudraCT, the database on clinical trials in the European Union, be increased with respect to clinical trials conducted in children. The PDCO, together with the EU Member States and the European Commission, contributed to a draft guideline on the EudraCT fields that include data on clinical trials in children and fields to be made public.
  - The PDCO provided the European Commission with its recommendation on a symbol for use on medicinal products granted a marketing authorisation for a paediatric indication.
  - The EMEA published a guidance document on the survey of all existing paediatric-use medicines.
  - The EMEA, together with the CMD(h), prepared for the coordination of paediatric data to be received early in 2008 on centrally and nationally authorised medicines.
  - The EMEA contributed to the European Commission guideline on 'Ethical considerations on clinical trials in paediatric populations'.
  - The EMEA organised training for assessors of national competent authorities on the new paediatric legislation and workshops for the pharmaceutical industry.
  - The EMEA organised workshops with DG Research in relation to its 7th Framework Programme for products to be developed in paediatrics.
- Improving the safety of medicines for children is an important aspect of the new legislation. The EMEA undertook a number of activities in 2007 to support paediatric pharmacovigilance in the context of the new legislation.
  - A final guideline on paediatric pharmacovigilance was published in 2007 and the implementation of its practical implications was started, notably in the area of signal detection, PSURs and product information.
  - The ENCePP project included paediatric networks in order to ensure the availability of appropriate expertise in paediatric pharmacovigilance and investigated new sources and methods for intensive monitoring of paediatric use of medicines.

Performance indicators

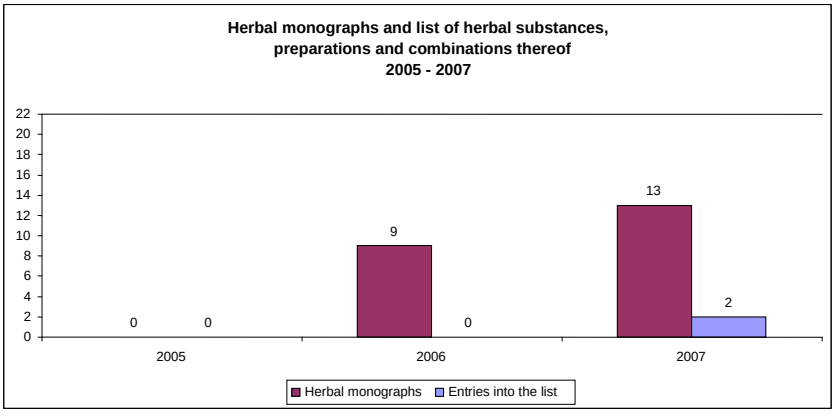
Performance indicator	Target	Outcome at end of 2007
Number of PIP or waiver opinions or decisions adopted within the legal timeframe	100% of procedures	100%

2.9 Herbal medicinal products

The Agency's activities in the area of herbal medicines include: the provision by the Committee on Herbal Medicinal Products (HMPC) 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.

2.9.1 Core activities

- The HMPC released for consultation 13 draft Community herbal monographs for traditional and well-established herbal medicinal products.
- Sixteen Community herbal monographs for traditional and well-established herbal medicinal products were finalised.
- The HMPC adopted 2 entries to the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. The number of list entries is limited because the HMPC has concerns about the availability and quality of genotoxicity data for some herbal substances.



2.9.2 Specific objectives in 2007

- The first three-year mandate of the Committee on Herbal Medicinal Products (HMPC) expired in 2007. Review of the first mandate and reconstitution of the new HMPC were important objectives for the year.
  - The 'HMPC Status report on the implementation of the provisions of Chapter 2a of Directive 2001/83/EC as amended by Directive 2004/24/EC as regards traditional herbal medicinal products' was published in August 2007.

- Revised HMPC rules of procedure were adopted in May 2007.

- Operation of the HMPC's working parties and drafting groups, in particular their cooperation with the CHMP, were also reviewed and proposals for modifications were made.
  - Mandate, objectives and rules of procedure of the Working Party on Community Monographs and Community List were revised.
- Relations with the HMPC's interested parties were strengthened by updating them on the Committee's operations and future challenges.
  - The HMPC met representatives of Interested Parties to discuss the Community herbal monographs adopted by the HMPC, as well as the process of preparation of and public consultation on such monographs, in March 2007.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Number of Community herbal monographs established	20 Community herbal monographs	13
Number of entries to the list of herbal substances, preparations and combinations thereof	10 entries to the list	2

2.10 Emerging therapies and new technologies

This area relates to the activities undertaken by the EMEA to support the scientifically sound development of advanced-therapy medicinal products, including gene therapy, somatic cell therapy or human tissue engineered products, and other emerging therapies and new technologies that are not within the scope of the regulation on advanced therapies.

2.10.1 Core activities

- The EMEA's Innovation Task Force (ITF), a multidisciplinary group that includes scientific, regulatory and legal competences, continued its activities.
  - The ITF held 18 briefing meetings with companies developing medicines in the area of emerging therapies and new technologies.
  - Sponsors may request advice on whether their product can be considered a medicinal product, thus being eligible for EMEA procedures. Thirty-one requests for classification were received.
  - The CHMP adopted 18 classification reports drafted by the ITF that describe the scientific and regulatory criteria for the definition of a medicinal product.

2.10.2 Specific objectives in 2007

- The Agency made good progress in promoting and encouraging early dialogue with sponsors of potential applications for advanced therapies and emerging products and technologies.
  - Implementation of new procedures to facilitate early dialogue with sponsors resulted in an increased number of requests for regulatory eligibility and briefing meetings.
  - The EMEA organised meetings to address scientific and regulatory matters arising from new products and approaches. Meetings included the EMEA-Infarmed-Expertissues joint workshop on

cell-based medicinal products, held in Lisbon in October 2007, and the EMEA-EFPIA joint workshop on methodology for adaptive designs in confirmatory clinical trials, organised in December 2007.

- Identifying expertise, expectations and bottlenecks related to the area of new treatment solutions was another EMEA objective for 2007.
  - Several meetings with learned societies and industry were held in order to extend the dialogue with academia and society at large. Meetings included joint sessions with the European Society of Human Genetics and CHMP Pharmacogenetics Working Party (PGWP); with ESGCT (European Society of Gene and Cell Therapy) and CHMP Gene Therapy Working Party (GTWP); with CliniGene (European Network for the Advancement of Clinical Gene Transfer and Therapy) and GTWP; and a joint workshop with ESGCT and CliniGene.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Briefing meetings organised within 60 days from receipt of a request	80% of meetings	95%
Regulatory advice on new-technology, emerging-therapy and borderline medicinal products given within 60 days	80% of requests	85%

2.11 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.

2.11.1 Core activities

- A summary of opinion was published at the time of the adoption of the opinion by the CHMP for all medicines that were recommended for initial authorisation or for which changes to the indications or contraindications were recommended.
- Sixty-two summaries of EPARs written in a manner understandable to the public (EPAR summaries for the public) were prepared for new marketing authorisations. In addition, the EMEA also started to publish these in cases of major variations.
- Efforts to provide product-related information in all EU languages continued throughout 2007. Compliance by Member States with the translation-checking process was very good overall, in both pre-authorisation and post-authorisation phases. In addition, feedback from the Member States indicated good quality overall of the translations provided by pharmaceutical industry.
- The EMEA coordinated the post-opinion linguistic review for 76 new applications and line extensions.
- The first two small- and medium-sized enterprises benefited from translation support for the product information of their medicines.

2.11.2 Specific objectives for 2007

- Interaction with and participation of the Agency's stakeholders (healthcare professionals, patients and consumers) was further developed and reinforced.
  - The publication of a monthly electronic newsletter providing information on medicines for human use to the patients' and consumers' organisations involved in the Patients' and Consumers' Working Party (PCWP) was trialled in a pilot phase in 2007.
  - A status report on the progress of the implementation plan of the framework of interaction with patients and consumers was presented to the PCWP during its December 2007 meeting.
  - The development of recommendations of the EMEA/CHMP Working Group with Healthcare Professionals (HCP WG) was started in 2007.
  - The development of a framework of interaction between the EMEA and healthcare professionals was started in 2007.
  - The first joint meeting with patients and healthcare professionals was held on 1 June 2007. Following this meeting, it was concluded that joint meetings would be held at least once a year, and that representatives from both groups would attend meetings of the PCWP and HCP WG respectively.
- In 2007, the Agency made efforts to improve the provision of 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.
  - The guideline on summary of product characteristic was revised in order to introduce new requirements in accordance with the new Paediatric Regulation. A draft was published for a three-month public consultation in December 2007.
  - Consultation of target patient groups on product information has been a mandatory element of marketing-authorisation applications for medicines since 2005. The EMEA reviewed the experience gained with 'user-testing' reports submitted in the context of new marketing authorisations with the aim to provide an overview of how companies and CHMP members deal with the legal requirement to perform user-testing. A document outlining a number of recommendations is currently under preparation.
  - The translation framework was reviewed in 2007. Based on information collected from various Member States, the EMEA will propose amendments to the framework policy and eventually the service contracts in terms of general handling and financial compensation. Discussions with Member States are ongoing.
  - Guidance for the assessment of user-testing results by the CHMP was prepared and adopted in agreement with the Coordination Group for Mutual Recognition and Decentralised Procedures (CMD(h)).
  - Following expiry of the derogation in May 2007, Maltese was smoothly phased in to the translation framework for product information for human and veterinary medicines. A linguistic-review process was established. Ninety-nine medicines for human use and 20 medicines for veterinary use went through this process in 2007.
  - Bulgaria and Romania were successfully included in the translations framework.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of summaries of opinions published at the time of the CHMP press release	90% of summaries of opinion	100%
Percentage of initial EPARs published within 2 weeks of the Commission decision	80% of marketing authorisations granted	44%
Percentage of EPAR summaries in a language understandable to the public, published together with the EPAR	80% of EPARs	100%
Percentage of assessment reports published within 2 months of withdrawal of a marketing-authorisation application	70% of assessment reports	None were published within 2 months of withdrawal of the marketing authorisation application
Percentage of refusal assessment reports published within 2 weeks of the Commission decision	70% of assessment reports	None were published within 2 weeks of the Commission decision
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	Community interest referrals: 100%* Article 107(2): 100% *In one instance a decision was taken not to publish a Q&A document

2.12 Scientific committees, working parties and scientific advisory groups

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 CHMP provides scientific advice and protocol assistance to pharmaceutical enterprises during the process of medicines development. The CHMP 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 scientific matter at the request of the European Commission or the Executive Director of the Agency. Furthermore, the CHMP is involved in work undertaken in the fields of harmonisation of technical requirements for pharmaceutical regulation, pharmacovigilance and public-health threats.

- The composition of the CHMP was renewed in June 2007, following expiry of the three-year mandate of most CHMP members.
- The CHMP elected Eric Abadie as new Chair and Thomas Salmonson as Vice-chair at its June 2007 meeting.
- The CHMP co-opted four new members in September 2007.

- The CHMP rules of procedure were revised in March 2007.
- An electronic meeting-documents system was introduced in order to move towards paperless CHMP meetings.
- The CHMP held 11 meetings in 2007, each of them lasting four days.

Committee for Orphan Medicinal Products

The Committee for 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 a policy on orphan medicinal products, and for assisting the liaison with international partners and patients' organisations on this issue. For more information, refer to section 2.1.

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

Committee on Herbal Medicinal Products

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

- Following completion of its three-year term and subsequent renomination of the majority its members, the HMPC met for the first time in its new composition on 31 October 2007. Dr Konstantin Keller was re-elected as Chair; Dr Ioanna Chinou was elected as Vice-chair.
- The HMPC met 6 times in 2007, with each meeting lasting one and a half days.

Paediatric Committee

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

- The first meeting of the PDCO took place on 4-5 July 2007.
- Daniel Brasseur, former Chair of the CHMP and the former Paediatric Working Party, was elected Chair; Gérard Pons was elected as Vice-chair.
- The PDCO met 7 times 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 discussed with the Member State competent authorities and the CHMP the mandate of the Pharmacovigilance Working Party (PhVWP). Implementation of the PhVWP mandate for non-centrally authorised medicines is ongoing, as is an exercise to optimise the interaction between the CHMP and the PhVWP.
- The EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) replaced the EMEA/CHMP Working Group with Patients' and Consumers' Organisations.
- An EMEA/CHMP Working Group with Healthcare Professionals' Organisations was established in 2007.
- Work continued on improving the cost-effectiveness of the arrangements for working parties. A review of the mandates of the working parties, the distribution of work, and support provided to them by the secretariat was begun, in order to improve the effectiveness of the arrangements for working parties.
- As a result of the new legislation on paediatric medicines and the establishment of the Paediatric Committee, the CHMP Paediatric Working Party ceased its activities during 2007.
- Eleven meetings of scientific advisory groups (SAGs) were held in 2007. The oncology and cardiovascular issues SAGs each held 3 meetings. The latter SAG was established in 2007.

2.13 Coordination Group for Mutual-Recognition and Decentralised Procedures–Human

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. The work of the CMD(h) is essential for the effective authorisation and maintenance of more than 90% of medicines entering the EU market. The mutual-recognition procedure (MRP) and the decentralised procedure (DCP) are the primary authorisation routes for generic applications within the EU. Through its work on referral procedures and the identification of SPC harmonisation lists, the CMD(h) supports the entry of such products into the EU market.

A full report on the CMD(h)'s activities in 2007 is available here:
http://www.hma.eu/uploads/media/CMDh_2007.pdf

- The CMD(h) met 11 times in 2007, with each meeting lasting two to three days.
- Forty-four MRP applications and 25 DCP applications were referred to the CMD(h) in 2007.

- Agreement was reached for 51 MRP and 12 DCP applications (applications submitted in 2006 or 2007).
- Fifteen MRP and 7 DCP applications were referred to the CHMP in accordance with Article 29(4) of Directive 2001/83/EC, as amended.
- The EMEA facilitated liaison of the CMD(h) with other scientific forums and with Interested Parties.
  - A document on interaction between PhVWP and CMD(h) was endorsed.
  - A meeting of the CMD(h) and the EMEA with representatives of Interested Parties, on the submission of paediatric studies in accordance with Articles 45 and 46 of the Paediatric Regulation, was held in May 2007.
  - A meeting between the CMD(h) and representatives from the European Generic Medicines Association (EGA) was held in June 2007 to discuss proposals for a work-sharing initiative for patient consultation across Europe.
- The EMEA provided support to CMD(h) sub-groups and working groups, including the Communication Tracking System (CTS) Working Group; the Sub-group on Harmonisation of SPCs; the Joint CMD(h)-PhVWP WG, in cooperation with the PhVWP Secretariat; the CMD(h)/EMEA Sub-group on Paediatric Regulation, in cooperation with the EMEA Paediatric Team; the Sub-group with GCP Inspectors; the Ad hoc Working Group on Validation issues/National requirements; the Ad hoc Working Group on work-sharing for patient consultation; and the Ad hoc Working Group on decentralised procedure.
- The CMD(h) agreed a new list of medicinal products for which a harmonised summary of product characteristics should be drawn up.

	Total started in 2007*	Under evaluation in 2007*	Ended positively in 2007*	Referrals to CMD(h) in 2007	Referrals to CHMP in 2007
New applications MRP	396	159	441	44	15
New applications DCP	1,033	1,038	386	25	7
Type-IA variations	5,864	134	5,640	N/A	N/A
Type-IB variations	2,355	236	2,298	N/A	2
Type-II variations	2,461	1,130	2,167	N/A	6

*The numbers include multiple procedures as stated at 31 December 2007.

2.14 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 develops and updates 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.

Regulatory support was provided in various ways in 2007.

- Regular training was continuously provided to EMEA staff on topics stemming from the 2004 2005 Community legislation.
- Various guidance documents were updated to better reflect the new legislative tools, including in the field of SMEs.
- Extensive preparatory work went into the implementation of the paediatric legislation, including the setting-up of the new Committee (PDCO).
- Preparations for the implementation of the advanced therapies legislation began in 2007.
- A revision of the guideline on invented names was finalised, following extensive discussions with the European Commission and pharmaceutical industry, and a public consultation.

3. MEDICINES FOR VETERINARY USE

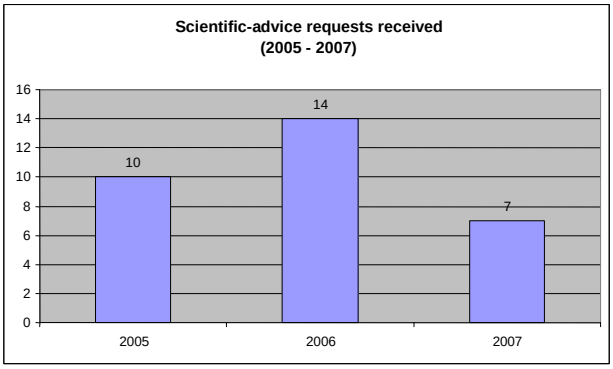
3.1 Scientific advice

Scientific advice is a priority area for the EMEA. The provision of scientific advice helps companies with their development programmes, and thus contributes towards bringing innovative medicines to the market more quickly.

The Agency provides advice on specific questions that typically arise during the research and development of medicinal products, relating to quality, safety or efficacy, or to the establishment of maximum residue limits.

3.1.1 Core activities

- The level of activity in relation to scientific advice was lower in 2007 than expected: 7 requests for scientific advice were received in contrast to the original, optimistic forecast of 16. By comparison, 14 requests were received in 2006, which was a very active year.
- At this stage, there is no suggestion that there is a general trend for decreasing activity in this area, but the level of activity will continue to be monitored.
- The average time required to finalise procedures for provision of scientific advice in 2007 was 48 days, which is a reduction from 55 days for 2006.
- Two marketing authorisations were issued in 2007 that had previously had scientific advice from the Committee, one a pharmaceutical for dogs to treat congestive heart failure and one a vaccine for pigs against porcine circovirus infection.



Free scientific advice for minor uses and minor species

- Free scientific advice was granted in 2007 under the provisions of the programme for minor uses and minor species for 2 applications, one related to development of a vaccine for sheep, goats and cattle and one concerning a live vaccine for wild rabbits. There is therefore continued interest in this measure designed to promote authorisation of products indicated for limited markets.

3.1.2 Specific objectives for 2007

- The EMEA completed an exercise to measure the level of satisfaction of applicants with the quality and conduct of scientific advice.
  - A survey was conducted on the views of applicants as to the quality of the scientific advice provided and the efficiency of the procedures. A total of 15 questionnaires were returned, out of

21 sent out, and these were analysed. The results indicated a very high level of satisfaction with the procedure (87% of applicants were either very satisfied or satisfied). Satisfaction was due to the clarity of the advice given, timely assessment of documentation, the smooth procedure and good guidance provided. In all, 87% of applicants indicated they would consider scientific advice in the future.

– Some improvements have been implemented already, such as amendments to the web guidance document to indicate the quality of advice is improved if applicants take a position and provide their reasoning rather than ask completely open questions.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Scientific-advice requests evaluated within the procedural timelines	100% of applications	100%

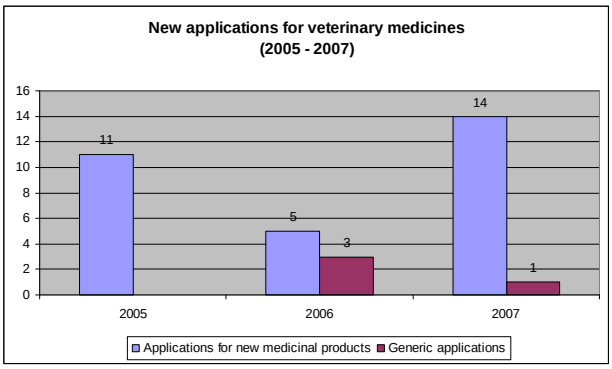
3.2 Initial evaluation

Applications for new medicines are reviewed by the Agency by means of assessment carried out by the Committee for Medicinal Products for Veterinary Use (CVMP). The CVMP assesses the quality, safety and efficacy of every new veterinary product that is subject to the Community or centralised procedure and, based on the overall balance of the benefits and risks of the medicine, gives its opinion on whether or not the European Commission should grant a Community-wide marketing authorisation.

3.2.1 Core activities

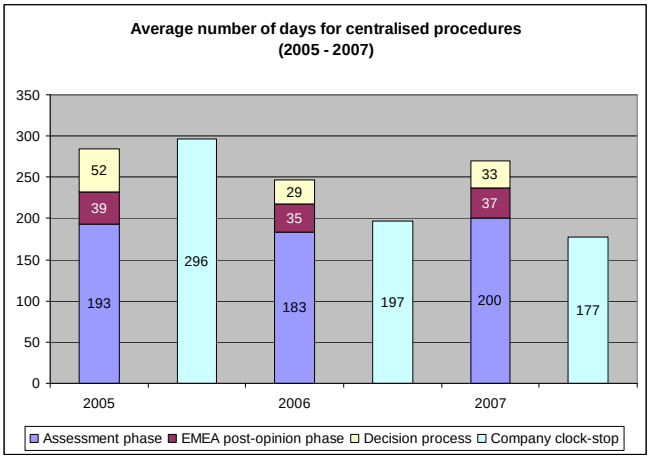
Applications received

- The Agency received a total of 15 initial marketing-authorisation applications, 8 of which were for pharmaceutical products and 7 for immunologicals.
- Of the 8 pharmaceutical applications, 1 was a generic application. Five concerned medicinal products for companion animals, principally dogs, and the other 3 concerned medicines indicated for pigs, cattle and rabbits.
- All 7 immunological applications were indicated for food-producing animals: 2 for poultry, 2 for pigs, 1 for cattle, 1 for both cattle and sheep, and 1 for horses.
- Two applications were made for medicines that had received free scientific advice under the programme for minor uses and minor species.
- Overall, these figures are consistent with a trend towards the introduction of immunological methods of control for disease problems in food-producing animals and an emphasis on companion-animal products in the field of veterinary pharmaceuticals.



Opinions adopted

- In 2007, the CVMP adopted a total of 9 positive opinions for initial marketing-authorisation applications; 4 less than in 2006.
- Two opinions were adopted following accelerated assessment of the application.
- The CVMP recommended a marketing authorisation under exceptional circumstances for 2 medicines.
- Assessment of new applications by the CVMP took an average of 200 days. This increase from 183 days in 2006 arose due to fewer accelerated procedures being completed in 2007.



Animal-health benefits of medicines recommended for approval in 2007

The CVMP recommended authorisation of 2 vaccines against avian influenza in poultry, mainly chickens. Applications for these 2 vaccines were evaluated on an accelerated timetable, with opinions adopted in 90 and 120 days, taking into account the epidemiological situation within the EU and the contribution of the Agency to pandemic preparedness. The vaccines were authorised under exceptional circumstances and are subject to specific obligations and follow-up measures, including enhanced pharmacovigilance measures, to ensure the safe use of the products.

The CVMP adopted positive opinions for 2 vaccines for pigs against porcine circovirus type 2. Porcine circovirus is involved in the aetiology of porcine multisystemic wasting syndrome (PMWS), which is considered one of the most significant challenges facing the pig industry in the EU, and the authorisation of these products should assist with control of this disease.

Other medicines that were recommended for approval included: a medicine to treat heart failure in dogs; a medicine to obtain temporary infertility in male dogs; a medicine for treatment of overweight and obese dogs; a generic medicine for treating musculoskeletal disorders in dogs.

3.2.2 Specific objectives in 2007

- The EMEA and its scientific committees have been extremely active in relation to preparing measures aimed at promoting the availability of products for limited markets, including products for minor use and minor species (MUMS).
  - The CVMP produced internal reflection papers on the criteria to be used for defining a limited market and on the procedure whereby the committee formally classifies a product as indicated for a limited market.
  - The CVMP endorsed a set of proposals for measures that could be provided by the EMEA to assist companies with the submission of applications through the centralised procedure relating to limited markets in line with the requirements of Article 79 of Regulation 726/2004. These proposals require contributions from both the Agency and national competent authorities. They form part of the overall response of the European regulatory network to the problem of the lack of availability of veterinary medicines.
  - Promoting access to vaccines against the major epizootic diseases of domestic livestock has remained a high priority for the Agency, in particular with respect to avian influenza and bluetongue. Bluetongue is an insect-borne disease of domestic ruminants, principally sheep, whose geographical range has now spread to include much of the EU. Vaccination is seen as an important method of control and there is therefore an urgent need to make available to competent authorities vaccines authorised through the centralised procedure for use in Commission-approved vaccination campaigns. To facilitate this procedure, the CVMP adopted a reflection paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue.
  - The Agency continues to give a high priority to authorisation of vaccines against avian influenza in chickens on the basis that control of the disease in chickens reduces the likelihood of a pandemic developing due to transfer from birds to man. In this context, the CVMP adopted a positive opinion for an H7 avian influenza vaccine.
  - In collaboration with IFAH-Global, the EMEA hosted a Global Animal Health Conference on 15-16 November 2007. This two-day meeting brought together all of the major stakeholders in animal health, including industry, academia, international animal-health organisations and regulators from around the world. The meeting considered the major challenges facing the development of new medicines and the continued availability of existing ones. A series of conclusions were reached that will assist decision-makers in the relevant organisations.
- The CVMP continued its efforts to ensure high-quality assessments and improvement of information to the public. In particular, the CVMP and the secretariat started work to develop a revised approach on peer-review of assessments with the intention of further enhancing the quality and consistency of the work of the CVMP.
- A prototype scientific-memory database related to veterinary applications was completed but a decision was taken not to progress to an operational version due to limited functionality. Further work to develop a scientific-memory database for veterinary applications will be progressed in parallel with future development of the corresponding human database.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of products evaluated within the regulatory timeline of 210 days	100% of applications	100%
Percentage of opinions sent to the European	100% of	0%*

Commission within the regulatory timeline of 15 days	applications	

* Compliance with this target requires timely action by applicants and Member States to enable EMEA to meet the 15-day deadline, which was not forthcoming in 2007. However, EMEA achieved 100% compliance with submitting the opinion to the Commission in English (only).

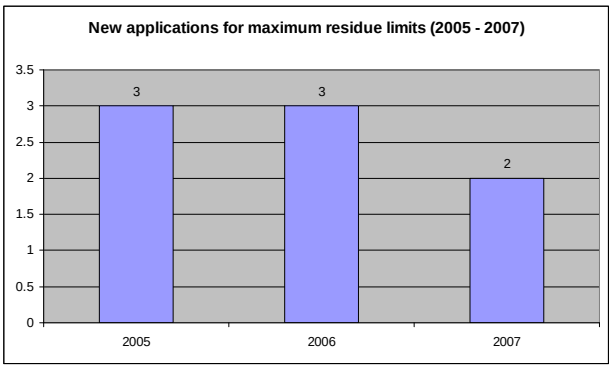
3.3 Establishment of maximum residue limits

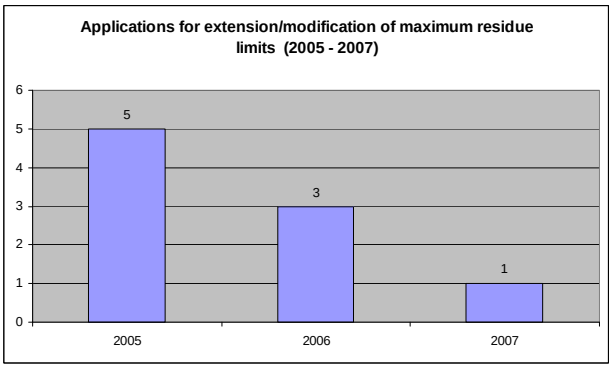
If food-producing animals are treated with medicines, residues may remain in the food produced by or from them. To obtain a marketing authorisation for a veterinary medicinal product intended for use in a food-producing species, so-called maximum residue limits (MRLs) for all pharmacologically active substances must be established in advance for the animal species concerned and for its tissues or products, e.g. meat, milk, honey, etc. An MRL is the safe level of residue in food that can be consumed by a person every day over a lifetime without it causing a harmful effect.

