European Medicines Agency

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Annual report of the

European Medicines Agency

2008

Adopted by the Management Board on 7 May 2009

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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

It is my pleasure to write a short message as a foreword to the Annual Report of the European Medicines Agency for 2008. The report provides an extensive overview of the substantial activities of the EMEA during the year. The reader will see that all of the core business activities in the EMEA saw substantially increased activity during the year, including a 14% increase in applications for scientific advice, a 20% increase in individual case safety reports reported through EudraVigilance, a 30% increase in the number of GMP inspections and a 60% increase in the number of GCP inspections, to mention but a few. There was also substantial activity in the area of paediatric implementation plans and slow but steady progress in the area of finalising herbal medicines monographs. Evaluation of veterinary medicines was at an equivalent level to the 2007 activities. A new committee, the Committee for Advanced Therapies, was established and I welcome the members and wish their activities every success. An advisory group was established for the EMEA involvement in the implementation of ENCePP.

The Agency continued to develop further its substantial international activities: cooperation with the FDA was expanded and implementation of the confidentiality arrangement with Health Canada progressed as planned. The appointment of an international liaison officer is a substantive move for the Agency and for the advancement of patient safety.

Interaction with patients, consumers and healthcare professionals continued at a high level and a report was published on the degree of satisfaction of these stakeholders, which showed good results for the EMEA.

The Management Board continued to operate diligently in its oversight role and took a further step in the area of communication and transparency by agreeing to the publication of its meeting documents.

I would like to thank all the members of the Management Board for their diligence during the year. I would also like to express my thanks to the Executive Director and all the staff of the Agency for their exceptional commitment throughout the year. I thank colleagues at the European Commission and Parliament for their ongoing support and guidance to my work as Chairman and to the work of the Agency. I also thank all colleagues from within the network of national medicines regulatory authorities throughout the Member States for their ongoing support.

INTRODUCTION BY THE EXECUTIVE DIRECTOR

Thomas Lönngren

The year 2008 was one of consolidation and steady progress for the European Medicines Agency, rather than one of major leaps and bounds.

'Quantum-leap' developments during the period from 2004 to 2007 — such as the enlargement of the European Union to 27 Member States, the successive introduction of major new EU pharmaceuticals legislation, the creation of our scientific committees for herbal and paediatric medicines — engendered organisational and operational changes that have now had time to settle and become embedded in the daily operations of the Agency, and are beginning to yield the public- and animal-health benefits they were designed to produce.

However, set against a background of continuing globalisation of the pharmaceutical sector, further rapid advances in medical science and the unrelenting pace of regulatory activity in the European medicines network, it was by no means a 'dull' year for the Agency.

As pharmaceutical development and clinical trials of medicines move increasingly beyond the traditional spheres of Europe and North America, regulators are becoming more keenly aware of the need for international cooperation on ensuring that safe and ethical practices are being used for the development and testing of medicinal products in all parts of the world. In 2008, the Agency appointed an International Liaison Officer to oversee and develop further the Agency's cooperation with its international partners, and to ensure we are contributing the best we can to global efforts for safer and better medicines around the world.

Closer to home, we continued as ever to work with our European partners on stimulating innovation in the pharmaceutical sector, strengthening our safety-monitoring of medicines, exchanging expertise on a wide range of issues, and forging closer relations to build the best possible regulatory system for Europe.

In terms of the core assessment work of the Agency, 2008 was a highly productive year. The number of positive opinions adopted on marketing-authorisation applications for medicines for human use was higher than in any year to date. As a result, 66 new medicines — for the prevention or treatment of serious and debilitating conditions such as bone-cancer in children, immune-system diseases, HIV and rheumatoid arthritis — will, once the approval process has been finalised, become available to European citizens.

Assessment work in relation to paediatric medicines, rare-disease medicines, herbal medicines and veterinary medicines was intensive in 2008 too, while the volume of work in relation to the provision of scientific advice, the drafting of guidelines, the processing of variation applications and the conduct of pharmacovigilance activities was reasonably high overall.

Of the many activities conducted by the Agency outside of these core areas, perhaps the most significant in 2008, and one to which the Agency devoted much effort during the year, was preparing for the entry into force of the EU's new Advanced Therapies Regulation — a piece of legislation that will greatly strengthen regulatory procedures relating to medicines at the cutting edge of medical science.

For details on all activities of the Agency this year, I invite you to read deeper into the pages of this annual report. It remains, here, for me to thank the Agency's staff, our colleagues within the national regulatory authorities of the Member States, our colleagues at the European Commission and Parliament, and all of the many other dedicated and generous people who contributed in so many ways towards helping the Agency deliver on its public-health mission in 2008.

1. EMEA IN THE EUROPEAN SYSTEM

1.1 Management Board

In 2008, the EMEA Management Board:

- adopted the Agency's work programme, budget and establishment plan for the year 2009;
- 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 2007.

1.2 European medicines network

The European medicines network — a partnership of more than 40 medicines regulatory authorities in the European Union (EU) and the European Economic Area (EEA) — is the basis of the EMEA's success. The network gives the EMEA access to a pool of 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.

Improved resource planning

- Resources in the network are scarce while the areas of activities are growing. Work continued during 2008 to develop planning processes leading to improved use and better efficiency of the available resources.
- The EMEA participated in the planning process at the level of the Heads of Medicines Agencies. In addition, the EMEA sent regular planning estimates of forthcoming applications for human medicines intended to be submitted through the centralised procedure to the Heads of Medicines Agencies.

Improving efficiency of the network

- Various initiatives were aimed at improving the day-to-day operation of the EU medicines network. These included: an early notification system alerting the Member States of envisaged communication activities on (emerging) safety-related concerns; a draft EU Regulatory System Incident Management Plan; draft key principles for signal management in the EU.
- Other initiatives related to the way meetings are run by the EMEA. These included a number of projects aimed at improving the organisation of working parties, and also the increased use of video- and teleconferencing facilities in order to reduce the need for experts to travel to the EMEA.
- In order to optimise efficiency in the EU regulatory network for veterinary pharmacovigilance for all medicinal products authorised in the Community, the Committee for Medicinal Products for Veterinary Use (CVMP) and its Pharmacovigilance Working Party continued to report to the Heads of Medicines Agencies and the Management Board, continued the review of the functioning of the Pharmacovigilance Working Party and continued to contribute to the European Surveillance Strategy for veterinary medicines.

Continuous competence development

- Training sessions for experts and assessors were held with a view to continuously developing the competence of the network.
- The Agency contributed to the work of the Joint Heads of Medicines Agencies/EMEA Training Project Team, aimed at developing a strategy for training within the European medicines network.

- As part of efforts to identify alternative ways of addressing continuous education needs of the national competent authorities and the EMEA, the Agency produced a DVD on influenza-pandemic preparedness training.

1.3 Transparency and communication

The Agency continued to provide high-quality, timely, targeted and understandable information.

Access to documents

- A draft 'EMEA policy on the practical operation of access to EMEA documents' was published in December 2008 for public consultation. The document responds to increasing demands for access to EMEA documents, by establishing a robust system, capable of handling the increasing number of requests in a more efficient and consistent way, hence facilitating the day-to-day operation of public access to EMEA documents.

Transparency of agendas and minutes

- Two meetings, with involvement of the Member States and the European industry associations, were held to make further progress on transparency of agendas and minutes of scientific committees.
- In December 2008, the Management Board agreed to publish Management Board meeting documents. As a general rule, the agenda, minutes and final Management Board documents agreed for publication by the Board will be published on the EMEA website after each meeting.

Access to EudraVigilance

- The EMEA prepared two policy documents on public access to EudraVigilance, one related to human medicines and one related to veterinary medicines. A public consultation exercise was launched by the end of 2008. EudraVigilance is the EU database on serious adverse drug reactions. The access policy will set out the rules for access of stakeholders, such as healthcare professionals, patients, pharmaceutical industry and the general public, to the data held in the database.

Redesign of the EMEA website

- The redesign of the Agency's website started in 2008 when EMEA began working with a web communications agency selected through a public procurement exercise. With support from the agency, EMEA is finding new ways to deliver online information on medicines in a more accessible way to patients and healthcare professionals as well as improving the online experience for industry and the regulatory world. An important component of the design project is user research and user testing to ensure that all new concepts and ideas are based on the reality of the user experience. Launch of the new website is set for December 2009.

1.4 Support for innovation and availability of medicines

Various EMEA activities are dedicated to contributing to innovation and availability of medicines.

Support to micro, small and medium-sized enterprises

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 Agency received 84 applications for fee reduction or deferral, 40 % above forecast and slightly more than in 2007 (81).
- A total of 84 requests for administrative assistance were received; an increase of 37% compared to 2007.
- 242 requests for qualification as SME were received, 34 % over forecast, 14 % more than in 2007. A proportion of these were re-assignments where companies failed to renew prior to expiry at the end of 2007.
- 159 requests for renewal of SME status were received. The majority of companies maintained their SME status active; reminders were sent to companies to process the renewal.
- A total of 337 decisions on qualification or renewal of SME status were adopted. 40 initial and 24 renewal requests were ongoing at the end of 2008.
- With respect to veterinary medicines, by the end of 2008, 14 companies had been recognised as SMEs developing exclusively veterinary products, and 15 as developing both human and veterinary products. Five applications for marketing authorisation of veterinary products were received overall from SMEs, of which three received a positive opinion.
- A revised and updated version of SME User Guide was published in November 2008.
- Work was started on identifying specific guidance needs related to the new legislation on advanced therapies.
- Support was provided to the concept of SME offices within the European medicines network. An update of national contact points was published in the annex to the User Guide in November 2008. Three national competent authorities have announced the establishment of "offices" to assist SMEs.

Advanced therapies

- Implementation of the legislation on advanced therapies was one of the Agency's main priorities for 2008.
- The Committee for Advanced Therapies (CAT) was constituted, ahead of its first meeting in January 2009. In addition, important procedures were prepared that will allow a smooth operation of the CAT within the existing framework of scientific committees and working parties at the EMEA.

1.5 European public and animal health activities

Work on public and animal health matters involves continuous collaboration with institutional and European partners, including the European Commission, other decentralised EU agencies and the European Directorate for the Quality of Medicines and HealthCare (EDQM).

Tropical and neglected diseases

- An addendum to the tuberculosis (TB) guideline was prepared and is currently under consultation.
- Several European centres of excellence on tropical medicine were contacted.

Antimicrobial resistance

- A project relating to the identification of gaps in the area of multi-resistant infectious agents was started in cooperation with the European Centre for Disease Control and Prevention (ECDC) and Duke University.
- The Agency agreed to a request from the European Commission to work with EFSA, ECDC and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to develop a joint report on the potential risk to man from the use of antimicrobials in animals.

Medicinal products that can be used against pathogenic agents that can be employed in biological warfare

- The database on medicinal products that can be used against pathogenic agents that can be employed in biological warfare was finalised and launched to the public on the EMEA website.
- Contact was established with the Heads of Medicines Agencies in order to obtain Member State-specific information to be linked in the published database.

Pandemic influenza

- The EMEA held a workshop with the national competent authorities to discuss pandemic preparedness at the level of the competent authorities in the Member States.
- The EMEA's pandemic preparedness measures were integrated into the Agency's general business-continuity planning.

Community Animal Health Policy

- The contribution of the EMEA to the Community Animal Health Policy was agreed with the European Commission and focuses on measures to promote the authorisation of vaccines against epizootic diseases, such as Foot-and-Mouth disease, Bluetongue and Avian Influenza, and on measures to minimise the risks from antimicrobial resistance arising as a result of the authorisation and use of veterinary medicines.

1.6 Preparations for future enlargement

Pre-enlargement activities were extended to the former Yugoslav Republic of Macedonia, Croatia and Turkey. The activities for the new Transitional IPA programme for pre-accession activities were proposed, discussed and agreed with the EMEA, the Commission and the candidate countries. A series of workshops were organised in the defined priority areas. In addition, representatives of candidate countries participated in selected meetings and training.

1.7 International cooperation

These activities cover cooperation at international level, including: the coordination of EMEA participation at the International Conference/Cooperation on Harmonisation (ICH and VICH); work with the World Health Organization (WHO) on medicinal products for use in developing countries; the Codex Alimentarius; the World Organisation for Animal Health (OIE); the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA); the Japanese and Canadian authorities in the implementation of confidentiality arrangements; and work with non-ICH regulatory authorities.

Appointment of International Liaison Officer

Recognising the importance of international cooperation for safer and better medicines around the world, the EMEA appointed an International Liaison Officer to oversee and develop further the Agency's cooperation with its international partners.

Confidentiality arrangements with third countries

- The EMEA made progress on implementing the confidentiality arrangements with the USA and started to work on the implementation plan for the confidentiality arrangements with the Canadian authorities.

- Implementation of the confidentiality arrangements with the Japanese health authorities developed at a slower rate.
- The project related to the identification of additional international cooperation with other non-EU countries is under development.

Collaboration with the WHO

- The EMEA continued to collaborate with the WHO on medicinal products intended for markets outside the EU, quality matters, and international non-proprietary names (INN), and participated in the launch of the WHO initiative 'Make medicines child size'.

Contribution to ICH and VICH

- The EMEA continued to contribute to the work of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). ICH is a unique project that brings together the regulatory authorities of Europe, Japan and the United States, and experts from the pharmaceutical industry in the three regions, to discuss scientific and technical aspects of product registration.
- Excellent progress was made between the VICH regions Japan, the US and Europe to agree on the controlled lists of terms to be used for electronic reporting in veterinary pharmacovigilance, and sign-off of the guidelines are expected early in 2009.

1.8 EMEA outcome assessment

This is a new area of activity coordinated by the Agency's Senior Medical Officer. It is aimed at assessing the EMEA's processes as measured by the attainment of a specified end result or outcome.

Project on benefit-risk assessment

- The pilot for a project on benefit-risk assessment was carried out in 2008. The project involves the use of a revised benefit-risk assessment section in the assessment report template by the Agency's Committee for Medicinal Products for Human Use (CHMP). The new template incorporates a structured list of benefit and risk criteria and guidance. The pilot is currently under evaluation.
- The EMEA also started a project on the application of quantitative methodologies for benefit-risk assessment in 2008, which is currently ongoing.

Scientific memory

- The prototype of a new database for an expansion of the existing scientific memory database to post-authorisation activities was established and used routinely as of November.
- A project plan was elaborated to include additional clinical trials information in this database during the course of 2009.

1.9 Integrated management at the Agency

Process improvement exercise

- The process improvement exercise that began in 2006 was maintained in 2008 and continuous process improvement is now embedded in the organisational culture. The Agency constantly strives to optimise key processes, improve its performance, maximise the cost-effectiveness of its operations, and achieve even higher satisfaction of its stakeholders. Improvement actions are identified by staff,

reviewed by management and implemented wherever possible. Issues raised have been taken into account when defining the scope of the 'Improving the Functioning of EMEA' restructuring exercise initiated in 2008.

Internal audit programme

- A programme of 10 internal audits was carried out in 2008, looking at key processes such as: missions; infrastructure planning; MRLs and assessment for veterinary medicines; access to information; data monitoring; assessment for human medicines; and the Agency's risk management system.

Internal control standards

- The level of implementation of standards for internal control was reviewed. A number of improvement actions were proposed and implementation of some of them started in 2008.

Benchmarking of medicine agencies

- The EMEA self- and external-assessment exercises, conducted in accordance with the Benchmarking of European Medicines Agencies (BEMA) programme, took place in the first half of the year. The improvement actions stemming from the exercise are in progress.

Management review

- The management review for 2008 took place throughout the year. The following topics were considered during indicated meetings: review of 2007 activities; planning and reporting activities; 1st quarter deviations; ex post controls review; annual review of internal control standards; process improvement; surveys at the EMEA; half year report; environmental analysis; risk management; review of audit reports; and follow-up on improvement actions stemming from audits.

2. MEDICINES FOR HUMAN USE

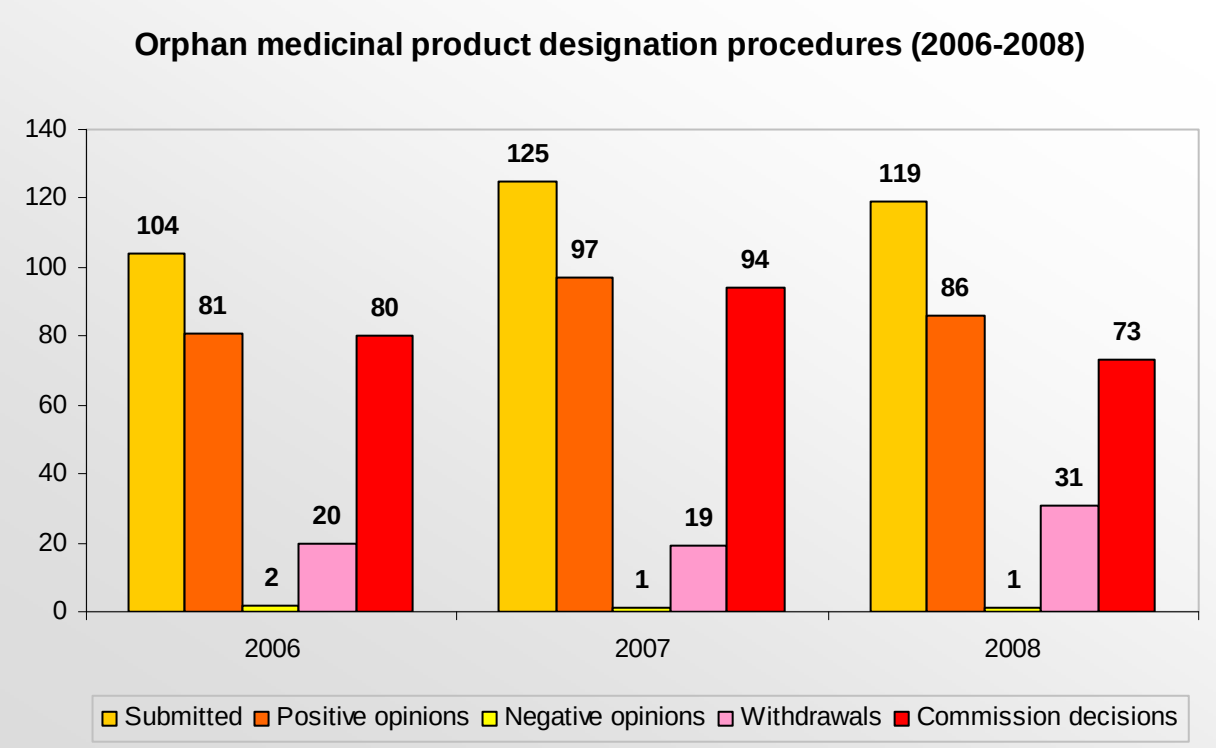
2.1 Orphan medicinal products

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.

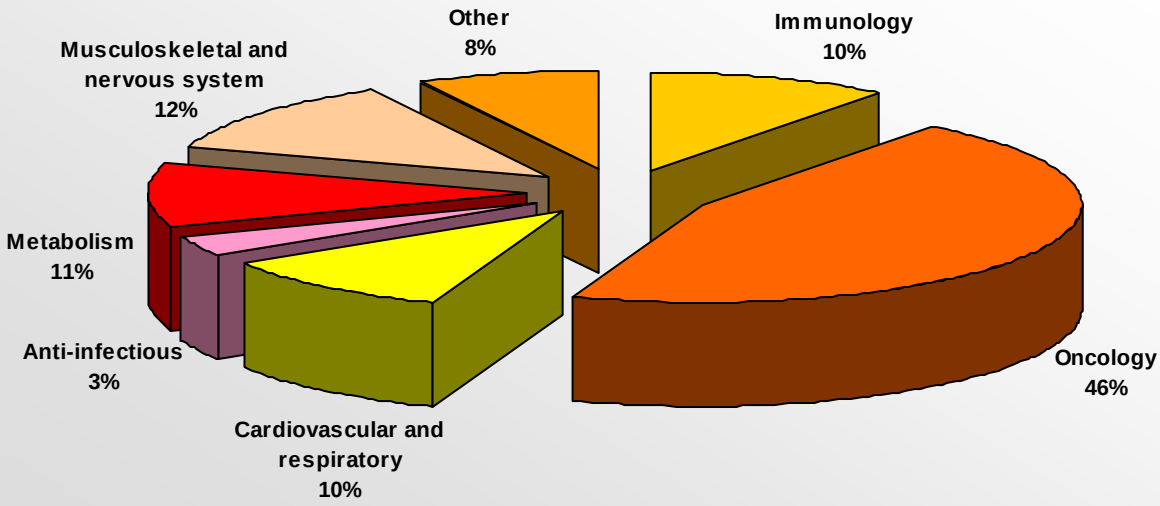
Core activities

Orphan designation

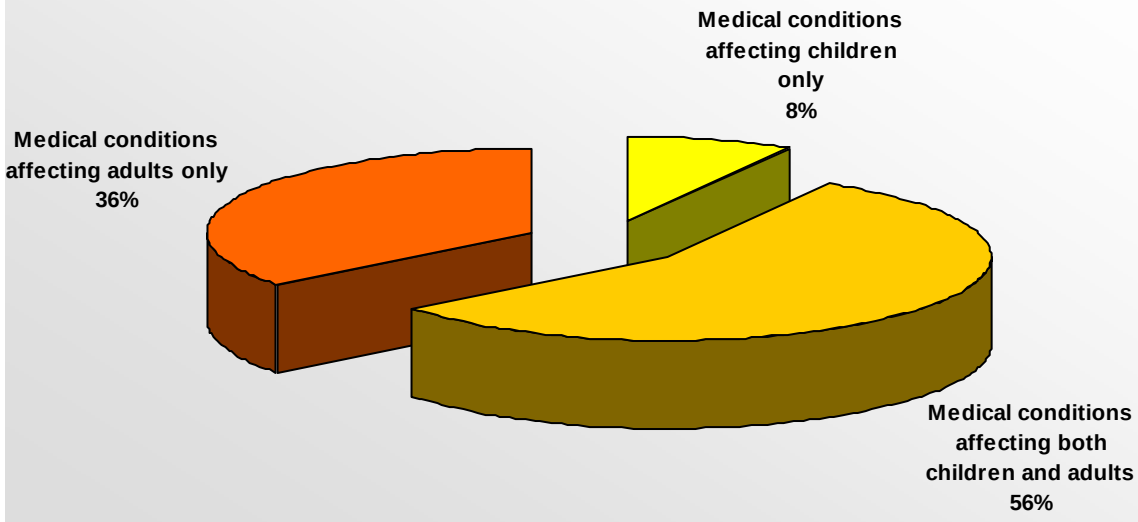
- For the fifth consecutive year, more than a hundred applications were received for the designation of orphan medicinal products: a total of 119 applications were submitted.
- The Committee for Orphan Medicinal Products (COMP) adopted 86 positive opinions and one negative opinion.
- The number of withdrawn applications (31) was higher than in the previous four years.
- As in previous years, cancer treatment was the most-represented therapeutic area for which the COMP adopted positive orphan-designation opinions.
- Almost two-thirds of designated orphan medicinal products were for conditions affecting children.
- The average time taken by the COMP to evaluate applications was 66 days — the same as in the previous year.

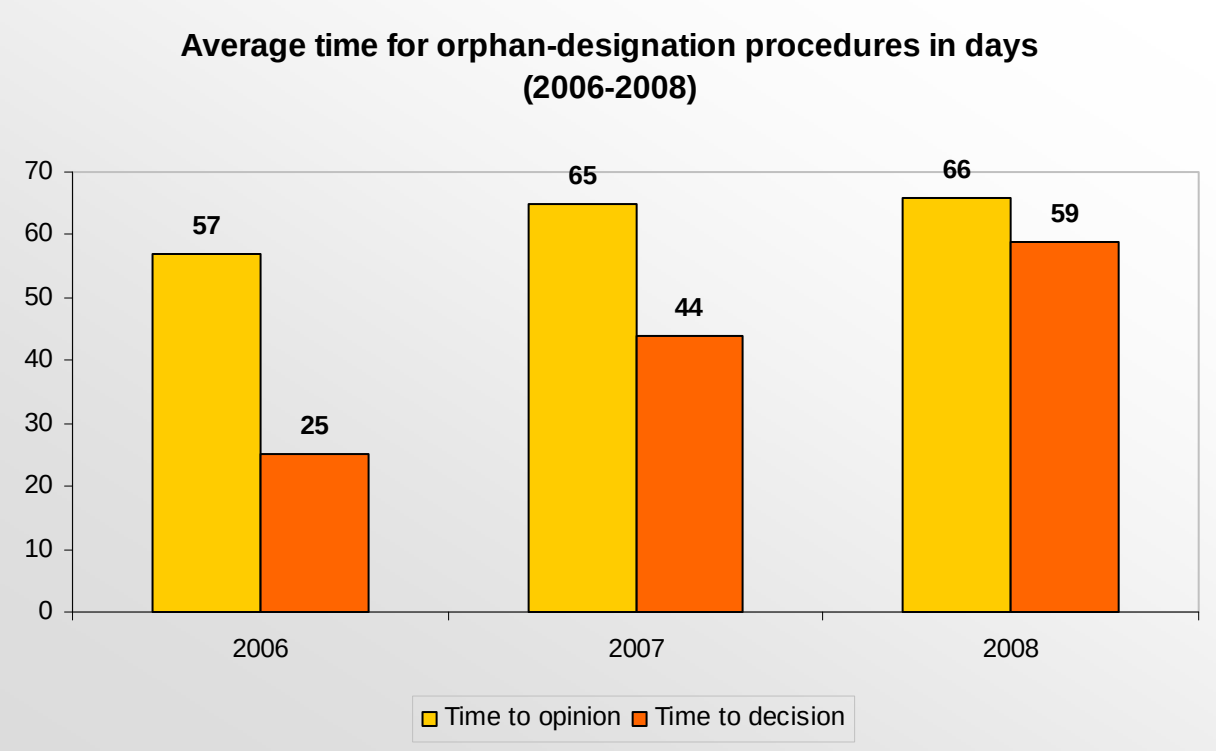


COMP opinions by therapeutic area (2008)



Designated orphan medicinal products for the treatment of children and adults (2008)



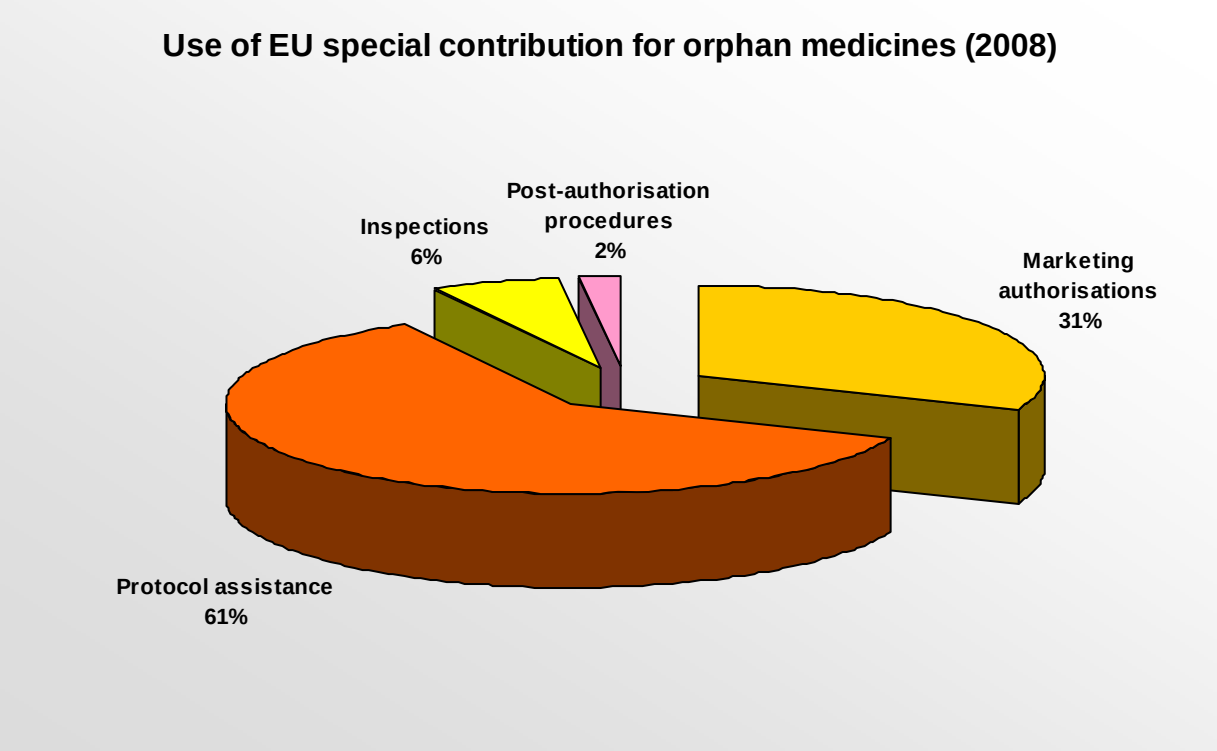


Performance indicators

Performance indicator	Target	Outcome at end of 2008
Percentage of applications evaluated within the 90-day timeline	100% of applications	100%
Percentage of summaries of COMP opinions published within 1 month of the European Commission's decision on designation	70% of summaries of opinion	100%

EU special contribution for orphan medicines

- A total of €4.77 million from the EU special contribution was used to grant fee reductions for orphan medicines in 2008. This accounts for 79% of the total fund of €6 million.
- The Agency's policy on fee reductions for orphan medicines focuses 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.



Specific objectives in 2008

Parallel designation of orphan medicines

- A process for parallel designation of orphan medicines at the EMEA and the United States Food and Drug Administration (FDA) was implemented in 2008. Thirty per cent of applications received were designated in parallel with the FDA.

Review of profitability of orphan medicines

- Following the publication in October 2008 of the Commission's 'Guideline on aspects of the application of Article 8(2) of Regulation (EC) No 141/2000: Review of the period of market exclusivity of orphan medicinal products', the Agency started streamlining its processes to review the profitability of orphan designated medicines. If available evidence shows that an orphan-designated medicine is sufficiently profitable, the period of market exclusivity may be reduced from ten to six years.

Electronic-only submission planned

- Following on from the positive experience with electronic-only submissions of applications for marketing authorisations, a project plan was agreed to implement electronic-only submissions for applications for orphan designation in 2009.

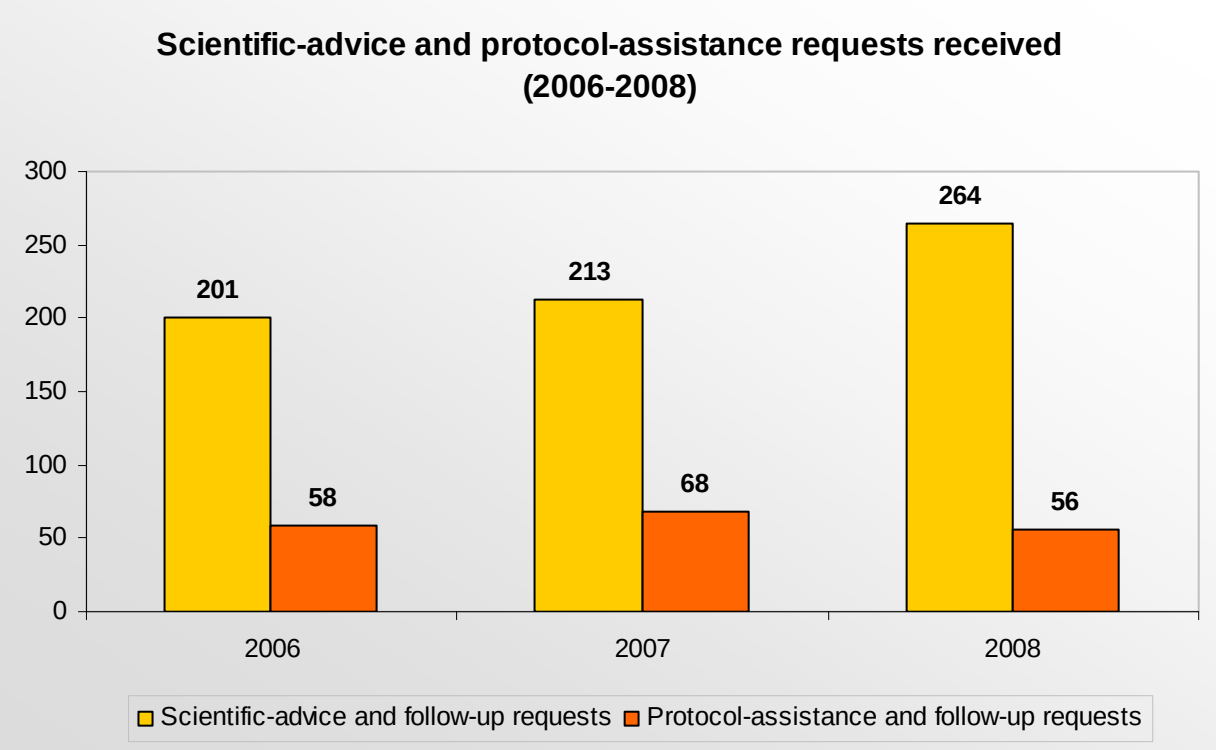
2.2 Scientific advice and protocol assistance

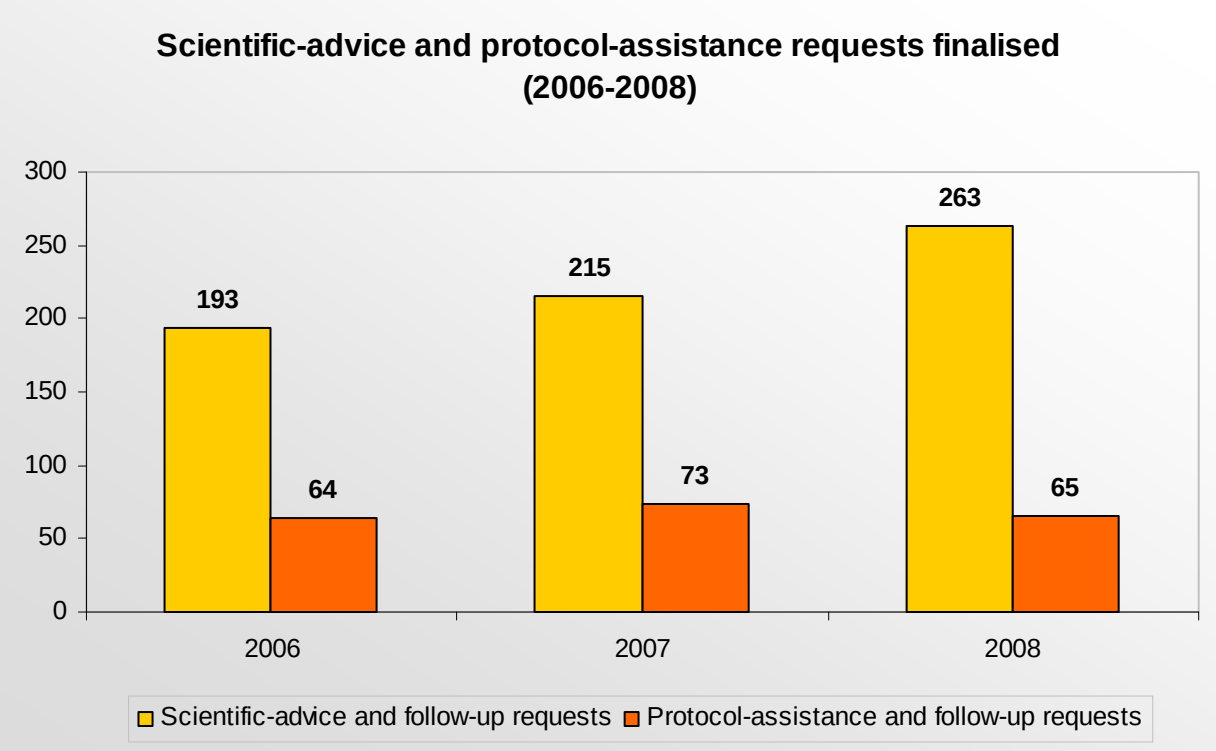
The Agency provides scientific advice and protocol assistance to sponsors during the phase of research and development of medicinal products. Scientific advice is provided on any aspect of research and development relating to quality, safety or efficacy of medicinal products. In addition, the Agency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

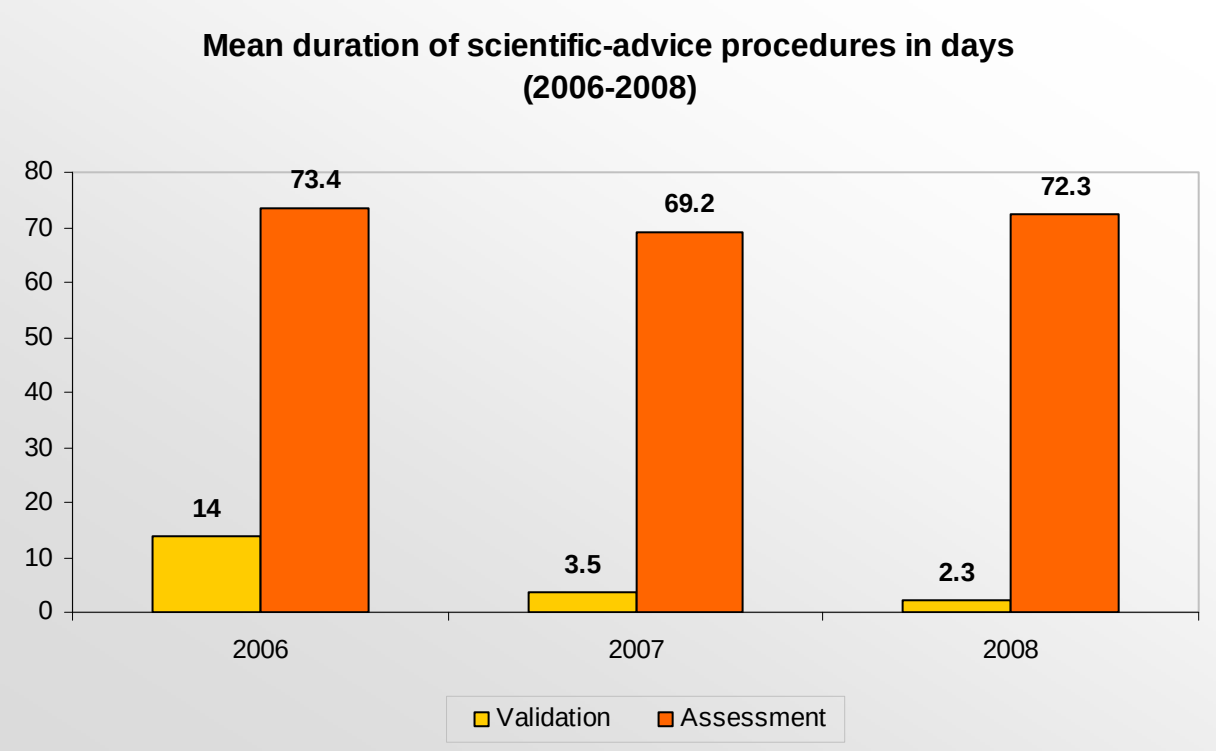
Scientific advice and protocol assistance are key areas of activity for the Agency, in particular with respect to fostering new innovative technologies and therapies. The Agency considers scientific advice as a means to facilitate and improve earlier availability of medicinal products to patients and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

Core activities

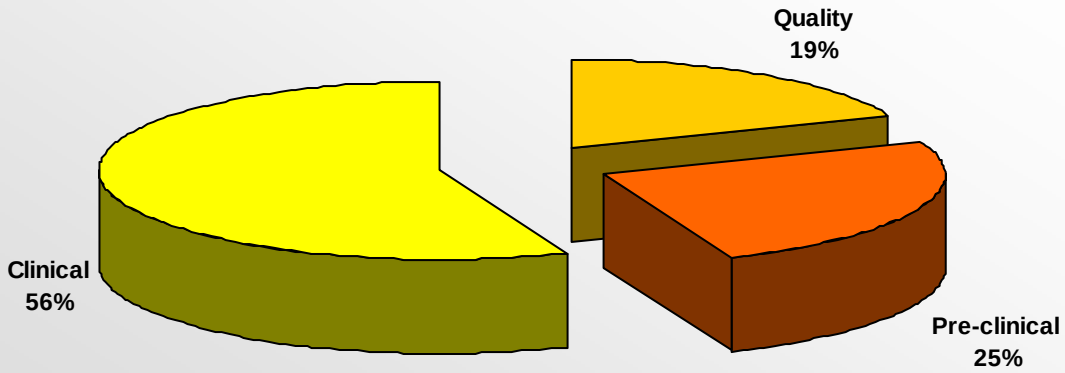
- The Agency received 264 requests for scientific advice, 24% more than in 2007.
- The number of requests for protocol assistance was 56, down by 18% compared to 2007.
- A record number of 328 scientific advice and protocol assistance requests were finalised in 2008, more than in any previous year.
- The timelines for the delivery of scientific advice and protocol assistance were very similar to those in previous years.
- The therapeutic area with the highest number of requests received was oncology, followed by metabolic and alimentary tract conditions, anti-infectives and central nervous system.