3.3.1 Core activities

Applications for MRLs

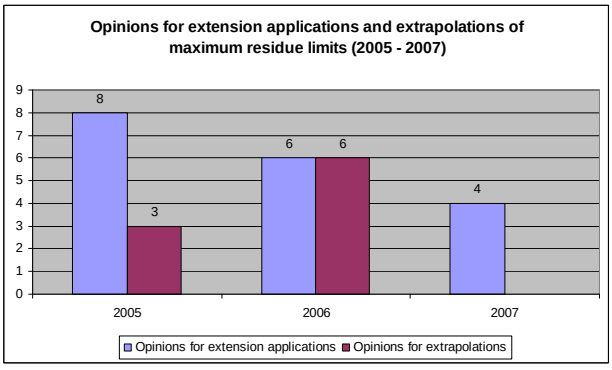
- In 2007, the EMEA received and validated 2 new applications for MRLs – 1 fewer than was forecast for the year.
- The small number of new MRL applications is of concern as it clearly shows that very few new molecules are being introduced onto the veterinary market. The ongoing decrease in MRL applications is consistent with the comparatively greater interest currently seen for the development of new pharmaceutical products for companion animals rather than for food-producing animals, and with the trend to develop more immunological products, as in both of these cases there is no requirements to establish an MRL for the active principle thereby reducing the cost and time of bringing a product to market.
- There was also a shortfall in the number of applications submitted for extension or modification of MRLs, with only 1 of the forecast 5 being submitted.
- The lack of uptake of extension applications is possibly related to the fact that many extensions that are of interest to companies have already been undertaken by the CVMP as free-of-charge extrapolations over recent years in the CVMP's efforts to facilitate authorisation of products for MUMS.
- However, concerns remain that this decrease of interest in MRL applications and extensions could mean that, despite the efforts of facilitating the marketing authorisations for MUMS products and establishing specific guidelines allowing reduced data requirements to cater for these specific products, an adequate incentive to develop products for minor species and minor uses has yet to be established. The matter will require further analysis.





Opinions on maximum residue limits

- The CVMP adopted 3 positive opinions for the establishment of new MRLs.
- One positive opinion related to the establishment of final MRLs further to previous provisional MRLs for a new substance.
- Four positive opinions related to the extension of existing MRLs to other species.
- All applications for new MRLs and for extension or modification of MRLs were processed within the 120-day legal timeframe.



3.3.2 Specific objectives in 2007

- Strengthened MRL review process.
- No actions were ultimately considered necessary in this area.
- Following a review of the MRL review process, the EMEA considered that no actions are necessary in this area.

- The Agency provided technical and scientific advice to the Commission in its work to revise the MRL Regulation (Council Regulation (EEC) No 2377/90) in line with 'Better Regulation' principles. Further input will be required during 2008 in this highly complex area.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of applications evaluated within the 120-day timeline	100% of applications	100%

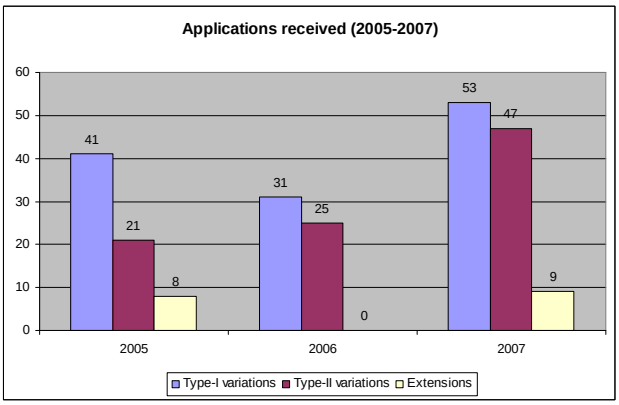
3.4 Post-authorisation activities

Changes to the terms of marketing authorisations are made frequently during the life of a medicine. Marketing authorisation holders may want to change the manufacturing process, alter or improve the medicinal product, or introduce additional warnings and contraindications. These changes, known as variations, require formal approval. Variations can involve either minor (type IA or IB) or major (type II) changes.

Besides variations, post-authorisation activities also include line extensions and transfers of marketing authorisation.

3.4.1 Core activities

- The overall number of applications for variations to marketing authorisations received in 2007 was significantly higher than in 2006, in part accounted for by the greater number of centrally authorised products on the market. It is therefore likely that this trend for an increase in post-authorisation activity will increase in coming years.
- A total of 53 type-I variation applications were received, relating to 29 type-IA and 24 type-IB variations.
- There were also 47 applications relating to the more complex type-II variations. Of these, 13 concerned pharmaceutical products and 34 concerned immunological products.
- Six of the variations concerning pharmaceuticals related to changes in quality, 5 related to clinical changes and 2 related to updates of summary of product characteristics (SPC) and the package leaflet (PL).
- Twenty variations concerning immunologicals related to quality changes, 8 related to clinical changes and 6 related to updates of SPC and PL.
- There were 9 applications for extension of marketing authorisation. Of these, 5 concerned pharmaceutical products (3 for a new pharmaceutical form, 1 additional target species and 1 deletion of a route of administration), whilst 4 concerned immunologicals (all relating to a quantitative change to the active substance).
- The total number of type-II opinions adopted in 2007 was 45. Of these, 11 were received in 2006 (2 for new indications, 1 for update of product literature and 8 quality changes), and 34 were received in 2007 (8 updates of SPC and PL, 1 new presentation, 7 new indications and 18 other quality changes).
- All variation applications were evaluated within the regulatory time limits.



3.4.2 Specific objectives in 2007

- EPAR summary updates for line extensions.
- EPAR summaries are now updated on a regular basis for line extensions.
- Assist Commission with revision of the regulation governing variations.
- Input was provided to the Commission with respect to how proposed revision of the variations regulation would affect processing of variations to centrally authorised veterinary medicinal products.
- Procedures for monitoring the actual placing on the market of medicines.
- A simplified reporting procedure for ensuring that marketing-authorisation holders meet the requirements of the 'sunset clause' was endorsed by the CVMP. This procedure is appropriate for the needs and resources available in the veterinary sector.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of applications for type-I and II variations and line extensions evaluated within the regulatory timelines	100% of applications	100%
Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion checking procedure	100% of applications	0%*

* Compliance with this target requires timely action by applicants and Member States to enable EMEA to meet the 27-day deadline, which was not forthcoming in 2007. However, EMEA achieved 100% compliance with submitting the opinion to the Commission in English (only).

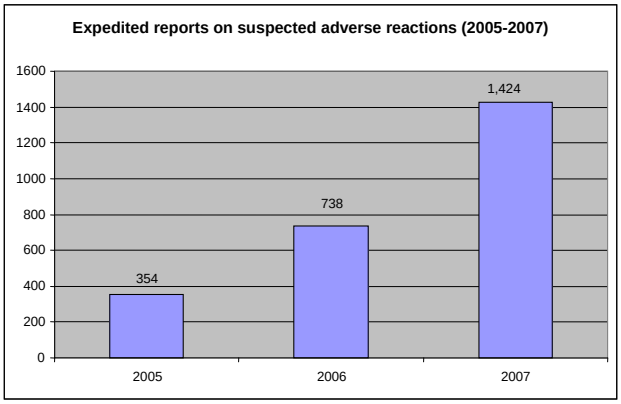
3.5 Pharmacovigilance and maintenance activities

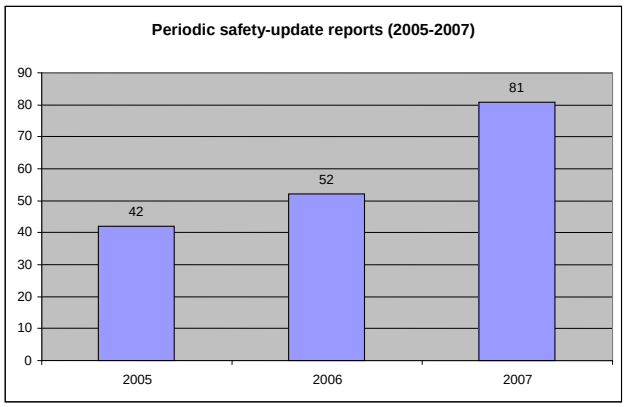
This activity relates to pharmacovigilance information, including adverse-drug-reaction reports (ADRs) and periodic safety-update reports (PSURs). Pharmacovigilance remained a high priority for the Agency in 2007, to ensure that effective risk-management was continuously applied to post-authorisation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

Pharmacovigilance in the veterinary sector in the EU continues to undergo changes triggered by the new legislation. The electronic exchange of pharmacovigilance information within the EU is improving, as are active surveillance, harmonisation and risk management.

3.5.1 Core activities

- A marked increase in expedited reporting of suspected adverse reactions was observed. The number of reports received was almost double the number of reports received in 2006. It is believed to result from, among other factors, the Agency's efforts to promote awareness of expedited reporting.
- For centrally authorised veterinary products, a total of 1,424 expedited spontaneous reports of suspected adverse reactions were reported within the 15-day legal timeframe in 2007.
- 1,212 of the 1,424 reports received related to suspected adverse reactions in animals and 213 to reactions in humans following exposure to a veterinary medicinal product.
- 133 reports received related to food-producing animals (mainly cattle, pigs and horses), following treatment of 17,459 animals, of which 4,428 showed suspected adverse reactions:
  - 659 related to suspected adverse reactions in dogs;
  - 389 related to suspected adverse reactions in cats;
  - 569 originated within the EU.
- 81 periodic safety-update reports (PSURs) were received in 2007 for centrally authorised products.
- Following its review of PSURs, the CVMP recommended in 6 cases that variations be submitted for the products concerned, mainly for the addition of new adverse-reaction information to the product literature.





3.5.2 Specific objectives in 2007

- The preparation of guidance documents is a continuous activity for the CVMP and its Pharmacovigilance Working Party. In 2007, this activity focused on the preparation of a new Volume 9B of the Rules Governing Medicinal Products in the European Union. Guidance prepared included:
  - pharmacovigilance of medicinal products for veterinary use, a guideline for marketing authorisation holders for monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections;
  - guidance for regulatory authorities concerning the assessment of PSURs.
- Further to the publication of the Simple Guide to Veterinary Pharmacovigilance in the EU in English in 2006, several Member States made this guide publicly available in their national language(s) as part of efforts to promote pharmacovigilance and safety reporting.
- Development of EudraVigilance Veterinary (EVV) continued in 2007.
  - EudraVigilance Veterinary became the main reporting tool used by national competent authorities, now containing a total of 11,000 case reports in the database.
  - Only a few reports were submitted electronically by marketing-authorisation holders, with the majority of the large veterinary pharmaceutical companies still being in the implementation and testing phase.
  - Development of EVV was delayed for a period of some 6 months during 2007 due to re-prioritisation of resources to further development of the Eudravigilance (human) data warehouse. Following resumption of activity on EVV, the Agency and the Vet Joint Implementation Group developed the EudraVigilance Veterinary Action Plan, which was endorsed by the EMEA Management Board and the Head of Medicines Agency. This plan now gives the required predictability to future development of EVV that is necessary for national competent authorities to commit the necessary resource to ensure its full and timely implementation.
  - Good progress was made on developing the DataWarehouse tool to facilitate continuous monitoring and signal detection of pharmacovigilance data in EudraVigilance Veterinary. The tool is now being tested by a subgroup of the Pharmacovigilance Working Party. The DataWarehouse is expected to become fully operational in 2008.
  - Following training sessions on the use of EudraVigilance Veterinary in previous years, a first training on scientific DataWarehouse queries took place. Assistance is provided on a day-to-day basis to Member States for the import of product-related data in the product dictionary of EudraVigilance Veterinary.
- Major milestones in the discussions for international standards outside the EU were reached, in particular with an agreement between Japan, the US and Europe within the VICH initiative on the required data elements for reporting and exchanging adverse-events data related to veterinary medicinal products.

- During the year, a refined action plan was established for the European Surveillance Strategy, now including priorities for promotion of adverse-reaction reporting, implementation of electronic reporting of these reactions, data analysis, and worksharing between Member States. Communication on safety issues between all stakeholders is also considered a high priority.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of PSURs evaluated within the established timeline of 60 days	80% of PSURs	49%*

* This target was not met in 2007 due to a higher than usual proportion of PSURs requiring follow-up and of PSURs associated with renewals, both of which extend the timeline for completion of the evaluation.

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 involving the interests of the Community or concerns relating to the protection of human or animal health or the environment (Articles 35 and 40 of Directive 2001/82/EC).

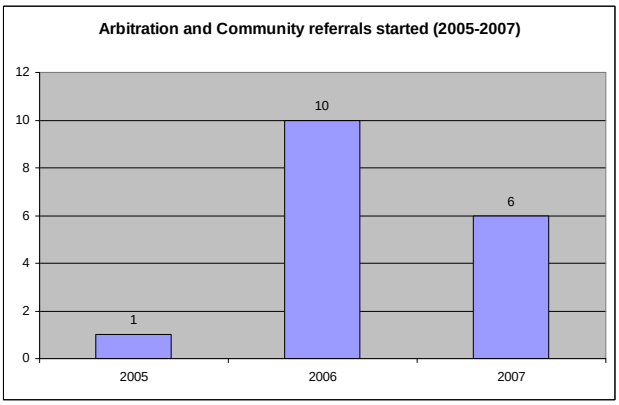
3.6.1 Core activities

Procedures started in 2007

- The number of referrals made to the CVMP in the framework of the mutual-recognition procedure was considerably lower than estimated.
- This is was in part due to the efforts made by the Coordination Group for Mutual-Recognition and Decentralised Procedures-Veterinary (CMD(v)) in cooperation with the CVMP to solve contentious issues between Member States before they become the subject of arbitration.
- A total of 6 referral procedures were initiated, in contrast to the 13 forecast, of which 1 related to safety concerns for existing products.
- Three of the referrals were made under Article 33 and 3 were made under Article 35 of Directive 2001/82/EC.

Referral procedures concluded in 2007

- The CVMP completed the assessment and issued opinions on 3 of the referral procedures started in 2007 and on 7 of the referral procedures started in 2006.
- All referrals were processed within the legal timeframe.



A list of referral procedures can be found in Annex 18.

3.6.2 Specific objectives in 2007

- Joint efforts continued between the CVMP and the Coordination Group for Mutual-Recognition and Decentralised Procedures-Veterinary (CMD(v)) to promote efficient cooperation in order to ensure harmonised and consistent scientific and regulatory approaches; to avoid duplication of efforts; and to ensure that arbitrations referred to the CVMP relate to scientific rather than regulatory or procedural issues.
  - The Chair of the CMD(v) attends meetings of the CVMP and its Strategic Planning Group to ensure effective liaison between the two Committees.
  - In consultation with the Commission, the CVMP made progress on the appropriate procedures for handling referrals that relate to the safety and efficacy of generic products. It is hoped that this will ultimately lead to fewer, but more appropriate, referrals to the Committee.

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100%

3.7 Committee for Medicinal Products for Veterinary Use

- The Committee for Medicinal Products for Veterinary Use (CVMP) met 11 times in 2007.
- The Committee completed the exercise to renew or replace the nominations of members following the expiry of the first mandates under the revised legislation.
- Gerard Moulin was re-elected Chair of the CVMP and Anja Holm was elected Vice-chair.
- The Committee reviewed the expertise available to it and appointed co-opted members to provide additional expertise as needed. A similar exercise was conducted where necessary for working parties.

Methodology for benefit-risk assessment

- The CVMP developed a methodology for the systematic assessment of the benefit-risk balance of medicines for veterinary use. The Committee considered in detail how to ensure that the analysis of the benefit-risk balance is conducted in a systematic and scientifically robust manner. A guideline on the evaluation of benefit-risk balance was prepared and published for consultation during 2007. Close

liaison was maintained with the CHMP, which is likewise developing a methodology in this area in relation to products for human use.

Environmental risk assessment

- The CVMP, with the support of its Working Party on Environmental Risk Assessment, continued to provide advice for the implementation of the requirements of the amended Veterinary Directive regarding environmental risk assessment. This is a high-profile and difficult area in which the requirements for a thorough environmental risk assessment need to be weighed against the impact that excessive data requirements could have on the availability of veterinary medicines. Detailed practical guidance to applicants and competent authorities that will facilitate carrying out the environmental risk assessments for veterinary medicinal products and allow for a harmonised approach was completed in 2007. Guidance aimed at clarifying the legal requirements has also been further advanced, in cooperation with the Commission, and is expected to be finalised in 2008.

Activities relating to antimicrobial resistance

- The CVMP, together with the Scientific Advisory Group on Antimicrobials (SAGAM), continued its activities in relation to antimicrobial resistance.
  - On the basis of recommendations from the SAGAM, the CVMP finalised its position statement on the use of quinolones and fluoroquinolones in the EU, critically reviewing recent data on their use and their potential impact on human and animal health.
  - Efforts continued to implement, together with Heads of Agencies of EU Member States, risk-management actions for (fluoro)quinolone-containing veterinary medicines.
  - The CVMP developed a proposal for antimicrobial-resistance surveillance as a post-marketing authorisation commitment.
  - The CVMP drafted a reflection paper on third- and fourth-generation cephalosphorins, similarly addressing their use and potential impact on resistance-development in relation to human and animal health.

Liaison with other scientific committees and EU institutions

- The committee maintained close working relationships with a number of other scientific committees of EU institutions to ensure consistency and relevant exchange of information. Notably, there were numerous exchanges with the scientific panels of the European Food Safety Authority.
  - The Committee provided input to the opinions of the Animal Health and Welfare Panel on bluetongue, avian influenza, echinococcus, ticks and fish vaccines.
  - There were exchanges with the Scientific Panel on Additives and Products or Substances used in Animal Feed to ensure consistency between scientific opinions for veterinary medicines and feed additives.
  - The CVMP and CHMP both provided input into a review of an opinion from the Panel on Genetically Modified Organisms on the use of an antibiotic-resistance gene as a marker in a genetically modified plant.

Working parties and scientific advisory groups

- The working parties to the CVMP were extremely active during 2007, developing a wide range of guidelines and guidance documents.
- Focus-group meetings and workshops were organised involving external stakeholders on the topics of fibrosarcomas at sites of injection of veterinary medicines in cats, anticancer treatments for dogs and cats, the CVMP guidance on user safety, and the description of pharmacovigilance systems and pharmacovigilance inspections.

- Training of assessors with the aim of ensuring a consistent level of knowledge and promoting harmonisation of assessments throughout the Community was provided by the CVMP working parties on environmental risk assessment, efficacy, pharmacovigilance and safety.

3.8 Coordination group

Heads of Medicines Agencies–Veterinary website: http://www.hma.eu/veterinary.html

The Coordination Group for Mutual-Recognition and Decentralised Procedures–Veterinary (CMD(v)) met on a monthly basis in 2007. One informal meeting was held in Helsinki, Finland.

Procedures started and concluded in 2007

- Eighty-four mutual-recognition procedures (MRPs) were started for a total of 75 products, and 80 decentralised procedures (DCPs) were started for a total of 65 products.
- Ninety mutual-recognition procedures were finalised for a total of 76 products, including 1 referral carried over from 2006. Thirty decentralised procedures were finalised for a total of 26 products, including 1 referral carried over from 2006.
- Four MRP products and 3 DCP products were referred to the CMD(v) and 4 products were referred to the CVMP for arbitration. One product did not reach Day 60 in 2007.

	Started products (procedures)	Finalised products (procedures)	CMD(v) referrals	CVMP referrals
MRP	75 (84)	76 (90)	4	2
DCP	65 (80)	26 (30)	3	2

- The CMD(v) addressed a number of questions from industry and from Member States, most of them in relation to the appropriate legal base for new applications and for variations to veterinary medicinal products. The administrative handling of products containing diluents was agreed and communicated, thus preventing unnecessary invalidation of applications. With regard to the availability of medicines, an ad hoc working group was set up to address industry's proposals to modify the label requirements for packaging texts.
- In consultation with the Heads of Medicines Agencies for veterinary medicines, the CMD(v) agreed on the principles for handling generic applications, in particular with regard to the European reference product and the situation where indications, withdrawal periods and target species have not been authorised for the reference product in a Member State.
- The group also drafted various best-practice guides, standard operating procedures and Q&A documents.
- Three meetings were held – with IFAH-Europe, the European Group for Generic Veterinary Products (EGGVP) and the Association for Veterinary Consultants (AVC) – to discuss regulatory issues.
- The EMEA provided full secretariat and administrative support to the CMD(v).

4. INSPECTIONS

4.1 Inspections

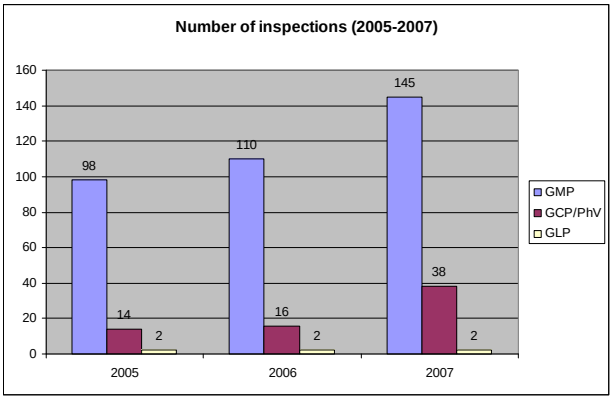
The EMEA coordinates the verification of compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP) and good laboratory practice (GLP), and with certain aspects of the supervision of authorised medicinal products in use in the European Community. It does this through inspections requested by the CHMP or CVMP in connection with the assessment of marketing-authorisation applications and/or the assessment of matters referred to these committees in accordance with Community legislation.

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.

4.1.1 Core activities

Inspections

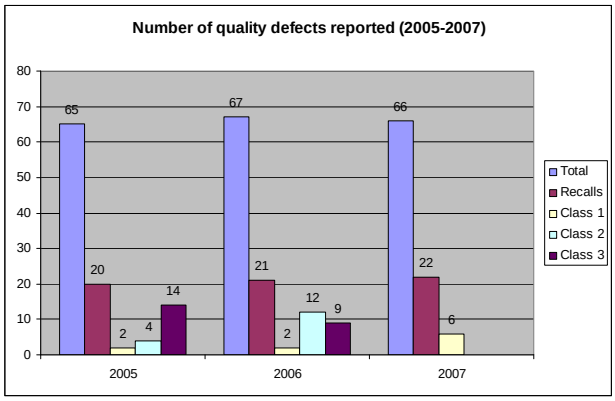
- GMP inspection numbers (including inspections in the context of plasma master files (PMFs) were higher than expected (145), showing a 32% increase compared with 2006 (110). This reflects the increasing number of authorised products requiring re-inspection, increasing numbers of variations and some unanticipated PMF inspections.
- GCP and pharmacovigilance inspection figures were also significantly over forecast, with more than double the number of inspections requested in 2006. This reflects an increase in the number of routine inspection requests in line with the policy on GCP inspections adopted in 2006, as well as in increasing focus on inspections in countries where there is little European experience.
- GLP (non-clinical) inspections are on target.
- All inspections were managed within the legislative deadlines.



Product defects and deviations

- Coordination work on quality defects and counterfeits also increased significantly during 2007, although actual numbers of defects were in line with figures from 2005 and 2006.
- 66 quality defects were successfully coordinated, 22 of which resulted in recalls.

- 6 of these were class-1 recalls, compared with 0 during all of 2006.
- One of the class-1 recalls (Viracept) led to a substantial amount of follow-up activities to prevent reoccurrence of similar issues (critical GMP failure leading to high-level contamination with genotoxic impurities) for any similar centrally authorised, MRP, decentralised or national products in the EU (mesilate and related active substances).
- Four out of the 6 class-1 recalls related to counterfeited centrally authorised products.



4.1.2 Specific objectives in 2007

- The first phase of the EudraGMP database on manufacturing authorisations and GMP certificates was launched on 27 April 2007; the second phase went into production on 6 December 2007, five months later than anticipated.
- A survey on the impact of the new legislation and procedural requirements on GMP for active substances was completed and the results analysed for the consideration by the European Commission of new approaches. The Commission published an online questionnaire to assess the approach on GMP for certain excipients and concluded that no legislative action was necessary in this area.
- Work on implementation of the new legislation continued, with publication of draft guidelines on good manufacturing practice for radiopharmaceuticals and medicinal gases.
- The EMEA coordinated activities relating to the joint audit programme for GMP inspectorates.
- Significant progress was made on implementing the ICH guidelines on quality risk management, with the publication of a revised text on quality management, training and qualification of inspectors, and the elaboration of a document for assessment purposes.
- In the area of pharmacovigilance inspection, a section on the pharmacovigilance system and on pharmacovigilance inspections was published in Volume 9 of EudraLex in February 2007.
- Revised SOPs on coordination of GxP pre-approval inspections and coordination of product defects were published, successfully harmonising practices in these areas.
- A report on major deficiencies found during GMP inspections performed in 2006 and an analysis of defects reported during 2006 and 2007 were completed and published.
- Cooperation between the Member States on inspection performances and outcomes continued to be an important aspect in 2007. Specific bilateral meetings with three competent authorities were held as part of the work towards improving cooperation within the European network. One of these focussed on GMP, while the two others also addressed GCP and pharmacovigilance inspections.
- Issues relating to bioequivalence studies for generic applications were addressed by a joint group involving GCP inspectors and members of the CMD(h).

Performance indicators

Performance indicator	Target	Outcome at end of 2007
Management of inspections within legislative timelines	100% of inspections	100%

GMP, GCP, GLP Inspectors Working Groups and Joint CHMP/CVMP Quality Working Party

- The three main working parties (GMP, GCP and Quality Working Party) under the responsibility of the Agency's inspection sector each met four times in 2007.
- A meeting of the ad hoc group of GLP inspectors took place in September 2007.
- Two meetings of pharmacovigilance inspectors took place, in February and September respectively, in conjunction with meetings of the GCP Inspectors Working Group, addressing compliance with Community procedures and information sharing.
- A number of training activities took place in the second half of 2007, including a GCP training event, a workshop on quality risk management (jointly organised with PIC/S) and a workshop on specialised quality-assessment issues.
- Cooperation between inspection and assessment functions continued to be developed, through the work of the Process Analytical Technology (PAT) team and a joint meeting of GMP inspectors and quality assessors in June, as well as through meetings between GCP inspectors and representatives of the CMD(h). A first joint workshop of the PAT team in cooperation with the Biologicals Working Party (BWP) was also organised.
- New names, mandates and terms of reference were agreed and published for the GMP/GDP and the GCP Inspectors Working Groups.

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.

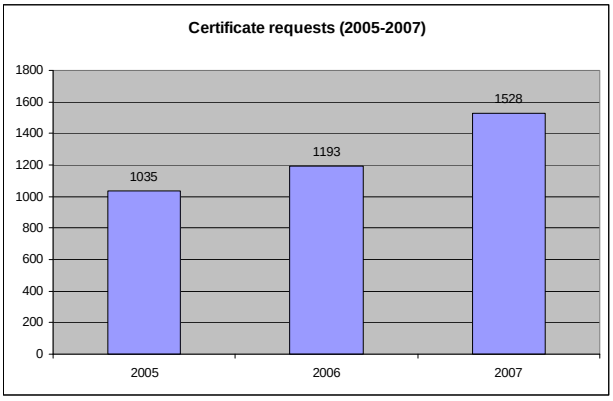
- The internal evaluation of new Member States in the context of the mutual-recognition agreements continued, despite delays encountered due to new legislative frameworks in some of the Member States concerned.
  - The Commission requested that Bulgaria and Romania indicate their readiness for evaluation.
- With the successful launch of the first phase of EudraGMP in May 2007, initial steps to extend it to MRA (and other international) partners were made and technical discussions are ongoing.
- The remaining external evaluation work in the context of the EC-Canada MRA is ongoing.
  - External evaluations of Malta and Cyprus by Canada were successfully completed.

- Dedicated discussions with the European Commission and Australian representatives on rewording of the MRA agreement took place, successfully facilitating the inclusion of new Member-State authorities within the scope.
- Although a number of observed inspections in the context of the Japanese MRA took place, there was little progress on the implementation of the full scope of the GMP Annex of the EC-Japan MRA.
- Analysis of the changes to GMP in view of the implementation of quality risk management discussions with MRA partners was postponed.

4.3 Certificates of medicinal products

The purpose of the EMEA scheme for certificates of medicinal products is to support the work of health authorities outside the European Union, in particular in developing countries. EMEA certificates are issued by the Agency, on behalf of the European Commission, to confirm the marketing-authorisation status of products authorised by the European Commission through the centralised procedure or products for which a centralised application has been submitted to the EMEA. The certificates also confirm compliance with good manufacturing practice (GMP) at the manufacturing site(s) where the medicinal product is produced in bulk pharmaceutical form.

- The number of certificate requests increased by 28% relative to 2006, compared with an expected increase of 16%.
- Certificates within the framework of cooperation with the WHO and certificates for SMEs also increased.
- The Agency did substantial work on rationalisation of the certification process, including staff re-allocation and IT developments, continuing to make the process more resource-efficient despite the increasing workload. A web-based application form was launched in October 2007, thus facilitating incorporation of requests into the database and helping to avoid errors. However, due to the increase in workload (50% increase since 2005), without a corresponding increase in resources, it was not possible to consistently meet the timelines indicated in the performance measures.



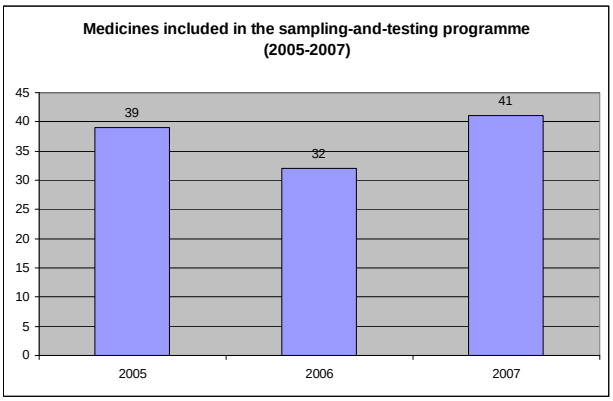
Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of certificates issued to requesting parties within the timeline	95% compliance	90% 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 European Directorate for the Quality of Medicines and HealthCare (EDQM). A selection of centrally authorised products is included in each annual programme.

- The EMEA, the EDQM and the national authorities in the programme continued their close collaboration in 2007, with a view to assure effective and continued post-marketing surveillance of the quality of medicines.
- Forty products were tested as part of the 2007 sampling and testing programme.
- A new risk-based approach to the selection of products and parameters for testing was discussed and agreed by the relevant working parties/groups for medicinal products for human use. Specific criteria for veterinary medicinal products require further development.
- The move to 'one laboratory testing' for chemical products was completed in 2007. A corresponding stepwise introduction for biological products remains under discussion.
- In the context of the considering the most appropriate way for generic medicinal products to be included in future programmes, associated selection criteria and the possibility of including packaging and labelling details were further investigated.



Performance indicators

Performance indicator	Target	Outcome at end of 2007
Percentage of planned products (40) actually tested	95% of planned products	100%

4.5 Implementation of the Clinical Trials Directives

The Agency provided continuing support for the implementation of Directive 2001/20/EC and Directive 2005/28/EC in 2007.

- The Agency organised a highly successful conference with a wide range of stakeholders, examining the operation of the Clinical Trials Directive after three years of practical experience, and published a report on the feedback provided.
- GCP-inspection-related procedures and guidelines progressed as planned, with finalisation of procedures relating to the conduct of inspections and the exchange of information.
- A number of joint sessions with the CMD(h) on issues relating to bioequivalence trials were organised, resulting in one targeted inspection of a bioequivalence site within the centralised procedure and several others relating to non-centrally authorised products.
- Work on the interpretation of GMP in the context of investigational medicinal products resulted in the finalisation of a number of documents, including a clarification of the respective responsibilities of the Qualified Person and the investigator.
- The EMEA continued to support the Clinical Trial Facilitation Group, particularly in relation to the EudraCT database.
  - Increasing transparency of some parts of EudraCT was addressed in the context of EudraPharm and the Paediatric Regulation.
  - Work in the context of the Paediatric Regulation focussed on communication and awareness raising, as well as on contributing to the development of a guideline.
- The EMEA also contributed to preparation of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products' (EMEA/CHMP/SWP/28367/07).

4.6 GMP harmonisation

Work continued on the preparation of guidelines and Community procedures associated with implementation of GMP-related aspects of the new legislation.

- GMP annexes on sterile medicinal products (Annex 1), herbal medicines (Annex 7) and radiopharmaceuticals (Annex 3) were finalised.
- Draft annexes on GMP for biological medicinal products (Annex 2) and medicinal gases (Annex 6) were released for consultation.
- A meeting with interested parties discussed: feedback on the published reflection paper on compliance with the requirements of the marketing authorisation; GMP requirements for substances whose main use is not in the pharmaceutical area (atypical actives); and the proposed ICH approach to Pharmaceutical Quality Systems (Q10).
- A survey on experience with the operation of the 2004 legislative requirements in relation to GMP for active substances was also completed and analysed.

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.

2007 was the fifth year of implementation of the EU telematics projects by the Agency.

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

System or process *(Status in 2006)*	**2007 milestones**
EudraNet (In production)	High performance of EudraNet was achieved both in terms of system availability and quality of management, development and operation of EudraNet applications (EudraNet II, EudraLink, ECD, Experts Database, etc.). Inspections agencies that are not part of the national medicines agencies have been added into the EudraNet. Further, advanced network-management and performance services were implemented.
EudraPharm (In production)	EudraPharm was updated in 2007. The new features include: 'Advanced Search', product information available in a number of EU languages in test; a new site map offering an improved navigation experience; and the inclusion of maximum residue limit (MRL) information for veterinary products.
EudraVigilance (In production)	The EudraVigilance DataWarehouse and Analysis System (EVDAS) was rolled out to the national competent authorities on 6 July 2007. It is designed to support signal-detection and the assessment of adverse-drug-reaction reports. Quantitative signal-detection methodologies were included in EVDAS and new functionalities facilitating the review of signals were added to EudraVigilance.
Eudra DataWarehouse (In pre-production)	Development of the Eudra DataWarehouse was ongoing. However, work on the interim DataWarehouse solution for EudraVigilance Human had severe impact on work in this area. A first version for use by national competent authorities was released in September 2007.
EudraCT (In production)	In addition to preliminary specification work for the next major upgrade, technical upgrades were implemented on the system.
EudraCT Paediatrics	Work on this has barely started, as guidelines fundamental to the

Database (At inception)	determination of the scope and functionality of the proposed system are not yet available in final form.
EudraGMP (In production)	The first version of EudraGMP was launched in April 2007, and version 1.1 was released into production in December 2007.
European Review System (Installation)	The roll-out across the NCAs has resulted in the majority of NCAs having an installation or having opted for a different tool. Work remained to be done in respect of a small number of NCAs.
PIM (Product Information Management) (In pilot production)	Pilot activities were undertaken in respect of both new and post-authorisation applications. A decision was taken to extend the pilot phase into 2008.
EU Telematics Controlled Terms (In pilot production)	Definition and implementation of EU Telematics controlled terms continued. The first pilot was released in September.

Operations

Operational support was put in place to complement the investment in systems and infrastructure over the past four years. The Eudra Service Desk provides assistance to users, and may be accessed by e-mail or telephone. Appropriate structures are 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	Outcome 2007
Project management in EU telematics		
Project delivery in accordance with stated timelines	All projects	5 out of 8 projects
Project delivery in line with the anticipated budget	All projects	2 out of 8 projects
Project deliverables perceived as being in line with expectations	All projects	7 out of 8 projects
Provision of service in EU telematics		
Availability of services (excluding planned maintenance downtime) (during EMEA office hours)	98%	99.8%
Response-time to 80% of EU telematics IT ServiceDesk requests	4 hours[1]	3.5 hours
Response-time to 15% of EU telematics IT ServiceDesk requests	2 days[1]	1.5 days
EudraNet availability of services (excluding local NCA downtime)	99%	98.5%
Response-time to 80% of EudraNet and EudraLink IT ServiceDesk requests	3 hours[1]	2.5 hours
Response-time to 15% of EudraNet and EudraLink IT ServiceDesk requests	1.5 days[1]	1.5 days

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

6. SUPPORT ACTIVITIES

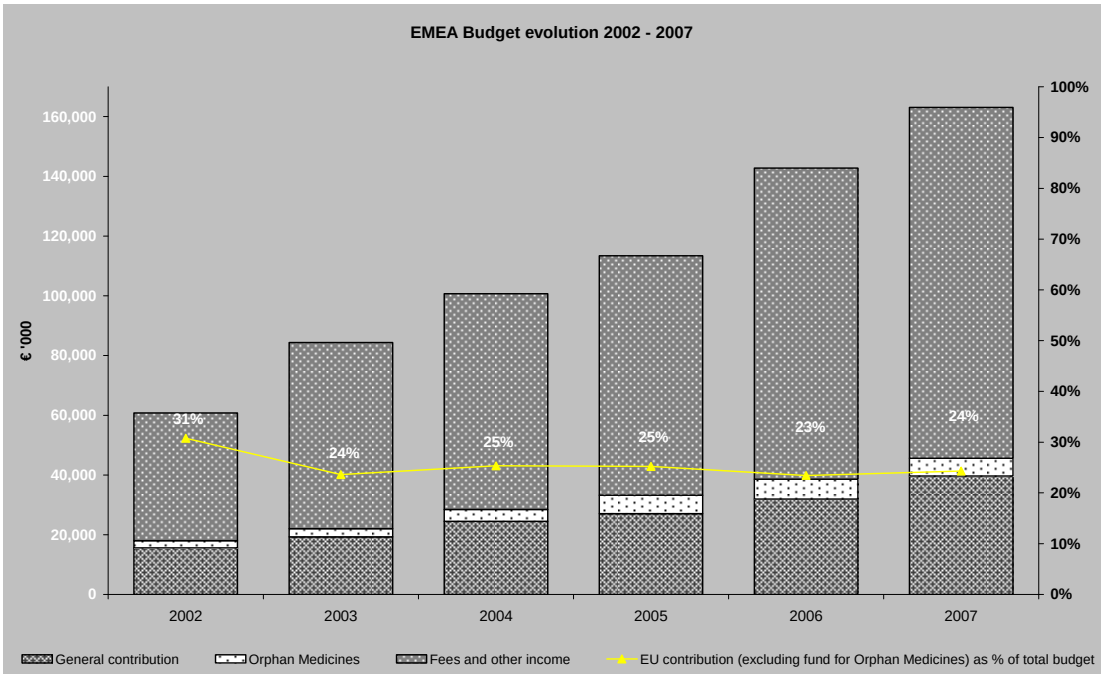
6.1 Administration

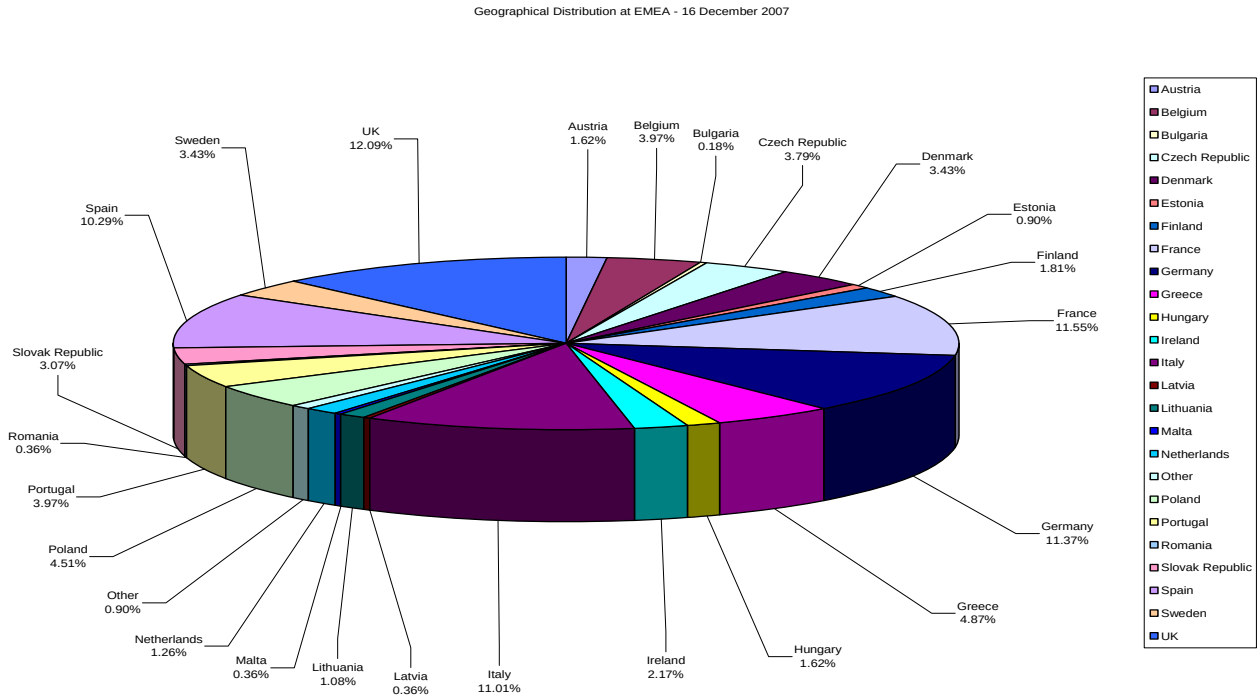
Administration tasks include managing revenue, expenditure and accounts according to existing rules and regulations, recruiting, managing and administering staff and seconded personnel, and providing and running the necessary infrastructure services for an effective functioning of the Agency. To achieve this, close cooperation is required with the European Parliament and the European 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.

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.

- The Agency's total budget in 2007 was €163,113,000.
- The number of staff employed at the EMEA was 441, plus 124 seconded national experts and contract agents.
- Twenty-nine internal and external recruitment procedures were carried out.
- The EMEA continued to invest in the professional development of staff. The number of training days taken by EMEA staff was up by almost 30% on the previous year, reaching a total of 4,166 days.
- Preparations for a tender procedure for insurance provider were undertaken. A contract notice for open tender procedure was published on 20 November 2007.
- An online missions system was tested in 2007. As the tested system revealed a number of difficulties, implementation had to be postponed.
- A 360-degree performance-evaluation system for managers was discussed; adoption of the new system is expected for 2008.





	2005 (final)	2006 (final)	2007 (final)
Workload			
Total staff	372[2] + 443[3]	435[2] + 62[3]	441[2] + 124[3]
EMEA budget	€107,322,031	€136,147,083	€163,113,000
Selection procedures	39	32	29
Mission claims	1,186	953	940
Salary payments	4,613	5,232	6,003
Staff mobility	318	446	486

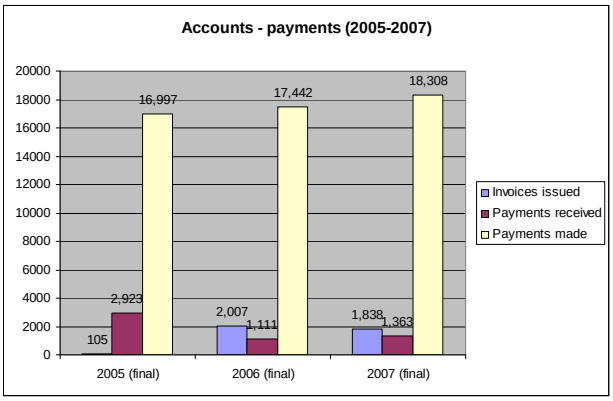
Accounts

The principal activities in the accounts area 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 relationships with the Agency's banks; providing accurate and timely financial information to management.

- Discharge for the 2006 accounts was given by the European Parliament.

[2] Establishment plan minus vacancy rate plus contract agents.
[3] Number of interims, trainees, auxiliary agents and national experts.

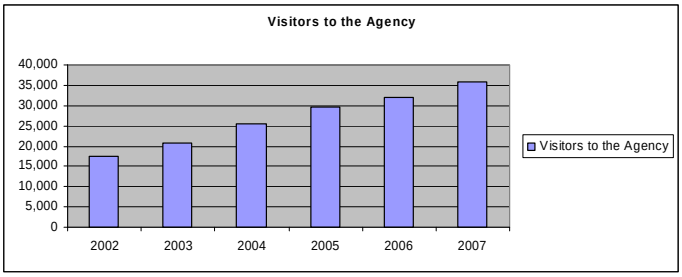
- A new budget and accounting system, replacing the current EMEA financial system, SI2, was selected in 2007. To this end, a feasibility study for a new integrated accounting system was carried out, which resulted in a recommendation for a new system.
- The introduction of a new batch-invoicing system leads to important efficiency gains in that a higher number of recoveries could be achieved by a smaller number of invoices.
- A contract for banking services was signed in December 2007.



Infrastructure services at the EMEA

The Agency's main aim in the area of infrastructure services is to ensure a safe and efficient working 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.

- New office and meeting facilities were made available to EMEA staff and delegates.
  - Refurbishment of the second floor of 7 Westferry Circus was finalised in the first half of 2007, providing a larger number of meeting rooms.
  - Refurbishment of the sixth floor of 1 Westferry Circus was finalised in the second half of 2007, providing office facilities for EMEA staff.
- The restaurant servery was refurbished.
- Good progress was made with business-continuity planning and arrangements.
  - A business-continuity exercise took place in September 2007, allowing EMEA staff to rehearse necessary procedures.
  - Following a tender procedure, a contract was awarded for an automated alert system to be used in a business-continuity scenario.
- The Agency progressed the introduction of e-procurement tools, systems and procedures. A process analysis to permit e-procurement under €25,000 is underway.
- A number of health & safety awareness campaigns for staff were carried out in 2007.
- Integration of a building-services helpdesk and a computer-aided facilities-management system is pending installation from IT.



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/she verifies (the 'four eyes' principle) whether the operation is legal, regular and compliant with the principle of sound financial management. He/she 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.

- The verification function was partly decentralised across the Agency. Following this, it has become more complex to coordinate and improve the verification in order to keep the efficiency and the effectiveness of the ex-ante controls.
- Following the implementation of the new staff regulation and financial regulation, all processes, work instructions and checklists had to be reviewed and updated simultaneously with an increasing workload.
- The complexity of regulations required more attention whereas the increasing workload required more time. Following remarks of the Internal Audit Service, the requirement for distinct operational ex-ante checks is being investigated.

Workload/Performance Indicators

	2005 (final)	**2006 (final)**	**2007 (final)**
Transactions checked*	24,500	27,150	20,050
Decentralised verification**			
Meeting reimbursements	*N/A*	*24%*	*23%*
Fee revenue & expenditure	*N/A*	*N/A*	*8%*
Administrative expenditure	*N/A*	*2%*	*2%*

* Corresponding to a number financial transactions having been checked by the centralised verifying officer.
** Corresponding to the percentage of low-risk transactions having been checked locally.

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 continued to be extended in 2007 through direct partnering with business units in order to develop and implement a range of critical applications.

- IT services were provided to staff, delegates and all users of pan-European systems.
- The Corporate Service Desk provided a very good service to users and delegates alike, responding to requests in most cases within 2 hours.
- The overall support function provided excellent levels of back-up, operation of servers, SAN, LAN, application of patches and bug fixes to the OS, operation, support and maintenance of all existing hardware and software of the Agency, virus protection, etc.
- New software to improve Service Desk support was identified and will be implemented in 2008. New hardware and software was procured to improve the archiving and back-up of data, while maintaining a high level of security and confidentiality for all data held on EMEA systems.
- A business-continuity IT solution to support a range of disaster-recovery scenarios initiated in 2006 was further progressed and tested in 2007, with parts of the solution becoming operational. This is an integral part of the EMEA's business-continuity plans and includes major improvements to back-up and storage systems. As part of this, additional secure-access facilities were provided in 2007 to allow for location-independent working of staff, a key component of the business-continuity solution.
- The virtual-meetings system Vitero was deployed in 2007, allowing attendees to participate in meetings using their PCs. This system, which is also developed towards the national competent authorities, provides for a new way of conducting meetings, and ultimately aims to reduce the number of reimbursed meetings. Pilot web broadcasts of scientific meetings were held in 2007. Video links for experts from national competent authorities were added.
- A range of EMEA core applications were further developed in 2007.
  - The first milestone in the multiannual project to deliver a new version of SIAMED, the application and product-tracking database, was delivered. This involved upgrading the underlying database, leading to better sharing of information with other systems.
  - The scientific-advice database was extended for use in relation to veterinary medicines, with deployment scheduled for 2008.
  - The Meeting Management System (MMS) was progressed in order to facilitate the smooth running of meetings of the scientific committees.
  - An enhanced recruitment database allowing online applications was implemented.
- IT infrastructure was provided for the new office and meeting room facilities at the EMEA.
- The project to introduce an electronic records-management system was initiated and work on the initial stages of the project completed in line with the overall plan.

Performance indicators

Performance indicator	Target	Outcome
Corporate availability of services (excluding planned maintenance downtime)	99.35%	99.8%
Response-time to 80% of corporate IT Service Desk requests	2 hours[4]	2 hours
Response-time to 15% of corporate IT Service Desk	1 day[4]	1 day

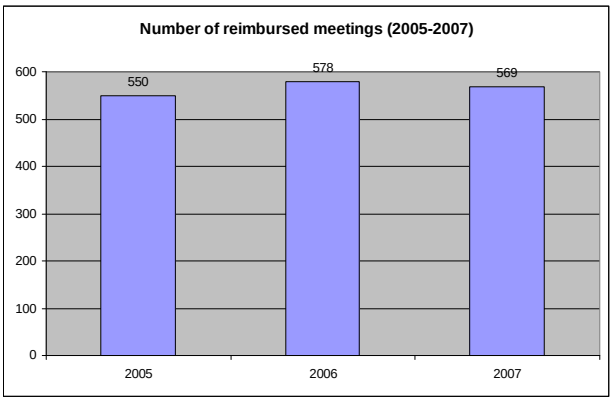
[4] These targets reflect the time required to fix the problem.

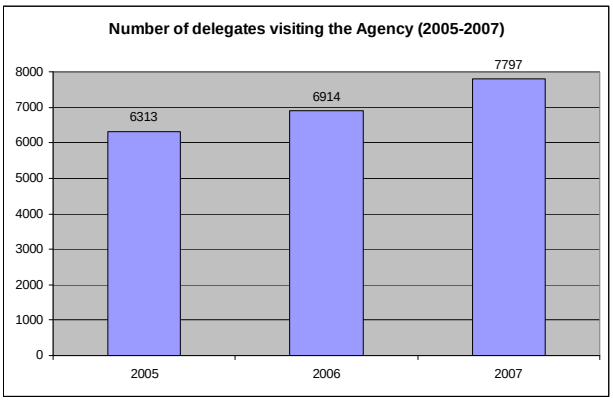
requests		

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 (MM&C) sector coordinates enlargement activities for new Member States and candidate countries.

- The number of meetings held at the EMEA in 2007 (569) was comparable to previous years.
- The number of delegates coming to the Agency increased by 12% to 7,797.
- A procedure to organise emergency meetings was established as part of the Agency's preparation for pandemic influenza.
- Measures were put in place to improve the efficiency of reimbursement procedures, including the introduction of a staff 'rota system' to avoid payment delays and provision of better information on payments made to the national competent authorities.
- The Agency carried out extensive negotiations with hotels regarding an EMEA corporate rate for the provision of accommodation to experts attending meetings at the EMEA.
- The Meeting Management System (MMS) module to allow participants to book their hotel and travel when attending meetings at the EMEA was delivered to be tested by staff in the MM&C Sector. When fully operational in 2008, it will save time for both staff and delegates by making these details available online.
- Room-based videoconferencing using a dedicated facility with special equipment was further developed. A number of scientific meetings were broadcast via the Internet, as part of a pilot programme.





In addition to the core activities in the area of meetings management, the following objectives were targeted.

Objectives

- The best-possible support was provided to delegates attending meetings and to EMEA staff members. A survey amongst delegates was carried out in 2007 showing a high level of satisfaction.
- The meetings-organisation workflow and procedures (Meeting Management System) was improved.
- Videoconferencing and meeting-broadcasting facilities were developed to assist national competent authorities and EMEA experts to facilitate virtual communication.
- Methods were developed to improve efficiency of reimbursement procedures, where appropriate, and the reimbursement rules were revised to streamline the reimbursement process. Adoption of the revised reimbursement rules was deferred to 2008.
- Negotiations with hotels were developed and extended. Delegates were consulted regarding their accommodation requirements.
- The ability to organise meetings within 24 hours, including outside of working hours and during weekends (in case of emergency situations such as pandemic influenza), was tested successfully.

Performance indicators

Performance indicator	Target	Outcome
Proportion of virtual meetings compared to all meetings	20% of all meetings	20%
Delegates' satisfaction regarding travel and accommodation bookings	95%	100%

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.

- The EMEA received a total of 92 requests for access to documents, an increase of more than 30% over 2006.
- Thirty-seven out of the 92 requests were refused.
  - 50% of refusals for access to documents at the initial stage concerned the protection of commercial interests of a natural or legal person (Article 3(2)(a) of the EMEA Implementing Rules).
  - 33% of refusals for access to documents at the initial stage concerned the protection of the Agency's decision-making process (Article 3(3) of the EMEA Implementing Rules).
  - 17% of refusals for access to documents at the initial stage concerned the protection of personal data (Article 3(1)(b)), the protection of the purpose of inspections (Article 3(2)(c)) or the protection of international relations (Article 3(1)(a)).
- 95% of requests for access to documents were processed within the established timelines.
- EMEA internal procedures for access to documents were strengthened. After finalisation of the internal EMEA policy on the practical operation of access to EMEA documents, standard operating procedures came into effect in April and October 2007. In addition, training sessions were organised for staff.
- 3.477 requests for information were received, 95% of which were processed within the established timelines.
- The EMEA copyright licensing policy was reviewed to take into account a revision of European copyright laws. As a result of this review, the EMEA copyright policy changed on 1 January 2008 and no longer requests copyright fees. The new policy allows for the reproduction and/or distribution of all EMEA public documents for both non-commercial and commercial purposes, as long as the EMEA is acknowledged.
- The electronic document management system (EDMS) was enhanced to assist with effective publishing of core business information to the web interface, and document-management, records-management (including retention policies) and mail-registration capabilities were further developed.
- Development and implementation of an electronic records management system was initiated.
- The Agency's translation policies were re-examined to take into account the increase in multilingual communication activities following EU enlargement and the growing volume of translations.
- Development and implementation of a terminology- and translation-memory database in order to maintain and improve the quality of translations of non-product information documents had to be postponed.

Performance indicators

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

Percentage of translations processed within established timelines	100%	100%

ANNEXES

Annex 1 **Members of the Management Board**

Annex 2 **Members of the Committee for Medicinal Products for Human Use**

Annex 3 **Members of the Committee for Medicinal Products for Veterinary Use**

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Annex 12 **CVMP opinions in 2007 on medicinal products for veterinary Use**

Annex 13 **COMP opinions in 2007 on designation of orphan medicinal products**

Annex 14 **HMPC Community herbal monographs**

Annex 15 **Entries to the 'List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'**

Annex 16 **PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2007**

Annex 17 **Guidelines and working documents in 2007**

Annex 18 **Arbitration and Community referrals overview 2007**

Annex 19 **EMEA contact points**

Annex 1 Members of the Management Board

Chair: Pat O'MAHONY[5]
EMEA contact: Martin HARVEY ALLCHURCH

Members

European Parliament	Guiseppe NISTICÓ[6], Björn LEMMER[7] (*Substitute:* Jozef HOLOMÁŇ[8])
European Commission	Heinz ZOUREK, Andrzej RYŚ (*Alternates:* Georgette LALIS, Bernard MERKEL)
Belgium	Xavier DE CUYPER[9] (*Alternate:* André LHOIR[10])
Bulgaria	Emil IVANOV HRISTOV[11] (*Alternate:* Meri BORISLAVOVA PEYTCHEVA[12])
Czech Republic	Eva NIKLÍČKOVÁ[13] (*Alternate:* Jiří BUREŠ[14])
Denmark	Jytte LYNGVIG (*Alternate:* Paul SCHÜDER)
Germany	Walter SCHWERDTFEGER (*Alternate:* Hans-Peter HOFMANN[15])
Estonia	Kristin RAUDSEPP (*Alternate:* Alar IRS)
Ireland	Pat O'MAHONY (*Alternate:* Joan GILVARRY)
Greece	Dimitrios VAGIONAS (*Alternate:* Catherine MORAITI[16])
Spain	Cristina AVENDAÑO-SOLÀ[17] (*Alternate:* Teresa PAGES)
France	Jean MARIMBERT[18] (*Alternate:* Pascale BRIAND[19])
Italy	Nello MARTINI (*Alternate:* Silvia FABIANI)
Cyprus	Panayiota KOKKINOU (*Alternate:* George ANTONIOU[20])
Latvia	Inguna ADOVICA[21] (*Alternate:* Dace ĶIKUTE[22])
Lithuania	Aurelija KULČICKIENĖ-GUTIENĖ[23] (*Alternate:* Juozas JOKIMAS)
Luxembourg	Mariette BACKES-LIES (*Alternate:* Claude A HEMMER)
Hungary	Tamás L PAÁL (*Alternate:* Beatrix HORVÁTH)
Malta	Patricia VELLA BONANNO (*Alternate:* Kenneth MIFSUD)
Netherlands	Aginus A W KALIS (*Alternate:* Rob DE HAAN)
Austria	Marcus MÜLLNER (*Alternate:* Christian KALCHER)
Poland	Piotr BLASZCZYK (*Alternate:* Jacek SPLAWINSKI)

[5] Replaced Hannes WAHLROOS as of June 2007 meeting.
[6] Replaced Gianmartino BENZI as of June 2007 meeting.
[7] Replaced José-Luis VALVERDE LÓPEZ as of June 2007 meeting.
[8] As of June 2007 meeting.
[9] Replaced Johan van CALSTER as of June 2007 meeting.
[10] Replaced André PAUWELS as of October 2007 meeting.
[11] As of 1.January 2007.
[12] As of 1.January 2007.
[13] Replaced Milan ŠMÍD as of June 2007 meeting.
[14] Replaced Alfred HERA as of June 2007 meeting.
[15] Replaced Ilse-Dore SCHÜTT as of June 2007 meeting.
[16] Replaced Vassilis KONTOZAMANIS as of June 2007 meeting.
[17] Replaced Val DIEZ as of October 2007 meeting.
[18] Replaced Philippe DUNETON as of October 2007 meeting.
[19] Replaced Jean MARIMBERT as of October 2007 meeting.
[20] Replaced Louis PANAYI as of June 2007 meeting.
[21] As of June 2007 meeting.
[22] Replaced Inguna ADOVICA as of June 2007 meeting.
[23] Replaced Mindaugas PLIESKIS as of October 2007 meeting.