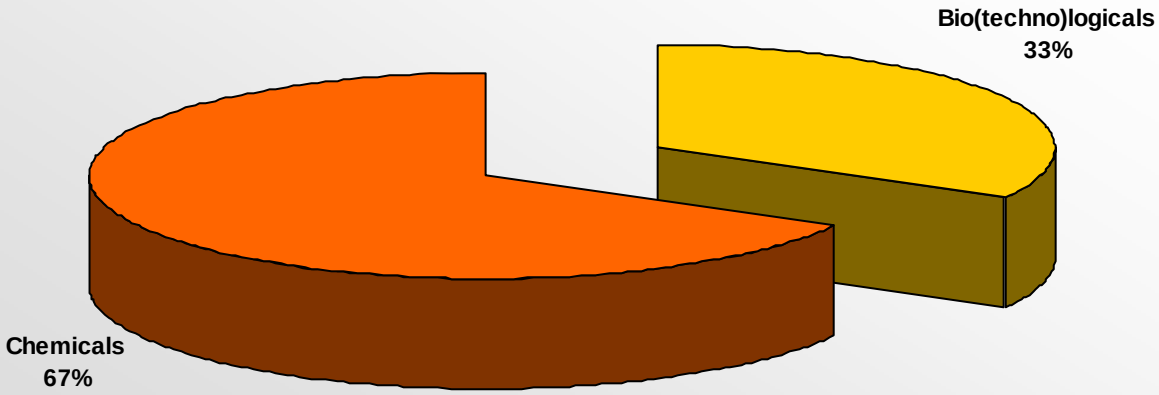

Scientific-advice and protocol-assistance requests finalised (2006-2008)
300
250
200
150
100
50
0
193
64
215
73
263
65
2006
2007
2008
Scientific-advice and follow-up requests
Protocol-assistance and follow-up requests

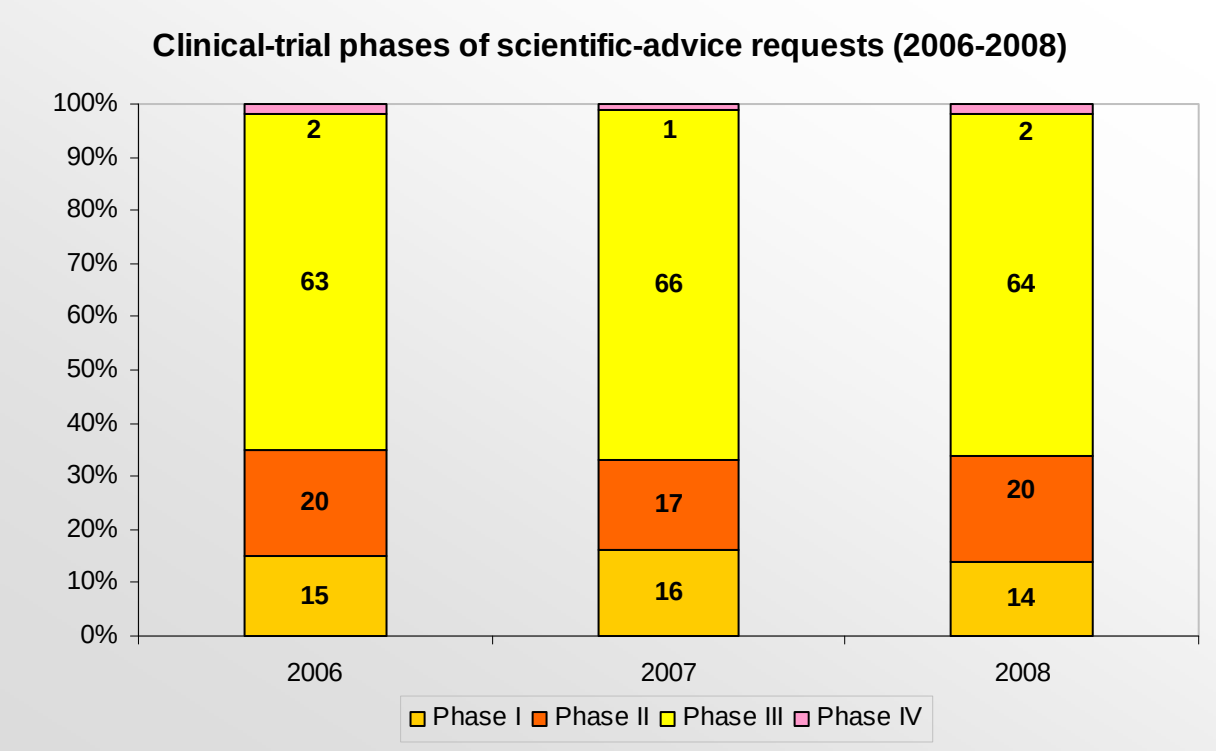

Mean duration of scientific-advice procedures in days (2006-2008)
80
70
60
50
40
30
20
10
0
14
73.4
3.5
69.2
2.3
72.3
2006
2007
2008
Validation
Assessment

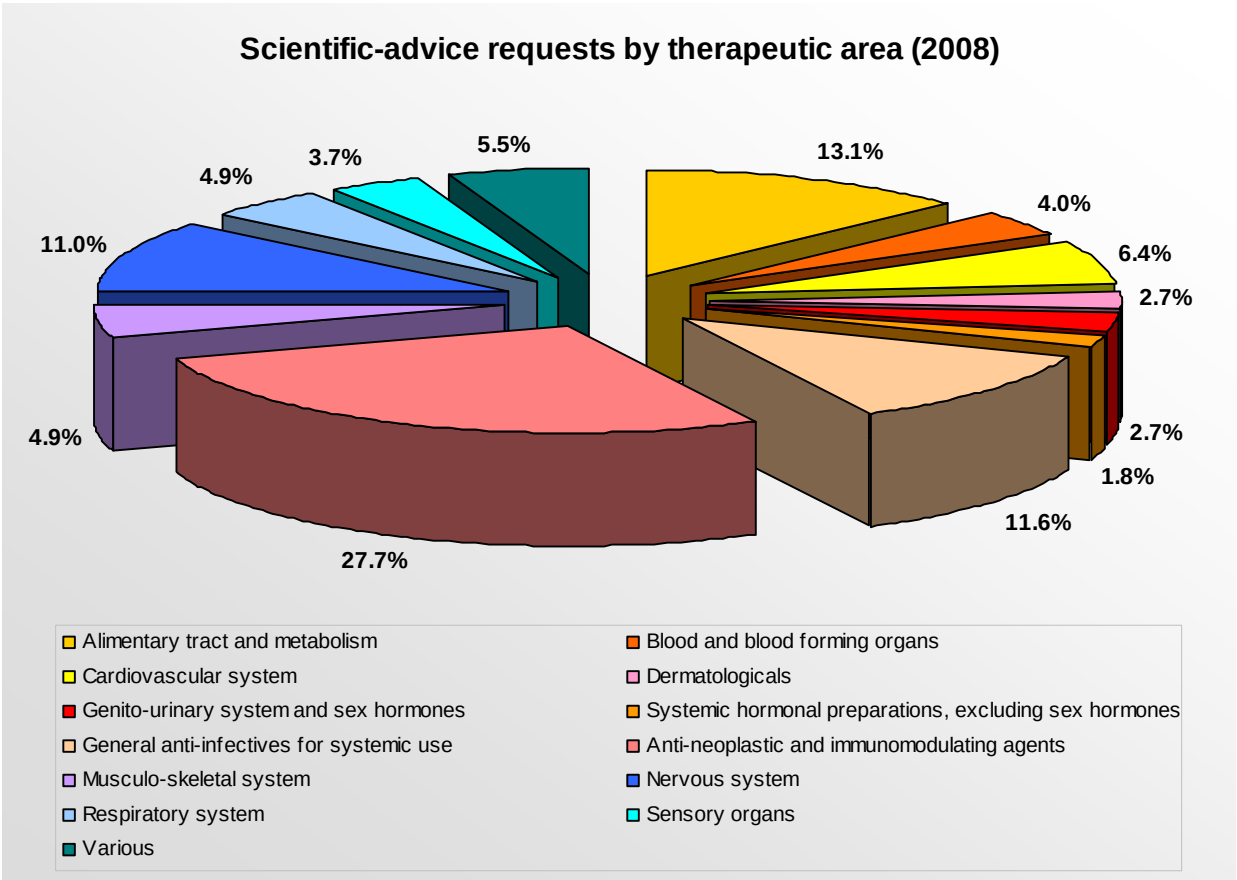
Scientific-advice requests by topic (2008)



Scientific-advice requests by product type (2008)




Clinical-trial phases of scientific-advice requests (2006-2008)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
2
63
20
15
1
66
17
16
2
64
20
14
2006
2007
2008
Phase I
Phase II
Phase III
Phase IV


Scientific-advice requests by therapeutic area (2008)
5.5%
3.7%
4.9%
11.0%
4.9%
27.7%
13.1%
4.0%
6.4%
2.7%
2.7%
1.8%
11.6%
Alimentary tract and metabolism
Blood and blood forming organs
Cardiovascular system
Dermatologicals
Genito-urinary system and sex hormones
Systemic hormonal preparations, excluding sex hormones
General anti-infectives for systemic use
Anti-neoplastic and immunomodulating agents
Musculo-skeletal system
Nervous system
Respiratory system
Sensory organs
Various

Specific objectives in 2008

Improving the scientific-advice and protocol-assistance procedures and quality assurance

- Scientific-advice and protocol-assistance procedures were peer-reviewed before finalisation of advice. The peer-review process was started in 2007 and has been continued systematically since then.
- A new procedure was set up to provide advice on biomarkers. A proposal was published for external consultation. Feedback received has been discussed. The final guidance is expected by the beginning of 2009.
- The abovementioned procedure for the provision of advice in relation to biomarkers was piloted in 2008, and three requests for such advice were received.
- Outcomes of a stakeholder survey on the quality of scientific advice were reviewed in 2008. The possibility of introducing a shorter scientific-advice procedure in 2009 is currently being discussed.

Electronic-only submission planned

- Following the positive experience gained with electronic-only submissions of applications for marketing authorisations, a project plan was agreed to implement electronic-only submissions for applications for scientific advice. Implementation is due to be finalised by the end of 2009.
- Plans to promote the exchange of information on advice given by the national competent authorities had to be postponed due to a lack of resources.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Scientific-advice and protocol-assistance requests evaluated within the procedural timelines	100% of requests	98%
External experts involved in procedures	At least 50% 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	40% (2 medicinal products representing a significant innovation received scientific advice out of 5 new applications)

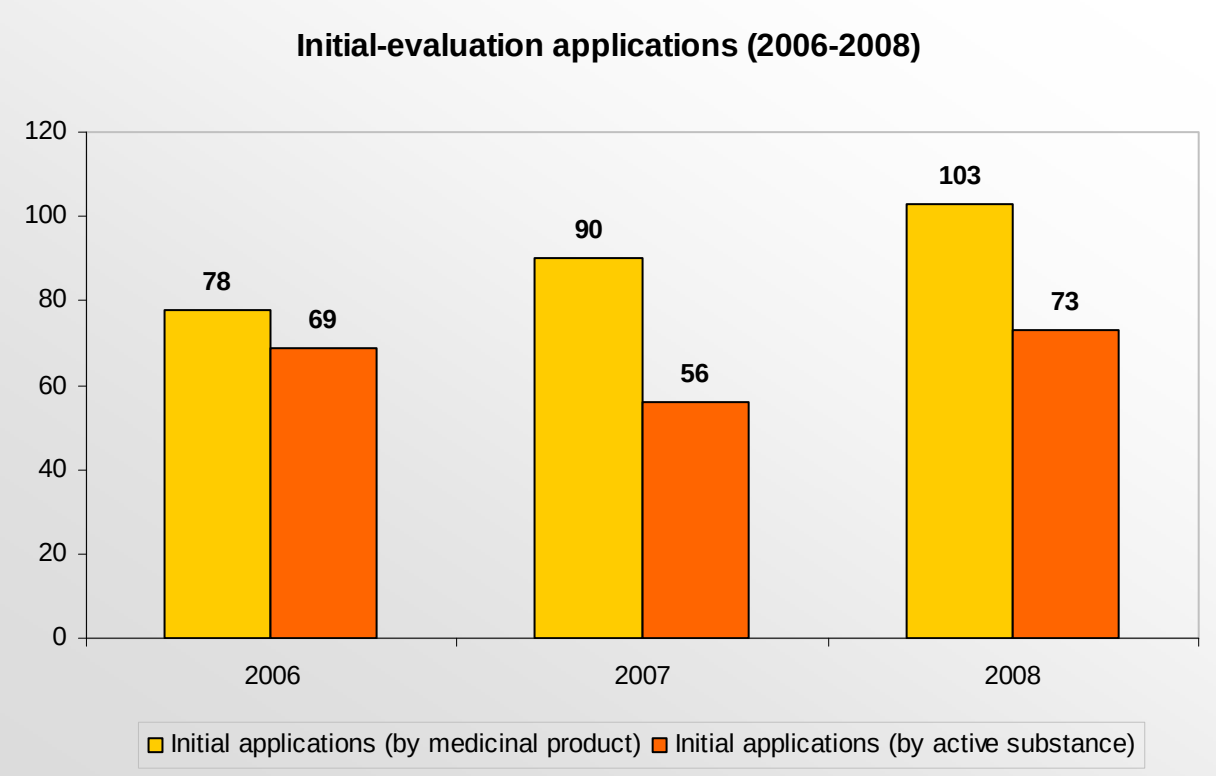
2.3 Initial evaluation

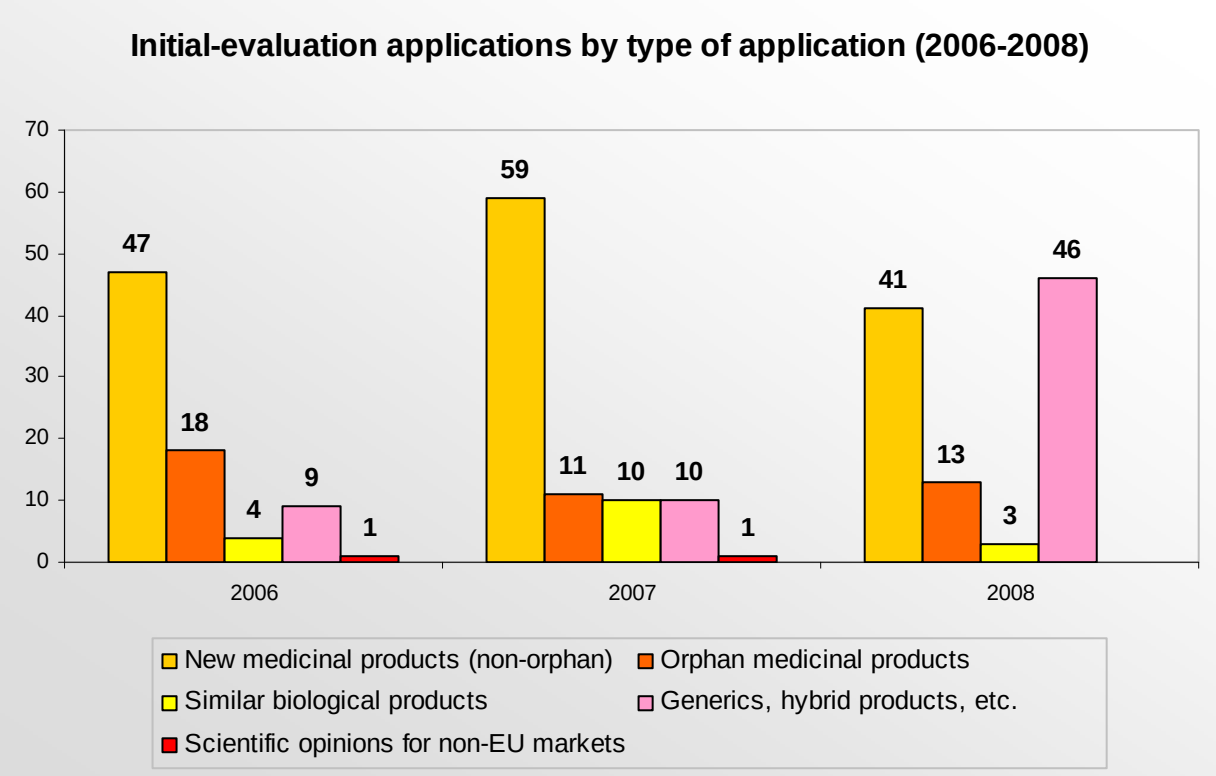
Initial evaluation covers activities relating to the processing of applications for medicinal products (orphan, non-orphan, similar biological (biosimilar), generic, etc.) from pre-submission discussion with future applicants, through evaluation by the CHMP, to the granting of a marketing authorisation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

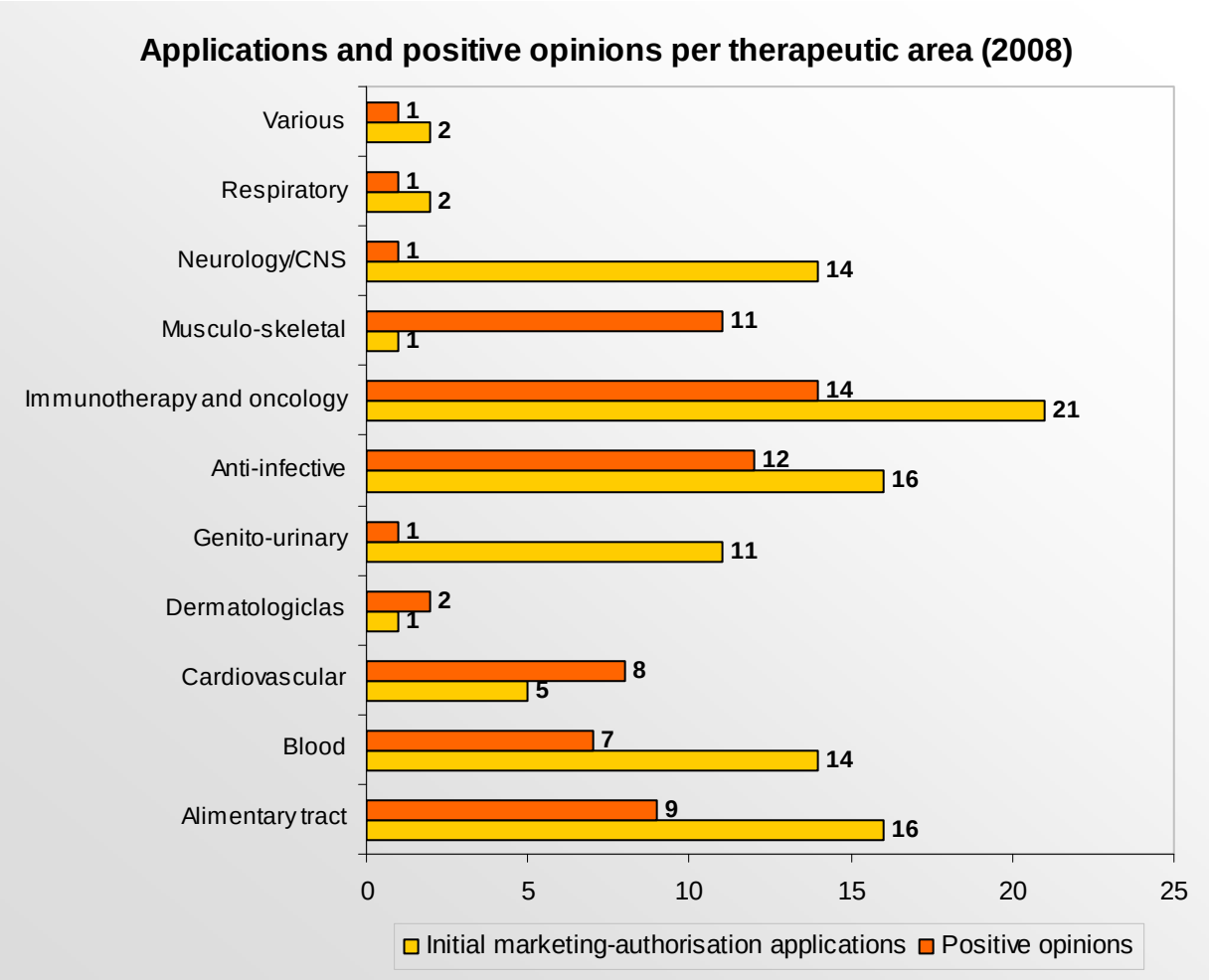
Core activities

New applications

- A total of 103 initial marketing-authorisation applications were received in 2008 — 14 % more than in the previous year.
- The number of applications submitted for non-orphan medicines (41) was almost a third lower than forecast. This may be attributed to fewer multiple applications being received, application submissions being delayed to 2009, and some impact of the new paediatric compliance requirements on applicants' preparedness to submit as planned.
- The number of applications for generic and hybrid medicines and informed consent applications was 46 — much higher than anticipated.
- Applications for new products for use in the treatment of cancer once again represented the highest proportion by therapeutic area in 2008. Anti-infectives and medicines intended for the treatment of metabolic and alimentary tract diseases were the next most-represented therapeutic groups.
- With the legal and regulatory framework for similar biological medicines now firmly established, 3 applications for these were received in 2008.

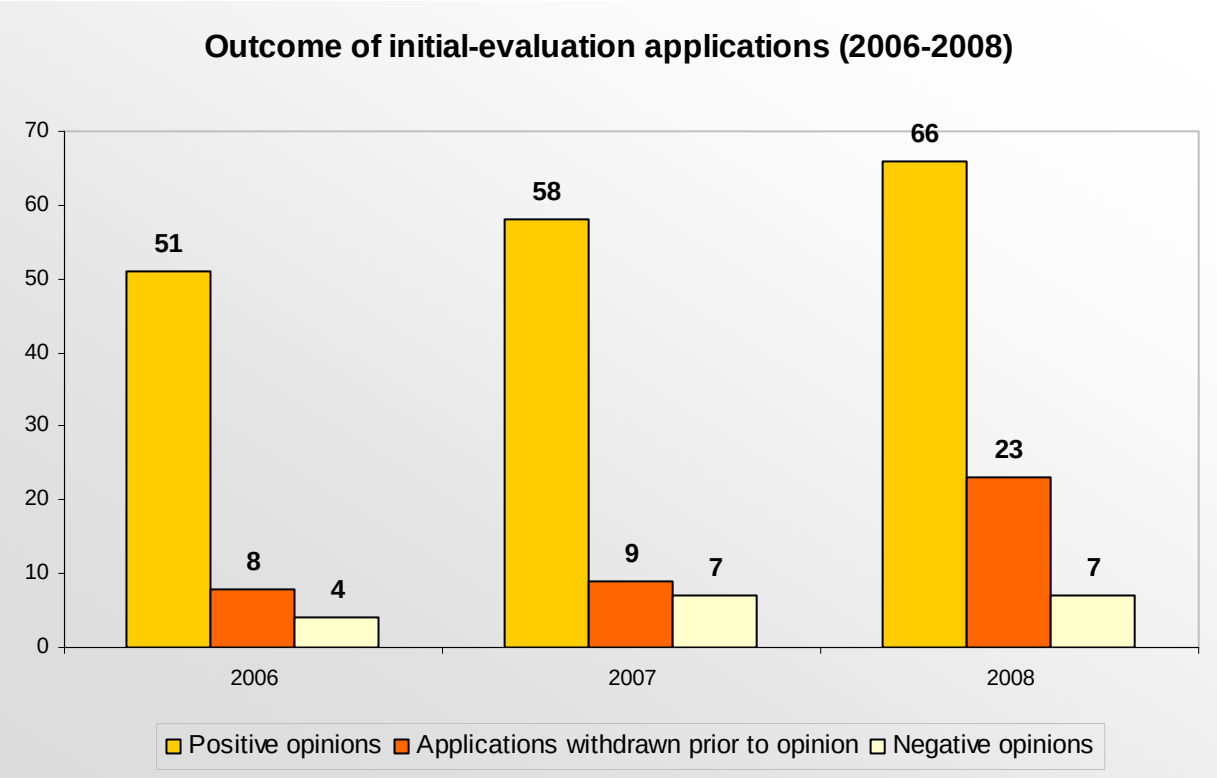


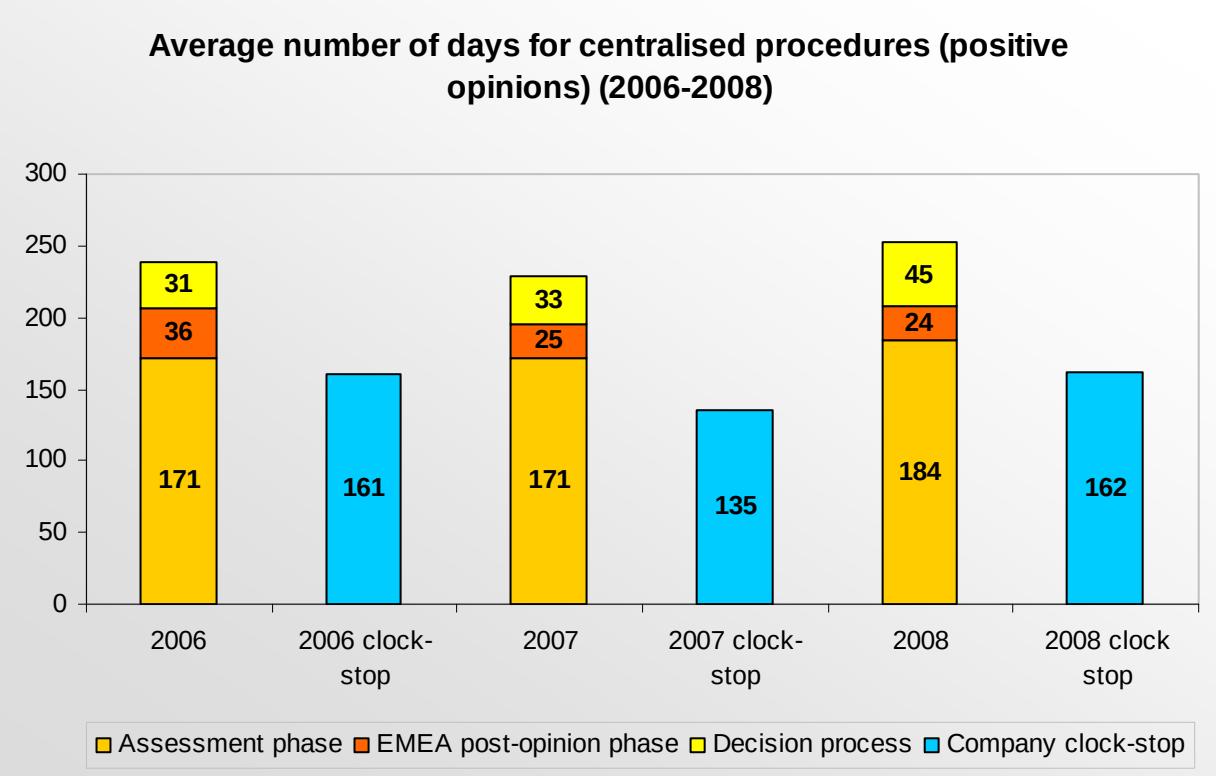

Initial-evaluation applications by type of application (2006-2008)
70
60
50
40
30
20
10
0
47
18
4
9
1
59
11
10
10
1
41
13
3
46
2006
2007
2008
New medicinal products (non-orphan)
Orphan medicinal products
Similar biological products
Generics, hybrid products, etc.
Scientific opinions for non-EU markets


Applications and positive opinions per therapeutic area (2008)
Various
1
2
Respiratory
1
2
Neurology/CNS
1
14
Musculo-skeletal
11
1
Immunotherapy and oncology
14
21
Anti-infective
12
16
Genito-urinary
1
11
Dermatologiclas
2
1
Cardiovascular
8
5
Blood
7
14
Alimentary tract
9
16
0
5
10
15
20
25
Initial marketing-authorisation applications
Positive opinions

Opinions

- In 2008, the EMEA's Committee for Medicinal Products for Human Use (CHMP) adopted 66 positive opinions on initial-evaluation applications — 14% more than in 2007, and the highest number of positive opinions adopted in any one year.
- The Committee adopted seven negative opinions, recommending that the marketing authorisation for these medicines be refused.
- 23 applications were withdrawn before adoption of a CHMP opinion.
- The highest number of positive opinions adopted was for cancer products, followed by anti-infectives and medicines used to treat neurology and central-nervous-system conditions.
- The CHMP adopted one opinion recommending granting of a conditional marketing authorisation.





* 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 2008

Medicines of notable public-health interest that received a positive opinion from the CHMP in 2008 included:

- The first medicine for use as maintenance treatment in adults with acute myeloid leukaemia, a type of cancer affecting the white blood cells, in combination with interleukin-2 (an anticancer medicine). It is used during the patients' first 'remission' (a period without symptoms of the disease after the first course of treatment).
- A designated orphan medicine to treat high-grade non-metastatic osteosarcoma (a bone cancer) in children, adolescents and young adults. It is used with other anticancer medicines after the cancer has been removed by surgery.
- A designated orphan medicine used in adults with long-term immune thrombocytopenic purpura (ITP), a disease in which the patient's immune system destroys the platelets (components in the blood that help it to clot). Patients with ITP have low platelet counts and are at risk of bleeding.
- A designated orphan medicine used for the treatment of adults who cannot have a bone marrow transplant and suffer from diseases called myelodysplastic syndromes, a group of conditions where too few blood cells are produced by the bone marrow.
- A designated orphan medicine used to treat hyperphenylalaninaemia (HPA, high levels of phenylalanine in the blood) in patients with the genetic disorders phenylketonuria (PKU) or tetrahydrobiopterin (BH4) deficiency.
- A new compound in an existing class of antiretroviral medicines used to treat adults who are infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS), and which is resistant to other compounds in this class. The new compound offers new treatment options for HIV-infected patients in whom treatment with other medicines has been unsuccessful.

- A medicine belonging to a new class of anti-rheumatic biological agents (interleukin-6 receptor antagonist), which can be used in combination with methotrexate, to treat adults with moderate to severe active rheumatoid arthritis (an immune-system disease causing inflammation of the joints). It is used in patients who have not responded adequately to, or who could not tolerate, other treatments, including conventional medicines for rheumatoid arthritis (such as methotrexate) or tumour necrosis factor (TNF) blockers.
- The first vaccine used to vaccinate adults against Japanese encephalitis, a disease that causes inflammation of the brain. Japanese encephalitis can be fatal or lead to long-term disability. It is transmitted by mosquitoes and is most common in South-East Asia and the Far East.
- Two new mock-up pandemic influenza vaccines intended for the prevention of influenza during an officially declared pandemic situation. (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.)
- The first pre-pandemic vaccine used to vaccinate adults against the H5N1 subtype of the influenza A virus, which may cause avian influenza in humans. It is intended for use from WHO influenza pandemic phase 3 (pandemic alert with no or very limited human-to-human transmission) onwards.
- Two medicines used to prevent the formation of blood clots in the veins (venous thromboembolism, VTE). Both medicines can be administered by mouth and do not require laboratory monitoring, representing an alternative to conventional therapy by injection. One is a factor Xa inhibitor (it blocks factor Xa, an enzyme that is involved in the production of thrombin, which is central to the process of blood-clotting) and is used in adults who are undergoing surgery to replace a hip or knee. The other product is used in adults who have had an operation to replace a hip or knee. It is an anticoagulant (prevents the blood from clotting) that blocks thrombin, therefore reducing the risk of blood clots forming in the veins.

Specific objectives for 2008

Mandatory scope extended

- On 24 May 2008, the mandatory scope of the centralised procedure was extended to cover all marketing-authorisation applications for new antiviral medicines and medicines intended to treat autoimmune diseases and other immune dysfunctions. Such applications must now be submitted centrally to the EMEA for assessment. All relevant guidance was finalised well ahead of the cut-off date.

Compliance check for paediatric investigation plans (PIPs)

- In July 2008, legislation on paediatric medicines introduced a new requirement that applicants have to submit the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan in order for their application for a marketing authorisation to be considered valid (unless they have obtained a waiver or a deferral for this obligation).
- The EMEA revised the procedure for validation of marketing-authorisation applications to include a compliance check with agreed PIPs by the EMEA's Paediatric Committee, where required. Application forms were revised and the procedure for compliance checks was published.

Improving assessment reports

- The current CHMP peer review of rapporteurs' and co-rapporteurs' assessment reports was revised to provide greater clarity on the responsibilities of the EMEA secretariat and CHMP members assigned as peer reviewers in the procedure leading up to the list of questions at day 120.

- The Agency continued to work on improving the content and presentation of information in the CHMP assessment report and European public assessment reports (EPARs), in order to better address stakeholders' expectations.
- A new template for the assessment report was tested in a pilot phase. The new template addresses in particular the assessment of the balance of benefits and risks, which is fundamentally important in any scientific evaluation of a medicine.
- Activities aimed at ensuring due care of ethical standards in clinical trials performed in non-EU countries as part of an initial marketing-authorisation application and their subsequent presentation in an EPAR were reinforced. A strategy paper and an EMEA action plan for 2008-2011 on acceptance of clinical trials conducted in third countries in support of marketing-authorisation applications were prepared, and a working group composed of representatives from the EMEA and its scientific committees was established.

Assessment procedures for similar medicinal products in the context of orphan medicines

- The assessment procedures for similar medicinal products in the context of orphan medicines were reviewed in preparation for a Commission guideline that was published in the third quarter of 2008. The EMEA implemented a procedure for evaluation of similarity of small molecules, which involved external experts and members of the Quality Working Party.

Preparing for electronic-only submissions

- Implementation work to realise electronic-only submissions of applications for marketing authorisation was on target in 2008. An implementation plan was announced and published on the EMEA website in February 2008. In July 2008, the Agency began accepting electronic-only submissions. The next milestone, announced in December 2008, is that from January 2009 onwards the Agency strongly recommends electronic-only submissions, with paper copies in exceptional cases only.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
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	100% compliance	No finalised procedures
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	100% compliance	98%
Number of opinions for compassionate use given by procedural deadline	80% compliance	None received in 2008

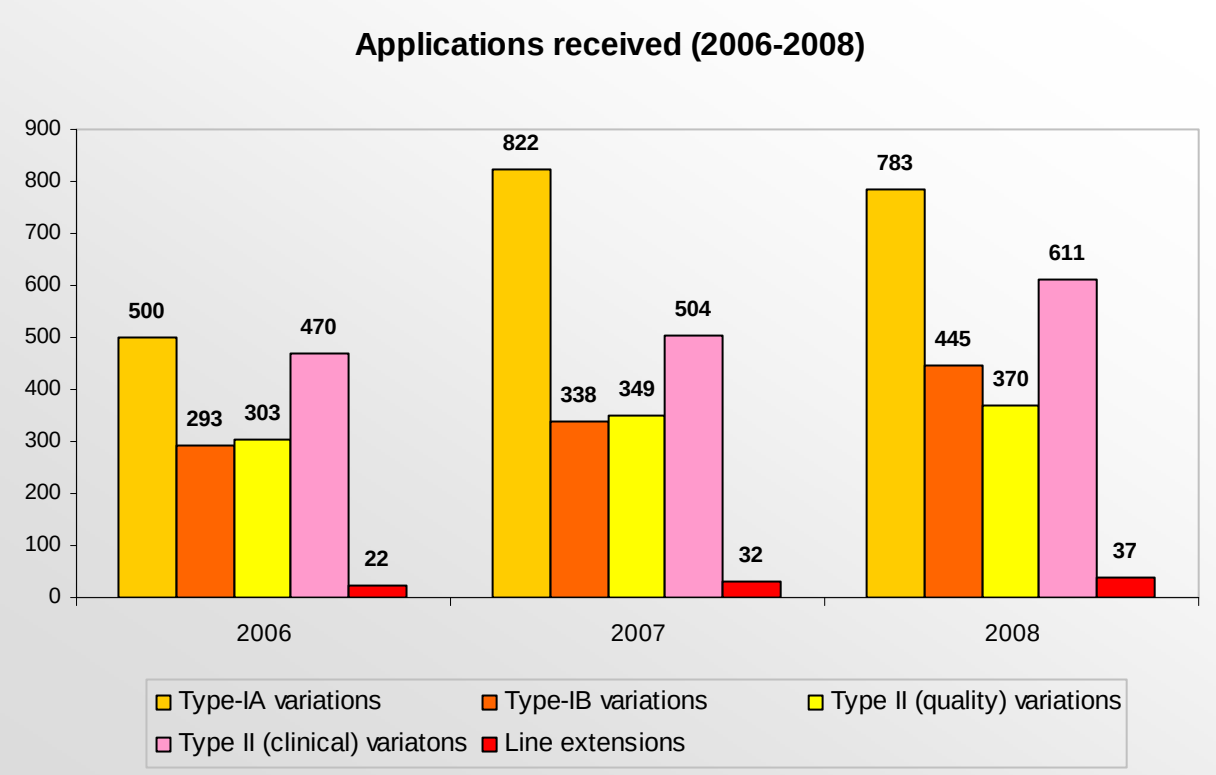
Percentage of plasma master file applications evaluated within the regulatory timeline	100% of applications	100%

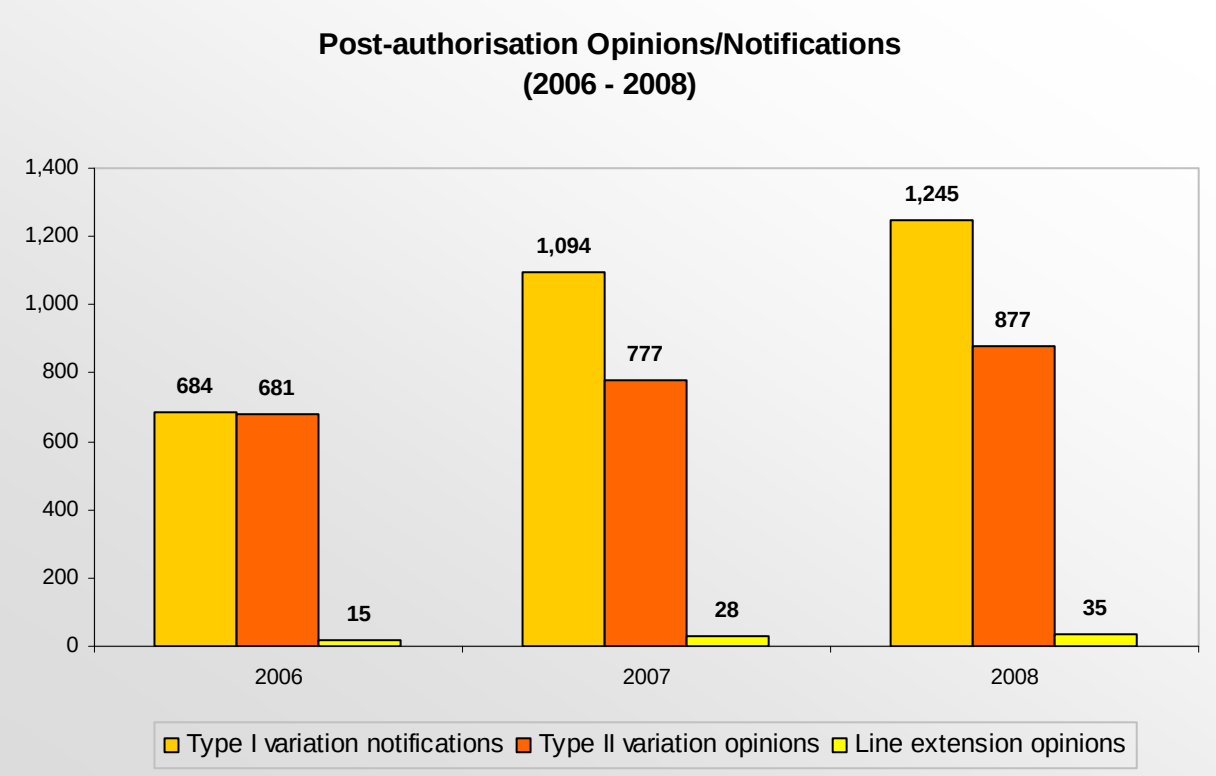
2.4 Post-authorisation activities

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.

Core activities

- The number of applications for variations and line extensions of marketing authorisations continues to rise. A total of 2,246 applications were received in 2008 — 10% more than in 2007.
- The increase was similar for adopted post-authorisation opinions and notifications. The number rose by 13% compared to the previous year.
- The CHMP adopted 32 opinions for extensions of indications applications. Out of these, 31 were positive opinions, providing additional treatment options for patients; 1 was negative, recommending the refusal of applications for an extension of indication. Four applications were withdrawn prior to the final CHMP opinion.
- The CHMP concluded more than 100 type-II variations pertaining to warnings and precautions for centrally authorised medicines or for classes of medicines (class labelling).





Public-health impact of the EMEA's post-authorisation activities in 2008

Positive opinions for new indications

The CHMP adopted 31 positive opinions on new indications, providing additional treatment options for patients.

- About half of the new indications adopted by the CHMP related to medicinal products approved for the treatment of various forms of cancer (e.g. advanced or metastatic non-small cell lung cancer, recurrent and/or metastatic squamous cell cancer of the head and neck, multiple myeloma, follicular lymphoma, vaginal cancer, metastatic colorectal cancer), and medicinal products approved for the treatment of infectious diseases (e.g. severe fungal infections, HIV, chronic hepatitis B and C).
- New indications were also approved in the field of diabetes and in cardiovascular, metabolic, rheumatoid, central nervous system, ophthalmic and dermatologic disorders.
- Six medicinal products had their use extended to include the treatment of children and adolescents having diabetes, severe fungal infections, chronic severe plaque psoriasis, active polyarticular juvenile idiopathic arthritis, and Niemann-Pick type C disease. The CHMP positive opinion to extend the use of Cancidas (caspofungin) to paediatric patients for the treatment of severe fungal infections was the first recommendation for the use of a medicine in children on the basis of data generated in accordance with an agreed paediatric investigation plan.

Negative opinions for new indications

The CHMP adopted a final negative opinion, recommending the refusal of extension of indication for Cymbalta/Xeristar (duloxetine hydrochloride) to the treatment of fibromyalgia with or without depression.

Restriction or deletion of indications

The CHMP also recommended the restriction of the indications of one centrally authorised medicine for safety reasons.

Contraindications, warnings and precautions for use

- The CHMP recommended new contraindications for 4 centrally authorised medicinal products, or classes of centrally authorised medicinal products (class labelling), and finalised more than 100 type II variations relating to special warnings and precautions for use for centrally authorised medicinal products or classes of medicinal products (class labelling).

Switch from prescription-only to non-prescription status

The CHMP recommended for the first time that the status for supply of a centrally authorised medicine in the European Union be switched from prescription-only to non-prescription. This enables patients to buy the medicine over the counter. The medicine concerned is Alli (orlistat), an anti-obesity medicine.

Specific objectives in 2008

Improving the variations procedures

- The Agency carried out an analysis of its current processes in relation to its post-authorisation activities.
- A new, simplified CHMP Assessment Report template for type-II variations was introduced for all quality type-II variations. A pilot phase using selected safety and efficacy type-II variations was performed. After analysis of this pilot, the template is aimed to be introduced for all type-II variations, excluding extension of indications.
- As part of the EMEA process improvement exercise, some improvements have been implemented for quality variations. Additional improvements require further development of IT tools and have been deferred.
- Improvements were made to post-opinion processing (i.e. the transmission of the Annexes of Opinions to the European Commission on Day 27 after the Opinions), resulting in 76% of processes being completed within the Day 27 timeframe, compared with only 47% in 2007.
- The product information for type-II variations is now provided by marketing authorisation holders to the EMEA in PDF format. A User Guide on the Preparation of PDF Versions of the Product Information was prepared and shared with the marketing authorisation holders to ensure a high quality and consistent format of the submitted product information in all European languages.

Performance indicators

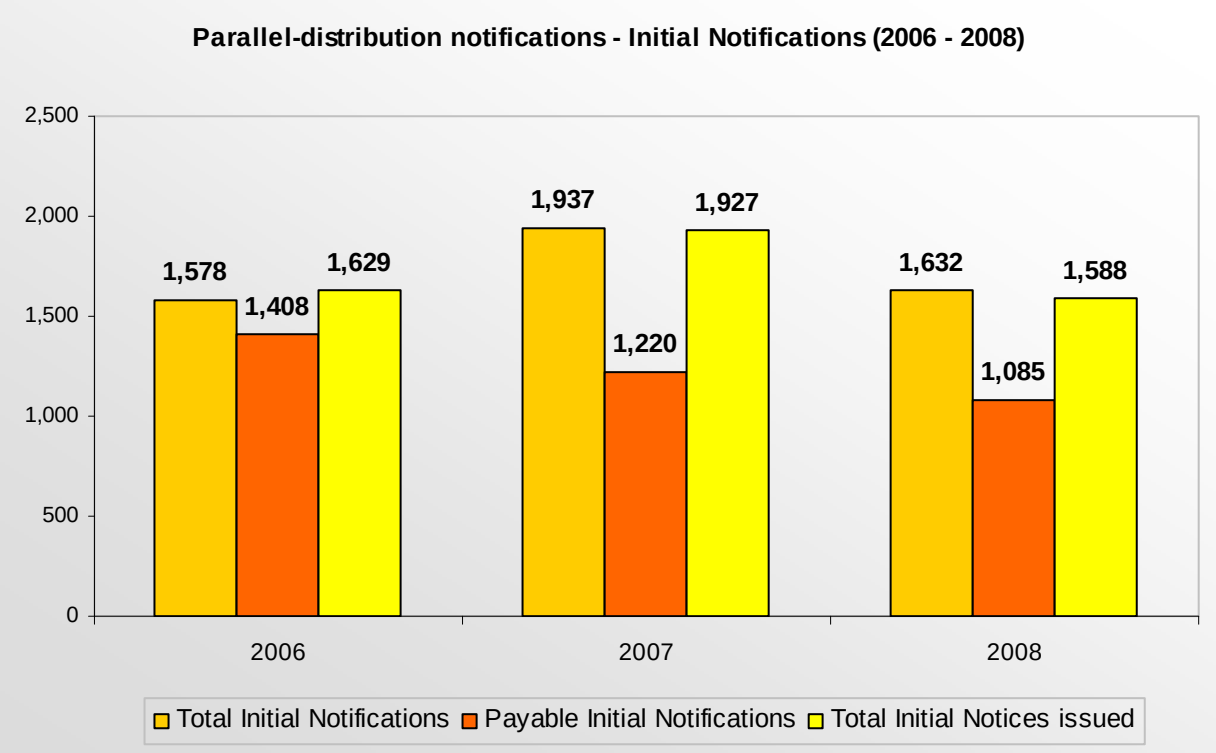
Performance indicator	Target	Outcome at end of 2008
Percentage of applications for post-authorisation procedures evaluated within the regulatory timelines	100% of applications	100%
Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check	100% of applications	76%

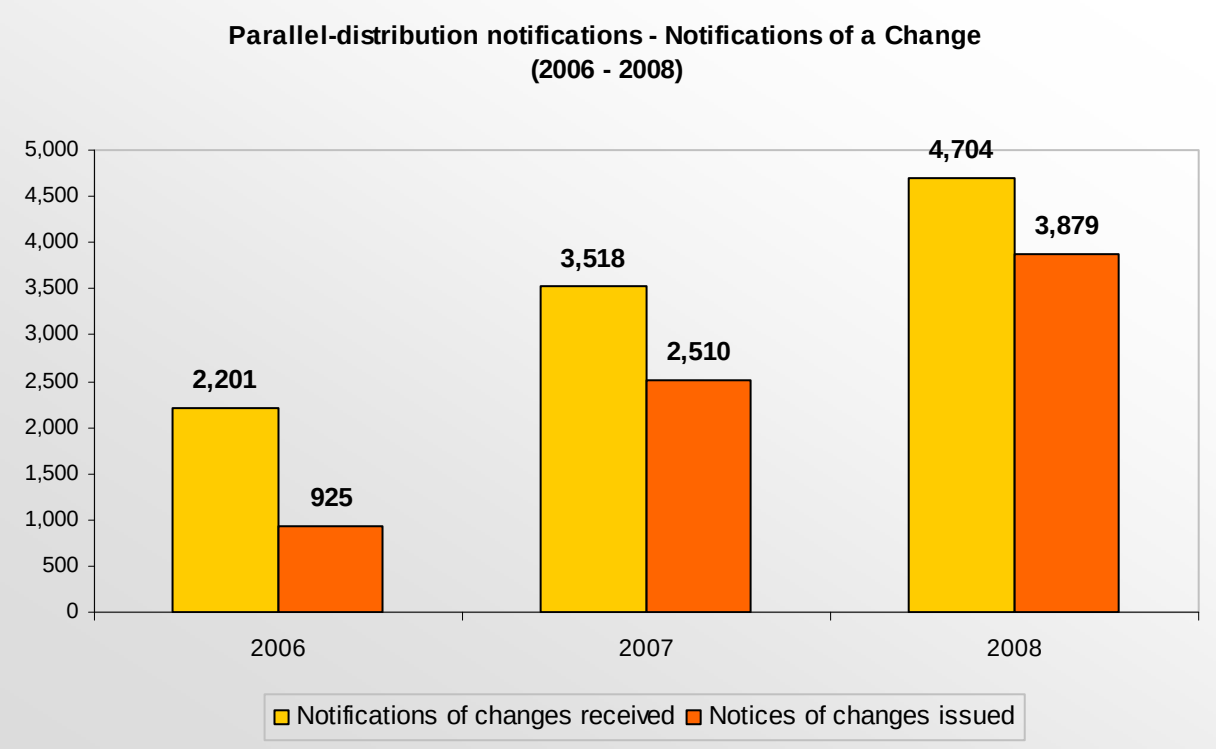
Parallel distribution

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.