Portugal	Vasco A J MARIA (*Alternate:* Hélder MOTA FILIPE)
Romania	Magdalena BADULESCU[24] (*Alternate:* Rodica BADESCU[25])
Slovenia	Martina CVELBAR[26] (*Alternate:* Vesna KOBLAR)
Slovakia	Ján MAZÁG[27] (*Alternate:* Dagmar STARÁ[28])
Finland	Hannes Wahlroos (*Alternate:* Pekka JÄRVINEN)
Sweden	Gunar ALVÁN (*Alternate:* Anders BROSTRÖM)
United Kingdom	Kent WOODS (*Alternate:* Steve DEAN)
Representatives of patients' organisations	Mary BAKER, Jean GEORGES
Representative of doctors' organisations	Lisette TIDDENS-ENGWIRDA *(Vice-chair[29])*
Representative of veterinarians' organisations	Fritz Rupert UNGEMACH

Observers

Iceland	Rannveig GUNNARSDÓTTIR[30] (*Alternate:* Ingolf J PETERSEN[31])
Liechtenstein	Brigitte BATLINER (*Alternate:* Sabine ERNE[32])
Norway	Gro Ramsten WESENBERG (*Alternate:* Hans HALSE)

[24] As of 1 January 2007.
[25] As of 1 January 2007.
[26] Replaced Stanislav PRIMOŽIČ as of June 2007 meeting.
[27] Replaced Dagmar STARÁ as of June 2007 meeting.
[28] As of June 2007 meeting.
[29] Replaced Jytte LINGVIG as of June 2007 meeting.
[30] Replaced Ingolf J PETERSEN as of June 2007 meeting.
[31] Replaced Rannveig GUNNARSDÓTTIR as of June 2007 meeting.
[32] Replaced Peter MALIN as of December 2007 meeting.

Annex 2 Members of the Committee for Medicinal Products for Human Use

Chair: Eric ABADIE*
EMEA contact: Anthony HUMPHREYS

Member

- Viorel Robert ANCUCEANU (Romania)
  Alternate: Victoria SUBTIRICA
- John Joseph BORG (Malta)
  Alternate: Patricia VELLA BONANNO
- János BORVENDÉG (Hungary)
  Alternate: Agens GYURASICS
- Gonzalo CALVO ROJAS (Spain)
  Alternate: Concepcion PRIETO YERRO
- Pierre DEMOLIS[1] (France)
  Alternate: Philipe LECHAT[2]
- Nikolaos DRAKOULIS (Greece)
  Alternate George AISLAITNER
- Harald ENZMANN (Germany)
  Alternate: Karl BROICH
- Jacqueline GENOUX-HAMES (Luxembourg)
  Alternate: nomination awaited[3]
- Robert James HEMMINGS[4] (United Kingdom) *(co-opted)*
- Ian HUDSON (United Kingdom)
  Alternate: Rafe SUVARNA[5]
- Alar IRS (Estonia)
  Alternate: Irja LUTSAR[6]
- Arthur ISSEYEGH (Cyprus)
  Alternate: Panayiota KOKKINOU
- Pirjo LAITINEN-PARKKONEN[7] (Finland)
  Alternate: Outi LAPATTO-REINILUOTO[8]
- Metoda LIPNIK-STANGELJ (Slovenia)
  Alternate: Maja LUŠIN[9]
- David LYONS (Ireland)
  Alternate: Patrick SALMON
- Romaldas MAČIULAITIS (Lithuania)
  Alternate: Donatas STAKIŠAITIS
- Ján MAZÁG (Slovakia)
  Alternate: Karol KRALINKSY[10]
- Pieter NEELS (Belgium)
  Alternate: Bruno FLAMION
- Giuseppe NISTICÒ (Italy)
  Alternate: Pasqualino ROSSI
- Sif ORMARSDÓTTIR (Iceland)
  Alternate: Magnús JÓHANNSSON
- Ingemar PERSSON (Sweden) *(co-opted)*
- Michał PIROŻYŃSKI (Poland)
  Alternate: Piotr SIEDLECKI
- Heribert PITTNER (Austria)
  Alternate: Andrea LASLOP[11]
- Juris POKROTNIEKS (Latvia)
  Alternate: Natalja KARPOVA[12]
- Jean-Louis ROBERT (Luxembourg) *(co-opted)*
- Sol RUIZ[13] (Spain) *(co-opted)*
- Tomas SALMONSON (Sweden) *(vice-chair)*[14]
  Alternate: Bengt LJUNGBERG
- Christian SCHNEIDER[15] (Germany) *(co-opted)*
- Beatriz SILVA LIMA (Portugal)
  Alternate: Cristina SAMPAIO

* Replaced Daniel BRASSEUR as of June 2007 meeting.
[1] Replaced Eric ABADIE as of October 2007 meeting.
[2] Replaced Jean-Hugues TROUVIN as of October 2007 meeting.
[3] Nomination awaited following appointment of Jean-Louis ROBERT as co-opted member in September 2004.
[4] Elected as Co-opted member from March 2008.
[5] Replaced Matthew THATCHER (who in turn replaced Julia DUNNE in September 2007) as of February 2008 meeting.
[6] Replaced Raul KIIVET as of January 2007 meeting.
[7] Member as of March 2007 meeting.
[8] Replaced Pirjo LAITINEN-PARKONNEN as of October 2007 meeting.
[9] Replaced Barbara RAZINGER-MIHOVEC as of May 2007 meeting.
[10] Alternate member as of November 2007 meeting.
[11] Replaced Josef SUKO as of May 2007 meeting.
[12] Replaced Indulis PURVINŠ as of May 2007 meeting.
[13] Elected as Co-opted member from September 2007.
[14] Vice-chair as of June 2007 meeting.
[15] Co-opted member from September 2007.

- Eva SKOVLUND (Norway)
  Alternate: Liv MATHIESEN
- Dimiter TERZIIVANOV NIKOLOV (Bulgaria)
  Alternate: Ivanka ATANASOVA
- Steffen THIRSTRUP (Denmark)
  Alternate: Jens ERSBØLL
- Barbara VAN ZWIETEN-BOOT (Netherlands)
  Alternate: Pieter DE GRAEFF[16]
- Martin VOTAVA[17] (Czech Republic)
  Alternate: Ondřej SLANAŘ[18]

[16] Replaced Frits LEKKERKERKER as of June 2007 meeting.
[17] Replaced Milan ŠMÍD as of May 2007 meeting.
[18] Alternate member as of May 2007 meeting.

Scientific Advice Working Party
Chair: Bruno FLAMION
EMEA contact: Spiros VAMVAKAS

Biologics Working Party
Chair: Jean-Hugues TROUVIN
EMEA contact: John PURVES

Blood Products Working Party
Chair: Rainer SEIZ
EMEA contact: John PURVES

Cell-based Products Working Party
Chair: Paula SALMIKANGAS[1]
EMEA contact: John PURVES

Efficacy Working Party
Chair: Barbara VAN ZWIETEN-BOOT
EMEA contact: Xavier LURIA

Gene Therapy Working Party
Chair: Klaus CICHUTEK
EMEA contact: Marisa PAPALUCA AMATI

Joint CHMP/CVMP Quality Working Party
Chair: Jean-Louis ROBERT
EMEA contact: Emer COOKE

Pharmacogenetics Working Party
Chair: Eric ABADIE
EMEA contact: Marisa PAPALUCA AMATI

Pharmacovigilance Working Party
Chair: June RAINE
EMEA contact: Panos TSINTIS

Safety Working Party
Chair: Beatriz SILVA LIMA
EMEA contact: Xavier LURIA

Vaccine Working Party
Chair: Daniel BRASSEUR[2]
EMEA contact: John PURVES

Paediatric Working Party
(until June 2007; replaced by Paediatric Committee)
Chair: Daniel BRASSEUR
EMEA contact: Agnès SAINT-RAYMOND

Working Party on Similar Biological (Biosimilar) Medicinal Products
Chair: Pekka KURKI
EMEA contact: Marisa PAPALUCA AMATI

Scientific Advisory Group on Anti-infectives
Chair: Barbara BANNISTER
EMEA contact: Xavier LURIA

Scientific Advisory Group on Cardiovascular Issues
Chair: Henry DARGIE
EMEA contact: Xavier LURIA

Scientific Advisory Group on Central Nervous System
Chair: Michael DONAGHY
EMEA contact: Xavier LURIA

Scientific Advisory Group on Diabetes/Endocrinology
Chair: Edwin GALE
EMEA contact: Xavier LURIA

Scientific Advisory Group on Diagnostics
Chair: Jean-Noël TALBOT
EMEA contact: Xavier LURIA

Scientific Advisory Group on HIV/Viral Diseases
Chair: Ian WELLER
EMEA contact: Xavier LURIA

Scientific Advisory Group on Oncology
Chair: Michel MARTY
EMEA contact: Xavier LURIA

Invented Name Review Group
Chair: Zaïde FRIAS
EMEA contact: Zaïde FRIAS

EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations
Chair: Frits LEKKERKERKER/Isabelle MOULON
EMEA contact: Isabelle MOULON

[1] Replaced Pekka KURKI as of December 2007 meeting.
[2] Replaced Roland DOBBELAER as of May 2007 meeting.

EMEA/CHMP Working Group with Healthcare Professionals' Organisations
Chair: Noël WATHION/Giuseppe NISTICO
EMEA contact: Isabelle MOULON

Working Group on Quality Review of Documents
Chair: Isabelle MOULON
EMEA contact: Isabelle MOULON

Annex 3 Members of the Committee for Medicinal Products for Veterinary Use

Chair: Gérard MOULIN
EMEA contact: David MACKAY

Members

- Birgit AASMÄE (Estonia)
  Alternate: Helen MAHLA
- Gabriel BEECHINOR (Ireland)
  Alternate: David MURPHY
- Rory BREATHNACH (Ireland)
  (co-opted)
- Jiří BUREŠ[1] (Czech Republic)
  Alternate: Alfred HERA[2]
- Peter EKSTRÖM[3] (Sweden) *(co-opted)*
- Christian FRIIS (Denmark) *(co-opted)*
- Irmeli HAPPONEN[4] (Finland)
  Alternate: Tita-Maria MUHONEN
- Judita HEDEROVÁ (Slovakia)
  Alternate: Eva CHOBOTOVA
- Anja HOLM (Denmark) *(vice-chair)*
  Alternate: Ellen-Margrethe VESTERGAARD
- Tonje HØY (Norway)
  Alternate: Hanne BERGENDAHL
- Laimis JODKONIS (Lithuania)
  Alternate: Juozas JOKIMAS
- Charalambos KAKOYIANNIS[5] (Cyprus)
  Alternate: Ioanna TALIOTI
- Ruth KEARSLEY[6] (United Kingdom)
  Alternate: Martin ILOTT[7]
- Boris KOLAR[8] (Slovenia) *(co-opted)*
- Reinhard KROKER (Germany)
  Alternate: Manfred MOOS
- Ioannis MALEMIS (Greece)
  Alternate: Georgios BATZIAS[9]
- Kenneth MIFSUD (Malta)
  Alternate: Joseph VELLA
- Cristina MUÑOS MADERO (Spain)
  Alternate: Consuelo Rubio MONTEJANO
- Eugen OBERMAYR (Austria)
  Alternate: Jean-Pierre BINDER
- Sigurður ÖRN HANSSON (Iceland)
  Alternate: Halldór RUNÓLFSSON
- Maria Helena PONTE (Portugal)
  Alternate: Berta Maria Fernandes[10]
- Jean-Claude ROUBY (France)
  Alternate: Michael HOLZHAUSER-ALBERTI
- G Johan SCHEFFERLIE[11] (Netherlands)
- Wilhelm SCHLUMBOHM[12] (Germany) *(co-opted)*
- Valda SEJANE[13] (Latvia)
- Tibor SOÓS (Hungary)
  Alternate: Gábor KULCSÁR
- Stane SRČIČ (Slovenia)
  Alternate: Katarina STRAUS[14]
- Lollita Sanda Camelia TABAN (Romania)
  Alternate: Simona STURZU
- Karolina TÖRNEKE (Sweden)
  Alternate: Henrik HOLST
- Maria TOLLIS (Italy)
  Alternate: Virgilio DONINI
- Bruno URBAIN (Belgium)
  Alternate: Frédéric DESCAMPS[15]
- Marc WIRTOR (Luxembourg)
  Alternate: Maurice HOLPER
- Paskal Todorov ZHELYAZKOV (Bulgaria). *Alternate*: Ilian GETCHEV
- Franciszek ŻMUDZIŃSKI[16] (Poland)

[1] Replaced Alfred Hera in June 2007.
[2] Replaced Jiří Bures in June 2007.
[3] Until November 2007.
[4] Replaced Liisa Kaartinen in January 2007.
[5] Replaced Giorgos Neophytou in October 2007.
[6] Replaced Martin Ilott in March 2007.
[7] Replaced Lesley Anne Johnson in March 2007.
[8] Since November 2007.
[9] Replaced Orestis Papadopoulos in August 2007.
[10] Replaced Leonor Maria Meisel in September 2007.
[11] Replaced Johannes P Hoogland in March 2007.
[12] Since November 2007.
[13] Replaced Arvils Jakovskis in May 2007.
[14] Replaced Blanka Emersic in June 2007.
[15] Replaced Lionel Laurier in June 2007.

[16] Replaced Katarzyna Krzyżańska in June 2007.

Working parties, ad hoc groups and scientific advisory groups

Efficacy Working Party
Chair: Michael HOLZHAUSER-ALBERTI
EMEA contact: Jill ASHLEY-SMITH

Immunologicals Working Party
Chair: Jean-Claude ROUBY
EMEA contact: Jill ASHLEY-SMITH

Pharmacovigilance Working Party
Chair: Cornelia IBRAHIM
EMEA contact: Kornelia GREIN

Joint CHMP/CVMP Quality Working Party
Chair: Jean-Louis ROBERT
EMEA contact: Emer COOKE

Safety Working Party
Chair: Johan G SCHEFFERLIE
EMEA contact: Kornelia GREIN

Scientific Advice Working Party
Chair: Rory BREATHNACH
EMEA contact: Jill ASHLEY-SMITH

Scientific Advisory Group on Antimicrobials
Chair: Karolina TÖRNEKE
EMEA contact: Kornelia GREIN

Environmental Risk Assessment (temporary working party)
Chair: Joop A DE KNECHT
EMEA contact: Kornelia GREIN

Annex 4 Members of the Committee for Orphan Medicinal Products

Chair: Kerstin WESTERMARK
EMEA contact: Agnès SAINT RAYMOND

Members

- Björn BEERMANN[1] (Sweden)
- Brigitte BLÖCHL-DAUM (Austria)
- Andrew BORG[2] (Malta)
- Heidrun BOSCH-TRABERG (Denmark)
- Vessela BOUDINOVA[3] (Bulgaria)
- Birthe BYSKOV HOLM (patients' organisation representative) *(vice-chair)*
- Yann LE CAM (patients' organisation representative)
- Ana CORRÊA NUNES (Portugal)
- Bożenna DEMBOWSKA-BAGIŃSKA (Poland)
- Julia DUNNE[4] (EMEA representative)
- Judit EGGENHOFER (Hungary)
- Rembert ELBERS (Germany)
- Pauline EVERS (patients' organisation representative)
- Lars GRAMSTAD (Norway)
- Evija GULBE (Latvia)
- Emmanuel HÉRON (France)
- Ioannis KKOLOS (Cyprus)
- Kateřina KUBÁČKOVÁ (Czech Republic)
- Magdaléna KUŽELOVÁ (Slovakia)
- André LHOIR (Belgium)
- David LYONS (EMEA representative)
- Greg MARKEY (United Kingdom)
- Aušra MATULEVIČIENĖ (Lithuania)
- Henri METZ (Luxembourg)
- Martin MOŽINA (Slovenia)
- Veijo SAANO (Finland)
- Flavia SALEH (Romania) [5]
- Patrick SALMON (Ireland)
- Miranda SIOUTI (Greece)
- Domenica TARUSCIO (Italy)
- Sigurður B. THORSTEINSSON (Iceland)
- Vallo TILLMANN (Estonia)
- Josep TORRENT-FARNELL (Spain)
- Bettie VOORDOUW (the Netherlands)

[1] Joined the Committee as of February 2007 meeting.
[2] Resigned in August 2007.
[3] Replaced Detelina IVANOVA as of October 2007 meeting.
[4] Resigned in August 2007.
[5] Replaced Daniela STANCIU as of December 2007 meeting.

Working parties and ad hoc groups

Working Group with Interested Parties
Chair: Yann LE CAM/Agnès SAINT RAYMOND
EMEA contact: Frida RIVIERE

Significant Benefit ad hoc Group
Chair: Kerstin WESTERMARK
EMEA contact: Jordi LLINARES-GARCIA

Annex 5 Members of the Committee on Herbal Medicinal Products

Chair: Konstantin KELLER
EMEA contact: Anthony HUMPHREYS

Members

- Linda ANDERSON (United Kingdom)
  Alternate: Sue HARRIS
- Mariette BACKES-LIES (Luxembourg)
  Alternate: Jacqueline GENOUX-HAMES
- Steffen BAGER (Denmark)
  Alternate: Kristine HVOLBY
- Zsuzsanna BIRÓ-SÁNDOR (Hungary)
  Alternate: Nóra Piroska FÜLÖP[1]
- Per CLAESON (Sweden)
  Alternate: Ubonwan CLAESON
- Caroline ATTARD[2] (Malta)
  Alternate: Everaldo ATTARD[3]
- Cora NESTOR[4] (Ireland)
  Alternate: Sinead HARRINGTON[5]
- Michal RÓŻAŃSKI[6] (Poland)
  Alternate: Iwona Dróżdż-Jablońska[7]
- Anneli TÖRRÖNEN (Finland)
  Alternate: Sari KOSKI
- Emiel VAN GALEN (Netherlands)
  Alternate: Burt H KROES
- Gloria GARCÍA LORENTE (Spain)
  Alternate: Adela Núñez Velázquez[8]
- Ioanna CHINOU (Greece) *(vice-chairman)*
  Alternate: Eleni SKALTSA
- Marie HEROUTOVÁ (Czech Republic)
  Alternate: Helena LÁTALOVÁ[9]
- Thorbjörg KJARTANDSDÓTTIR (Iceland)
  Alternate: Sesselja ÓMARSDOTTIR
- Peter POTÚČEK[10] (Slovakia)
  Alternate: Milan NAGY[11]

[1] Alternate member as of September 2007 meeting.
[2] Replaced Christian CUSCHIERI as of January 2007 meeting.
[3] Replaced Caroline ATTARD as of September 2007 meeting.
[4] Replaced Dairíne DEMPSEY as of January 2007 meeting.
[5] Replaced Cora NESTOR as of January 2007 meeting.
[6] Replaced Wojciech DYMOWSKI as of October 2007 meeting.
[7] Replaced Elżbieta WOJTASIK as of October 2007 meeting.
[8] Replaced Adela VELÁZQUEZ as of October 2007 meeting.
[9] Alternate member as of July 2007 meeting.
[10] Replaced Dáša SALUGOVÁ as of January 2007 meeting.
[11] Replaced Pavol MUČAJI as of March 2007 meeting.

- Artūras KAŽEMEKAITIS (Lithuania)
  Alternate: Kristina RAMANAUSKIENĖ[12]
- Steinar MADSEN (Norway)
  Alternate: Gro FOSSUM
- Ana Paula MARTINS (Portugal)
  Alternate: Maria Helena PINTO FERREIRA
- Samo KREFT (Slovenia)
  Alternate: Barbara RAZINGER-MIHOVEC
- Dailonis PAKALNS (Latvia)
  Alternate: Dace KALKE
- Heribert PITTNER (Austria)
  Alternate: Reinhard LÄNGER[13]
- Werner KNÖSS (Germany)
  Alternate: Christine WERNER
- Marje ZERNANT (Estonia)
  Alternate: Ain RAAL
- Antoine SAWAYA (France)
  Alternate: Jacqueline VIGUET POUPELLOZ
- Marisa DELBÓ[14] (Italy)
  Alternate: Monica CAPASSO[15]
- Panayiotis Triantafyllis (Cyprus)
  Alternate: Maria STAVROU
- Heidi NEEF[16] (Belgium)
  Alternate: Arnold J Vlietinck[17]
- Stefan NIKOLOV (Bulgaria)
  Alternate: Elena MUSTAKEROVA
- Maria NICULESCU (Romania)
  Alternate: Robert ANCUCEANU[18]

Co-opted members

- Ulrike WISSINGER-GRÄFENHAHN (Germany)
- Olavi PELKONEN (Finland)
- Gert LAEKEMAN (Belgium)
- Kurt WIDHALM (Austria)

[12] Alternate member as of September 2007 meeting.
[13] Replaced Wolfgang KUBELKA as of October 2007 meeting.
[14] Replaced Vittorio SILANO as of October 2007 meeting.
[15] Replaced Marisa DELBÓ as of October 2007 meeting.
[16] Replaced Arnold J VLIETINCK as of October 2007 meeting.
[17] Alternate member as of October 2007 meeting.
[18] Replaced Laurentia RUSCAN as of October 2007 meeting.

Observers

- Michael WIERER (EDQM)
- Melanie BALD[19] (EDQM)
- Josipa CVEK[20] (Croatia)
- Ivan KOSALEC[21] (Croatia)
- Meral GÜNDOĞAN[22] (Turkey)
- Mehtap VAREL[23] (Turkey)
- Yasemin SAZAK[24] (Turkey)

Working parties, ad hoc groups and Scientific Advisory Groups

Working party on Community Monographs and Community List
Chair: Heribert PITTNER
EMEA contact: Anthony HUMPHREYS

Organisational Matters Drafting Group
Chair: Emiel VAN GALEN
EMEA contact: Anthony HUMPHREYS

Quality Drafting Group
Chair: Burt KROES[25] Dairíne DEMPSEY
EMEA contact: Anthony HUMPHREYS

[19] Replaced Ellen PEL as of January 2007 meeting.
[20] Observer as of January 2007 meeting.
[21] Observer as of January 2007 meeting.
[22] Observer as of January 2007 meeting.
[23] Observer as of January 2007 meeting.
[24] Observer as of March 2007 meeting.
[25] Replaced Dairíne DEMPSEY as of January 2007 meeting.

Annex 6 Members of the Paediatric Committee

Chair: Daniel BRASSEUR
EMEA contact: Agnès SAINT RAYMOND

Members

- Alar IRS (CHMP, Estonia)
  Alternate: Irja LUTSAR
- Romaldas MAČIULAITIS (CHMP, Lithuania)
  Alternate: Donatas STAKIŠAITIS
- Robert ANCUCEANU (CHMP, Romania)
  Alternate: Victoria SUBTIRICA
- Jan MAZAG (CHMP, Slovakia)
  Alternate: Karol KRALINSKI
- Ian HUDSON (CHMP, United Kingdom)
  Alternate: Matthew THATCHER
- Christoph MALE (Austria)
  Alternate: Thomas FRISCHER
- Hugo DEVLIEGER (Belgium)[1]
  Alternate: Christophe LAHORTE
- Margarita GUIZOVA (Bulgaria)
  Alternate: Dobrin KONSTANTINOV
- Eleni TOFARIDOU (Cyprus)
  Alternate: pending
- Hubert MOTTL (Czech Republic)
  Alternate: Peter SZITANYI
- Marianne ORHOLM (Denmark)
  Alternate: Karen TORNØE
- Maria VIRKKI (Finland)
  Alternate: Jaana JOENSUU
- Gérard PONS (France) *Vice Chair*
  Alternate: Sophie FORNAIRON
- Dirk MENTZER (Germany)
  Alternate: Birka LEHMANN
- Christos KATTAMIS (Greece)[2]
  Alternate: Angeliki ROBOTI[3]
- Lajos KOSAS (Hungary)
  Alternate: pending
- Kevin CONNOLLY (Ireland)
  Alternate: Yvonne LOONEY
- Paolo ROSSI (Italy)
  Alternate: Francesca ROCCHI
- Dina APELE-FREIMANE (Latvia)
  Alternate: Ilze BĀRENE
- Carine de BEAUFORT (Luxembourg)
  Alternate: pending
- John Joseph BORG (Malta)
  Alternate: Herbert LENICKER
- Johannes TAMINIAU (The Netherlands)
  Alternate: Hendrik van den BERG
- Marek MIGDAL (Poland)
  Alternate: Mieczyslaw LITWIN
- Helena FONSECA (Portugal)
  Alternate: Cristina TRINDADE
- Janez JAZBEC (Slovenia)
  Alternate: Tadej BATTELINO
- Fernando de ANDRÉS TRELLES (Spain)
  Alternate: Maria Jesús FERNÁNDES CORTIZO
- Marta GRANSTRÖM (Sweden)
  Alternate: Marie JOHANNESSON
- Gylfi OSKARSSON (Iceland)
  Alternate: pending
- Siri WANG (Norway)
  Alternate: Ingvild AALØKEN

[1] Replaced Daniel Brasseur, September 2007.
[2] Replaced Andreas Papapetropoulus, October 2007.
[3] Replaced Katerina Karamani-Kehagia, November 2007.

Annex 7 National competent authority partners

Further information on the national competent authorities is also available on the national authorities' Internet sites: http://www.hma.eu/human_heads.html and http://www.hma.eu/veterinary_heads.html

BELGIUM

Xavier DE CUYPER
Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten - Agence Fédérale des Médicaments et des Produits de Santé
Eurostation Blok 2
Victor Hortaplein 40 bus 40
Eurostation Bloc 2 - 8D030
place Victor Horta, 40 / 40
B-1060 Brussels - Bruxelles

Tel. (32-2) 524 84 00
Fax (32-2) 524 80 03
E-Mail: xavier.decuyper@fagg-afmps.be

BULGARIA

Emil IVANOV HRISTOV
General Executive
Изпълнителна агенция по лекарствата
26 Yanko Sakazov Blvd
BG – 1504 Sofia

Tel. (359-2) 943 40 46
Fax (359-2) 943 44 87
E-Mail: hristov@bda.bg

Jeko BAICHEV
Национална ветеринарномедицинска служба
National Veterinary Service
бул. "Пенчо Славейков" № 15А
15a, Pencho Slaveykov Blvd.
BG – 1606 Sofia

Tel. (359-2) 91 59 821
Fax (359-2) 91 59 846
E-Mail: j.baichev@nvms.government.bg

CZECH REPUBLIC

Martin BENEŠ
Director
Státní ústav pro kontrolu léčiv
Šrobárova 48
CZ – 100 41 Praha 10

Tel. (420-2) 72 18 58 34
Fax (420-2) 72 73 99 95
E-Mail: martin.benes@sukl.cz
Internet: http://www.sukl.cz

Alfred HERA
Director
Ústav pro státní kontrolu veterinárních biopreparátů a léčiv
Hudcova 56a
Medlánky
CZ – 621 00 Brno

Tel. (420-541) 21 00 22
Fax (420-541) 21 26 07
E-mail: hera@uskvbl.cz
Internet: http://www.uskvbl.cz

DENMARK

Jytte LYNGVIG
Direktør
Lægemiddelstyrelsen
Axel Heides Gade 1
DK – 2300 København S

Tel. (45-44) 88 95 95
Fax (45-44) 88 95 99
E-mail: jyl@dkma.dk
Internet: http://www.dkma.dk

GERMANY

Johannes LÖWER
Präsident
Bundesamt für Sera und Impfstoffe
Paul-Ehrlich-Institut
Paul-Ehrlich Straße 51-59
D – 63225 Langen

Tel. (49-6103) 77 10 00
Fax (49-6103) 77 12 40
E-mail: loejo@pei.de
Internet: http://www.pei.de

Reinhard KROKER
Leiter des Fachbereichs
Bundesamt für Verbraucherschutz und
Lebensmittelsicherheit
Diedersdorfer Weg 1
D – 12277 Berlin

Tel. (49-1888) 412 23 64
Fax (49-1888) 412 29 65
E-mail: reinhard.kroker@bvl.bund.de
Internet: http://www.bvl.bund.de

Reinhard KURTH
Kommissarischer Leiter
Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM)
Kurt-Georg-Kiesinger-Allee 3
D – 53175 Bonn

Tel. (49-228) 207 32 03
Fax (49-228) 207 55 14
E-mail: kurth@bfarm.de
Internet: http://www.bfarm.de

ESTONIA

Kristin RAUDSEPP
Director Gerneral
Ravimiamet
Nooruse 1
50411 Tartu

Tel. (372-7) 37 41 40
Fax (372-7) 37 41 42
E-mail: kristin.raudsepp@ravimiamet.ee
Internet: http://www.ravimiamet.ee

GREECE

Dimitrios VAGIONAS
President
National Organization for Medicines
284 Mesogeion Av.
Holargos
GR – 155 62 Athens

Tel. (30-210) 650 72 16
Fax (30-210) 654 95 86
E-mail: president@eof.gr
Internet: http://www.eof.gr

SPAIN

Cristina AVENDAÑO SOLÁ
Director
Agencia Española de Medicamentos y Productos Sanitarios
Calle Alcalá 56
E – 28071 Madrid

Tel. (34-91) 822 50 44
Fax (34-91) 822 50 10
E-mail: sdaem@agemed.es
Internet: http://www.agemed.es

FRANCE

Jean MARIMBERT
Directeur Général
Agence Française de Sécurité Sanitaire des Produits de Santé
143-147, boulevard Anatole France
F – 93285 Saint-Denis Cedex

Tel. (33-1) 55 87 30 14
Fax (33-1) 55 87 30 12
E-mail: jean.marimert@afssaps.sante.fr
Internet: http://afssaps.sante.fr

Patrick DEHAUMONT
Directeur ANMV
Agence Française de Sécurité Sanitaire des Aliments
Laboratoire des Médicaments Vétérinaires
BP 90 203 Javené
F – 35302 Fougères Cedex

Tel. (33-2) 99 94 78 71
Fax (33-2) 99 94 78 99
E-mail: p.dehaumont@anmv.afssa.fr
Internet: http://www.afssa.fr

IRELAND

Pat O'MAHONY
Chief executive officer
Irish Medicines Board - Bord Leigheasra na hÉirann
Earlsfort Centre
Earlsfort Terrace
IRL – Dublin 2

Tel. (353-1) 676 49 71
Fax (353-1) 661 47 64
E-mail: pat.omahony@imb.ie
Internet: http://www.imb.ie

ITALY

Nello MARTINI
Direttore Generale del Agenzia Italiana del Farmaco
Viale della Sierra Nevada 60
I – 00144 Roma

Tel. (39-06) 59 78 42 05
Fax (39-06) 59 78 40 54
E-mail: n.martini@sanita.it
Internet: http://www.agenziafarmaco.it

Romano MARABELLI
Direttore Generale
Ministero della Salute
Servizi Veterinari Roma
Piazzale Marconi 25
I – 00144 Roma

Tel. (39-06) 59 94 69 45
Fax (39-06) 59 94 62 17
E-mail: alimentivet@sanita.it
Internet: http://www.ministerosalute.it

Enrico GARACI
President
Istituto Superiore di Sanità
Viale Regina Elena 299
IT – 00161 Roma

Tel. (39-06) 44 86 94 55
Fax (39-06) 44 86 94 40
E-mail: presidenza@iss.it
Internet: http://www.iss.it

CYPRUS

Panayiota KOKKINOU
Ministry of Health
Pharmaceutical services
7 Larnakas Avenue
CY – 1475 Lefkosia

Tel. (357-22) 40 71 03
Fax (357-22) 40 71 49
E-mail: pkokkinou@phs.moh.gov.cy
Internet: http://moi.gov.cy

Giorgos NEOPHYTOU
Ministry of Agriculture, Natural Resources and Environment
Athalassa
CY – 1417 Nicosia

Tel. (357-22) 80 52 00/1
Fax (357-22) 30 52 11
E-Mail: gneophytou@vs.moa.gov.cy
Internet: http://www.moa.gov.cy

LATVIA

Inguna ADOVIČA
Director
Valsts zāļu aģentūra
Jersikas iela 15
LV – 1003 Riga IV

Tel. (371-70) 784 24
Fax (371-70) 784 28
E-mail: info@vza.gov.lv
Internet: http://www.vza.gov.lv

Vinets VELDRE
Pārtikas un veterinārais dienests
Republikas laukums 2
LV – 1010 Riga

Tel. (371-70) 952 30
Fax (371-73) 227 27
E-mail: pvd@pvd.gov.lv
Internet: http://www.pvd.gov.lv

LITHUANIA

Aurelija KULČICKIENĖ GUTIENĖ
Director
Valstybinė vaistų kontrolės tarnyba
Traku g. 14
LT – 01132 Vilnius

Tel. (370-5) 263 92 64
Fax. (370-5) 263 92 65
E-mail: vvkt@vvkt.lt
Internet: http://www.vvkt.lt

Juozas JOKIMAS
Director
Valstybinė maisto ir veterinarijos tarnyba
J. Naujalio g. 21B
LT – 3026 Kaunas 26s

Tel. (370-37) 31 15 58
Fax (370-37) 36 12 41
E-mail: vet.prep.lab@vet.lt
Internet: http://www.vet.lt

LUXEMBOURG

Mariette BACKES-LIES
Pharmacien-Inspecteur - Chef de Division
Ministère de la Santé
Direction de la Santé
Division de la Pharmacie et des Médicaments
Villa Louvigny – 1er étage
Parc de la Ville – Allée Marconi
L – 2120 Luxembourg

Tel. (352) 478 55 90
Fax (352) 26 20 01 47
E-mail: luxdpm@ms.etat.lu
Internet: http://www.ms.etat.lu

HUNGARY

Tamás PAÁL
Director General
Országos Gyógyszer Intézet
Zrínyi U. 3
HU – 1051 Budapest

Tel. (36-1) 317 40 44
Fax (36-1) 317 14 88
E-mail: tpaal@ogyi.hu
Internet: http://www.ogyi.hu

Tibor SOÓS
Director
Institute for Veterinary Medicinal Products
Szállás u. 8
HU – 1107 Budapest

Tel. (36-1) 433 03 45
Fax (36-1) 262 28 39
E-mail: soos@oai.hu
Internet: http://www.ivmp.gov.hu

MALTA

Patricia VELLA BONANNO
Medicines Authority
198 Rue D'Argens
MT – GRZ 003 Gzira

Tel. (356-23) 43 90 00
Fax (356-23) 43 91 61
E-mail: patricia.vella@gov.mt
Internet: http://www.gov.mt

Joseph VELLA
Ministry for Rural Affairs and the Environment
Food and Veterinary Regulation Division
The Abattoir
Albert Town
MT – CMR 02 Marsa

Tel. (356-21) 24 26 94
Fax (356-21) 23 81 05
E-mail: joseph-john.vella@gov.mt
Internet: http://www.gov.mt

NETHERLANDS

Aginus A W KALIS
Executive Director
College Ter Beoordeling van Geneesmiddelen
Agentschap
Kalvermarkt 53
Postbus 16229
NL – 2500 CB Den Haag

Tel. (31-70) 356 74 00
Fax (31-70) 356 75 15
E-mail: aaw.kalis@cbg-meb.nl
Internet: http://www.cbg-meb.nl

AUSTRIA

Hubert HRABCIK
Bundesministerium für Gesundheit und Frauen
Radetzkystraße 2
A – 1030 Wien

Tel. (43-1) 711 00 47 17
Fax (43-1) 711 00 48 30
E-mail: hubert.hrabcik@bmgf.gv.at
Internet: http://www.bmgf.gv.at

Marcus MÜLLNER
Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES)
Schnirchgasse 9
A – 1030 Vienna

Tel. (43-50) 55 53 60 00
Fax (43 50) 55536009
E-Mail: marcus.muellner@ages.at
Internet: http://www.ages.at/

POLAND

Leszek BORKOWSKI
Urząd Rejestracji Produktów Leczniczych
Wyrobow Medycznych i Produktów
Biobójczych
Ząbkowska 41
PL – 03-736 Warszawa

Tel. (48-22) 492 11 00
Fax (48-22) 492 11 09
E-Mail: justyna.madejska@urpl.gov.pl
Internet: http://www.urpl.gov.pl

Monika MARCZAK
Urząd Rejestracji Produktów Leczniczych,
Wyrobow Medycznych i Produktów
Biobójczych
ul. Ząbkowska 41
PL – 03-736 Warszawa

Tel. (48-22) 492 11 00
Fax (48-22) 492 11 09
E-Mail : monika.marczak@urpl.gov.pl
Internet: http://www.urpl.gov.pl

PORTUGAL

Vasco de JESUS MARIA
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (INFARMED)
Parque de Saúde de Lisboa
Av. do Brasil, 53
PT – 1749-004 Lisboa

Tel. (351-21) 798 71 09
Fax (351-21) 798 71 20
E-mail: vasco.maria@infarmed.pt
Internet: http://www.infarmed.pt

Carlos AGRELA PINHEIRO
Direcção Geral de Veterinária
Largo da Academia Nacional de Belas Artes, 2
PT – 1249-105 Lisboa

Tel. (351-21) 323 95 00
Fax (351-21) 346 35 18
E-mail: dirgeral@dgv.min-agricultura.pt
Internet: http://www.min-agricultura.pt

ROMANIA

Mrs Magdalena Badulescu
Nationa Medicines Agency
Str. Aviator Sănătescu 48
Sector 1
RO – 011478 Bucharest

Tel. (402-13) 16 10 79
Fax (402-13) 16 34 97
E-Mail : magdalena.badulescu@anm.ro

Gabriel PREDOI
National Sanitary Veterinary and Food Safety Authority
Str. Negostori nr.1 bis
Sector 2
RO – 023951 Bucharest

Tel. (402-13) 15 78 75
Fax (402-13) 12 49 67
E-Mail: predoi@ansv.ro

Razvan TIRU
National Sanitary Veterinary and Food Safety Authority
Str. Negostori nr.1 bis
Sector 2
RO – 023951 Bucharest

Tel. (402-13) 15 78 75
Fax (402-13) 12 49 67
E-Mail: tiru@ansv.ro

SLOVENIA

Martina CVELBAR
Director
Javna agencija Republike Slovenije za zdravila in medicinske pripomočke
Ptujska ulica 21
SI - 1000 Ljubljana

Tel. (386-8) 20 00 508
Fax (386-8) 20 00 510
E-Mail: martina.cvelbar@jazmp.si
Internet: http://www.jazmp.si

Vesna KOBLAR
Deputy Director
Javna agencija Republike Slovenije za zdravila in medicinske pripomočke
Ptujska ulica 21
SI - 1000 Ljubljana

Tel. (386-1) 20 00 502
Fax (386-1) 20 00 510
E-mail: vesna.koblar@jazmp.si
Internet: http://www.jazmp.si

SLOVAKIA

Ján MAZÁG
Director
Štátny ústav pre kontrolu liečiv
Kvetná 11
SK – 825 08 Bratislava 26

Tel. (421-2) 50 70 11 19
Fax (421-2) 55 56 41 27
E-mail: martinec@sukl.sk
Internet: http://www.sukl.sk

Ladislav SOVÍK
Director
Ústav štátnej kontroly veterinárnych biopreparátov a liečiv
Biovetská 4
SK – 949 01 Nitra

Tel. (421-37) 651 55 03
Fax (421-37) 651 79 15
E-mail: uskvbl@flynet.sk
Internet: http://www.uskvbl.sk

FINLAND

Hannes WAHLROOS
Director General
Lääkelaitos
Mannerheimintie 103b
FIN – 00300 Helsinki

Tel. (358-9) 47 33 42 00
Fax (358-9) 47 33 43 45
E-mail: hannes.wahlroos@nam.fi
Internet: http://www.nam.fi

Pekka KURKI
Lääkelaitos
P.O.Box 55
Mannerheiminitie 103b
FIN – 00301 Helsinki

Tel. (358-9) 47 33 42 25
Fax (358-9) 47 33 43 50
E-Mail : pekka.kurki@nam.fi
Internet: http://www.nam.fi

SWEDEN

Gunnar ALVÁN
Generaldirektör
Läkemedelsverket
Dag Hammarskjölds väg 42
S – 751 83 Uppsala

Tel. (46-18) 17 46 00
Fax (46-18) 54 85 66
E-mail: gunnar.alvan@mpa.se
Internet: http://www.mpa.se

UNITED KINGDOM

Kent WOODS
Chief Executive
Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
UK – London SW8 5NQ

Tel. (44-20) 70 84 25 46
Fax (44-20) 70 84 25 48
E-mail: kent.woods@mhra.gsi.gov.uk
Internet: http://www.mhra.gov.uk

Steve DEAN
Chief Executive
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone
UK – Surrey KT15 3LS

Tel. (44-1932) 33 83 01
Fax (44-1932) 33 66 18
E-mail: s.dean@vmd.defra.gsi.gov.uk
Internet: http://www.vmd.gov.uk

ICELAND

Rannveig GUNNARSDÓTTIR
Director
Lyfjastofnun
Eidistorg 13-15
PO Box 180
IS – 172 Seltjarnarnes

Tel. (354) 520 21 00
Fax (354) 561 21 70
E-mail: rannveig.gunnarsdottir@lyfjastofnun.is
Internet: http://www.lyfjastofnun.is

LIECHTENSTEIN

Brigitte BATLINER
Kontrollstelle für Arzneimittel, beim Amt für
Lebensmittelkontrolle und Veterinärwesen
Postplatz 2
Postfach 37
FL – 9494 Schaan

Tel. (423) 236 73 25
Fax (423) 236 73 10
E-mail: brigitte.batliner@alkvw.llv.li
Internet: http://www.llv.li

NORWAY

Gro Ramsten WESENBERG
Director General
Statens legemiddelverk
Sven Oftedals vei 8
N – 0950 Oslo

Tel. (47-22) 89 77 01
Fax (47-22) 89 77 99
E-mail: gro.wesenberg@legemiddelverket.no
Internet: http://www.legemiddelverket.no
http://www.noma.no

Annex 8 EMEA budget summaries 2006–2008

The summarised comparative budget statements for 2006 to 2008 are as follows:

		2006		2007[1]		2008[2]	
		€ '000	%				
Revenue							
Fees		92,580	*66.76*	108,570	*66.56*	126,318	*72.89*
General EU contribution		22,000	*15.87*	19,813	*12.15*	16,816	*9.70*
EU contribution for SME policy				3,895	*2.39*	3,702	*2.14*
EU contribution for Paediatrics policy		n/a	*0.00*	2,022	*1.24*	2,710	*1.56*
EU contribution for IT Telematics strategy		8,000	*5.77*	13,914	*8.53*	8,772	*5.06*
Special EU contribution for orphan medicinal products		7,400	*5.34*	6,000	*3.68*	6,000	*3.46*
Contribution from EEA		650	*0.47*	904	*0.55*	765	*0.44*
Community programmes		760	*0.55*	706	*0.43*	600	*0.35*
Other		7,286	*5.25*	7,289	*4.47*	7,624	*4.40*
TOTAL REVENUE		**138,676**	*100.00*	**163,113**	*100.00*	**173,307**	*100.00*
Expenditure							
Staff							
11	Staff in active employment	41,376	*29.84*	47,259	*28.97*	54,411	*31.40*
13	Mission expenses	586	*0.42*	660	*0.40*	639	*0.37*
14	Socio-medical infrastructure	440	*0.32*	459	*0.28*	603	*0.35*
15	Exchange of civil servants and experts	1,119	*0.81*	1,205	*0.74*	2,437	*1.41*
16	Social welfare	155	*0.11*	55	*0.03*	55	*0.03*
17	Entertainment and representation expenses	31	*0.02*	37	*0.02*	38	*0.02*
18	Staff insurances	1,214	*0.88*	1,457	*0.89*	1,657	*0.96*
	Total Title 1	*44,921*	*32.39*	***51,132***	*31.35*	***59,840***	*34.53*
Building/equipment							
20	Investment in immovable property, renting of building and ass costs	17,260	*12.45*	16,740	*10.26*	15,618	*9.01*
21	Expenditure on data processing	14,623	*10.54*	25,460	*15.61*	20,502	*11.83*
22	Movable property and ass costs	1,057	*0.76*	3,148	*1.93*	1,617	*0.93*
23	Other administrative expenditure	756	*0.55*	792	*0.49*	861	*0.50*
24	Postage and communications	684	*0.49*	983	*0.60*	1048	*0.60*
25	Expenditure on formal and other meetings	74	*0.05*	75	*0.05*	79	*0.05*
	Total Title 2	*34,454*	*24.84*	***47,198***	*28.94*	***39,725***	*22.92*
Operational expenditure							
300	Meetings	6,355	*4.58*	7,144	*4.38*	8,156	*4.71*
301	Evaluations	49,827	*35.93*	53,632	*32.88*	60,406	*34.85*
302	Translation	2,215	*1.60*	3,183	*1.95*	4,001	*2.31*
303	Studies and consultants	170	*0.12*	100	*0.06*	80	*0.05*
304	Publications	124	*0.09*	74	*0.05*	499	*0.29*
305	Community programmes	610	*0.44*	650	*0.40*	600	*0.35*
	Total Title 3	*59,301*	*42.76*	***64,783***	*39.72*	***73,742***	*42.55*
TOTAL EXPENDITURE		**138,676**	*100.00*	**163,113**	*100.00*	**173,307**	*100.00*

[1] Appropriation/Budget 2007 as of 31 December 2007.
[2] Appropriation/Budget 2008 as adopted by the Management Board on 13 December 2007 with adjusted split of contributions.

Annex 9 EMEA establishment plan

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

[3] Revised as of 23 February 2007.

[4] **Excluding** the six additional posts for Paediatrics legislation as per decision by the Management Board (EMEA/MB/244582/2007).

Annex 10 IT projects and operational activities

Service or project	Description of measure	Details of progress
Business Continuity IT Infrastructure	Success of deployment and ability to recover data in BCP scenarios	Phases 1 and 2 completed in 2007. Deploy phases 3 and 4 in 2008
Citrix Rollout	Success of deployment and ability to provide LIW to selected users	Pilot successfully completed in 2007. Deploy phase 1 in April 2008
Exchange Upgrade	Success of upgrade and ability to provide new features to users	Planning completed in 2007. Deploy upgrade in April 2008
Virtual meetings	Deploy 2 VITERO meeting rooms and fully test and pilot	Successfully completed in 2007
Paediatrics Database	Success of deployment of PIP PDF form.	PIP Modification Form to be completed in 2008
Paediatrics Database	Success of deployment of phase 1 Flex application (Registering of PDF Forms)	Application will be further developed in 2008
SIAMED	Success of database migration from FoxPro to Oracle	MRL part was also refined and put into production
EURS	Central Repository has been installed	Database will be further populated in 2008 and access for NCAs will be tested
EV DWH	Deploy Datawarehouse solution for EudraVigilance	Successfully completed in 2007
EudraGMP	Deploy first EudraGMP release	Successfully completed in 2007
ECD, ECDManager	Delegated user management has been introduced, NCAs manage their own users and allow access to EudraGMP	Further significant growth on the number of external users is expected in 2008
ITIL tool introduction (INFRA)	Introduce best practices compliant to ITIL and supporting toolset	Most suitable vendor has been selected and pilot has been successfully completed
Percentage of systems "down-time"	0.01% downtime	Achieved in 2007
Delivery of IT Projects against plan and budget	95% delivered against plan/budget	Achieved in 2007
Effective transition to production/operation	95% moved into production	Achieved in 2007
Percentage of EudraNet "down-time"	99% availability	Achieved in 2007

Annex 11 CHMP opinions in 2007 on medicinal products for human use

CHMP positive opinions in 2007 on non-orphan medicinal products for human use

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Xelevia ▪ sitagliptin phosphate monohydrate	▪ Merck Sharp & Dohme	▪ A10BH01 ▪ Improvement of glycaemic control in combination with metformin and PPAR gamma agonist in patients with type 2 diabetes mellitus	▪ 06.09.2006 ▪ 24.01.2007 ▪ 85 days ▪ 44 days	▪ 21.02.2007 ▪ 21.03.2007 ▪ 23.03.2007 ▪ OJ C 92 of 27.04.2007, p. 15
▪ Januvia ▪ sitagliptin phosphate monohydrate	▪ Merck Sharp & Dohme	▪ A10BH01 ▪ Improvement of glycaemic control in combination with metformin and PPAR gamma agonist in patients with type 2 diabetes mellitus	▪ 29.03.2006 ▪ 24.01.2007 ▪ 202 days ▪ 99 days	▪ 21.02.2007 ▪ 21.03.2007 ▪ 23.03.2007 ▪ OJ C 92 of 27.04.2007, p. 15
▪ Focetria ▪ Influenza virus surface antigens	▪ Chiron Behring GmbH	▪ J07BB02 ▪ Prophylaxis of influenza in a pandemic situation	▪ 31.01.2006 ▪ 22.02.2007 ▪ 162 days ▪ 224 days	▪ 27.03.2007 ▪ 02.05.2007 ▪ 04.05.2007 ▪ OJ C 144 of 29.06.2007, p. 5
▪ Docetaxel Winthrop ▪ docetaxel	▪ Aventis Pharma S.A.	▪ L01CD02 ▪ Treatment of breast cancer, non-small cell lung cancer, prostate cancer, gastric adeno-carcinoma and head and neck cancer	▪ 27.12.2006 ▪ 22.02.2007 ▪ 60 days ▪ 0 days	▪ 22.03.2007 ▪ 20.04.2007 ▪ 24.04.2007 ▪ OJ C 115 of 25.05.2007, p. 3
▪ Advagraf ▪ tacrolimus	▪ Astellas Pharma GmbH	▪ L04AA05 ▪ Primary immunosuppression in adult liver or kidney allograft recipients; treatment of allograft rejection resistant to treatment with other immunosuppressive drugs	▪ 01.03.2006 ▪ 22.02.2007 ▪ 201 days ▪ 157 days	▪ 23.03.2007 ▪ 23.04.2007 ▪ 25.04.2007 ▪ OJ C 115 of 25.05.2007, p. 3
▪ Sebivo ▪ telbivudine	▪ Novartis Europharm Limited	▪ J05AF11 ▪ Treatment of chronic hepatitis B in patients with evidence of viral replication and active liver inflammation	▪ 01.03.2006 ▪ 22.02.2007 ▪ 210 days ▪ 148 days	▪ 23.03.2007 ▪ 24.04.2007 ▪ 26.04.2007 ▪ OJ C 115 of 25.05.2007, p. 3
▪ Toviaz ▪ fesoterodine fumarate	▪ Schwarz Pharma	▪ G04BD11 ▪ Symptomatic treatment of overactive bladder syndrome	▪ 29.03.2006 ▪ 22.02.2007 ▪ 210 days ▪ 120 days	▪ 22.03.2007 ▪ 20.04.2007 ▪ 24.04.2007 ▪ OJ C 115 of 25.05.2007, p. 3
▪ Orencia ▪ abatacept	▪ Bristol-Myers Squibb Pharma EEIG	▪ L04AA24 ▪ Treatment of patients with severe rheumatoid arthritis	▪ 28.12.2005 ▪ 22.03.2007 ▪ 204 days ▪ 245 days	▪ 19.04.2007 ▪ 21.05.2007 ▪ 23.05.2007 ▪ OJ C 144 of 29.06.2007, p. 5
▪ Altargo ▪ retapamulin	▪ Glaxo Group Ltd.	▪ D06AX13 ▪ Treatment of uncomplicated skin and skin structure infections	▪ 19.07.2006 ▪ 22.03.2007 ▪ 191 days ▪ 55 days	▪ 24.04.2007 ▪ 24.05.2007 ▪ 29.05.2007 ▪ OJ C 144 of 29.06.2007, p. 5

Product ▪ Brand name ▪ INN	Marketing authorisation holder	Therapeutic area ▪ ATC code ▪ Summary of indication	EMEA.CHMP ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	European Commission ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Invega ▪ paliperidone	▪ Janssen-Cilag International NV.	▪ N05AX13 ▪ Treatment of adult schizophrenia including maintenance treatment	▪ 24.05.2006 ▪ 26.04.2007 ▪ 202 days ▪ 135 days	▪ 25.05.2007 ▪ 25.06.2007 ▪ 27.06.2007 ▪ OJ C 174 of 27.07.2007, p. 3
▪ Circadin ▪ melatonin	▪ Neurim Pharmaceuticals EEC Ltd	▪ N05CH01 ▪ Short-term treatment of primary insomnia characterised by poor quality of sleep in patients who are aged 55 or over	▪ 26.10.2005 ▪ 26.04.2007 ▪ 209 days ▪ 338 days	▪ 06.06.2007 ▪ 29.06.2007 ▪ 05.07.2007 ▪ OJ C 174 of 27.07.2007, p. 3
▪ Pergoveris ▪ follitropin alfa lutropin alfa	▪ Serono Europe Ltd	▪ G03GA05 ▪ Stimulation of follicular development in women with LH and FSH deficiency	▪ 29.03.2006 ▪ 26.04.2007 ▪ 208 days ▪ 185 days	▪ 29.05.2007 ▪ 25.06.2007 ▪ 01.08.2007 ▪ OJ C 203 of 31.08.2007, p. 3
▪ Optaflu ▪ A (H1N1), A (H3N2) and B	▪ Novartis Vaccine and Diagnostics GmbH	▪ J07BB02 ▪ Prophylaxis of influenza in adults	▪ 19.07.2006 ▪ 26.04.2007 ▪ 202 days ▪ 79 days	▪ 16.05.2007 ▪ 01.06.2007 ▪ 05.06.2007 ▪ OJ C 174 of 27.07.2007, p. 3
▪ Orlistat GSK ▪ orlistat	▪ Glaxo Group Ltd	▪ A08AB01 ▪ Weight loss in obese or overweight adults in conjunction with a mildly hypocaloric diet	▪ 25.03.2007 ▪ 24.05.2007 ▪ 60 days ▪ 0 days	▪ 20.06.2007 ▪ 23.07.2007 ▪ 25.07.2007 ▪ OJ C 203 of 31.08.2007, p. 3
▪ Aerinaze ▪ desloratadine 2.5mg pseudoephedrine sulphate 120 mg	▪ Shering - Plough Europe	▪ R06AX27 R01BA52 ▪ Sypmptomatic treatment of seasonal allergic rhinitis accompanied by nasal congestion	▪ 16.08.2006 ▪ 24.05.2007 ▪ 196 days ▪ 85 days	▪ 03.07.2007 ▪ 30.07.2007 ▪ 01.08.2007 ▪ OJ C 203 of 31.08.2007, p. 3
▪ Optimark ▪ gadoversetamide	▪ Tyco Healthcare Deutschland GmbH	▪ V08CA06 ▪ Use with magnetic resonance imaging (MRI) of the central nervous system and the liver	▪ 24.05.2006 ▪ 24.05.2007 ▪ 196 days ▪ 169 days	▪ 20.06.2007 ▪ 23.07.2007 ▪ 25.07.2007 ▪ OJ C 203 of 31.08.2007, p. 3
▪ Mircera ▪ pegserepoetin alfa	▪ Roche Registration Ltd	▪ B03XA03 ▪ Treatment of anaemia associated with chronic kidney disease	▪ 24.05.2006 ▪ 24.05.2007 ▪ 176 days ▪ 189 days	▪ 21.06.2007 ▪ 20.07.2007 ▪ 25.07.2007 ▪ OJ C 203 of 31.08.2007, p. 3
▪ Riprazo ▪ aliskiren	▪ Novartis Europharm Ltd.	▪ C09XA02 ▪ Treatment of essential hypertension	▪ 25.03.2007 ▪ 21.06.2007 ▪ 77 days ▪ 11 days	▪ 18.07.2007 ▪ 22.08.2007 ▪ 24.08.2007 ▪ OJ C 228 of 28.09.2007, p. 2
▪ Flebogammadif ▪ human immunoglobin (IVIg)	▪ Instituto Grifols S.A.	▪ Not yet assigned ▪ Replacement therapy in: immunodeficiency syndromes, myeloma or chronic lymphatic leukaemia with severe secondary hypogamma-globulinemia and recurrent infections	▪ 27.09.2006 ▪ 21.06.2007 ▪ 177 days ▪ 90 days	▪ 24.07.2007 ▪ 25.07.2007 ▪ 27.08.2007 ▪ OJ C 228 of 28.09.2007, p. 3
▪ Rasilez ▪ aliskiren	▪ Novartis Europharm Ltd	▪ C09XA02 ▪ Treatment of essential hypertension	▪ 27.09.2006 ▪ 21.06.2007 ▪ 194 days ▪ 73 days	▪ 18.07.2007 ▪ 22.08.2007 ▪ 24.08.2007 ▪ OJ C 228 of 28.09.2007, p. 2