Core activities

- The number of initial parallel distribution notifications decreased in 2008; with 1,632 notifications received, the number was 18% lower than in 2007.
- The number of notifications of change, however, continued to increase. 4,704 were received, 33% more than in 2007.
- The average handling time for initial notifications was 43 days, considerably shorter than in previous years. Although still not within the regulatory timeline of 35 days, this confirms the positive trend of a steady decrease of handling times over previous years (148 days in 2005; 95 days in 2006; 72 days in 2007).
- Monthly overviews of parallel distribution notifications issued by the EMEA were systematically published on the EMEA website (http://www.emea.europa.eu/htms/human/parallel/introduction.htm).





Specific objectives in 2008

Improving the handling process of parallel distribution notifications

- The EMEA developed a new internal database and has started exploring systems for electronic submission and handling of parallel distribution notifications.

Verification of compliance of parallel distributors

- As a first step to put in place a process to verify compliance of parallel distributors with the mandatory notification procedure and the notices issued by the EMEA, it was agreed that parallel distributed medicines should be included in the 2009 EMEA sampling and testing plan.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
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	67% of applications were handled in 35 working days.

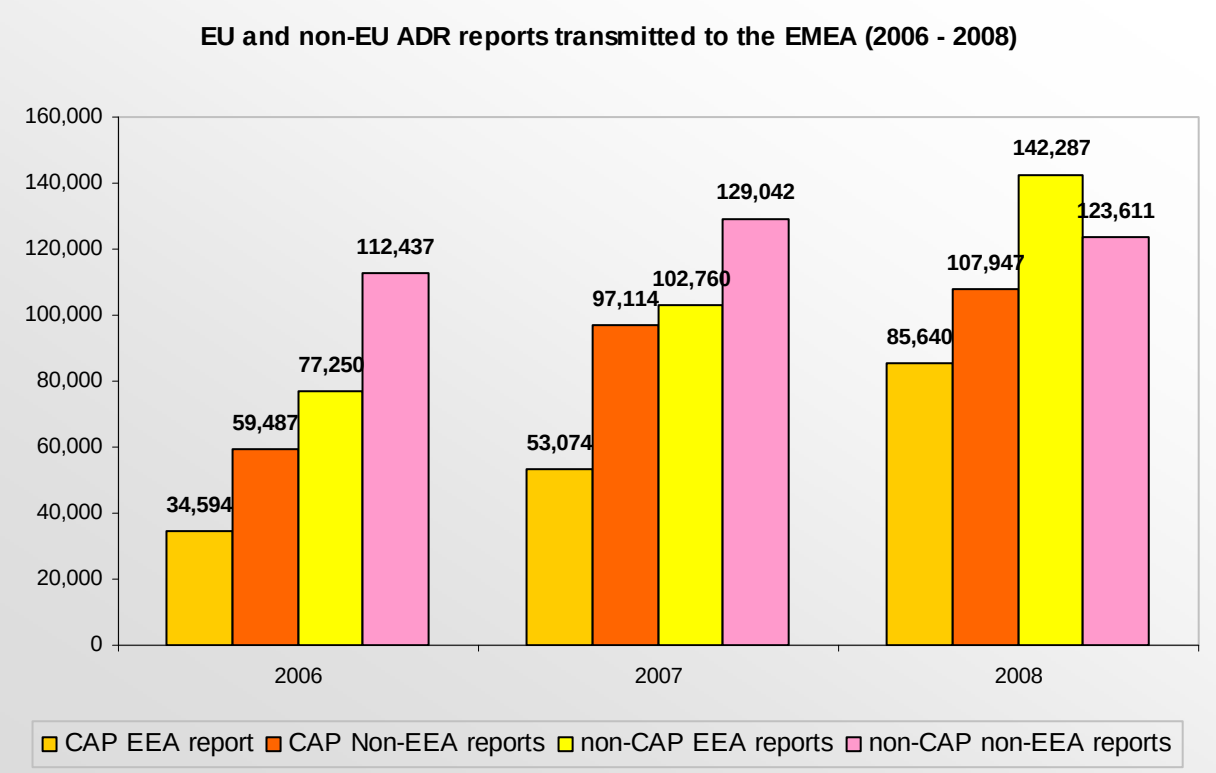
2.5 Pharmacovigilance and maintenance activities

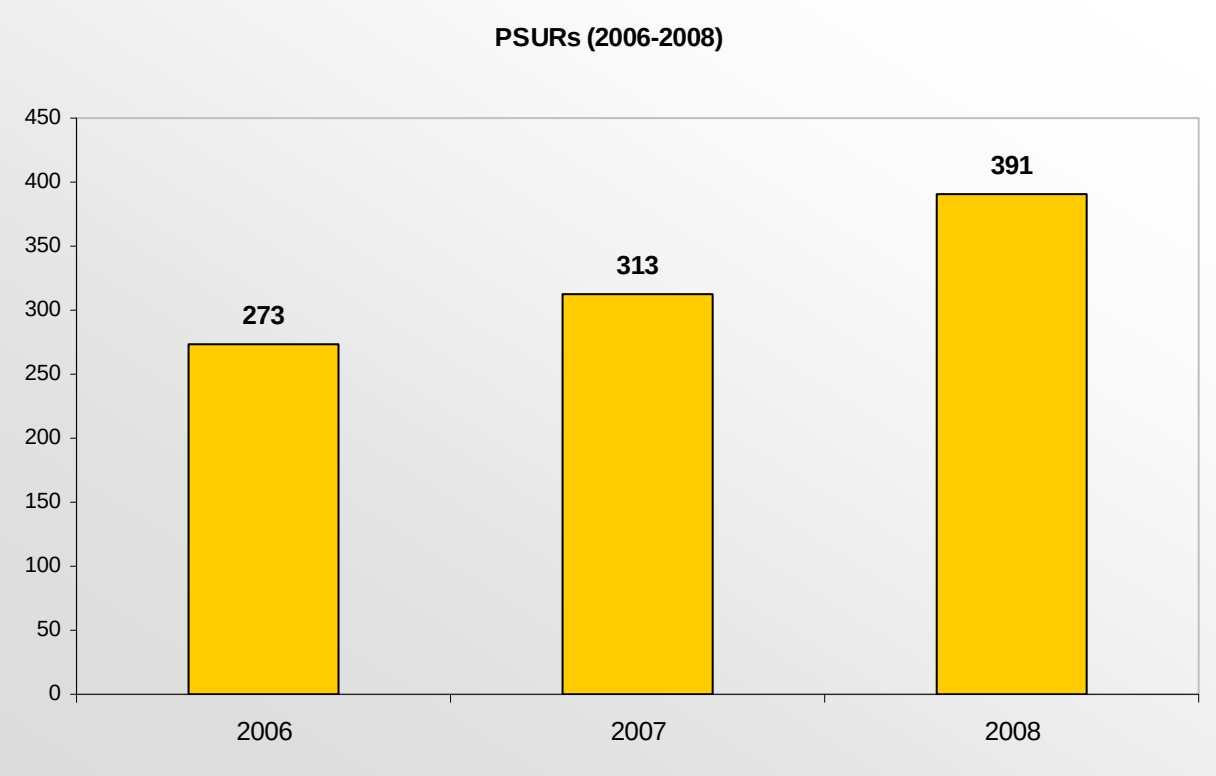
Pharmacovigilance activities include the management of suspected adverse drug reactions in the pre- and post-authorisation phases (individual case safety reports (ICSRs)), periodic safety-update reports (PSURs) and risk-management plans (RMPs). Maintenance activities relate to post-authorisation commitments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

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

Core activities

- The Agency received a total of 459,485 individual case safety reports (ICSRs) of adverse drug reactions in 2008 – an increase of 20% compared to the previous year. 40% of the reports related to centrally authorised medicines.
- The EMEA received 80,258 reports concerning investigational medicines, i.e. adverse drug reactions observed during clinical trials. This is an increase of 27% compared to 2007.
- In the EudraVigilance Medicinal Product Dictionary (EVMPD), 32,900 authorised and investigational medicinal products were entered or updated by marketing authorisation holders and sponsors of clinical trials.
- As regards EU Risk Management Plans, 172 Annex 1 EudraVigilance Interface templates were submitted by Applicants and MAHs. Those templates contain a summary of the identified and potential risks in structured electronic format for integration in EudraVigilance and the support of signal detection and risk monitoring for centrally authorised medicinal products.
- 391 Periodic Safety Update Reports (PSURs) were reviewed in 2008, 25% more than in 2007.





Specific objectives in 2008

- The EMEA continued to apply a proactive approach to safety of medicines by progressing various initiatives coming within the scope of both the EMEA Road Map and the European Risk Management Strategy (ERMS).

Implementation of the ERMS

- The main initiatives undertaken within the framework of the ERMS relate to the introduction as of the February 2008 CHMP meeting of an early notification system for communication within the EU Regulatory System Network as well as with the FDA on envisaged CHMP regulatory action due to safety related concerns. This new procedure has allowed the EMEA to take a more proactive and coherent approach towards communication on (emerging) safety issues. It has also helped to improve coordination of communication activities within the EU Regulatory System Network.
- Work also progressed on the development of an EU Regulatory System Incident Management Plan. In November 2008, the Heads of Medicines Agencies agreed on key principles and on a procedure. This comes ahead of the launch of a pilot phase in the first half of 2009.
- The Heads of Medicines Agencies also agreed on key principles on revised signal management in the EU. A pilot phase was launched in November 2008.
- A tracking system for the Pharmacovigilance Working Party (PhVWP) has been developed. It will allow for online access by the Member States and the European Commission. Further developments are planned in order to include signal management and aspects of Risk Management Plans (RMPs) in this tracking system.

Strengthening EudraVigilance

- Maintaining and further strengthening of the EudraVigilance system was again high on the agenda for the EMEA. In order to achieve improvements in the area of spontaneous reporting of adverse drug reactions, the EMEA undertook a number of initiatives aimed at improving the quality of data entered into the system. The Agency has prepared a call for tenders for launch in early 2009 to address aspects

such as recoding and data cleaning. Work on the validation of the EudraVigilance Datawarehouse and Analysis System (EVDAS) continued during 2008, resulting in a more available, reliable and better performing EVDAS.

- In addition, agreement was reached on the release for public consultation of the draft EudraVigilance Access Policy, which was undertaken on 22 December 2008.

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

- The ENCePP Implementation Advisory Group (ENCIAG) was established in March 2008. ENCIAG is an interim body, expected to champion the ENCePP project and support the EMEA in the establishment and initial operation of the network.
- A draft Implementation Strategy has been prepared. The document has been discussed by ENCIAG.
- The EMEA held a second meeting with all ENCePP partners in April 2008.
- Four permanent Working Groups were created to elaborate on important aspects of ENCePP, such as research standards and accreditation, transparency and independence, data sources and methodologies, and on inventory of research centres.
- A scientific convention on EU healthcare databases for pan-EU pharmacoepidemiological research was held on 25 November 2008.
- Information on the project is available on a specific website, which was launched on 22 December 2008: http://www.encepp.eu

Risk Management Plans (RMPs)

- In a 'review and learning' project, the EMEA looked at the experience gained with the practical application of the concept of RMP. This has resulted in a two-year work plan, which among others will focus on the review of risk minimisation activities at Member State level.
- Scientific advice on risk management plans was provided to companies developing medicines for children.

Preparation for advanced therapies

- The 'Guideline on Safety and Efficacy Follow-up - Risk Management of Advanced Therapy Medicinal Products' came into effect in December 2008 following public consultation.

International activities

- Considerable input was provided in the field of cooperation at international level, with primary focus on ICH M5 and ISO SDOs, ICH E2B and ISO SDOs, ICH M1 (MedDRA), ICH E2F.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Percentage of ICSRs reported electronically for centrally authorised products (CAPs)	100% of ICSRs	100%
Percentage of RMPs that are peer-reviewed by the EMEA as part of the assessment of variations and line extensions that result in a significant change to a marketing authorisation	80% of RMPs	85.7% for line-extension applications and 100% for extension-of-indication applications

Review of PACs within the agreed timeframe	80% of PACs	74% of all PACs were reviewed within a 60-day timeframe (78% for quality PACs and 72% for clinical PACs)
Submission of outcome reports for PACs to applicants/MAHs within 2 weeks of the CHMP meeting	100% of reports	96.7%

2.6 Arbitration and Community referrals

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

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

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

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

Article 107 procedures 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.

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

Core activities

Procedure type	2006	2006	2007	2007	2008	2008
	Started	Finalised	Started	Finalised	Started	Finalised
Article 6(12) of Commission Regulation (EC) No 1084/2003	0	2	6	2	0	4
Article 6(13) of Commission Regulation (EC) No 1084/2003	0	4	0	0	0	0
Article 29 of Directive 2001/83/EC	20	12	22	18	17	16
Article 30 of Directive 2001/83/EC	1	4	14	1	11	18
Article 31 of Directive 2001/83/EC	3	1	4	4	2	3
Article 36 of Directive 2001/83/EC	7	7	4	4	2	0
Article 5(3) of Regulation (EC) No 726/2004	3	2	2	2	3	3

Article 16c(1) and (4) of Directive 2001/83/EC (as amended)	0	0	0	0	1	1
Article 107(2) of Directive 2001/83/EC	0	0	5	5	1	1
Article 29 of Regulation (EC) No 1902/2006			0	0	1	1
Totals	**34**	**32**	**57**	**36**	**38**	**47**

Procedures of high public-health interest finalised in 2008

- Review of Actira, Avalox, Octegra and associated names (moxifloxacin hydrochloride 400mg), because of differences among Member States on whether the indication of these products should be extended to include treatment of mild to moderate pelvic inflammatory disease without an associated tubo-ovarian or pelvic abscess. The CHMP considered that the data submitted demonstrate that the benefits of the medicines outweigh the risks in the indication applied for (Article 6(12) procedure).
- Review of etoricoxib-containing medicines due to concerns over the cardiovascular safety of Arcoxia (etoricoxib) medicines when used to treat ankylosing spondylitis at a dose of 90mg once a day (Article 6(12) procedure) and for etoricoxib-containing medicinal products when used in the treatment of rheumatoid arthritis at the same dose (Article 31 procedure). The CHMP concluded that these medicines can be used to treat rheumatoid arthritis and ankylosing spondylitis, but recommended that their product information concerning the risk of cardiovascular side effects be updated.
- Review of ergot-derived dopamine agonists containing medicines, due to safety concerns over the risk of fibrosis and cardiac valvulopathy associated with long-term use. The CHMP concluded that marketing authorisations for these medicines should be maintained, but that new warnings and contraindications should be added to their product information. These changes to the product information vary among the medicines as the risk is not equally established for all ergot-derived dopamine agonists (Article 31 procedure).
- Review of oral norfloxacin-containing medicines, because of concerns over the efficacy of oral formulations of the medicine for complicated pyelonephritis, in comparison with other fluoroquinolones. The CHMP concluded that there was not enough clinical data to demonstrate the efficacy of oral treatment with norfloxacin-containing medicines in complicated pyelonephritis and that their use in this indication could no longer be supported (Article 31 procedure).
- Review of issues relating to increased risk of death with conventional antipsychotics in elderly patients with dementia. The CHMP concluded that, as with atypical antipsychotics, conventional antipsychotics are likely to be associated with a small increase in the risk of death when used in elderly people with dementia. However, there was insufficient evidence to give a firm estimate of the precise magnitude of the risk. The CHMP concluded that a warning on the increased risk of death when used in elderly patients with dementia should be included in the Product Information of all conventional antipsychotics (Article 5(3) procedure).
- Review of antidepressants relating to the results of a published meta-analysis that questioned the efficacy and clinically relevant effects of antidepressants in the treatment of patients with major depression. The CHMP concluded that the approval of antidepressants for the treatment of patients with major depression is based on data which provides robust and sufficient evidence of clinically meaningful benefits for patients with major depression (Article 5(3) procedure).
- Review of issues related to the contamination of medicines containing or derived from heparins. Oversulphated chondroitin sulphate' (OSCS, a contaminant) has been identified mainly in medicines containing standard heparins, but it has also been found in low levels in enoxaparin, a low molecular weight heparin. The CHMP recommended the recall of standard heparin from the market. Because of shortages, the CHMP recommended that batches of medicines containing enoxaparin can continue to be used, until they are replaced by OSCS-free batches and provided that measures are put in place to minimise the risk of side effects (Article 5(3) procedure).

- Review of oral moxifloxacin-containing medicines, following concerns over their liver safety when used for acute bacterial sinusitis, acute exacerbation of chronic bronchitis and community-acquired pneumonia. The CHMP concluded that the benefits of oral moxifloxacin medicines continue to outweigh their risks. However, due to safety concerns, mainly related to an increased risk of adverse hepatic reactions, the CHMP recommended restricting their use in these indications, as well as new warnings to be introduced into the product information (Article 107 procedure).

Procedures of high public-health interest started but not yet finalised in 2008

- Review of medicinal products containing a fixed combination of dextroproxyphene and paracetamol, triggered by concerns related to overdose (Article 31).
- Review of gadolinium-containing contrast agents, triggered due to the lack of harmonisation of the product information and risk minimisation measures in relation to the use of these medicines (Article 31 procedure) for medicines authorised by Member States, and for centrally authorised medicines Optimark (gadoversetamide) and Vasovist (gadofosveset)) (Article 20 procedure) (see also III.5).
- Review of Forair/Atimos modulate 12 microgram (formoterol) and associated names, triggered by concerns that therapeutic equivalence of these medicines with the reference medicine is not established for children aged 5 years and above (Article 36 procedure).

Specific objectives in 2008

More transparency and information

- The EMEA published question-and-answer documents at the time of finalisation of all safety-related referrals.
- Since December 2008, the EMEA now publishes question-and-answer documents for referrals initiated under Articles 29 and 30 of Directive 2001/83/EC as amended.

Revision of the current CHMP referral assessment report

- A revision was initiated in November 2008 in the context of referrals under Articles 29 and 30 of Directive 2001/83/EC as amended.

Performance indicators

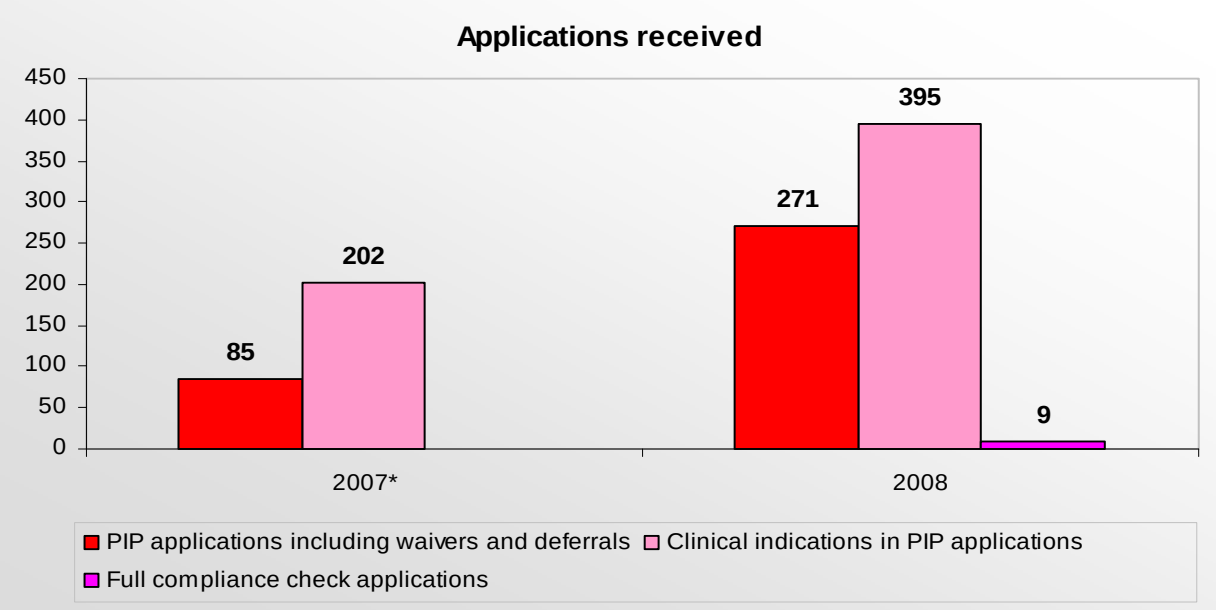
Performance indicator	Target	Outcome at end of 2008
Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100%

2.7 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 (PDCO) 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.