Product ▪ Brand name ▪ INN	Marketing authorisation holder	Therapeutic area ▪ ATC code ▪ Summary of indication	EMEA.CHMP ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	European Commission ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Tekturna ▪ aliskiren	▪ Novartis Europharm Ltd.	▪ C09XA02 ▪ Treatment of essential hypertension	▪ 25.03.2007 ▪ 21.06.2007 ▪ 77 days ▪ 11 days	▪ 18.07.2007 ▪ 22.08.2007 ▪ 24.08.2007 ▪ OJ C 228 of 28.09.2007, p. 3
▪ Enviage ▪ aliskiren	▪ Novartis Europharm Ltd.	▪ C09XA02 ▪ Treatment of essential hypertension	▪ 25.03.2007 ▪ 21.06.2007 ▪ 77 days ▪ 11 days	▪ 18.07.2007 ▪ 22.08.2007 ▪ 24.08.2007 ▪ OJ C 228 of 28.09.2007, p. 2
▪ Sprimeo ▪ aliskiren	▪ Novartis Europharm Ltd.	▪ C09XA02 ▪ Treatment of essential hypertension	▪ 25.03.2007 ▪ 21.06.2007 ▪ 77 days ▪ 11 days	▪ 18.07.2007 ▪ 22.08.2007 ▪ 24.08.2007 ▪ OJ C 228 of 28.09.2007, p. 2
▪ Celsentri ▪ maraviroc	▪ Pfizer Limited	▪ J05AX09 ▪ For use in HIV-1 treatment-experienced HIV-1 infected patients in combination with other antiretroviral medicinal products	▪ 27.12.2006 ▪ 19.07.2007 ▪ 169 days ▪ 35 days	▪ 15.08.2007 ▪ 18.09.2007 ▪ 20.09.2007 ▪ OJ C 251 of 26.10.2007, p. 10
▪ Galvus ▪ vildagliptin	▪ Novartis Pharma AG	▪ A10BH02 ▪ Treatment of type 2 diabetes mellitus as add-on therapy in combination with metformin, sulphonylurea or pioglitazone	▪ 16.08.2006 ▪ 19.07.2007 ▪ 203 days ▪ 134 days	▪ 16.08.2007 ▪ 26.09.2007 ▪ 28.09.2007 ▪ OJ C 251 of 26.10.2007, p. 10
▪ Cervarix ▪ human papilloma virus	▪ GlaxoSmithKline Biologicals	▪ Not yet assigned ▪ Prevention of cervical cancer	▪ 29.03.2006 ▪ 19.07.2007 ▪ 202 days ▪ 275 days	▪ 13.08.2007 ▪ 20.09.2007 ▪ 24.09.2007 ▪ OJ C 251 of 26.10.2007, p. 10
▪ Ecalta ▪ anidulafungin	▪ Pfizer Ltd	▪ J02AX06 ▪ Treatment of invasive candidiasis in adult non-neutropenic patients	▪ 27.09.2006 ▪ 19.07.2007 ▪ 210 days ▪ 85 days	▪ 10.09.2007 ▪ 20.09.2007 ▪ 24.09.2007 ▪ OJ C 251 of 26.10.2007, p. 10
▪ Pioglitazone metformin ▪ pioglitazone metformin	▪ Takeda Europe R&D Centre Ltd	▪ A10BD05 ▪ Treatment of type 2 diabetes mellitus patients	▪ 23.07.2007 ▪ 20.09.2007 ▪ 59 days ▪ 0 days	▪ 21.09.2007 ▪ 11.12.2007 ▪ 13.12.2007 ▪
▪ Cyanokit ▪ hydroxocobalamin	▪ Merck Sante s.a.s.	▪ V03AB33 ▪ Treatment of known or suspected cyanide poisoning	▪ 27.12.2006 ▪ 20.09.2007 ▪ 177 days ▪ 90 days	▪ 26.09.2007 ▪ 23.11.2007 ▪ 27.11.2007 ▪ OJ C 316 of 28.12.2007, p. 42
▪ Eucreas ▪ vildagliptin. metformin	▪ Novartis Europharm Ltd	▪ Not yet assigned ▪ Treatment of type 2 diabetes mellitus patients with insufficient glycaemic control with oral metformin alone	▪ 24.01.2007 ▪ 20.09.2007 ▪ 177 days ▪ 62 days	▪ 18.10.2007 ▪ 14.11.2007 ▪ 16.11.2007 ▪ 28.12.2007 OJ C 316, p. 42
▪ Avamys ▪ fluticasone furoate	▪ Glaxo Group	▪ R01AD12 ▪ Treatment of allergic rhinitis	▪ 16.08.2006 ▪ 18.10.2007 ▪ 202 days ▪ 226 days	▪ 24.10.2007 ▪ 11.01.2008 ▪ 16.01.2008 ▪
▪ Atripla ▪ efavirenz emtricitabine tenofovir	▪ Bristol-Myers Squibb, Gilead Sciences and MSD Ldt	▪ Not yet assigned ▪ Combination treatment of HIV infected adults	▪ 25.10.2006 ▪ 18.10.2007 ▪ 202 days ▪ 156 days	▪ 15.11.2007 ▪ 13.12.2007 ▪ 18.12.2007 ▪

Product ▪ Brand name ▪ INN	Marketing authorisation holder	Therapeutic area ▪ ATC code ▪ Summary of indication	EMEA.CHMP ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	European Commission ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Abraxane ▪ paclitaxel	▪ American BioScience Inc.	▪ L01CD01 ▪ Treatment of breast cancer	▪ 27.09.2006 ▪ 18.10.2007 ▪ 202 days ▪ 184 days	▪ 24.10.2007 ▪ 11.01.2008 ▪ 15.01.2008 ▪
▪ Nevanac ▪ nepafenac	▪ Alcon Laboratories Ltd	▪ S01BC10 ▪ Prevention and treatment of post-operative pain and inflammation associated with cataract surgery	▪ 24.01.2007 ▪ 18.10.2007 ▪ 205 days ▪ 62 days	▪ 14.11.2007 ▪ 11.12.2007 ▪ 13.12.2007 ▪
▪ Ivemend ▪ aprepitant	▪ Merck Sharp & Dohme	▪ Not yet assigned ▪ Prevention of chemotherapy-induced nausea and vomiting (CINV)	▪ 24.05.2006 ▪ 15.11.2007 ▪ 197 days ▪ 343 days	▪ 21.11.2007 ▪ 11.01.2008 ▪ 16.01.2008 ▪
▪ Isentress ▪ raltegravir	▪ Merck Sharp & Dohme	▪ Not yet assigned ▪ Treatment of HIV-1 infection in combination with other anti-retrovial agents	▪ 23.05.2007 ▪ 15.11.2007 ▪ 141 days ▪ 35 days	▪ 30.11.2007 ▪ 20.12.2007 ▪ 02.01.2008 ▪
▪ Tesavel ▪ sitagliptin phosphate monohydrate	▪ Merck Sharp & Dohme	▪ A10BH01 ▪ Improvement of glycaemic control in combination with metformin and PPAR gamma agonist in patients with type 2 diabetes mellitus	▪ 16.09.2007 ▪ 15.11.2007 ▪ 60 days ▪ 0 days	▪ 21.11.2007 ▪ 10.01.2008 ▪ 14.01.2008 ▪
▪ Tyverb ▪ lapatinib	▪ GlaxoSmithKline	▪ L01XE07 ▪ Treatment of advanced or metastatic breast cancer	▪ 25.10.2006 ▪ 13.12.2007 ▪ 202 days ▪ 212 days	▪ 13.01.2008 ▪ ▪ ▪
▪ Vectibix ▪ panitumumab	▪ Amgen Europe B.V.	▪ L01XC08 ▪ Treatment of metastatic carcinoma of the colon or rectum	▪ 24.05.2006 ▪ 24.05.2007 ▪ 204 days ▪ 161 days	▪ 05.12.2007 ▪ 03.12.2007 ▪ 05.12.2007 ▪

CHMP positive opinions in 2007 on orphan medicinal products for human use

Product ▪ Brand name ▪ INN	Marketing authorisation holder	Therapeutic area ▪ ATC code ▪ Summary of indication	EMEA.CHMP ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	European Commission ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Revlimid ▪ lenalidomide	▪ Celgene Europe Ltd	▪ L04AX04 ▪ Treatment of multiple myeloma	▪ 29.03.2006 ▪ 22.03.2007 ▪ 199 days ▪ 159 days	▪ 16.05.2007 ▪ 14.06.2007 ▪ 19.06.2007 ▪ OJ C 174 of 27.07.2007, p. 3
▪ Soliris ▪ eculizumab	▪ Alexion Europe	▪ L04AA25 ▪ Treatment of patients with paroxysmal nocturnal hemoglobinuria	▪ 25.10.2006 ▪ 26.04.2007 ▪ 147 days ▪ 36 days	▪ 31.05.2007 ▪ 20.06.2007 ▪ 22.06.2007 ▪ OJ C 174 of 27.07.2007, p. 3
▪ Siklos ▪ hydroxycarbamide	▪ OTL Pharma	▪ L01XX05 ▪ Prevention of vaso-occlusive crises in patients suffering from sickle cell syndrome	▪ 26.10.2005 ▪ 26.04.2007 ▪ 208 days ▪ 339 days	▪ 25.05.2007 ▪ 29.06.2007 ▪ 05.07.2007 ▪ OJ C 174 of 27.07.2007, p. 3

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Increlex ▪ mecasermin	▪ Tercica Inc (US)	▪ H01AC03 ▪ Long-term treatment of growth failure in children with severe primary IGF-1 deficiency	▪ 28.12.2005 ▪ 24.05.2007 ▪ 208 days ▪ 304 days	▪ 05.07.2007 ▪ 03.08.2007 ▪ 06.08.2007 ▪ OJ C 228 of 28.09.2007, p. 2
▪ Atriance ▪ nelarabine	▪ GlaxoSmithKline	▪ L01BB07 ▪ Treatment of T-cell acute lymphoblastic leukaemia and T-cell lymphoblastic lymphoma	▪ 21.06.2006 ▪ 21.06.2007 ▪ 203 days ▪ 162 days	▪ 04.07.2007 ▪ 22.08.2007 ▪ 24.08.2007 ▪ OJ C 228 of 28.09.2007, p. 3
▪ Gliolan ▪ 5-aminolevulinic hydrochloride	▪ Medac	▪ L01XD04 ▪ Visualisation of malignant tissue during surgery for malignant glioma	▪ 24.05.2006 ▪ 21.06.2007 ▪ 199 days ▪ 194 days	▪ 25.07.2007 ▪ 07.09.2007 ▪ 12.09.2007 ▪ OJ C 251 of 26.10.2007, p. 10
▪ Yondelis ▪ trabectedin	▪ PharmaMar S.A.	▪ L01CX01 ▪ Treatment of patients with soft tissue sarcoma	▪ 16.08.2006 ▪ 19.07.2007 ▪ 210 days ▪ 127 days	▪ 17.08.2007 ▪ 17.09.2007 ▪ 20.09.2007 ▪ OJ C 251 of 26.10.2007, p. 10
▪ Torisel ▪ temsirolismus	▪ Wyeth Europa Ltd.	▪ L01XE09 ▪ Treatment of patients with advanced renal cell carcinoma	▪ 25.10.2006 ▪ 20.09.2007 ▪ 203 days ▪ 127 days	▪ 18.10.2007 ▪ 19.11.2007 ▪ 21.11.2007 ▪ OJ 316 of 28.12.2007
▪ Tasigna ▪ nilotinib	▪ Novartis Pharma AG	▪ L01XE08 ▪ Treatment of chronic myelogenous leukaemia	▪ 25.10.2006 ▪ 20.09.2007 ▪ 200 days ▪ 130 days	▪ 22.10.2007 ▪ 19.11.2007 ▪ 21.11.2007 ▪

CHMP positive opinions in 2007 on similar biological medicinal products for human use

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Binocrit ▪ epoetin alfa	▪ Sandoz GmbH	▪ B03XA01 ▪ Treatment of anaemia associated with chronic kidney disease and in oncology patients and to reduce blood transfusion requirements in oncology patients and prior to elective orthopaedic surgery	▪ 29.03.2006 ▪ 21.06.2007 ▪ 205 days ▪ 244 days	▪ 19.07.2007 ▪ 28.08.2007 ▪ 31.08.2007 ▪ OJ C 228 of 28.09.2007, p. 2
▪ Abseamed ▪ epoetin alfa	▪ MEDICE ARZNEIMITTEL PÜTTER GMBH & CO. KG	▪ B03XA01 ▪ Treatment of anaemia associated with chronic kidney disease and in oncology patients and to reduce blood transfusion requirements in oncology patients and prior to elective orthopaedic surgery	▪ 29.03.2006 ▪ 21.06.2007 ▪ 205 days ▪ 244 days	▪ 19.07.2007 ▪ 28.08.2007 ▪ 31.08.2007 ▪ OJ C 228 of 28.09.2007, p. 3
▪ Epoetin alfa Hexal ▪ epoetin alfa	▪ Hexal Biotech ForschungsGmbH	▪ B03XA01 ▪ Treatment of anaemia associated with chronic kidney disease and in oncology patients and to reduce blood transfusion requirements in oncology patients and prior to elective orthopaedic surgery	▪ 29.03.2006 ▪ 21.06.2007 ▪ 205 days ▪ 244 days	▪ 19.07.2007 ▪ 28.08.2007 ▪ 03.09.2007 ▪ OJ C 228 of 28.09.2007, p. 3
▪ Retacrit ▪ epoetin zeta	▪ Hospira Enterprises B.V.	▪ B03XA01 ▪ Treatment of anaemia associated with chronic kidney disease and in oncology patients to treat anaemia and reduce blood transfusion requirements, and to increase the yield of autologous blood in a pre-donation programme	▪ 20.05.2007 ▪ 18.10.2007 ▪ 85 days ▪ 66 days	▪ 15.11.2007 ▪ 18.12.2007 ▪ 20.12.2007 ▪
▪ Silapo ▪ epoetin zeta	▪ Stada R&D GmbH	▪ B03XA01 ▪ Treatment of anaemia associated with chronic kidney disease and in oncology patients to treat anaemia and reduce blood transfusion requirements, and to increase the yield of autologous blood in a pre-donation programme	▪ 19.07.2006 ▪ 18.10.2007 ▪ 202 days ▪ 254 days	▪ 15.11.2007 ▪ 18.12.2007 ▪ 20.12.2007 ▪

CHMP positive opinions in 2007 on generic medicinal products for human use

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Zalasta ▪ olanzapine	▪ Krka d.d. Novo Mesto	▪ N05AH03 ▪ Treatment of schizophrenia; treatment of moderate to severe manic episode and recurrence in bipolar disorder	▪ 25.10.2006 ▪ 19.07.2007 ▪ 177 days ▪ 90 days	▪ 17.08.2007 ▪ 27.09.2007 ▪ 01.10.2007 ▪ OJ C 251 of 26.10.2007, p. 11
▪ Olanzapine Neopharma ▪ olanzapine	▪ Cipla Ltd.	▪ N05AH03 ▪ Treatment of schizophrenia; treatment of moderate to severe manic episode and recurrence in bipolar disorder	▪ 25.10.2006 ▪ 20.09.2007 ▪ 205 days ▪ 127 days	▪ 18.10.2007 ▪ 14.10.2007 ▪ 16.11.2007 ▪ 28.12.2007 OC C 316, p. 42
▪ Olanzapine Teva ▪ olanzapine	▪ Teva Pharmanceuticals Ltd.	▪ N05AH03 ▪ Treatment of schizophrenia; treatment of moderate to severe manic episode and recurrence in bipolar disorder.	▪ 27.12.2006 ▪ 18.10.2007 ▪ 177 days ▪ 118 days	▪ 14.11.2007 ▪ 12.12.2007 ▪ 1412.2007 ▪ Not yet published
▪ Myfenax ▪ mycophenolate mofetil	▪ TEVA Pharmaceuticals Europe B.V.	▪ L04AA06 ▪ Prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants	▪ 20.07.2007 ▪ 13.12.2007 ▪ 138 days ▪ 8 days	▪ 21.12.2007 ▪ ▪ ▪
▪ Mycophenolate mofetil Teva ▪ mycophenolate mofetil	▪ TEVA Pharmaceuticals Europe B.V.	▪ L04AA06 ▪ Prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants	▪ 20.07.2007 ▪ 13.12.2007 ▪ 138 days ▪ 8 days	▪ 21.12.2007 ▪ ▪ ▪

CHMP negative opinions in 2007 on medicinal products for human use

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Genasense ▪ oblimersen sodium	▪ Genta Development	▪ L01XX36 ▪ Treatment of advanced or metastatic melanoma	▪ 31.03.2006 ▪ 26.04.2006 ▪ 210 Days ▪ 239 Days	▪ 14.09.2007 ▪ 15.10.2007 ▪ 18.10.2007 ▪ 316 of 28.12.2007, p. 57
▪ Cimzia ▪ certolizumab pegol	▪ UCB S.A	▪ L04AB05 ▪ Treatment of Crohn's disease	▪ 24.05.2006 ▪ 15.11.2007 ▪ 202 Days ▪ 338 Days	
▪ Kiacta ▪ eprodisate	▪ Neurochem Luco II SARL	▪ Not yet assigned ▪ Treatment of patients with amyloidosis	▪ 27.09.2006 ▪ 13.12.2007 ▪ 202 Days ▪ 240 Days	
▪ Rhucin ▪ rhC1INH	▪ Pharming Group N.V	▪ Not yet assigned ▪ Treatment of acute attacks of edema in patients with hereditary angioedema	▪ 16.08.2006 ▪ 13.12.2007 ▪ 176 Days ▪ 308 Days	
▪ Mycograb ▪ myctumab	▪ NeuTec Pharma plc	▪ Not yet assigned ▪ Treatment of invasive candidiasis	▪ 14.03.2005 ▪ 20.03.2007 ▪ 207 Days ▪ 391 Days	▪ 12.04.2007 ▪ 22.05.2007 ▪ 29.05.2007 ▪ OJ 144 of 29.06.2007, p. 6
▪ Natalizumab ▪ natalizumab	▪ Elan Pharma International Ltd.	▪ L04AA23 ▪ Treatment of moderately to severely active Crohn's disease for the reduction of signs and symptoms	▪ 18.10.2004 ▪ 19.07.2007 ▪ 204 Days ▪ 800 Days	▪ 13.12.2007 ▪ 11.01.2008 ▪ 15.01.2008
▪ Mylotarg ▪ gemtuzumab ozogamicin	▪ Wyeth Europa Ltd	▪ L01XC05 ▪ Treatment of CD33-positive acute myeloid leukaemia patients in first relapse who are not candidates for other cytotoxic chemotherapy	▪ 28.12.2005 ▪ 20.09.2007 ▪ 200 Days ▪ 431 Days	

Centralised applications for medicinal products for human use – withdrawals in 2007 prior to opinion

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Date of withdrawal ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Garenoxacin mesylate ▪ garenoxacin mesylate	▪ SP Europe	▪ Not yet assigned ▪ Treatment of bronchitis, sinusitis, pneumonia, skin and skin structure and post-surgical infections	▪ 24/05/2006 ▪ 25/07/2007 ▪ 174 ▪ 253	
▪ Gastromotal ▪ 13C-octanoic acid	▪ INFAI	▪ Not yet assigned ▪ In vivo diagnosis of gastric emptying rate	▪ 24/05/2006 ▪ 05/11/2007 ▪ 193 ▪ 337	
▪ Arxxant ▪ ruboxistaurin	▪ Elli Lilly and Company Limited	▪ Not yet assigned ▪ Treatment of diabetic retinopathy	▪ 21/06/2006 ▪ 13/03/2007 ▪ 117 ▪ 148	
▪ Iplex ▪ mecasermin	▪ Insmed Europe Ltd	▪ Not yet assigned ▪ Treatment of growth failure in children with severe primary IGF-1 deficiency	▪ 21/06/2006 ▪ 22/03/2007 ▪ 117 ▪ 157	
▪ Retisert ▪ fluociolone acetonide	▪ Bausch & Lomb Inc.	▪ S01BA15 ▪ Treatment of chronic non-infectious uveitis affecting the posterior segment of the eye	▪ 25/10/2006 ▪ 18/07/2007 ▪ 117 ▪ 149	
▪ Sinerem ▪ superpara-magneticiron oxidenano-particles	▪ Guerbet S.A.	▪ V08C B03 ▪ Contrast agent for magnetic resonance imaging for the diagnosis of lymph node metastases in pelvic cancers	▪ 22/11/2006 ▪ 12/12/2007 ▪ 175 ▪ 210	
▪ Voraxaze ▪ glucarpidase	▪ Protherics PLC	▪ V03AF09 ▪ Adjunctive treatment of patients experiencing or at risk of methotrexate toxicity due to delayed elimination or inadvertent overdose	▪ 17/08/2005 ▪ 21/05/2007 ▪ 174 ▪ 468	
▪ Vitragan ▪ ovine hyaluronidase	▪ ISTA Pharma Limited	▪ B06A A03 ▪ Treatment of vitreous hemorrhage to improve visual acuity and to facilitate diagnosis of underlying retinal pathology	▪ 28/12/2005 ▪ 25/04/2007 ▪ 174 ▪ 308	
▪ Cerepro ▪ adenovirus-mediated HSV thymidine kinase gene	▪ Ark therapeutics Ltd	▪ Not yet assigned ▪ In conjunction with ganciclovir sodium for treatment of patients with operable high-grade glioma	▪ 26/10/2005 ▪ 13/07/2007 ▪ 210 ▪ 336	

Annex 12 CVMP Opinions in 2007 on Medicinal Products for Veterinary Use

Centralised applications – Positive opinions

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Slentrol ▪ Dirlotapide	▪ Pfizer	▪ Dogs ▪ Obesity	▪ 21/02/2006 ▪ 14/02/2007 ▪ 209 ▪ 148	▪ 19/02/2007 ▪ 13/04/2007 ▪ ▪ OJ C 174/9
▪ Suprelorin ▪ Deslorelin	▪ Cyton Biosciences Ltd	▪ Dogs ▪ Temporary infertility in male dogs	▪ 20/09/2005 ▪ 15/05/2007 ▪ 211 ▪ 301	▪ 12/062007 ▪ 10/07/2007 ▪ ▪ OJ C 203/8
▪ Nobilis Influenza H7N1 ▪ Vaccine	▪ Intervet International bv	▪ Chickens ▪ Vaccine against avian influenza	▪ 18/10/2006 ▪ 14/03/2007 ▪ 120 ▪ 28	▪ 15/03/2007 ▪ 14/05/2007 ▪ ▪ OJ C 144/10
▪ Prilactone ▪ Spironolactone	▪ Ceva Sante Animale	▪ Dogs ▪ Heart failure	▪ 07/06/2005 ▪ 17/04/2007 ▪ 210 ▪ 469	▪ 22/05/2007 ▪ 20/06/2007 ▪ ▪ OJ C 174/9
▪ Circovac ▪ Inactivated vaccine	▪ Merial	▪ Pigs ▪ Passive immunity against porcine circovirus type 2.	▪ 21/12/2005 ▪ 17/04/2007 ▪ 210 ▪ 274	▪ 15/05/2007 ▪ 21/06/2007 ▪ ▪ OJ C 174/9
▪ Nobilis Influenza H5N6 ▪ Vaccine	▪ Intervet International BV	▪ Birds ▪ Prevention of avian influenza	▪ 13/02/2007 ▪ 11/07/2007 ▪ 90 ▪ 28	
▪ Meloxivet ▪ Meloxicam	▪ Janssen Pharmaceutica N.V.	▪ Dogs ▪ Musculo-skeletal disorders	▪ 19/12/2006 ▪ 12/09/2007 ▪ 210 ▪ 57	▪ 18/09/2007 ▪ 14/11/2007
▪ Rheumocam ▪ Meloxicam	▪ Chanelle Pharmaceuticals	▪ Dogs ▪ Musculo-skeletal disorders	▪ 18/08/2006 ▪ 07/11/2007 ▪ 208 ▪ 231	
▪ Ingelvac CircoFLEX ▪ Porcine Circovirus	▪ Boehringer Ingelheim Vetmedica GmbH	▪ Pigs ▪ Imunisation against porcine circovirus type 2	▪ 13/02/2007 ▪ 12/12/2007 ▪ 210 ▪ 92	

Establishment of maximum residue limits for new substances

Substance INN	**Therapeutic area** ▪ Target species	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of regulation ▪ Official Journal
▪ Avilamycin	▪ Pigs, poultry and rabbits	▪ 13/01/2005 ▪ 10/10/2007 ▪ 120 ▪ 670	▪ 24/10/2007
▪ Monensin	▪ Dairy Cattle	▪ 17/02/2005 ▪ 15/05/2007 ▪ 119 ▪ 698	▪ 12/06/2007

Substance INN	Therapeutic area ▪ Target species	EMEA/CVMP ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	European Commission ▪ Opinion received ▪ Date of regulation ▪ Official Journal
▪ Gamithromycin	▪ Bovine	▪ 10/08/2006 ▪ 10/10/2007 ▪ 117 ▪ 215	▪ 24/10/2007

Annex 13 COMP opinions in 2007 on designation of orphan medicinal products

Positive COMP designation opinions

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
(1R,2R)-octanoic acid[2-(2',3'-dihydro-benzo[1,4] dioxin-6'-yl)-2-hydroxy-1-pyrrolidin-1-ylmethyl-ethyl]-amide-L-tartaric acid salt (Genz-112638)	Genzyme Europe BV - The Netherlands	Treatment of Gaucher Disease	▪ 29/06/2007 ▪ 13/07/2007 ▪ 10/10/2007 ▪ 89 days	▪ 30/10/2007 ▪ 04/12/2007
(manganese, dichloro [(4aR, 13aR, 17aR, 21aR)-1, 2, 3, 4, 4a, 5, 6, 12, 13, 13a, 14, 15, 16, 17, 17a, 18, 19, 20, 21, 21a-eicosahydro-11, 7-nitrilo-7H-dibenzo[b,h] [1,4,7,10] tetraazacycloheptadecine-κN5, κN13, κN18, κN21, κN22]-) (M40403)	Celtic Bio-Pharma Services Ltd - UK	Prevention of oral mucositis in head and neck cancer patients undergoing radiation therapy	▪ 24/08/2007 ▪ 10/09/2007 ▪ 05/12/2007	▪ 17/12/2007 ▪ Pending
(R)-2-Methyl-6-nitro-2-{4-[4-(4-trifluoromethoxyphenoxy)piperidin-1-yl]phenoxymethyl}-2,3-dihydroimidazo[2,1-b]oxazole	Otsuka Pharmaceutical Europe Ltd - UK	Treatment of tuberculosis	▪ 27/09/2007 ▪ 15/10/2007 ▪ 05/12/2007	▪ 17/12/2007 ▪ Pending
(S)-2-nitro-6-(4-trifluoromethoxy) benzyloxy)-6,7-dihydro-5H-imidazo[2,1-b] [1,3] oxazine (PA-824)	Dr Ulrich Granzer - Germany	Treatment of tuberculosis	▪ 13/07/2007/ ▪ 13/08/2007 ▪ 10/10/2007/ ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007
1-{3-[3-(4-chlorophenyl)propoxy]propyl} piperidine, hydrochloride (Procognil)	Bioprojet - France	Treatment of narcolepsy	▪ 16/10/2006 ▪ 05/03/2007 ▪ 31/05/2007 ▪ 87 days	▪ 15/06/2007 ▪ 10/07/2007
17-(allylamino)-17-demethoxygeldanamycin, hydroquinone, hydrochloride (IPI-504)	MedImmune Oncology, Inc. - The Netherlands	Treatment of malignant gastrointestinal stromal tumours	▪ 23/07/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007
3-methoxy-pregnenolone	MAPREG SAS - France	Treatment of spinal cord injury	▪ 27/07/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 04/12/2007
4-[3,5-bis(trimethylsilyl)benzamido] benzoic acid	Quintiles Ireland Ltd - Ireland	Treatment of hepatocellular carcinoma	▪ 31/05/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 22/10/2007
4-Amino-1-[5-O-[(2R,4S)-2-oxido-4-(4-pyridinyl)-1,3,2-dioxaphosphorinan-2-yl]-β-D-arabinofuranosyl]-2(1H)-pyrimidinone (MB07133)	Interface International Consultancy Ltd - United Kingdom	Treatment of hepatocellular carcinoma	▪ 31/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 14/09/2007
4-ethoxy-2-(piperazin-1-yl)-7-(pyridin-4-yl)-5H-pyrimido[5,4-b]indol	Curacyte Discovery GmbH - Germany	Treatment of chronic lymphocytic leukaemia	▪ 27/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 14/11/2007
5(S)-(2'-hydroxy ethoxy)-20(S)-Camptothecin	ClinTec International Ltd - UK	Treatment of osteosarcoma	▪ 13/02/2007 ▪ 05/03/2007 ▪ 12/04/2007 ▪ 38 days	▪ 04/05/2007 ▪ 08/06/2007