Core activities

- The EMEA received applications for PIPs relating to 395 clinical indications. These correspond to 271 validated applications.
- Opinions were adopted for 141 applications relating to 204 clinical indications. This includes four negative opinions and eight opinions on modification of a PIP.
- 85 applications were submitted for product-specific full waivers, for which 48 opinions were adopted.
- The EMEA adopted 35 decisions on class waivers by the end of 2008. If a class waiver exists for a certain condition, applicants do not have to submit product-specific waiver applications for medicines that fall within this class. The Agency received 65 requests for confirmation of the applicability of class waivers.
- Following the implementation of the procedure for checking of compliance with PIPs, the PDCO received 9 applications for compliance check and adopted 5 opinions. Compliance check is necessary before an application for a marketing authorisation can be considered valid. When performing such a check, the EMEA verifies that all studies and measures required have been carried out in accordance with the PIP.
- In September 2008, the EMEA made its first recommendation to extend the use of a centrally-authorised medicine to children on the basis of clinical-trial data generated in accordance with an agreed PIP. The medicine concerned is authorised for the treatment of adults with severe fungal infections and is now also approved for use in children.



* 2007 figures are for the period July to December

Specific objectives in 2008

Streamlining the assessment processes of the PDCO

- Following the publication of the final EC guideline on format and content of paediatric investigation plans (2008/C 243/01) the EMEA published updated versions of application forms and procedural guidance documents.
- A procedure to request modification of PIPs was implemented. The necessary application forms were published. Further guidance is under preparation.
- Similarly, a procedure to request a re-examination of a PDCO opinion was implemented and the accompanying guidance was published.
- A number of key processes were reviewed in 2008 and improvements were implemented. This includes: the summary report; assessment process; class waiver; assessment after re-start; opinion.

Establishment of paediatric specialist groups

- Paediatric specialist groups are intended to pool specialist expertise in the assessment of PIPs. Expert groups established include the PDCO/EMEA formulations subgroup (which looks into all issues related to paediatric formulations), a non-clinical PDCO working group, and ad hoc expert groups for PIPs or guidelines including groups on influenza vaccines, cystic fibrosis and diabetes.

Workshops

- The following workshops were held with internal and external experts: a workshop on a strategy for paediatric formulations; workshop on neonatal immunisation; workshop on modelling and simulation.

Public access to information about paediatric clinical trials and their results in EudraCT

- The EMEA participated in developing the draft Commission guidance on information concerning paediatric clinical trials to be entered into EudraCT and on information to be made public by the EMEA. As part of its participation, the Agency organised a workshop with patients' and healthcare professionals' representatives.
- Following publication of the final guideline in October, an IT implementation plan was drawn up.

Implementation of a strategy for exchange of paediatric information with Member States makes good progress

- A procedure for the handling of Articles 45 and 46 procedures was agreed with the Coordination Group for the mutual-recognition and decentralised procedure.
- More than 10,000 responses from industry on medicines with paediatric information have been received.
- A list of priorities was established.

Other priorities

- Work on the implementation of the network on paediatric research had to be postponed due to lack of resources.
- Follow-up on the collection of information on off-label paediatric use of medicines by Member States was postponed.
- Interactions between the FDA Paediatrics Office and the EMEA paediatric team are ongoing.

Performance indicators

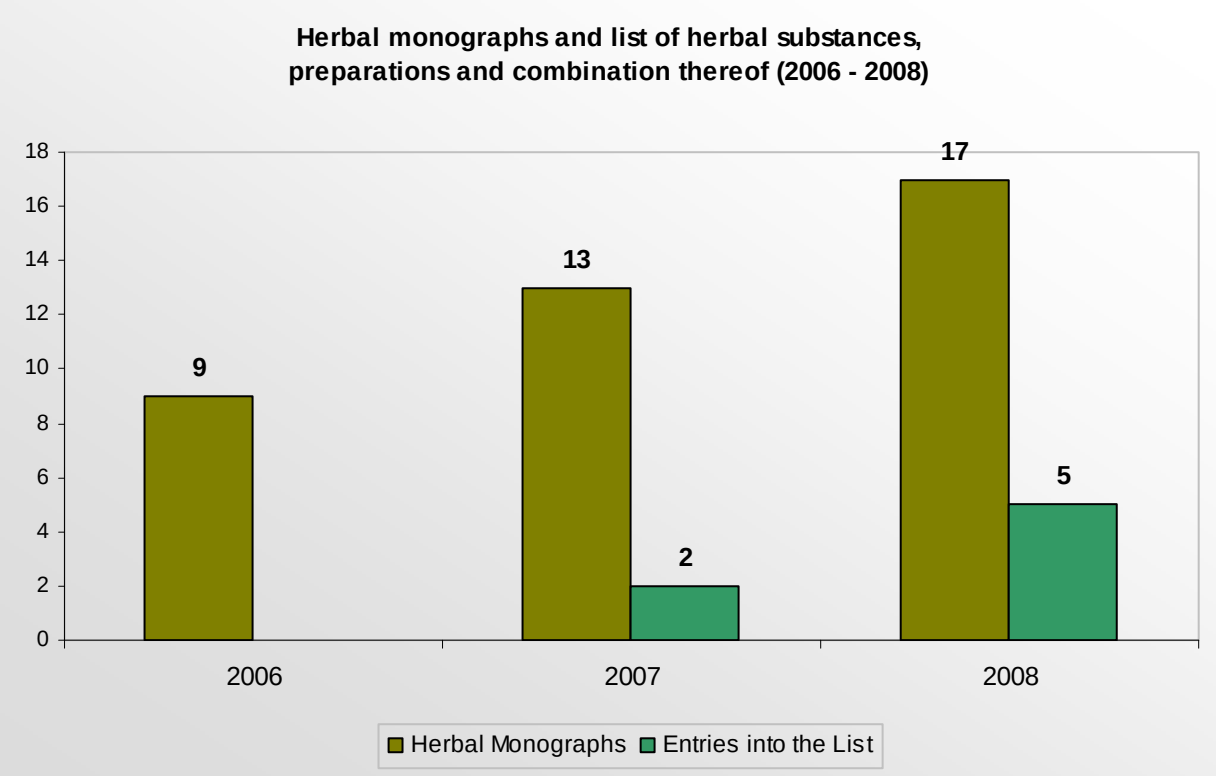
Performance indicator	Target	Outcome at end of 2008
Number of PIP or waiver opinions or decisions adopted within the legal timeframe	100% of procedures	100%

2.8 Herbal medicinal products

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

Core activities

- The HMPC finalised 17 Community herbal monographs for traditional and well-established herbal medicinal products.
- 14 draft Community herbal monographs for traditional and well-established herbal medicinal products were released for public consultation.
- The HMPC adopted 5 entries to the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. One draft entry was released for public consultation.
- The first referral procedure under Article 16c (1) of Directive 2001/83/EC as amended was initiated and finalised in 2008. The procedure concerned a traditional-use registration application for a fixed combination herbal medicinal product for which the number of ingredients had been reduced during 30 years of medicinal use.



Specific objectives in 2008

Improving the functioning of the HMPC

- A peer-review step was introduced in the process of establishment of herbal monographs and list entries.

Borderline issues: therapeutic indications versus health claims for herbal ingredients

- A dedicated HMPC ad hoc group was set up to work on the borderline between therapeutic indications and health claims for herbal ingredients.
- The HMPC further developed its interaction with the various scientific groups at the European Food Safety Authority (EFSA).
- Agreement was reached to establish a joint expert group with representatives from the HMPC and the EFSA panel on dietetic products, nutrition and allergies (NDA) to cooperate on issues related to health claims for food supplements and herbal medicines.

Involvement in alternative treatments continues

- The HMPC continued to be involved in the field of alternative treatments, such as anthroposophic, Ayurvedic and traditional Chinese medicines.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Number of Community herbal monographs established	20 Community herbal monographs	17 Community herbal monographs were finalised 14 draft Community herbal

		monographs were released for public consultation
Number of entries to the list of herbal substances, preparations and combinations thereof	10 entries to the list	5 list entries were finalised. One draft list entry was released for public consultation

2.9 Advanced therapies and other 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 Advanced Therapies Regulation.

The new EU regulation on advanced therapy medicinal products was adopted on 13 November 2007 and entered into force on 30 December 2008. This will give the EMEA a new range of tasks.

Implementation of the new regulation on advanced therapy medicinal products on target

- The Committee for Advanced Therapies (CAT) was constituted on time, and held its first meeting on 15-16 January 2009.
- New procedures for the assessment of advanced therapy medicinal products were agreed. This also includes a clarification of the roles and responsibilities of CAT rapporteurs, joint CHMP/CAT members and CHMP coordinators.
- The Agency established procedures for the interaction between the CAT and the Committee for Medicinal Products for Human Use (CHMP) in the evaluation of marketing authorisation applications for advanced therapy medicinal products.

Meetings and workshops

- Stakeholders were informed about regulatory and scientific aspects of the advanced therapy legislation through the EMEA's participation in workshops, conferences and other fora.
- An EMEA-EFPIA joint workshop on methodology for adaptive designs in confirmatory clinical trials was organised in December 2008.

Identifying expertise, expectations and bottlenecks

- 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 the European Society of Gene and Cell Therapy (ESGCT) and the CHMP Gene Therapy Working Party (GTWP), and with CliniGene (European Network for the Advancement of Clinical Gene Transfer and Therapy) and the GTWP. A joint workshop with the ESGCT and CliniGene was also held. Dedicated discussion meetings on ATMP implementation were held with EuropaBio, EBE and Eucomed.
- As part of the preparations in the network for the arrival of advanced therapy medicines in the regulatory framework, the Agency and the Member States reviewed their scientific expertise and conducted a gap analysis. Proposals on how to fill gaps were made, which included targeted recruitment and a training plan for the EMEA scientific secretariat.

Innovation Task Force (ITF)

- The EMEA's ITF, a multidisciplinary group that includes scientific, regulatory and legal competences, continued its activities in 2008.
- The ITF held 25 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, and is thus being eligible for EMEA procedures. 18 requests for classification were received and finalised during 2008.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Briefing meetings organised within 60 days from receipt of a request	80% of meetings	92%
Regulatory advice on new-technology, emerging-therapy and borderline medicinal products given within 60 days	80% of requests	88%

2.10 Provision of information to patients and healthcare professionals

The Agency has implemented processes and procedures aimed at the provision of targeted, understandable and accessible information for patients and healthcare professionals. In addition to summaries of opinions, European public assessment reports (EPARs), and information on arbitrations and referrals, the Agency provides a wide range of information. This includes EPAR summaries for the public and information on withdrawals of applications prior to Commission Decision and on negative decisions, for both new applications and extensions to existing indications.

Interaction with patients' and healthcare professionals' organisations and provision of information

- Interactions with both patients' and healthcare professionals' organisations continued in line with the established Work Plans for 2008. Discussions are ongoing on how their involvement in EMEA activities can be further strengthened. The involvement of patients in the review of package leaflets was further reinforced by extending it to initial applications. A report analysing and monitoring the degree of satisfaction of patients' and consumers' organisations was published on the EMEA website.
- In the area of provision of information the EMEA published 'question and answer' documents intended for patients and the general public for 17 procedures addressing significant safety issues.

Quality of product information

- In the field of the quality of product information, including the quality of translations, improvement actions have been implemented and a regular monitoring is being undertaken. Of note is that the 'user consultation' will also be monitored through analysis of all user-testing reports submitted between 2007 and 2008.

Transparency

- Further progress was made in the area of transparency. Two meetings, with involvement of the Member States and the European industry associations, were held to make further progress on transparency of agendas and minutes.
- Preparatory work for the development of an EMEA transparency policy was started in 2008.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
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	90% of marketing authorisations granted	49%
Percentage of EPAR summaries in language understandable by the public, published together with the EPAR	90% of EPARs	100%
Percentage of assessment reports published within 2 months of withdrawal of a marketing-authorisation application	70% of assessment reports	52%
Percentage of refusal assessment reports published within 2 weeks of the Commission decision	70% of assessment reports	33%
Publication of 'question and answer' documents at the time of CHMP opinion	90%	100%

2.11 Scientific committees, working parties and scientific advisory groups

Committee for Medicinal Products for Human Use (CHMP)

The 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 CHMP held 11 meetings in 2008, 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 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.

The HMPC met 6 times in 2008, with each meeting lasting one and a half days.

Paediatric Committee

The Paediatric Committee (PDCO) conducts assessment and agreement of paediatric investigation plans, and verifies their compliance. The PDCO also establishes lists of waivers of specific medicines or classes of medicines 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 PDCO met 12 times in 2008, 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.

Specific objectives in 2008

Improving the functioning of the CHMP

- The operation of the CHMP working parties has been under review, with a view to identifying areas for rationalisation of resources made available by the national competent authorities. A pilot project for the centralisation of the EMEA coordination of working parties was started, with involvement of the Efficacy Working Party (EWP) and the Pharmacogenomics Working Party (PGWP)

Interaction with PDCO and CAT

- The rules of procedure of the CHMP were reviewed in order to reflect the Committee's future interaction with the CAT.
- The interaction between the PDCO, the CHMP and the Scientific Advice Working Party were integrated in the CHMP work plan.

Improve efficiency in using available expertise

- The use of virtual meetings via tele- and video-conferences instead of live meetings was increased in 2008.

- PDCO members were requested to identify paediatric experts in different therapeutic areas for inclusion in the EMEA experts database.
- Statistics on participation of experts in EMEA activities were shared regularly with the Heads of Medicines Agencies.

EMEA-CHMP Think Tank report on innovation and related Innovative Medicines Initiative (IMI) actions

- The identification of experts' networks in areas such as paediatrics, advanced therapies, epidemiology or statistics is ongoing.
- The scope of briefing meetings was extended.
- Activities related to translational medicine were included in the CHMP work programme.
- Two workshops were held: one on the use of pharmacogenomics in early clinical development and one on statistical methodology.

Implementation of electronic systems for management of meetings

- Building on the experience with the electronic management of meetings of the CHMP, the system was rolled out to the Biologics Working Party (BWP).

Coordination with ECDC regarding pandemic influenza

- Coordination activities with the European Centre for Disease Control and Prevention (ECDC) on pandemic influenza were initiated.

2.12 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 CMD(h) activities in 2008 is available here:
http://www.hma.eu/uploads/media/CMDh_2008.pdf

- The CMD(h) met 11 times in 2008, with each meeting lasting two to three days.
- The CMD(h) was able to reach agreement for 62 (32 MRP and 30 DCP) of the 81 referral procedures finalised.
- 19 applications were referred to the CHMP for arbitration in 2008 (including 3 multiple applications, thus corresponding to 16 different applications for 15 different active substances).
- The percentage of applications referred to the CHMP has decreased slightly over the past years, i.e. from 29% in 2006 and 26% in 2007 to 23% in 2008. It is expected that the percentage of applications referred to the CHMP will be kept between 20-25%.

Election of chair

- The CMD(h) secretariat supported the procedure for the election of its chair and the re-appointment of CMD(h) members for a new 3-year term.

Coordination of referral procedure

- The CMD(h) continued to interact with the CHMP and its working parties, particularly in areas where a common approach in the interpretation of guidelines is needed throughout the EU. The CMD(h) liaised, in particular, with the pharmacokinetics subgroup of the CHMP Efficacy Working Party.
- The CMD(h) has worked with the EMEA, CHMP and pharmacokinetics subgroup of the Efficacy Working Party with a view to publishing the advice received from the Working Party in the framework of CMD(h) referral procedures.

Facilitating liaison with other scientific fora and Interested Parties

- Individual meetings with AESGP, EFPIA and EGA were organised in the first half of 2008, to discuss transparency of agendas and minutes, mainly in relation to ongoing procedures.
- The CMD(h) Secretariat supported a meeting of the CMD(h) with representatives of AESGP, to share experience and improve use of the MRP/DCP for non-prescription medicinal products.
- The CMD(h) Secretariat also supported a meeting of the CMD(h) with representatives of Interested Parties to discuss issues of common interest, such as Member States' resources in the MR and DC procedures, electronic submissions, work-sharing initiatives and the functioning of the CMD(h).
- As part of the evaluation of the functioning of the CMD(h), the CMD(h) considered it to be very important to collect the views of Interested Parties, and agreed on a questionnaire which was subsequently sent to Interested Parties and published on the CMD(h) website. An action plan, based on the feedback received from Interested Parties, was discussed at the CMD(h) meeting with representatives of Interested Parties.

Subgroups and working groups

- The CMD(h) secretariat supported the following subgroups and working groups, and streamlined their interaction with the CMD(h):
  - CTS Working Group;
  - CMD(h) Sub-Group on Harmonisation of SPCs;
  - CMD(h)/EMEA Sub-Group on Paediatric Regulation;
  - CMD(h)/PhVWP Working Group, together with the PhVWP Secretariat;
  - CMD(h)/GCP Inspectors Sub-Group, together with GCP Inspectors Secretariat;
  - Working Group on Validation issues/National requirements.
- In addition to the abovementioned subgroups/working groups, the CMD(h) and CMD(v) set up a Variation Sub-group, to facilitate the implementation of the revised variation legislation and to liaise with the EMEA on topics of common interest.

Preparation of the 2008 list of medicinal products for which a harmonised summary of product characteristics (SPC) should be drawn up

- The new list of medicinal products for SPC harmonisation was agreed and published on the CMD(h) website in October 2008.

Procedures in 2008

	Total started in 2008[1]	Under evaluation in 2008[1]	Ended positively in 2008[1]	Referrals to CMD(h) in 2008	Referrals to CHMP in 2008
New applications MRP	433	82	441	39	12
New applications DCP	1,466	1,709	733	43	7
Type-IA variations	6,757	616	6,275	N/A	N/A
Type-IB variations	2,846	492	2,590	N/A	0
Type-II variations	3,020	1,508	2,642	N/A	0

[1] The numbers include multiple procedures as stated at 31 December 2008.

2.13 Regulatory activities

The Agency provides regulatory and procedural advice to the pharmaceutical industry during the lifecycle of medicinal products, from scientific advice and pre-submission meetings with applicants through to post-authorisation and annual meetings with marketing-authorisation holders. It 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 2008.

Regulatory support for PDCO and for establishment of CAT

- In addition to the regulatory support provided throughout the lifecycle of medicinal products, emphasis has been on regulatory support provided to various aspects handled at the level of the Paediatric Committee, and regulatory advice to prepare for the setting-up of the Committee on Advanced Therapies.
- Revision of the Variations Regulation
- The EMEA provided extensive and detailed comments and proposals on the various drafts of the revised Variations Regulation, by the requested deadlines, and participated in meetings with the Member States, the European Commission and pharmaceutical industry. Drafting of procedural guidance started in the second half of 2008 and will continue throughout 2009.

Guidance for generic/hybrid applications

- The document 'EMEA procedural advice for users of the centralised procedure for generic/hybrid applications' was published to give guidance when these types of applications are submitted to the EMEA. This was the result of constructive discussions held between the EMEA and the European Generics Association.
- An EMEA/AESGP platform was created to facilitate dialogue between the EMEA and AESGP (the umbrella organisation of manufacturers of non-prescription medicines in Europe) and to address critical issues in the context of access to the centralised procedure for non-prescription medicines.

Regular training of staff

- Regular training was provided to EMEA staff on various topics stemming from Community legislation and new regulatory procedures.

New EMEA web section on regulatory and procedural guidance available

- An extensive review of all regulatory/procedural guidance available on the EMEA website was finalised, resulting in the publication of a new external 'Regulatory and Procedural Guidance' section that provides easy access to all regulatory/procedural guidance documents relevant to the operation of the centralised procedure.

Improving CHMP opinion handling process

- Detailed guidance on regulatory and consistency issues to consider when preparing CHMP opinions was provided to EMEA Staff.
- In addition, the EMEA, together with the European Commission, set up a training session on the decision-making process, aimed at further clarifying the requirements in the post-opinion phase.

Guideline on the acceptability of names for human medicinal products

- The Name Review Group (NRG) finalised its fifth revision of the 'Guideline on the acceptability of names for human medicinal products processed through the centralised procedure'. The update included the implementation of provisions in the revised Community legislation, the elimination of restrictions not based on public health, and the development of product specific guidance for non-prescription medicines and generic/hybrid/similar biological medicines.

Procedural advice to CHMP members

- The document 'Procedural advice to CHMP members' (EMEA/361945/2007), published in August 2008, outlines the roles, responsibilities and tasks of CHMP members, and describes interactions with EMEA staff or applicants in relation to the different activities undertaken at CHMP level, irrespective of whether the members are acting as rapporteur, co-rapporteur, peer reviewer or CHMP member. The document was prepared for use by both CHMP members and EMEA staff, to ensure that a consistent approach is taken with respect to all evaluations and monitoring of activities in the centralised procedure, allowing a smooth running of each procedure and of CHMP plenary sessions.

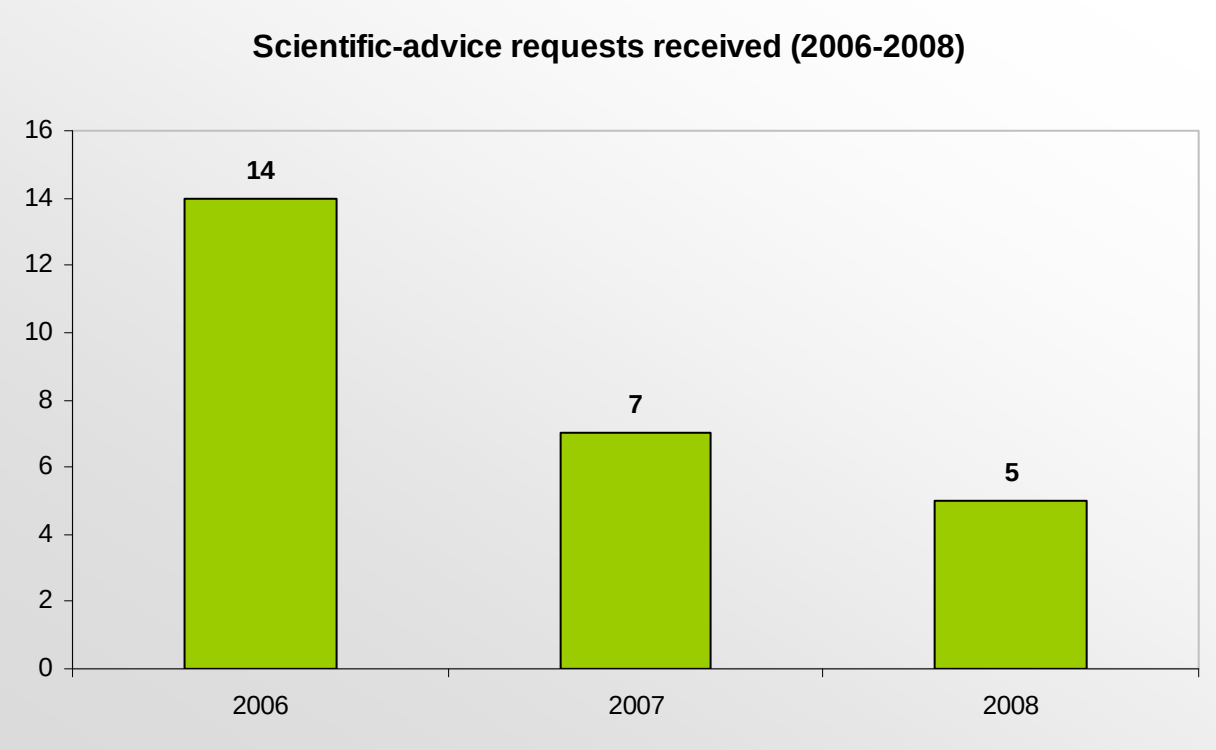
3. MEDICINES FOR VETERINARY USE

3.1 Scientific advice

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

Core activities

- The level of activity in relation to scientific advice was lower in 2008 than expected: 5 requests for scientific advice were received in contrast to the forecast of 10. By comparison, 7 requests were received in 2007.
- The number of requests for scientific advice remains significantly below target. The reasons for this are not entirely understood, but measures are in place to try to increase the interest of industry in this scheme.



Specific objectives for 2008

- The EMEA implemented the results and action points resulting from the analysis of the questionnaire on satisfaction with scientific advice, completed in 2007.

Promoting awareness for scientific advice

- A workshop took place with industry on 19 June 2008. The workshop addressed a number of topics, including: parallel scientific advice with the FDA; scientific advice for SMEs; and incentives for companies developing medicines intended for minor uses and minor species (MUMS), as well as dossier requirements for applications for these types of medicines.
- The Committee for Medicinal Products for Veterinary Use (CVMP) discussed the outcome of the workshop to identify actions that may improve uptake by industry; initiatives include more contact

between the Scientific Advice Working Party and applicants, and ensuring that high-quality advice is given.

- In September 2008, an exchange with the FDA's CVM in Rockville took place, to gain experience on how the FDA deals with scientific advice procedures, in particular with MUMS applications.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Scientific-advice requests evaluated within the procedural timelines	90% of applications	100%

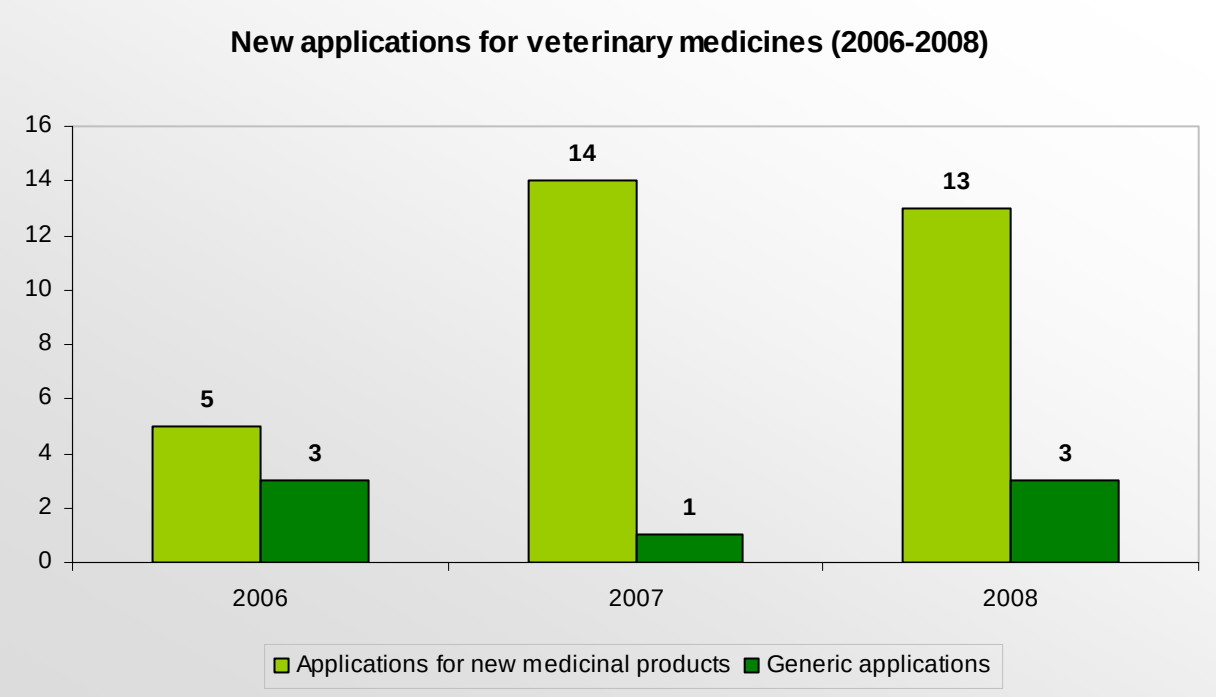
3.2 Initial evaluation

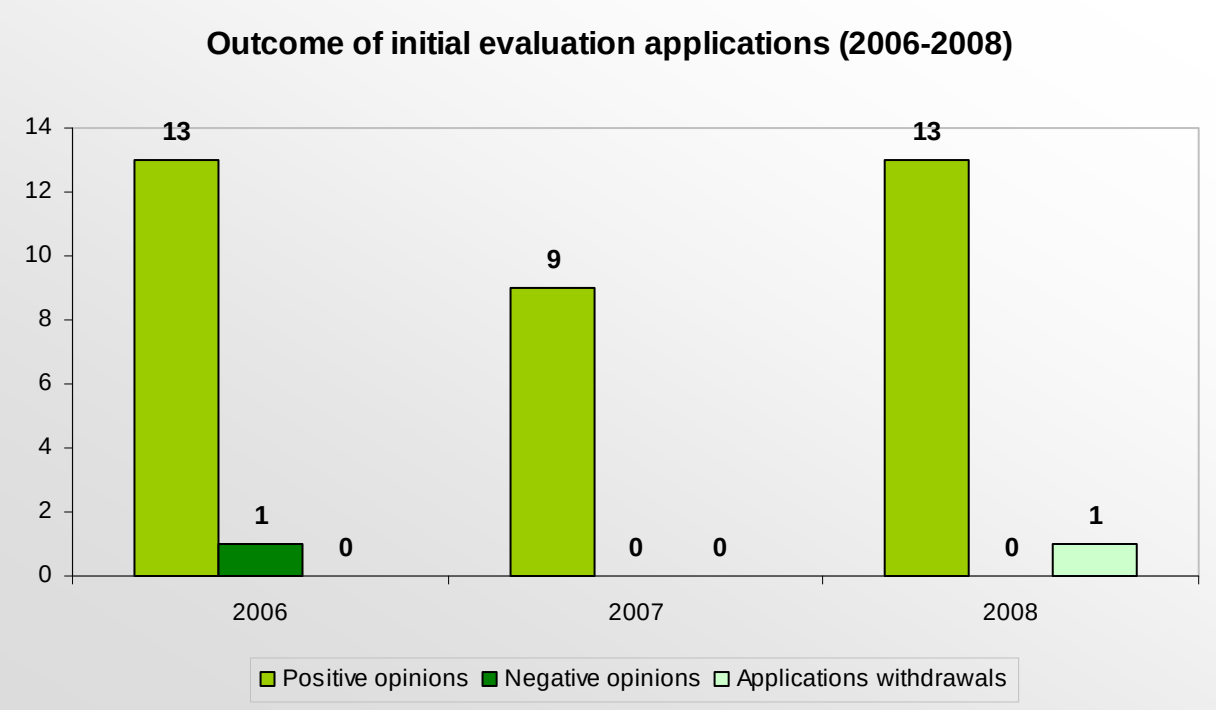
The initial evaluation phase covers a number of EMEA activities ranging from pre-submissions with future applicants, through evaluation by the CVMP, to the granting by the European Commission of the marketing authorisation. The EMEA publishes a European public assessment report (EPAR) once the Commission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

Core activities

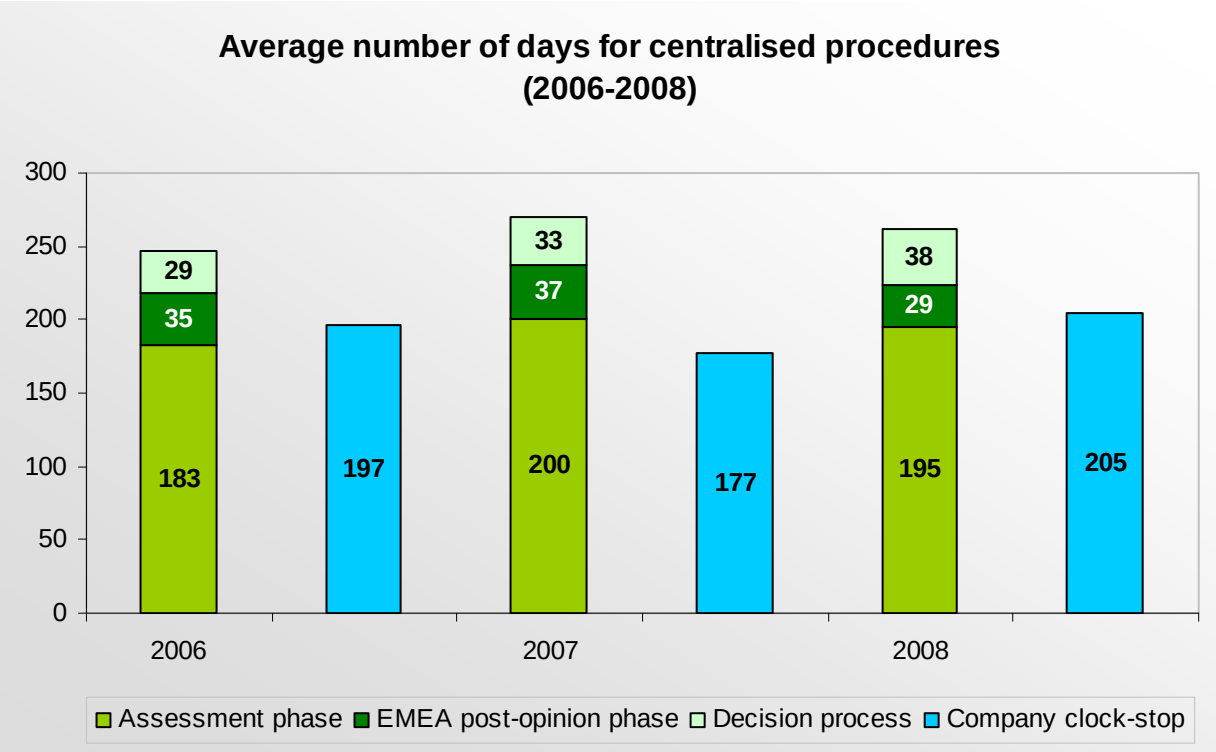
Applications received

- The Agency received a total of 16 initial marketing-authorisation applications: 13 were applications for new medicinal products and 3 were for generic applications. There was a surge in applications for authorisation of vaccines against Bluetongue Serotype 8, leading to the target for the first 6 months being exceeded. Excluding this, the underlying pattern of submission remains as predicted.





- The EMEA and its scientific committees have been extremely efficient in ensuring timely and effective assessment of applications for marketing authorisation.
- All initial evaluations were carried out within the 210-day regulatory time limit.



Specific objectives in 2008

- High-quality assessments and improvement of information to the public.
- The CVMP and the secretariat finalised the Peer Review Project Procedures, further enhancing the quality and consistency of the work of the CVMP.
- The CVMP produced a guidance document detailing a new process to streamline the preparation of the CVMP Assessment Report and EPAR. The pilot for the new process was reviewed at an informal CVMP meeting in May 2008. The pilot had mixed results, and the need for improvement of the procedures was identified. On this basis, the CVMP agreed that the pilot should be extended to more applications. A dedicated session on the assessment report template, which will address proposed improvements to facilitate the work of the rapporteurs, is anticipated for the CVMP in February 2009.
- The survey of procedures with IFAH–Europe as part of the response to the IFAH benchmarking survey conducted in 2006 was restarted using a revised questionnaire. The analysis and report are under preparation.
- The provision of appropriate and timely regulatory and procedural advice and guidance documents to the pharmaceutical industry to optimise the use of the centralised procedures is an ongoing activity; queries are answered on a regular basis and guidance is regularly updated.

Support for MUMS/limited-market products

- In line with the EMEA policy to support applications for products indicated for minor use/minor species (MUMS) and limited markets, the Agency accepted one application for marketing authorisation and one application for post-authorisation activities for such products with a reduced fee.
- The Agency also accepted requests to grant fee reductions for products indicated for MUMS and limited markets for one MRL extension and one line extension.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Percentage of products evaluated within the regulatory timeline of 210 days	100% of applications	100%

3.3 Establishment of maximum residue limits

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

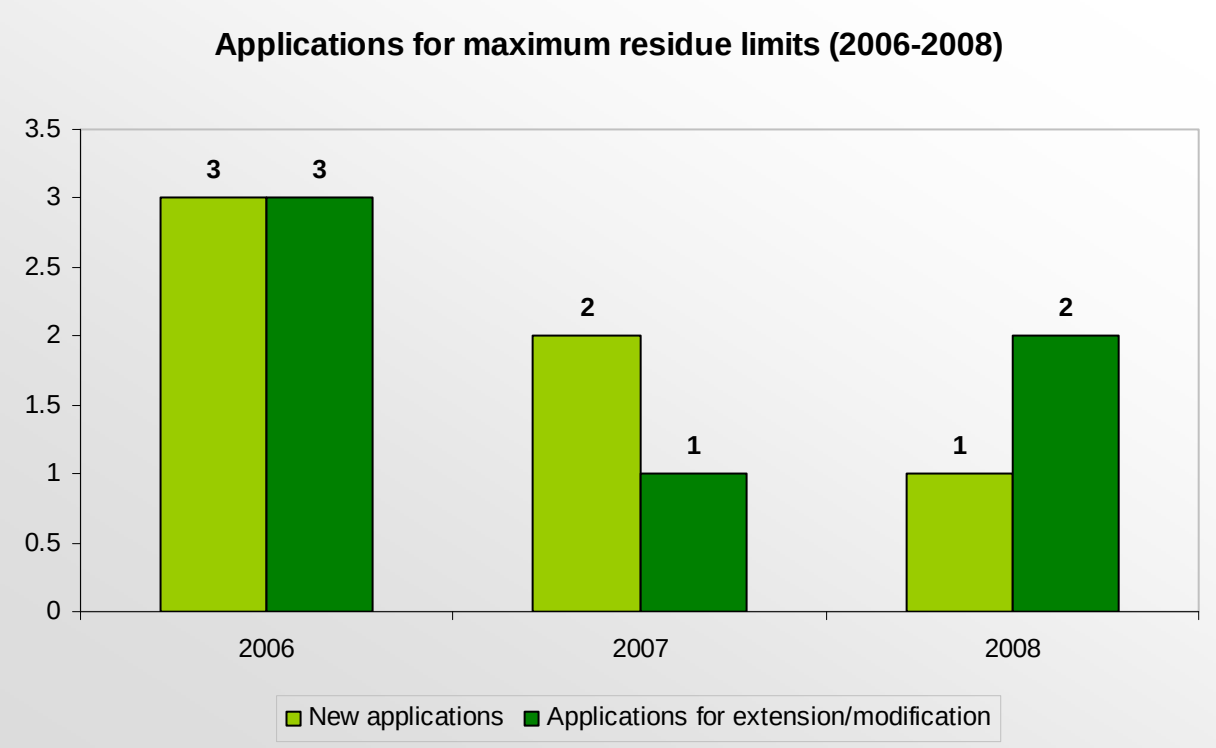
Core activities

Applications for MRLs

- In 2008, the EMEA received and validated 1 new application for MRLs — 2 fewer than were forecast for the year.
- The continuing trend of small numbers of new MRL applications is of concern, as it demonstrates 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. In both of these cases there is no

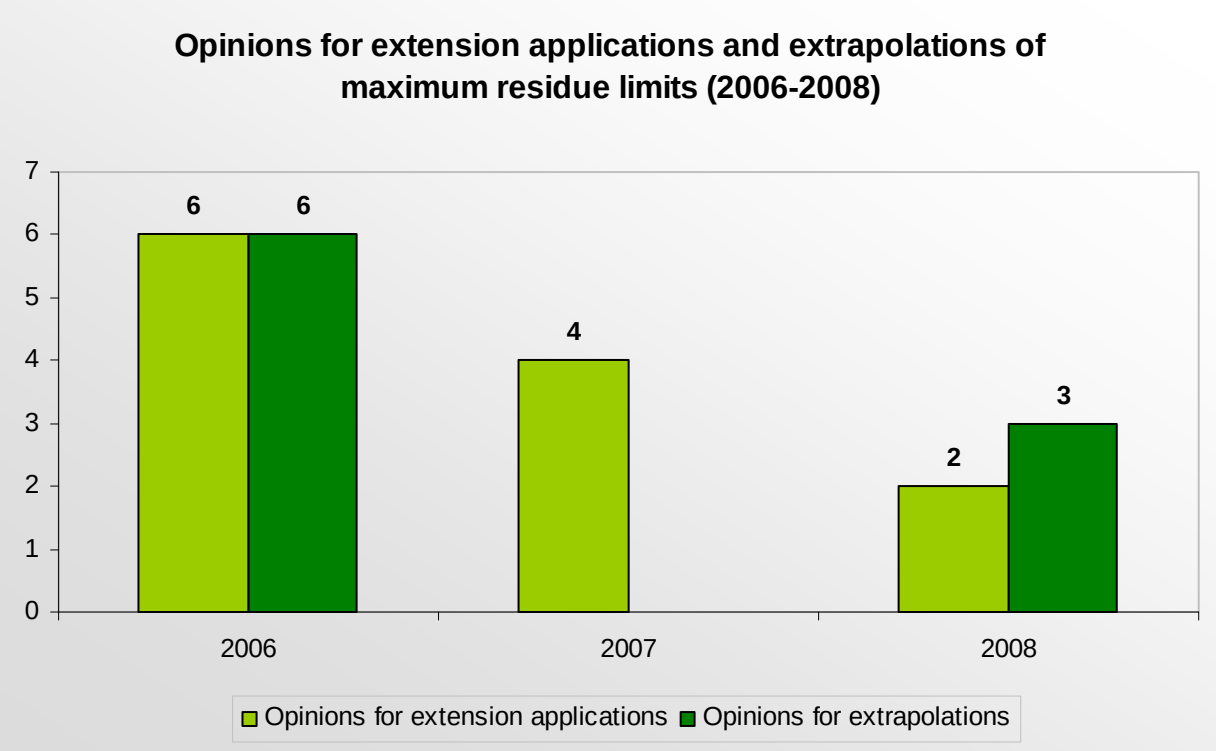
requirement to establish an MRL for the active principle, so the cost and time of bringing a product to market are reduced.

- There was also a shortfall in the number of applications submitted for extension or modification of MRLs, with only 2 of the forecast 3 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. It remains to be seen how much the new MRL Regulation can influence this trend.



Opinions on maximum residue limits

- The CVMP adopted 2 opinions for the establishment of new MRLs, of which 1 was negative.
- Two 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.



Specific objectives in 2008

Better MRL assessments

- The CVMP review process, including MRL assessment, was further strengthened.
- To ensure the quality and consistency of the scientific assessment, a peer-review pilot process, which included MRL applications, started in September 2008.

Assistance to the European Commission

- In order to assist the Commission with finalisation of the revised MRL Regulation and then implement changes introduced in the revised legislation, including revision of CVMP guidelines and procedures, the EMEA secretariat attended and assisted the Commission (DG ENTR, SANCO) with technical advice.