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
5'-O-(trans-9"-octadecenoyl)-1-ß-D-arabinofuranosyl cytosine (Elacyt)	Clavis Pharma ASA - Norway	Treatment of acute myeloid leukaemia	▪ 31/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 14/09/2007
Adenovirus associated viral vector serotype 4 containing the human RPE65 gene	Centre Hospitalier Universitaire de Nantes - France	Treatment of retinitis pigmentosa	▪ 30/05/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 14/11/2007
Adenovirus associated viral vector serotype 4 containing the human RPE65 gene	Centre Hospitalier Universitaire de Nantes - France	Treatment of Leber's congenital amaurosis	▪ 30/05/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 22/10/2007
Alginate oligosaccharide (G-block) fragment	AlgiPharma AS - Norway	Treatment of cystic fibrosis	▪ 05/01/2007 ▪ 27/04/2007 ▪ 25/07/2007 ▪ 89 days	▪ 02/08/2007 ▪ 14/09/2007
Alpha1-proteinase inhibitor (inhalation use)	CSL Behring GmbH - Germany	Treatment of cystic fibrosis	▪ 30/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 14/09/2007
Alvocidib	Sanofi Aventis - France	Treatment of patients with chronic lymphocytic leukaemia	▪ 27/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 23/10/2007
Amonafide L-malate (Xanafide)	INC Research UK Ltd - UK	Treatment of acute myeloid leukaemia	▪ 29/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 22/10/2007
Antisense oligonucleotide (TATCCGGAGGGCTCGCCATGCTGCT) (GS 101)	Gene Signal SAS - France	Prevention of corneal graft rejection	▪ 20/11/2006 ▪ 11/12/2006 ▪ 08/03/2007 ▪ 87 days	▪ 21/03/2007 ▪ 17/04/2007
Arsenic trioxide	Cephalon Europe - France	Treatment of acute myeloid leukaemia	▪ 10/04/2007 ▪ 27/04/2007 ▪ 27/06/2007 ▪ 61 days	▪ 09/07/2007 ▪ 02/08/2007
Artesunate	ACE Pharmaceuticals BV - The Netherlands	Treatment of malaria	▪ 26/10/2006 ▪ 10/11/2006 ▪ 10/01/2007 ▪ 61 days	▪ 24/01/2007 ▪ 20/02/2007
Artesunate	Sigma-tau Pharma UK - UK	Treatment of malaria	▪ 27/07/2007 ▪ 13/07/2007 ▪ 10/10/2007 ▪ 58 days	▪ 26/09/2007 ▪ 06/12/2007
Autologous CD34+ cells transfected with lentiviral vector containing the human arylsulfatase A cDNA	Fondazione Telethon - Italy	Treatment of metachromatic leukodystrophy	▪ 27/12/2006 ▪ 15/01/2007 ▪ 08/03/2007 ▪ 52 days	▪ 22/03/2007 ▪ 13/04/2007
Autologous dendritic cells pulsed with autologous tumour cell lysate	Dorian Regulatory Affairs BV - The Netherlands	Treatment of glioma	▪ 27/09/2006 ▪ 10/11/2006 ▪ 10/01/2007 ▪ 61 days	▪ 24/01/2007 ▪ 15/02/2007
Aviptadil	mondoBIOTECH Laboratories Anstalt - Liechtenstein	Treatment of sarcoidosis	▪ 14/02/2007 ▪ 27/04/2007 ▪ 30/07/2007 ▪ 93 days	▪ 02/08/2007 ▪ 14/09/2007
Azacitidine (Vidaza)	Pharmion Ltd - United Kingdom	Treatment of acute myeloid leukaemia	▪ 27/07/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Chimeric-anti-interleukin 6 monoclonal antibody	Centocor, B.V. - The Netherlands	Treatment of Castleman's disease	▪ 26/07/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 30/11/2007
Ciclosporin	Novagali Pharma SA - France	Prevention of corneal graft rejection	▪ 27/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 22/10/2007
Ciclosporin	Novagali Pharma SA - France	Treatment of herpes simplex virus stromal keratitis	▪ 27/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 29/10/2007
Ciprofloxacin (inhalation use)	Bayer HealthCare AG (Wuppertal) - Germany	Treatment of cystic fibrosis	▪ 24/11/2006 ▪ 30/03/2007 ▪ 27/06/2007 ▪ 89 days	▪ 09/07/2007 ▪ 03/08/2007
Cisplatin (liposomal) (Lipoplatin)	Regulon AE - Greece	Treatment of pancreatic cancer	▪ 29/12/2006 ▪ 15/01/2007 ▪ 12/04/2007 ▪ 87 days	▪ 04/05/2007 ▪ 08/06/2007
Cyclo {{(E,Z)-(2S,3R,4R)-3-hydroxy-4-methyl-2-(methylamino)nona-6,8-dienoyl}-L-2-aminobutyryl-N-methyl-glycyl-N-methyl-L-leucyl-L-valyl-N-methyl-L-leucyl-L-alanyl-D-alanyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl} (LX211)	Lux Biosciences GmbH - Germany	Treatment of chronic non-infectious uveitis	▪ 24/08/2006 ▪ 27/04/2007 ▪ 25/07/2007 ▪ 89 days	▪ 02/08/2007 ▪ 14/09/2007
Dihydroartemisinin, piperaquine (Eurartesim)	Sigma Tau Industrie Farmaceutiche Riunite S.p.A - Italy	Treatment of malaria	▪ 14/03/2007 ▪ 30/03/2007 ▪ 27/06/2007 ▪ 87 days	▪ 09/07/2007 ▪ 03/08/2007
Doxorubicin hydrochloride (drug eluting beads) (CM-BC1) L01DB01	CellMed AG - Germany	Treatment of glioma	▪ 31/05/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007
Elafin	Proteo Biotech AG - Germanay	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension	▪ 13/10/2006 ▪ 11/12/2006 ▪ 07/02/2007 ▪ 89 days	▪ 22/02/2007 ▪ 20/03/2007
Eltrombopag olamine (Revolade)	GlaxoSmithKline Research & Development Limited (Harlow) - UK	Treatment of idiopathic thrombocytopenic purpura	▪ 13/04/2007 ▪ 27/04/2007 ▪ 27/06/2007 ▪ 61 days	▪ 09/07/2007 ▪ 03/08/2007
Enzastaurin hydrochloride	Eli Lilly Nederland B.V. - The Netherlands	Treatment of diffuse large B cell lymphoma	▪ 24/11/2006 ▪ 11/12/2006 ▪ 07/02/2007 ▪ 58 days	▪ 22/02/2007 ▪ 20/03/2007
Eptacog alfa (activated)	Novo Nordisk A/S - Denmark	Treatment of post-neonatal intracerebral haemorrhage	▪ 26/10/2006 ▪ 11/12/2006 ▪ 07/02/2007 ▪ 89 days	▪ 22/02/2007 ▪ 20/03/2007
Everolimus (RAD001)	Novartis Europharm Limited - UK	Treatment of renal cell carcinoma	▪ 14/02/2007 ▪ 05/03/2007 ▪ 12/04/2007 ▪ 38 days	▪ 04/05/2007 ▪ 05/06/2007

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Everolimus	Novartis Europharm Limited - UK	Treatment of gastro-entero-pancreatic neuroendocrine tumours	▪ 29/05/2007 ▪ 15/06/2007 ▪ 12/09/2007 ▪ 89 days	▪ 26/09/2007 ▪ 14/11/2007
Ex-vivo cultured adult human mesenchymal stem cells (Prochymal)	Quintiles UK Limited - UK	Treatment of Graft-versus-Host disease	▪ 24/08/2006 ▪ 10/11/2006 ▪ 10/01/2007 ▪ 61 days	▪ 24/01/2007 ▪ 20/02/2007
Fampridine	Dr Ulrich Granzer - Germany	Treatment of Guillain-Barré syndrome	▪ 28/12/2006 ▪ 05/03/2007 ▪ 31/05/2007 ▪ 87 days	▪ 15/06/2007 ▪ 10/07/2007 ▪
H-Arg-Leu-Phe-Phe-Tyr-Arg-Lys-Ser-Val-OH, acetate salt& H-Tyr-Leu-Phe-Phe-Tyr-Arg-Lys-Ser-Val-OH, acetate salt	Vaxon Biotech - France	Treatment of TERT positive non-small cell lung cancer in HLA-A2 positive patients	▪ 26/07/2007 ▪ 13/18/2007 ▪ 08/11/2007 ▪ 87 days	▪ 23/11/2007 ▪ 18/12/2007
Heterologous human adult liver derived stem cells	Prof Etienne Sokal - Belgium	Treatment of Crigler-Najjar syndrome	▪ 29/05/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007
HLA class I/II binding tumour associated peptides (ADF-APO-CCN-GUC-K67-MET-MMP-MUC-RGS)	Immatics Biotechnologies GmbH - Germany	Treatment of renal cell carcinoma	▪ 26/07/2006 ▪ 10/11/2006 ▪ 10/01/2007 ▪ 61 days	▪ 24/01/2007 ▪ 15/02/2007
Human autologous bone-forming cells derived from bone marrow stem cells	Bone Therapeutics SA - Belgium	Treatment of non-traumatic osteonecrosis	▪ 31/05/2007 ▪ 15/06/2007 ▪ 12/09/2007 ▪ 89 days	▪ 26/09/2007 ▪ 29/10/2007
Human coagulation factor X	Bio Products Laboratory - United Kingdom	Treatment of hereditary factor X deficiency	▪ 30/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 17/09/2007
Human heterologous liver cells (for infusion)	Cytonet GmbH & Co. KG - Germany	Treatment of ornithine-transcarbamylase deficiency	▪ 29/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 14/09/2007
Human papilloma virus type 16 E6/E7synthetic long peptides	ISA Pharmaceuticals BV - The Netherlands	Treatment of epithelial neoplasia of the vulva positive for human papilloma virus	▪ 24/07/2007 ▪ 13/08/2007 ▪ 08/11/2007 ▪ 87 days	▪ 23/11/2007 ▪ 20/12/2007
Human plasminogen	Kedrion S.p.A. - Italy	Treatment of ligneous conjunctivitis	▪ 11/04/2007 ▪ 27/04/2007 ▪ 27/06/2007 ▪ 61 days	▪ 09/07/2007 ▪ 03/08/2007
Hydrocortisone (modified release tablets) (Chronocort)	Phoqus Pharmaceuticals Limited - UK	Treatment of adrenal insufficiency	▪ 24/11/2006 ▪ 11/12/2006 ▪ 07/02/2007 ▪ 58 days	▪ 22/02/2007 ▪ 20/03/2007
Idebenone	Santhera Pharmaceuticals (Deutschland) GmbH - Germany	Treatment of Duchenne muscular dystrophy	▪ 08/09/2006 ▪ 11/12/2006 ▪ 07/02/2007 ▪ 89 days	▪ 22/02/2007 ▪ 20/03/2007
Idebenone	Santhera Pharmaceuticals (Deutschland) GmbH - Germany	▪ Treatment of Leber's hereditary optic neuropathy	▪ 14/09/2006 ▪ 13/10/2006 ▪ 10/01/2007 ▪ 89 days	▪ 24/01/2007 ▪ 15/02/2007
Interferon beta (Traumakine) L03AB02	Faron Pharmaceuticals Limited - Finland	Treatment of acute lung injury	▪ 26/07/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Interferon gamma	Foundation for Fatal Rare Diseases - Liechtenstein	Treatment of idiopathic pulmonary fibrosis	▪ 22/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 29/10/2007
Iodine (131I) Chlorotoxin	The Weinberg Group LLC - UK	Treatment of glioma	▪ 29/05/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 22/10/2007
Iodine (131I) iobenguane (Azedra Ultratrace Iobenguane ^{131}I) V10XA02	Molecular Insight Limited - UK	Treatment of neuroblastoma	▪ 28/09/2007 ▪ 15/10/2008 ▪ 05/12/2007	▪ 17/12/2007 ▪ pending
Irinotecan hydrochloride (drug eluting beads) (CM-BC2)	CellMed AG - Germany	Treatment of glioma	▪ 31/05/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007
Isofagomine tartrate	Amicus Therapeutics UK Ltd - United Kingdom	Treatment of Gaucher disease	▪ 27/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 23/10/2007
Lenalidomide (Revlimid) L04 AX04	Celgene Europe Limited - UK	Treatment of chronic lymphocytic leukaemia	▪ 29/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 25/10/2007 ▪ 19/11/2007
L-threo-3,4-dihydroxyphenylserine	The Weinberg Group LLC - UK	Treatment of orthostatic hypotension in patients with multiple system atrophy	▪ 11/04/2007 ▪ 27/04/2007 ▪ 27/06/2007 ▪ 61 days	▪ 09/07/2007 ▪ 02/08/2007
L-threo-3,4-dihydroxyphenylserine	The Weinberg Group LLC - UK	Treatment of orthostatic hypotension in patients with pure autonomic failure	▪ 11/04/2007 ▪ 27/04/2007 ▪ 27/06/2007 ▪ 61 days	▪ 09/07/2007 ▪ 02/08/2007
Lusupultide (Venticute)	Nycomed GmbH - Germany	Treatment of aspiration pneumonitis requiring intubation and mechanical ventilation	▪ 15/02/2007 ▪ 05/03/2007 ▪ 31/05/2007 ▪ 87 days	▪ 15/06/2007 ▪ 10/07/2007
Lutetium (177Lu)-N-[(4,7,10-Tricarboxymethyl-1,4,7,10-tetraazacyclododec-1-yl)acetyl]-D-phenylalanyl-L-cysteinyl-L-tyrosyl-D-tryptophanyl-L-lysyl-L-threoninyl-L-cysteinyl-L-threonine-cyclic(2-7)disulfide	BioSynthema Global Operations B.V - The Netherlands	Treatment of gastro-entero-pancreatic neuroendocrine tumours	▪ 27/09/2007 ▪ 15/10/2007 ▪ 05/12/2007	▪ 17/12/2007 ▪ pending
Maribavir	ViroPharma Limited - UK	Prevention of cytomegalovirus (CMV) disease in patients with impaired cell-mediated immunity deemed at risk	▪ 29/06/2007/ ▪ 13/08/2008 ▪ 08/11/2007 ▪ 87 days	▪ 23/11/2007 ▪ 18/12/2007
Mercaptopurine (oral liquid) (Loulla)	Only For Children Pharmaceuticals - France	Treatment of acute lymphoblastic leukaemia	▪ 28/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 22/10/2007
Methotrexate (oral liquid) (Philla)	Only For Children Pharmaceuticals - France	Treatment of acute lymphoblastic leukaemia	▪ 28/06/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 24/10/2007

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Methyl 4,6-diamino-2-[1-(2-fluorobenzyl)-1H-pyrazolo[3,4-b]pyridine-3-yl]-5-pyrimidinyl(methyl)carbamate (BAY 63-2521) C & R	Bayer HealthCare AG (Leverkusen) - Germany	Treatment of pulmonary arterial hypertension including treatment of chronic thromboembolic pulmonary hypertension	▪ 24/08/2007 ▪ 10/09/2007 ▪ 08/11/2007 ▪ 59 days	▪ 23/11/2007 ▪ 20/12/2007
N- (2-Amino-phenyl)-4-[(4-pyridin-3-yl-pyrimidin-2-ylamino)-methyl] benzamide (MGCD0103)	Pharmion Ltd - United Kingdom	Treatment of acute myeloid leukemia	▪ 28/09/2007/ ▪ 15/10/2007 ▪ 05/12/2007	▪ 17/12/2007 ▪ pending
N-(2-amino-phenyl)-4-[(4-pyridin-3-yl-pyrimidin-2-ylamino)-methyl] benzamide (MGDC0103)	Pharmion Ltd - United Kingdom	Treatment of Hodgkin's lymphoma	▪ 31/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 14/09/2007
N-[4-(3-amino-1H-indazol-4 yl)phenyl]-N'-(2-fluoro-5-methylphenyl) urea	Abbott Laboratories Limited - UK	Treatment of hepatocellular carcinoma	▪ 24/08/2007 ▪ 10/09/2007 ▪ 08/11/2007 ▪ 59 days	▪ 23/11/2007 ▪ 20/12/2007
N-adamantanyl-N'-Geranyl-ethylenediamine	RLM Consulting - Belgium	Treatment of tuberculosis	▪ 21/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 14/09/2007
Naptumomab estafenatox	Active Biotech Research AB - Sweden	Treatment of renal cell carcinoma	▪ 31/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 14/09/2007
Nilotinib hydrochloride monohydrate (Tasigna)	Novartis Europharm Limited - UK	Treatment of gastrointestinal stromal tumours	▪ 24/11/2006 ▪ 11/12/2007 ▪ 08/03/2007 ▪ 87 days	▪ 22/03/2007 ▪ 13/04/2007
Olaparib	AstraZeneca AB - Sweden	Treatment of ovarian cancer	▪ 28/06/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 06/12/2007
Panobinostat lactate	Novartis Europharm Limited - UK	Treatment of cutaneous T-Cell Lymphoma	▪ 09/03/2007 ▪ 27/04/2007 ▪ 27/06/2007 ▪ 61 days	▪ 09/07/2007 ▪ 02/08/2007
Picoplatin	Kendle International Ltd - UK	Treatment of small cell lung cancer	▪ 25/06/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 06/12/2007
Polihexanide	S.I.F.I. Società Industria Farmaceutica Italiana S.p.A. - Italy	Treatment of acanthamoeba keratitis	▪ 25/05/2007 ▪ 13/07/2007 ▪ 12/09/2007 ▪ 61 days	▪ 26/09/2007 ▪ 14/11/2007
Pralatrexate	Oxford Regulatory Solutions Ltd - UK	Treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/disseminated)	▪ 19/12/2006 ▪ 15/01/2007 ▪ 08/03/2007 ▪ 52 days	▪ 22/03/2007 ▪ 13/04/2007
Pyridoxalated hemoglobin polyoxyethylene (Hemoximer)	Curacyte AG - Germany	Treatment of cardiogenic shock	▪ 15/03/2007 ▪ 27/04/2007 ▪ 27/06/2007 ▪ 61 days	▪ 09/07/2007 ▪ 02/08/2007
R-1-[2,3-dihydro-2-oxo-1-pivaloylmethyl-5-(2-pyridyl)-1 H-1,4-benzodiazepin-3-yl]-3-(3-methylaminophenyl)urea (Eclant)	Trio Medicines Ltd - UK	Treatment of gastric carcinoid	▪ 20/02/2007 ▪ 05/03/2007 ▪ 12/04/2007 ▪ 38 days	▪ 04/05/2007 ▪ 14/06/2007

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Recombinant adeno-associated viral vector containing human acid alfa-glucosidase-gene	The Matthews Consultancy Ltd - UK	Treatment of glycogen storage disease type II (Pompe's disease)	▪ 01/02/2007 ▪ 05/03/2007 ▪ 31/05/2007 ▪	▪ 15/06/2007 ▪ 09/07/2007
Recombinant adeno-associated viral vector containing human alpha-1 antitrypsin gene	The Matthews Consultancy Ltd - UK	Treatment of congenital alpha-1 antitrypsin deficiency	▪ 06/09/2006 ▪ 11/12/2006 ▪ 07/02/2007 ▪ 58 days	▪ 22/02/2007 ▪ 20/03/2007
Recombinant fusion protein consisting of human coagulation factor IX attached to the Fc domain of human IgG1	Biovitrum AB - Sweden	Treatment of haemophilia B (congenital factor IX deficiency)	▪ 16/02/2007 ▪ 05/03/2007 ▪ 12/04/2007 ▪ 38 days	▪ 04/05/2007 ▪ 08/06/2007
Recombinant human C1-inhibitor	Pharming Group N.V. - The Netherlands	Prevention of delayed graft function after solid organ transplantation	▪ 17/08/2006 ▪ 10/11/2006 ▪ 10/01/2007 ▪ 89 days	▪ 24/01/2007 ▪ 20/02/2007
Recombinant human hepatitis C monoclonal antibody against C4 region of E1	GENimmune, N.V. - Belgium	Prevention of recurrent hepatitis C virus induced liver disease in liver transplant recipients	▪ 27/06/2007 ▪ 13/07/2007 ▪ 10/10/2007 ▪ 89 days	▪ 30/10/2007 ▪ 06/12/2007
Recombinant human histone H1.3 and recombinant human N-bis-met-histone H1.3 (Oncohist)	SymbioTec GmbH - Germany	Treatment of acute myeloid leukemia	▪ 24/08/2007 ▪ 10/09/2007 ▪ 08/11/2007 ▪ 59 days	▪ 23/11/2007 ▪ 20/12/2007
Recombinant human monoclonal antibody to human IL-1beta of the IgG1/K class (ACZ885)	Novartis Europharm Limited - UK	Treatment of cryopirin-associated periodic syndromes (Familial Cold Urticaria Syndrome (FCUS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID), also known as Chronic Infantile Neurological Cutaneous Articular Syndrome (CINCA))	▪ 25/08/2006 ▪ 11/12/2006 ▪ 07/02/2007 ▪ 58 days	▪ 22/02/2007 ▪ 20/03/2007
Recombinant human rod derived cone viability factor	Fovea Pharmaceuticals SA - France	Treatment of retinitis pigmentosa	▪ 23/07/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007
Recombinant human soluble Fc-gamma receptor I I b	SuppreMol GmbH - Germany	Treatment of idiopathic thrombocytopenic purpura	▪ 12/04/2007 ▪ 27/04/2007 ▪ 27/06/2007 ▪ 61 days	▪ 09/07/2007 ▪ 02/08/2007
Rilonacept	Regeneron UK Limited - UK	Treatment of cryopirin-associated periodic syndromes (Familial Cold Urticaria Syndrome (FCUS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID), also known as Chronic Infantile Neurological Cutaneous Articular Syndrome (CINCA))	▪ 12/03/2007 ▪ 30/03/2007 ▪ 31/05/2007 ▪ 62 days	▪ 15/06/2007 ▪ 10/07/2007
R-salbutamol (ASF-1096 Cream 0.5%)	Astion Pharma A/S - Denmark	Treatment of cutaneous forms of lupus erythematosus	▪ 13/04/2007 ▪ 27/04/2007 ▪ 25/07/2007 ▪ 89 days	▪ 02/08/2007 ▪ 14/09/2007
Sulfonated monophosphorylated mannose oligosaccharide	Constella Group Ltd - UK	Treatment of hepatocellullar carcinoma	▪ 31/05/2007 ▪ 15/06/2007 ▪ 25/07/2007 ▪ 40 days	▪ 02/08/2007 ▪ 14/09/2007

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Talactoferrinum alfa	Agennix Limited - UK	Treatment of renal cell carcinoma	▪ 16/02/2007 ▪ 05/03/2007 ▪ 12/04/2007 ▪ 38 days	▪ 04/05/2007 ▪ 05/06/2007
Tegafur, gimeracil, oteracil potassium	sanofi Aventis - France	Treatment of gastric cancer	▪ 16/07/2007 ▪ 13/08/2007 ▪ 08/11/2007 ▪ 87 days	▪ 23/11/2007 ▪ 20/12/2007
Terguride	Ergonex Licensing and Regulatory Services AG - Liechtenstein	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension	▪ 30/07/2007 ▪ 13/08/2007 ▪ 10/10/2007 ▪ 58 days	▪ 30/10/2007 ▪ 29/11/2007
Zanolimumab	Serono Europe Limited - United Kingdom	Treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/disseminated)	▪ 24/11/2006 ▪ 11/12/2006 ▪ 07/02/2007 ▪ 58 days	▪ 22/02/2007 ▪ 20/03/2007

Negative COMP designation opinions

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Chelidonii radix special liquid extract (Ukrain)	▪ Now Pharm AG - Luxembourg	Treatment of pancreatic cancer	▪ 06/02/2007 ▪ 05/03/2007 ▪ 31/05/2007 Opinion after appeal: 10/10/2007	▪ 29/10/2007 ▪ 04/12/2007

Annex 14 HMPC Community herbal monographs

Reference number	Document title	Status
EMEA/HMPC/137423/2007	Community herbal monograph on Anisi fructus	Adopted July 2007
EMEA/HMPC/263273/2006	Community herbal monograph on Anisi aetheroleum	Adopted July 2007
EMEA/HMPC/137428/2006	Community herbal monograph on Foeniculi amari fructus	Adopted July 2007
EMEA/HMPC/263292/2006	Community herbal monograph on Foeniculi amari fructus aetheroleum	Adopted July 2007
EMEA/HMPC/263293/2006	Community herbal monograph on Foeniculi dulcis fructus	Adopted July 2007
EMEA/HMPC/5341/2007	Community herbal monograph on Melissae folium	Adopted October 2007
EMEA/HMPC/349466/2006	Community herbal monograph on Menthae piperitae aetheroleum	Adopted October 2007
EMEA/HMPC/230962/2006	Community herbal monograph on Passiflorae herba	Adopted September 2007
EMEA/HMPC/64684/2007	Community herbal monograph on Primulae flos	Adopted September 2007
EMEA/HMPC/143370/2006	Community herbal monograph on Primulae radix	Adopted September 2007
EMEA/HMPC/513579/2006	Community herbal monograph on Rhamni purshianae cortex	Adopted September 2007
EMEA/HMPC/189624/2007	Community herbal monograph on Rhei radix	Adopted October 2007
EMEA/HMPC/234113/2006	Community herbal monograph on Thymi herba	Adopted October 2007
EMEA/HMPC/202966/2007	Community herbal monograph on Avenae herba	Released for public consultation October 2007
EMEA/HMPC/368600/2007	Community herbal monograph on Avenae fructus	Released for public consultation October 2007
EMEA/HMPC/260019/2006	Community herbal monograph on Betulae folium	Released for public consultation May 2007
EMEA/HMPC/179281/2007	Community herbal monograph on Calendulae flos	Released for public consultation July 2007
EMEA/HMPC/104945/2006	Community herbal monograph on Echinaceae purpureae herba	Released for public consultation March 2007
EMEA/HMPC/394894/2007	Community herbal monograph on Equiseti herba	Released for public consultation October 2007
EMEA/HMPC/244569/2006	Community herbal monograph on Eleutherococci radix	Released for public consultation July 2007
EMEA/HMPC/513617/2006	Community herbal monograph on Lupuli flos	Released for public consultation July 2007
EMEA/HMPC/354177/2007	Community herbal monograph on Meliloti herba	Released for public consultation October 2007
EMEA/HMPC/193909/2007	Community herbal monograph on Menthae piperitae folium	Released for public consultation July 2007
EMEA/HMPC/261938/2007	Community herbal monograph on Rusci aculeati rhizoma	Released for public consultation September 2007
EMEA/HMPC/295338/2007	Community herbal monograph on Salicis cortex	Released for public consultation September 2007
EMEA/HMPC/283166/2007	Community herbal monograph on Sambuci flos	Released for public consultation September 2007

Reference number	Document title	Status
EMEA/HMPC/285758/2007	Community herbal monograph on Solidaginis virgaureae herba	Released for public consultation October 2007
EMEA/HMPC/170261/2006	Community herbal monograph on Urticae herba	Released for public consultation September 2007
EMEA/HMPC/395213/2007	Community herbal monograph on Verbasci flos	Released for public consultation October 2007

Annex 15 Entries to the 'List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'

Reference number	Document title	Status
EMEA/HMPC/428817/2006	Community list entry on Foeniculi amari fructus	Adopted September 2007
EMEA/HMPC/428963/2006	Community list entry on Foeniculi dulcis fructus	Adopted September 2007
EMEA/HMPC/297757/2007	Community list entry on Anisi fructus	Released for public consultation July 2007
EMEA/HMPC/179283/2007	Community list entry on Calendulae flos	Released for public consultation July 2007
EMEA/HMPC/189629/2007	Community list entry on Echinaceae purpureae herba	Released for public consultation May 2007
EMEA/HMPC/83756/2007	Community list entry on Eleutherococci radix	Released for public consultation July 2007

Annex 16 PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2007

Product INN/ Invented Name	**Applicant**	**Condition**	**PIP/ Full waiver**	**PDCO** ▪ Start date ▪ Opinion	**EMEA Decision**
Everolimus	Novartis Europham Ltd	Renal cell carcinoma and pancreatic neuroendocrine tumour	Full waiver	▪ 30/08/2007 ▪ 26/10/2007	11/12/2007
Candesartan/Hydrochlorothiazide (Atacand Plus and associated names)	AstraZeneca AB	Essential hypertension	Full waiver	▪ 30/08/2007 ▪ 26/10/2007	11/12/2007
Candesartan/ Hydrochlorothiazide (Blopress Comp and associated names)	Takeda Global Research & Development Centre Ltd	Essential hypertension	Full waiver	▪ 30/08/2007 ▪ 26/10/2007	11/12/2007
Lasofoxifene tartrate	Pfizer Limited	Treatment of osteoporosis in postmenopausal women at increased risk of fracture	Full waiver	▪ 27/09/2007 ▪ 23/11/2007	07/01/2008
Tacrolimus monohydrate (Prograf and associated names, Advagraf)	Astellas Pharma GmbH	Transplant of whole organ	PIP	▪ 02/08/2007 ▪ 20/12/2007	
Recombinant L-Asparaginase	Medac Gesellschaft für Klinische Spezialpraeparate mbH	Acute lymphoblastic leukaemia, lymphoblastic lymphoma	PIP	▪ 02/08/2007 ▪ 20/12/2007	
Telmisartan / ramipril	Boehringer Ingelheim International GmbH	Risk of myocardial infarction, stroke, death from cardiovascular causes, or hospitalization for congestive heart failure in patients at high risk of developing major cardiovascular events.	Full waiver	▪ 25/10/2007 ▪ 20/12/2007	`
Indacaterol maleate	Novartis Europharm Ltd	Chronic obstructive pulmonary disease	Full waiver	▪ 25/10/2007 ▪ 20/12/2007	
Glycopyrronium bromide	Novartis Europharm Ltd	Chronic obstructive pulmonary disease	Full waiver	▪ 25/10/2007 ▪ 20/12/2007	
Indacaterol maleate / Glycopyrronium bromide	Novartis Europharm Lt	Chronic obstructive pulmonary disease	Full waiver	▪ 25/10/2007 ▪ 20/12/2007	
Rosiglitazone maleate	GlaxoSmithKline R&D Limited	Alzheimer's disease	Full waiver	▪ 25/10/2007 ▪ 20/12/2007	
Panobinostat lactate salt	Novartis Europharm Ltd	Cutaneous T-cell lymphoma (including mycosis fungoides and Sezary's disease)	Full waiver	▪ 25/10/2007 ▪ 20/12/2007	

Annex 17 Guidelines and working documents in 2007

Committee for Medicinal Products for Human Use (CHMP)

CHMP guidelines overview

Working Party/Group	Total number of adopted guidelines/ documents for which working party/group is responsible	Number of concept papers/ guidelines/ documents initiated during 2007	Number of concept papers/ guidelines/ documents in progress during 2007	Number of guidelines/ documents adopted during 2007
CHMP Biologics Working Party	57	7	27	11
CHMP Blood Products Working Party	26	0	7	4
CHMP Efficacy Working Party	227	15	33	15
CHMP Gene Therapy Working Party	6	5	8	4
CHMP Paediatrics Working Party	19	2	10	7
CHMP Pharmacogenetics Working Party	10	5	5	4
CHMP Pharmacovigilance Working Party				
CHMP Safety Working Party	44	4	12	5
CHMP Similar Biological (Biosimilar) Medicinal Products Working Party	19	0	3	2
CHMP Vaccine Working Party	8	13	11	7
CHMP Working Party on Cell-based Products	0	1	2	3
EMEA Human Scientific Committees Working Party with Patients and Consumers' Organisations				
CHMP Working Group with Health-Care Professionals' Organisations				
CHMP Invented Name Review Group				
Joint CHMP/CVMP Quality Working Party				

CHMP guidelines

Working Party/Group	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
CHMP Biologics Working Party	Process analytical technology (PAT) for quality control of biological medicinal products (report of workshop) Cell and gene therapy and tissue engineered products (guidelines)
CHMP Blood Products Working Party	Factor VIII inhibitors (report of international workshop)
CHMP Efficacy Working Party	Tuberculosis, HIV and hepatitis C (guidelines)
CHMP Gene Therapy Working Party	Clinical monitoring and follow-up of patients treated with gene therapy medicinal products (guideline) Environmental Risk Assessment of gene therapy medicinal products (guideline) Non-clinical studies required before first clinical use of gene therapy medicinal products (guideline) Medicinal products containing genetically modified cells (guideline)
CHMP Paediatrics Working Party	Neonates (guideline) Off-patent medicines (priority research list) Paediatric needs for several therapeutic areas (lists of paediatric needs)
CHMP Pharmacogenetics Working Party	Sampling and handling of pharmacogenomic DNA and RNA-containing specimens, and ensuring scientific reliability of results obtained (reflection paper) Use of genomics in cardiovascular clinical trials intended for medicinal product development (reflection paper) Use of pharmacogenetics in pharmacokinetic evaluation of medicinal products (reflection paper)
CHMP Safety Working Party	First-in-man clinical trials (guideline)
CHMP Similar Biological (Biosimilar) Medicinal Products Working Party	Immunogenicity assessment of biotechnology-derived therapeutic proteins (guideline) Biosimilar medicinal products containing recombinant interferon alpha (guideline) Biosimilar medicinal products containing low molecular weight heparins (guideline)
CHMP Vaccine Working Party	Pandemic and pre-pandemic influenza vaccines (guideline, core SPC) Clinical evaluation of vaccines (guideline) Live recombinant vector vaccines (concept paper) DNA vaccines (concept paper)
CHMP Working Party on Cell-based Products	Xenogeneic cell therapy products (concept paper) Human cell-based medicinal products (guideline)
CHMP Biologics Working Party	Process analytical technology (PAT) for quality control of biological medicinal products (report of workshop) Cell and gene therapy and tissue engineered products (guidelines)
CHMP Blood Products Working Party	Factor VIII inhibitors (report of international workshop)
CHMP Efficacy Working Party	Tuberculosis, HIV and hepatitis C (guidelines)
CHMP Gene Therapy Working Party	Clinical monitoring and follow-up of patients treated with gene therapy medicinal products (guideline) Environmental Risk Assessment of gene therapy medicinal products (guideline) Non-clinical studies required before first clinical use of gene therapy medicinal products (guideline) Medicinal products containing genetically modified cells (guideline)

Committee for Medicinal Products fro Veterinary Use (CVMP)

CVMP Efficacy

Reference number	Document title	Status
EMEA/CVMP/EWP/170208/2005	Guideline on the summary of product characteristics for anthelmintics	Adopted July 2007
EMEA/CVMP/EWP/362275/2007-CONSULTATION	Concept paper for the revision of the guideline on "Veterinary medicinal products controlling *Varroa destructor* and *Acarapis woodi* parasitosis in bees"	Adopted for consultation September 2007. (End of consultation: March 2008)
EMEA/CVMP/EWP/85954/2007-CONSULTATION	Concept paper for the revision of the "Guideline on Efficacy of veterinary medicinal products for use in farmed aquatic species"	Adopted for consultation October 2007 (end of consultation: January 2008)
EMEA/CVMP/EWP/005/2000-Rev.2	Guideline for the Testing and Evaluation of the Efficacy of Antiparasitic Substances for the Treatment and Prevention of Tick and Flea Infestation in Dogs and Cats	Adopted November 2007 (Implementation 1 June 2008)

CVMP Environmental Risk Assessment (ERA)

Reference number	Document title	Status
EMEA/CVMP/ERA/418282/2005	Guideline on Environmental Impact Assessment for VMPs in support of the VICH guidelines GL6 and GL38	Adopted April 2007

CVMP Immunologicals

Reference number	Document title	Status
EMEA/CVMP/IWP/23332/2006	Guideline on user safety for immunological veterinary medicinal products"	Adopted April 2007
EMEA/CVMP/IWP/222624/2006	Guideline on data requirements for an authorisation under exceptional circumstances for vaccines in birds against avian influenza"	Adopted April 2007
EMEA/CVMP/IWP/205351/2006	Guideline on the procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with bovine viral diarrhoea (BVD) virus"	Adopted April 2007
EMEA/CVMP/IWP/105008/2007	Reflection paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue"	Adopted April 2007
EMEA/CVMP/IWP/501304/2006	Concept paper on the need for requiring data to demonstrate the influence of maternally derived antibody on the vaccination of very young animals"	Adopted April 2007
EMEA/CVMP/IWP/90459/2007	Concept paper on requirements for multi-strain dossiers"	Adopted April 2007
EMEA/CVMP/IWP/123243/2007	Guideline on data requirements for immunological veterinary medicinal products intended for minor use or minor species/limited markets	Adopted July 2007

CVMP Pharmacovigilance

Reference number	Document title	Status
EMEA/CVMP/PhVWP/73213/2007	EMEA Public Bulletin 2006 on Veterinary Pharmacovigilance on activities regarding pharmacovigilance for veterinary medicinal products during the past year	Adopted February 2007
EMEA/INS/PhV/47075/2007	Guideline on monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections	Adopted February 2007. Published on the European Commission website on 4 April 2007
SOP/V/4023	Procedure for management of Periodic Safety Update Reports (PSURs) for centrally authorised products	Adopted March 2007
EMEA/CVMP/413/99-Rev.4	VEDDRA list of clinical terms for adverse reactions in animals	Adopted June 2007
EMEA/CVMP/891/04-Rev.2	VEDDRA list of clinical terms for adverse reactions in humans	Adopted June 2007
EMEA/CVMP/553/03-Rev.2	List of species and breeds	Adopted June 2007
Published by the European Commission's EudraLex	Phamacovigilance for Veterinary Medicinal Products – Procedures for Marketing Authorisation Holders	Adopted June 2007
EMEA/CVMP/PhVWP/4550/2006-CONSULTATION	Guideline on Management and Assessment of Periodic Safety Update Reports (PSURs) of Veterinary Medicinal Products	Adopted for consultation October 2007 (end of consultation: April 2008)

Joint CHMP/CVMP Quality

Reference number	Document title	Status
EMEA/CVMP/VICH/899/99-Rev.1	Stability testing of new veterinary drug substances and medicinal products	Adopted February 2007
EMEA/CVMP/VICH/837/99-Rev.1	Impurities in new veterinary drug substances	Adopted February 2007
EMEA/CVMP/VICH/838/99-Rev.1	Impurities in new veterinary medicinal products	Adopted February 2007
EMEA/CVMP/QWP/103377/2007	Concept Paper on the revision of the CVMP guideline on stability testing of existing active substances and related finished products	Adopted April 2007
EMEA/HMPC/CHMP/CVMP/287539/2005	Guideline on the Declaration of Herbal Substances in the SPC	Adopted July 2007
EMEA/CHMP/CVMP/QWP/221930/2007-CONSULTATION	Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products	Adopted for consultation July 2007 (end of consultation October 2007)
EMEA/CVMP/QWP/846/99-Rev.1	Revised Guideline on Stability Testing: Stability testing of existing active substances and related finished products	Adpted for consultation October 2007 (end of consultation: April 2008)
EMEA/CVMP/QWP/544461/2007-CONSULTATION	Guideline on the quality aspects of single-dose veterinary spot-on products	Adopted for consultation December 2007 (end of consultation: June 2008)
EMEA/CVMP/422/99-Rev.3	Guideline on the declaration of storage conditions	Adopted December 2007

CVMP Safety

Reference number	Document title	Status
EMEA/CVMP/95682/2007-CONSULTATION	Reflection paper on assessment of bioavailability of bound residues in food commodities of animal origin in the context of Council Regulation (EEC) No 2377/90	Adopted for consultation May 2007 (end of consultation November 2007)
EMEA/CVMP/VICH/1052/2004	"VICH GL41 Target animal safety: examination of live veterinary vaccines in target animals for absence of reversion to virulence"	Adopted September 2007 (Implementation: July 2008)

EMEA/CVMP/VICH/359665/2005-CONSULTATION	"VICH GL44 Guideline Target Animal Safety for veterinary live and inactivated vaccines"	Adopted for consultation September 2007 (end of consultation: March 2008)
EMEA/CVMP/IWP/339116/2007-CONSULTATION	Reflection paper on consideration of adjuvants and preservatives under Council Regulation (EEC) No 2377/90	Adopted for consultation December 2007 (end of consultation: March 2008)

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
EMEA/CVMP/SAGAM/383441/2005	Revised guideline on the SPC for antimicrobial products	Adopted Novemper 2007 (Implementation 1 May 2008)
EMEA/CVMP/SAGAM/184651/2005	Public statement on the use of (fluoro)quinolones in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted February 2007

CVMP General

Reference number	Document title	Status
EMEA/CVMP/422/04-Rev.1	Revised CVMP rules of procedure	Adopted in February 2007
EMEA/4789/2007	Procedure for the nomination and appointment of co-opted members of the Committee	Adopted March 2007
SOP/INSP/2019	Coordination of pre-approval GxP Inspections	Adopted April 2007
EMEA/328/98-Rev.3-CONSULTATION	The acceptability of names for veterinary medicinal products processed through the centralised procedure	Adopted for consultation June 2007 (end of consultation: September 2007)
EMEA/CVMP/425558/2006	Reflection paper on Withdrawals of Marketing Authorisation Applications for Veterinary Medicinal Products	Adopted July 2007
EMEA/CVMP/459912/2006	Reflection paper on the publication of the CVMP's Negative Opinion and Refusal to Recommend the granting of a Marketing Authorisation for Veterinary Medicinal Products	Adopted July 2007
EMEA/CVMP/248499/2007-CONSULTATION	Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products	Adopted for consultation September 2007. (end of consultation March 2008)
EMEA/CVMP/2128/2007	Guideline on procedures for re-examination of CVMP opinions	Adopted September 2007
EMEA/358850/2007-CONSULTATION	Concept paper on the classification of veterinary medicinal products authorised by the Community	Adopted for consultation September 2007. (end of consultation: November 2007)
EMEA/CVMP/120559/2006	Questions and answers document regarding application of the so-called 'sunset clause' to centrally authorised veterinary medicinal products	Adopted October 2007

Committee for Orphan Medicinal Products (COMP) guidelines overview

Scientific Committee	Total number of adopted guidelines/ documents for which committee is responsible	Number of concept papers/ guidelines/ documents initiated in 2007	Number of concept papers/ guidelines/ documents in progress during 2007	Number of guidelines/ documents adopted in 2007
Committee for Orphan Medicinal Products	5	1	1	0

Scientific Committee	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest	
	Initiated	Adopted
Committee for Orphan Medicinal Products	Review of the designation criteria prior to marketing authorisation (addendum to current COMP draft guideline on elements required to support the medical plausibility and the assumption of significant benefit for an orphan designation)	None

Committee on Herbal Medicinal Products (HMPC) *

Reference number	Document title	Status
EMEA/HMPC/139800/2004 Rev.1	Committee on Herbal Medicinal Products: Rules of Procedure	Revision adopted May 2007
EMEA/HMPC/107079/2007	Guideline on the assessment of genotoxic constituents in herbal substances/preparations	Released for public consultation October 2007
EMEA/HMPC/317913/2006	Reflection paper on the risks associated with furocoumarins contained in preparations of *Angelica archangelica* L.	Draft released for public consultation January 2007 Adopted October 2007
EMEA/HMPC/102655/2007	Reflection paper on the adaptogenic concept	Released for public consultation July 2007
EMEA/HMPC/269258/2006 Rev.1	Assessment of case reports connected to herbal medicinal products containing Cimicifugae racemosae rhizoma (Black cohosh, root)	Revision adopted May 2007

* Including documents prepared by the HMPC Working Party on Community monographs and Community list (MLWP)

HMPC Quality Drafting Group

Reference number	Document title	Status
EMEA/HMPC/CHMP/CVMP/287539/2005	Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC	Adopted May 2007
EMEA/HMPC/CHMP/CVMP/214869/2006	Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products	Released for public consultation March 2007

HMPC Organisational Matters Drafting Group

Reference number	Document title	Status
EMEA/HMPC/107399/2005 Rev.1	Guideline on the documentation to be submitted for inclusion in the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'	Adopted July 2007
EMEA/HMPC/107436/2005 Rev.2	Template for a Community herbal monograph	Revision adopted January 2007

Reference number	Document title	Status
EMEA/HMPC/126542/2005 Rev.1	Timetable for the establishment of a Community list entry and/or a Community herbal monograph	Revision adopted March 2007
EMEA/HMPC/182352/2005 Rev.2	Procedure for the preparation of Community monograph for herbal medicinal products with well-established medicinal use	Revision adopted January 2007
EMEA/HMPC/182320/2005 Rev.2	Procedure for the preparation of Community monograph for traditional herbal medicinal products	Revision adopted January 2007
EMEA/HMPC/418902/2005	Assessment report template for the development of Community herbal monographs and for inclusion of herbal substance(s), preparation(s) or combinations thereof in the Community list	Adopted January 2007
EMEA/HMPC/57137/2007	Procedure for the preparation of an entry to the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'	Adopted July 2007
EMEA/HMPC/439705/2006 Rev.2	Template for a Community list entry	Revision adopted July 2007
EMEA/HMPC/71049/2007	Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products	Release for public consultation May 2007
EMEA/HMPC/1004/2006 Rev.1	Procedure for calls for scientific data for use in HMPC assessment work	Revision adopted September 2007
EMEA/HMPC/328575/2007	Procedure on management of proposals from interested parties for Community list entries and Community herbal monographs	Release for public consultation October 2007
EMEA/HMPC/494079/2007	Inventory of herbal substances for assessment	Adopted October 2007

Paediatric Committee (PDCO) guidelines

Reference number	Document title	Status
EMEA/267484/2007	Guideline on the Investigation of Medicinal Products in the Term and Preterm Neonates	Adopted
EMEA/495049/2007	Guidance on the content and the format of data to be collected by the Member States on all existing uses of medicinal products in the paediatric population	Adopted
EMEA/252191/2007	Practical aspects on how to submit an application for paediatric investigation plan and requests for waiver and deferral	Adopted

Annex 18 Arbitration and Community referrals overview 2007

Referrals made to the CHMP

Procedures started

Type of referral	Date of CHMP start of procedure	International non-proprietary name (INN)
Article 29(4) of Directive 2001/83/EC	24/01/2007	fentanyl
Article 29(4) of Directive 2001/83/EC	22/02/2007	histrelin acetate
Article 29(4) of Directive 2001/83/EC	22/03/2007	simvastatin, formoterol fumarate, fentanyl
Article 29(4) of Directive 2001/83/EC	26/04/2007	clostridium botulinum type A neurotoxin complex, bicalutamide, hib/menC conjugate vaccine
Article 29(4) of Directive 2001/83/EC	21/06/2007	nimesulide
Article 29(4) of Directive 2001/83/EC	19/07/2007	budesonide
Article 29(4) of Directive 2001/83/EC	20/09/2007	doxycycline
Article 29(4) of Directive 2001/83/EC	18/10/2007	fentanyl citrate
Article 29(4) of Directive 2001/83/EC	15/11/2007	levonorgestrel/ethinylestradiol, ciclesonide
Article 29(4) of Directive 2001/83/EC	13/12/2007	atorvastatin calcium
Article 30 of Directive 2001/83/EC	22/03/2007	losartan potassium, losartan potassium/hydrochlorothiazide, lamotrigine
Article 30 of Directive 2001/83/EC	24/05/2007	venlafaxine
Article 30 of Directive 2001/83/EC	21/06/2007	gemcitabine HCI
Article 30 of Directive 2001/83/EC	19/07/2007	ciprofloxacin
Article 30 of Directive 2001/83/EC	20/09/2007	risperidone, montelukast sodium
Article 30 of Directive 2001/83/EC	18/10/2007	cetirizine
Article 30 of Directive 2001/83/EC	15/11/2007	mirtazapine, sertraline
Article 31 of Directive 2001/83/EC	21/06/2007	bromocriptine, cabergoline, dihydroergocryptine, lisuride and pergolide
Article 31 of Directive 2001/83/EC	19/07/2007	methylphenidate
Article 31 of Directive 2001/83/EC	20/09/2007	etoricoxib
Article 31 of Directive 2001/83/EC	20/09/2007	norfloxacin
Article 36 of Directive 2001/83/EC	20/09/2007	cetirizine dihydrochloride
Article 107 of Directive 2001/83/EC	20/09/2007	clobutinol
Article 107 of Directive 2001/83/EC	20/09/2007	carisoprodol
Article 107 of Directive 2001/83/EC	15/11/2007	aprotinin
Article 107 of Directive 2001/83/EC	15/11/2007	lumiracoxib
Article 5(11) Of Commission Regulation (EC) N. 1084/2003	18/10/2007	drospirenone, ethinyl estradiol
Article 6(12) Of Commission Regulation (EC) N. 1084/2003	24/05/2007	clomadinone acetate/ethinylestradiol
Article 6(12) Of Commission Regulation (EC) N. 1084/2003	20/09/2007	etoricoxib
Article 6(12) Of Commission Regulation (EC) N. 1084/2003	15/11/2007	moxifloxacin
Article 20 of Council Regulation (EC) No 726/2004	19/06/2007	nelfinavir mesylate
Article 22 of Council Regulation (EC) No 726/2004	25/01/2007	telithromycin
Article 107 of Directive 2001/83/EC	24/05/2007	nimesulide

Procedures finalised

Type of referral	Date of CHMP opinion	International non-proprietary name (INN)
Article 29(4) of Directive 2001/83/EC	24/01/2007	ciprofloxacin lactate, alendronate
Article 29(4) of Directive 2001/83/EC	26/04/2007	alteplase, cefuroxime axetil
Article 29(4) of Directive 2001/83/EC	24/05/2007	histrelin acetate
Article 29(4) of Directive 2001/83/EC	21/06/2007	lansoprazole
Article 29(4) of Directive 2001/83/EC	19/07/2007	fentanyl, clostridium botulinum type A neurotoxin complex
Article 29(4) of Directive 2001/83/EC	20/09/2007	bicalutamide
Article 29(4) of Directive 2001/83/EC	15/11/2007	ciprofloxacin, simvastatin, formoterol fumarate, fentanyl, hib/menC conjugate vaccine
Article 30 of Directive 2001/83/EC	22/02/2007	lornoxicam
Article 31 of Directive 2001/83/EC	24/05/2007	bicilutamide
Article 31 of Directive 2001/83/EC	22/03/2007	mifepristone
Article 31 of Directive 2001/83/EC	21/06/2007	piroxicam
Article 31 of Directive 2001/83/EC	19/07/2007	veralipride
Article 36 of Directive 2001/83/EC	18/10/2007	cetirizine dihydrochloride
Article 5(11) Of Commission Regulation (EC) N. 1084/2003	13/12/2007	drospirenone, ethinyl estradiol
Article 6(12) Of Commission Regulation (EC) N. 1084/2003	13/12/2007	clomadinone acetate/ethinylestradiol
Article 20 of Council Regulation (EC) No 726/2004	21/06/2007	nelfinavir mesylate
Article 22 of Council Regulation (EC) No 726/2004	22/03/2007	telithromycin
Article 107 of Directive 2001/83/EC	20/09/2007	nimesulide
Article 107 of Directive 2001/83/EC	18/10/2007	clobutrinol
Article 107 of Directive 2001/83/EC	15/11/2007	carisoprodol
Article 107 of Directive 2001/83/EC	13/12/2007	lumiracoxib

Referrals made to the CVMP

Type of referral	Date of CVMP opinion	▪ Product name ▪ INN
Referral for arbitration – Art. 33(4) Directive 2001/82/EC	17/1/2007	▪ Equimectin 12mg/g ▪ Ivermectin
Referral for arbitration – Art.40 Directive 2001/82/EC	17/01/2007	▪ Suvaxyn Parvo E ▪ Inactivated porcine parvovirus, strain S-80, Inactivated Erysipelothrix rhusiopathiae, strain B-7 (serotype 2)
Referral for arbitration – Art.40 Directive 2001/82/EC	17/01/2007	▪ Suvaxyn Ery ▪ Inactivated Erysipelothrix rhusiopathiae, strain B-7 (serotype 2)
Referral for arbitration – Art. 33(4) Directive 2001/82/EC	14/02/2007	▪ Doxyprex ▪ Doxycycline base as hyclate
Referral for arbitration – Art. 33(4) Directive 2001/82/EC	17/04/2007	▪ Bovilis BVD ▪ Inactivated BVDV strain C-86
Referral for arbitration – Art. 33(4) Directive 2001/82/EC	18/04/2007	▪ Enurace 50 ▪ Ephedrine
Referral for arbitration - Art. 33(4) Directive 2001/82/EC	11/07/2007 (clock start)	▪ Ecomectin 18.7 mg/g ▪ Ivermectin
Referral for arbitration – Art. 35 of Directive 2001/82/EC	12/12/2007	▪ Tribrissen oral paste for horses (including associated names) ▪ Trimethoprim and sulfadiazine
Referral under – Art. 35 of Directive 2001/82/EC	11/10/2007 (clock start)	▪ Products containing toltrazuril for pultry ▪ Toltrazuril
Referral for arbitration – Art. 34(1) Directive 2001/82/EC	10/10/2007	▪ Methoxasol-T ▪ Trimethoprim and sulfamethoxazole
Referral for arbitration – Art. 33(4) Directive 2001/82/EC	12/12/2007	▪ Equibactin vet ▪ Trimethoprim and sulfadiazine
Referral for arbitration – Art. 33(4) Directive 2001/82/EC	12/12/2007 (clock start)	▪ Solacyl ▪ Sodium salicylate
Referral under – Art. 35 of Directive 2001/82/EC	12/12/2007 (clock start)	▪ Oral solutions powders incicated for calves and pigs, containing sodium salicilate ▪ Sodium salicylate

Annex 19 EMEA contact points

Pharmacovigilance and product 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 from within the EU and outside concerning centrally authorised medicinal products and coordinates action relating to the safety and quality of medicinal products.

For matters relating to pharmacovigilance for medicinal products for human use:	Sabine BROSCH Direct telephone: (44-20) 74 18 85 69 E-mail: pharmacovigilance@emea.europa.eu
For matters relating to pharmacovigilance for medicinal products for veterinary use:	Fia WESTERHOLM Direct telephone: (44-20) 74 18 85 81 E-mail: vet-phv@emea.europa.eu
For product defect and other quality-related matters:	E-mail: qualitydefects@emea.europa.eu. Fax: (44-20) 74 18 85 90 Out of hours telephone: (44-7880) 55 06 97

SME Office

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

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

Certificates of a medicinal product

The EMEA issues certificates of a medicinal product in conformity with the arrangements laid down by the World Health Organization. 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

EMEA PMF/VAMF certificates

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

For enquiries concerning PMF certificates:

Silvia DOMINGO ROIGÉ
Direct telephone: (44-20) 74 18 85 52
Fax: (44-20) 74 18 85 45
E-mail: PMF@emea.europa.eu

For enquiries concerning VAMF certificates:

Ragini SHIVJI
Direct telephone: (44-20) 74 18 86 98
Fax: (44-20) 74 18 85 45
E-mail: VAMF@emea.europa.eu

Documentation services

A wide range of documents has now been published by the EMEA, 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 e-mail request to: info@emea.europa.eu
- by fax to: (44-20) 74 18 86 70
- by writing to:
  EMEA Documentation service
  European Medicines Agency
  7 Westferry Circus
  Canary Wharf
  UK – London E14 4HB

European experts list

Approximately 4 000 European experts are used by the EMEA in its scientific evaluation work. The list of these 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: europeanexperts@emea.europa.eu

Integrated quality management

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