Outcome assessment

- The first draft of the project to conduct outcomes investigations in relation to setting MRLs for injectable products for food-producing species was prepared, but no further progress of the project was made, due to limited resources.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Percentage of applications evaluated within the 120-day timeline	100% of applications	100%

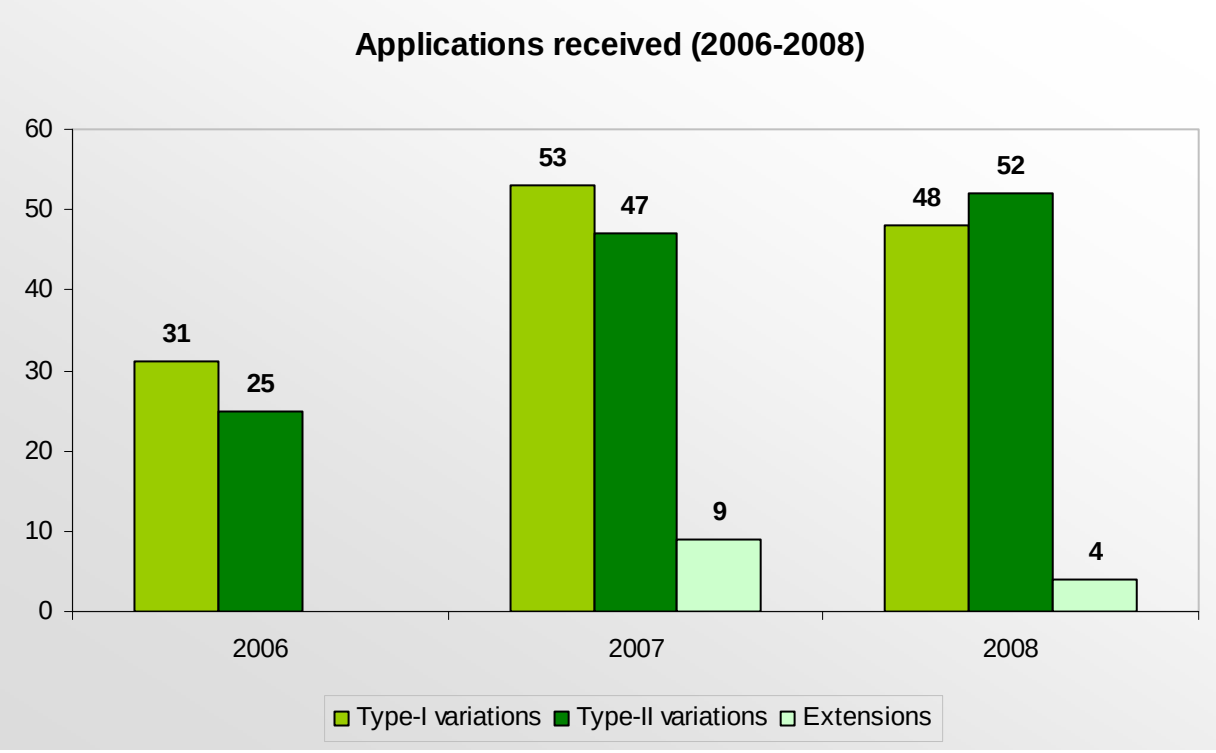
MRL applications received (input)	Forecast	Actual at the end of 2008
New MRL applications	3	1
MRL ext./mod. applications	3	2
MRL extrapolations	2	3[1]

3.4 Post-authorisation activities

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

Core activities

- The overall number of applications for variations to marketing authorisations received in 2008 was identical to the number received in 2007, and showed no deviation of note from the work plan.
- A total of 48 type-I variation applications were received, while 66 had been forecast for 2008.
- There were also 52 applications relating to the more complex type-II variations — significantly more than the 31 forecast for 2008.
- Four of the 11 line-extension applications forecast for 2008 were received.



[1] of which one relates to the extrapolation of MRLs for 3 substances to include buffalo

Specific objectives in 2008

Process improvements achieved

- The quality and consistency of assessment of post-authorisation applications and, in particular, extensions was strengthened via the peer-review process.
- The implementation of a new process to streamline the preparation of CVMP assessment reports and EPAR updates started, with the inclusion of one extension application in the pilot phase. More extension applications have been identified and they will be added to the ongoing pilot in order to gain additional experience.
- Following the adoption of the new Variation Regulations, the Agency's Veterinary Unit contributed to the development of procedural and classification guidance.
- A new section of the EMEA website was created to consolidate all post-authorisation guidance in one area — an initiative greatly welcomed by marketing-authorisation holders.

Performance indicators

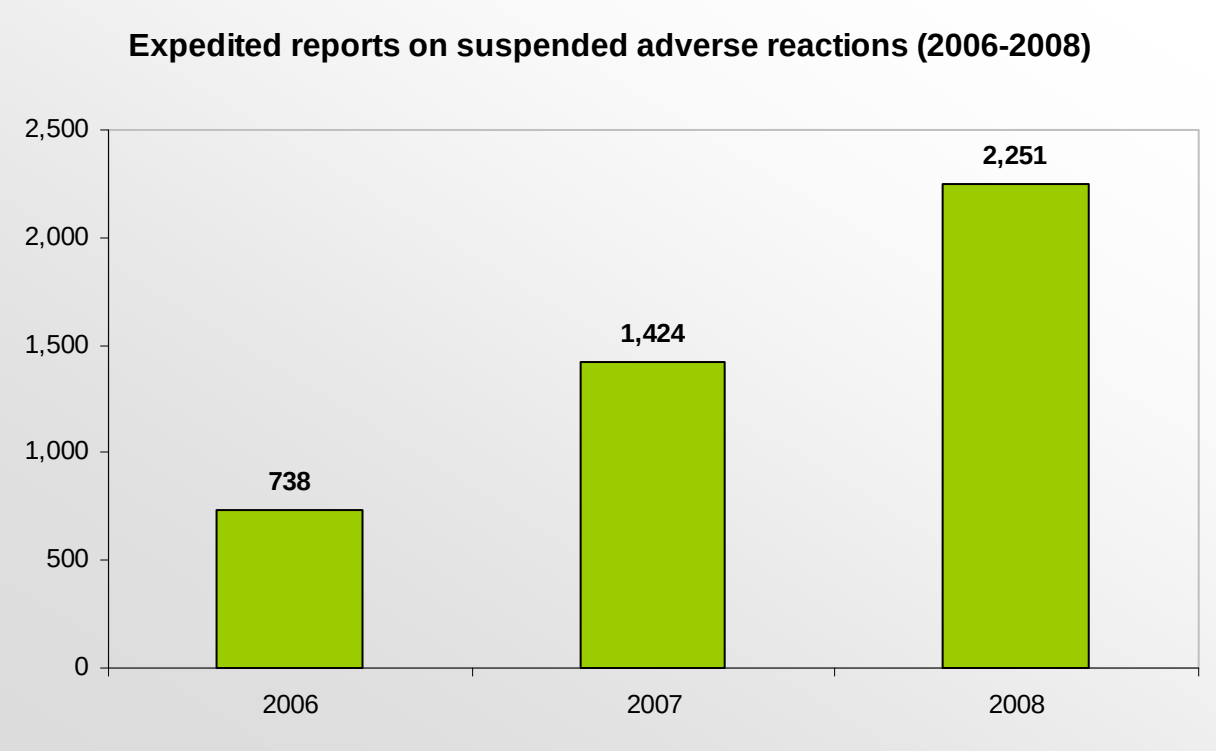
Performance indicator	Target	Outcome at end of 2008
Percentage of applications for type-I and II variations and line extensions evaluated within the regulatory timelines	100% of applications	100%

3.5 Pharmacovigilance and maintenance activities

This activity relates to pharmacovigilance information, including adverse reaction reports and periodic safety-update reports (PSURs). Pharmacovigilance remained a high priority for the Agency in 2008, to ensure that post-authorisation monitoring and effective risk-management are continuously applied to veterinary medicines throughout the EU.

Core activities

- The number of serious adverse reaction and human adverse reaction reports has increased continuously over recent years, reaching over 2,000 reports in 2008.
- In total, 2,251 serious adverse reaction and human reaction reports were received, with the highest increase concerning reports from the EU/EEA — almost doubling the number of reports. This indicates a continuing increase of awareness of veterinary pharmacovigilance in the EU, rather than an absolute increase in the number of reactions occurring.
- 1,943 of the 2,251 reports received concerned suspected adverse reactions in animals, and 308 concerned reactions in humans following exposure to a veterinary medicinal product.
- Of the 1,943 suspected adverse reactions in animals, 1,712 were in companion animals (971 in dogs and 704 in cats) and 231 in food-producing animals.
- There was a considerable increase in the number of reports received for food-producing animals, to 231 (compared with 133 reports in 2007). The higher number of reports represents a positive signal in the awareness of pharmacovigilance in the network of professionals.
- 91 PSURs and 4 PSUR addendum reports were received, in line with the forecast for 2008.



Specific objectives in 2008

Promoting awareness for veterinary pharmacovigilance

- The CVMP continued its reflections on awareness and risk-management systems, and on communication of safety issues to the general public and healthcare professionals, and established a drafting group, comprising members of the CVMP and the PhVWP-V, for the development of a concept paper.
- The CVMP adopted the annual bulletin on pharmacovigilance, to be published early in 2009.

Implementation of EudraVigilance Veterinary

- The implementation and development of EudraVigilance Veterinary (EVVet) continued in 2008, in accordance with the EVVet Action Plan. Submission of adverse event reports is now only accepted via electronic means. EVVet remained the main reporting tool used by national competent authorities. In total, 182 users are registered from 80 organisations. Testing continues among Member States' Gateway users and some of the major companies.
- A sharp increase in the number of entered reports was observed in 2008. EVVet now contains over 23,000 adverse event reports in animals and over 1,100 in humans, compared to 11,000 reports at the end of 2007. About 1,400 veterinary medicines are now contained in the EudraVigilance Product Dictionary (EVVetMPD).
- A further development stage of the EudraVigilance Veterinary Data Warehouse was concluded, providing scientific query tools to analyse data. The tools have already been tested by a subgroup of the PhVWP-V and by other experts from the national competent authorities.

Guidance to stakeholders

- The guidance for regulatory authorities concerning the assessment of PSURs was finalised following public consultation; an assessor training session was organised to promote common understanding and

implementation of the new guideline throughout the EU, in relation to all marketing authorisations, irrespective of the authorisation procedure involved.

- The PhVWP-V drafted Volume 9B of 'The rules governing medicinal products in the European Union', which follows the structure and many of the principles of Volume 9A (the equivalent guidance for human medicines), and was discussed with industry at an expert meeting on 24 June 2008. The CVMP adopted the document in September 2008, and submitted it to the Commission with a detailed technical explanatory note in December 2008.
- The draft EMEA policy on access to data contained in EVVet was finalised and was endorsed by the Heads of Medicines Agencies and by the Management Board. The document has in the meantime been published for consultation.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Percentage of PSURs evaluated within the established timelines	80% of PSURs	82%
Percentage of SARs evaluated within the established timelines	100% of SARs	100% (2,251 SARs).
SARs including reports on reactions in humans (input)	2,000 reports	2,251 reports (112.5% of the forecast number)
Periodic safety-update reports received (Input)	95 reports	95 reports (100% of the forecast number)
Procedures under Article 78 of Directive 2001/82/EC		One large and complex procedure was completed, relating to certain products containing alpha-2 agonists, concerning over 100 products.

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).

Core activities

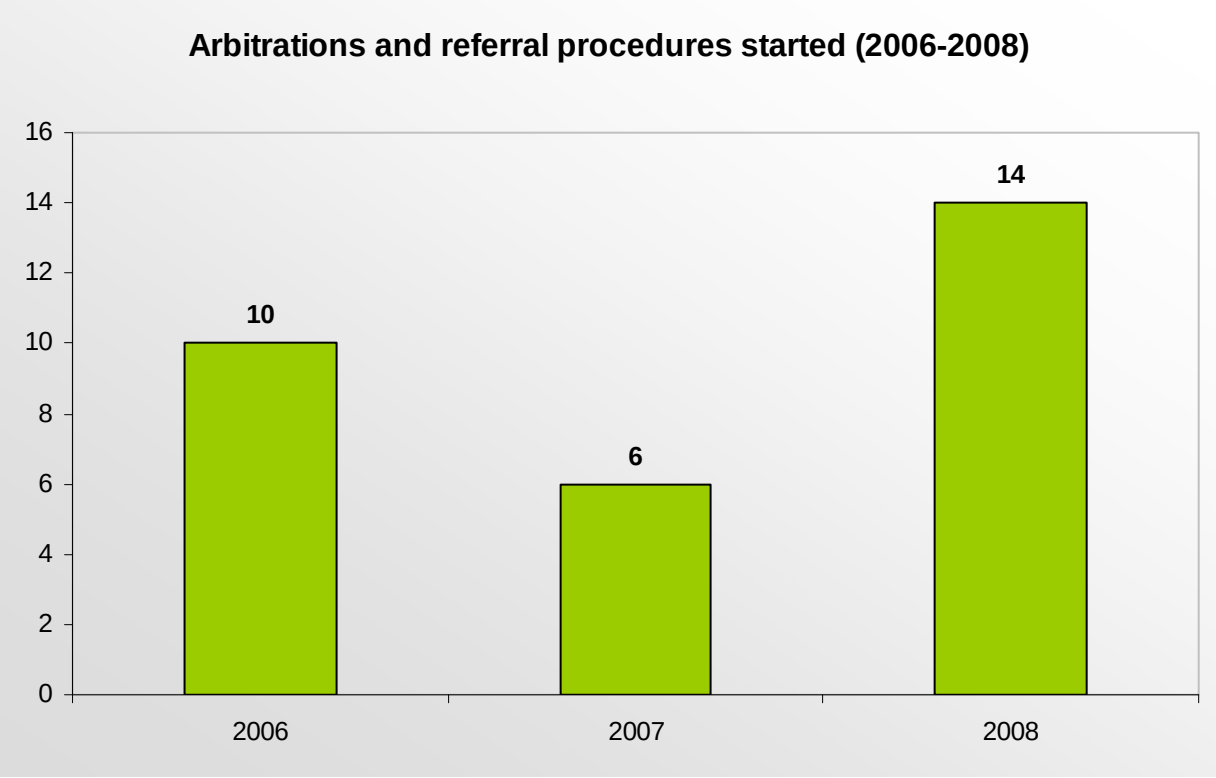
Procedures started in 2008

- A total of 14 referral procedures were initiated. The number of referrals made to the CVMP in the framework of the mutual-recognition procedure was higher than the 10 forecast on the basis of the 2007 referral statistics, due to the fact that five referrals were received in 2008, which increased the overall number of referrals.
- 5 of the 14 referral procedures related to environmental risk-assessment issues, all of which concerned generics.
- 1 of the 14 referral procedures is a large and complex referral in relation to withdrawal periods for injectable veterinary medicines containing ivermectin indicated for use in cattle, concerning nearly 300 marketing authorisations.

- Ten of the referrals were made under Article 33. Three were made under Article 34, and the one concerning ivermectin-containing medicines was made under Article 35 of Directive 2001/82/EC.
- There has been an increase in the number of referrals, particularly in relation to those concerning medicinal products which potentially pose a serious risk to the environment, and to those arising directly or indirectly from consideration of applications for generics by the CMD(v).
- This volume of work represents a significant increase in activity for the veterinary sectors, with a consequent requirement for resources.
- Current indications are that this high level of activity is expected to continue for several years, resulting as it does from changes introduced in the 2004 revision of EU legislation.

Referral procedures concluded in 2008

- The CVMP completed the assessment and issued opinions on 2 of the referral procedures that started in 2008.
- The CVMP completed the assessment and issued opinions on 2 of the referral procedures that started in 2007.
- The CVMP completed the assessment and issued an opinion on one referral procedure that started in 2006.
- All referrals were processed within the legal timeframe.



Specific objectives in 2008

Promoting efficient cooperation

- The CVMP established an ad hoc Working Group on Referrals, to develop CVMP guidance and to review lessons learned from past experience.
- The CVMP finalised an SOP on referral procedures.

- Additional instructions to be included in an SOP on translation of referrals documentation and of additional guidance have been drafted and will be published shortly.
- Discussions were held with the CMD(v) with a view to reducing the number of issues being referred to the CVMP that could be resolved through means other than arbitration.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Percentage of arbitration and referral procedures managed within the legal timeline	100% of procedures	100%

3.7 Scientific committee

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

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. The draft guideline on the evaluation of benefit-risk balance was revised, taking into consideration the comments received during a second round of public consultation in 2008. 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 with regard to 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 is being finalised, following public consultation of a reflection paper in 2008.

Activities related 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 adopted a reflection paper on third- and fourth-generation cephalosphorins, critically reviewing recent data on their use and their potential impact on resistance-development in relation to human and animal health. The paper was published for consultation.
- The Agency, together with the Heads of Medicines Agencies, continued its efforts to implement risk-management actions for (fluoro)quinolone-containing veterinary medicines, as proposed by a previously prepared, similar CVMP position paper regarding this group of products.
- The CVMP adopted guidance for antimicrobial-resistance surveillance as a post-marketing authorisation commitment.

- The CVMP and SAGAM experts are collaborating with the European Food Safety Authority (EFSA) and the European Centre for Disease prevention and Control (ECDC) on a coordinated scientific position on MRSA, to assess the impact of use of antimicrobials in livestock and companion animals on the risk of colonisation or infection with MRSA, and to provide advice on management options for animals.
- Activities in the field of minimising the potential risk to man from antimicrobial resistance arising from the use of antimicrobials in animals have been initiated with the aim of producing a joint report, following a request from the European Commission. These activities involve cooperation between the EMEA, EFSA, ECDC and DG SANCO's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), in consultation with the Community Reference Laboratory.
- The CVMP provided technical support to the European Commission on its involvement in the Codex Alimentarius Intergovernmental Task Force on Antimicrobial Resistance, which aims to develop methodology for risk assessment and risk management in relation to food-borne antimicrobial resistant micro-organisms.
- The EMEA is assessing the methodology resources required to act as catalyser for the collection of data on use of antimicrobials in food-producing species and companion animals.

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 CVMP working parties continued to be very active during 2008, developing a wide range of guidelines and guidance documents.
- Focus-group meetings and workshops involving external stakeholders were organised on the topics of PK/PD modelling, environmental risk assessment and the guidance on veterinary pharmacovigilance provided in Volume 9B.
- The CVMP Efficacy and Pharmacovigilance Working Parties provided training to assessors, with the aim of ensuring a consistent level of knowledge and promoting harmonisation of assessments throughout the Community.

3.8 Coordination Group for Mutual-Recognition and Decentralised Procedures – Veterinary

The Agency provides secretarial support to the Coordination Group for Mutual-Recognition and Decentralised Procedures – Veterinary (CMD(v)) and its subgroups/working groups.

- The Coordination Group for Mutual-Recognition and Decentralised Procedures–Veterinary (CMD(v)) met 11 times in 2008.

- The EMEA provided secretariat support to:
  - the main CMD(v) meetings;
  - 6 Document Management Subgroup meetings;
  - 5 labelling/packaging meetings;
  - several ad hoc group meetings.
- The EMEA also provided secretariat support to the organisation of informal meetings in Slovenia and France.
- The handling of generic applications where a concerned Member State has a potential serious risk issue with the reference product was an important cause of referrals in 2007. The matter was discussed at the CMD(v) and addressed to Heads of Medicines Agencies and the European Commission. This, as well as precedents set by the outcome of CVMP referrals, resulted in guidance for CMD(v) and CVMP.
- Labelling/packaging conclusions and recommendations were presented to Heads of Medicines Agencies and industry.
- The involvement of the EMEA in the effectiveness of MRP/DCP monitored through the annual IFAH-Europe/CMD(v) survey was limited to providing basic data on procedures.
- The EMEA initiated a self-assessment of the CMD(v) by its members. The results of the self-assessment questionnaire are currently being further analysed to identify opportunities for improvement.
- A discussion of the proposal to create a database for all regulatory and scientific decisions was initiated at the informal meeting in Slovenia. Work on exploring the CMD(v)'s needs was started. A business case was elaborated and presented to the ICTSC.

Procedures started and concluded in 2008

- 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.

Procedures in 2008

	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

4. INSPECTIONS

4.1 Inspections

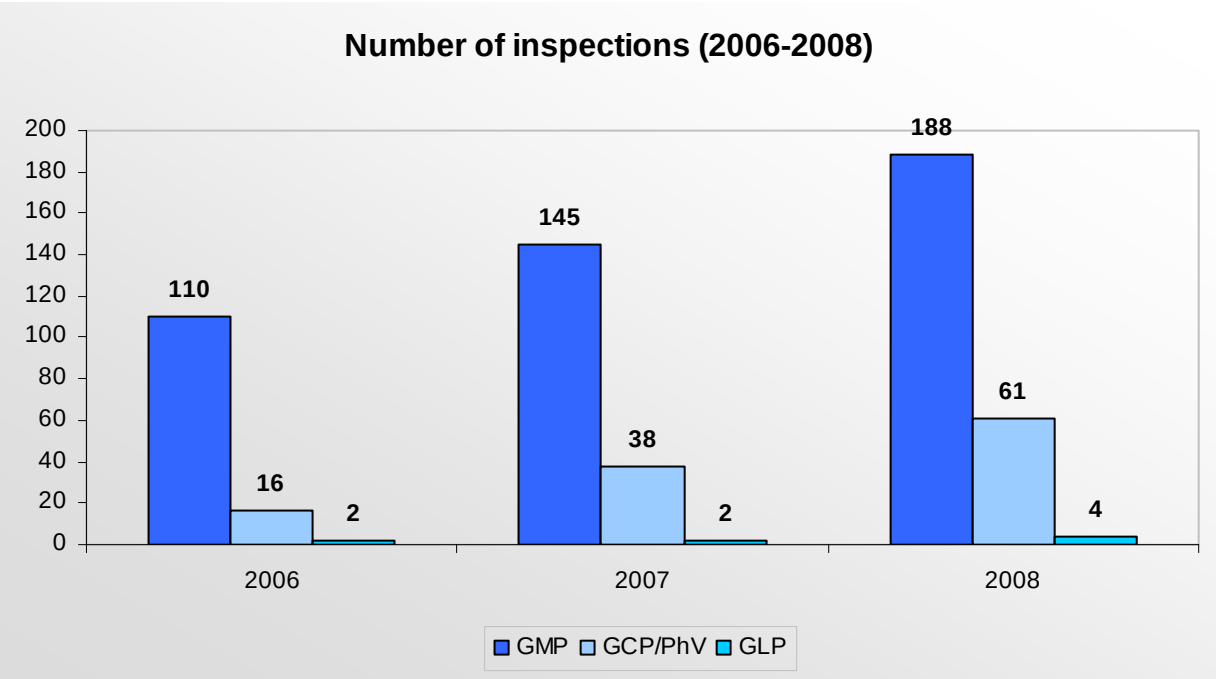
The EMEA coordinates the verification of compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP) and good laboratory practice (GLP), and with certain aspects of the supervision of authorised medicinal products in use in the European Community. It does this through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

Core activities

Inspections

- The numbers of GMP inspections rose as predicted, representing an increase of 30% compared to 2007. Plasma master file inspections represent 6% of the total number of GMP inspections.
- GCP and pharmacovigilance inspection increased by 60% compared to the numbers a year ago. Of the 61 inspections in this group, 50 were GCP inspections and 11 were pharmacovigilance inspections.
- GLP inspections were also significantly above the forecast. This reflects the fact that a number of dossiers include information on GLP studies performed in countries without existing GLP monitoring bodies.
- Quality defect numbers and complexity increased significantly during 2008, requiring significant additional input from the Agency. There is an apparent trend in the seriousness and complexity of quality defects being reported, and in the corresponding regulatory actions and communications needed.

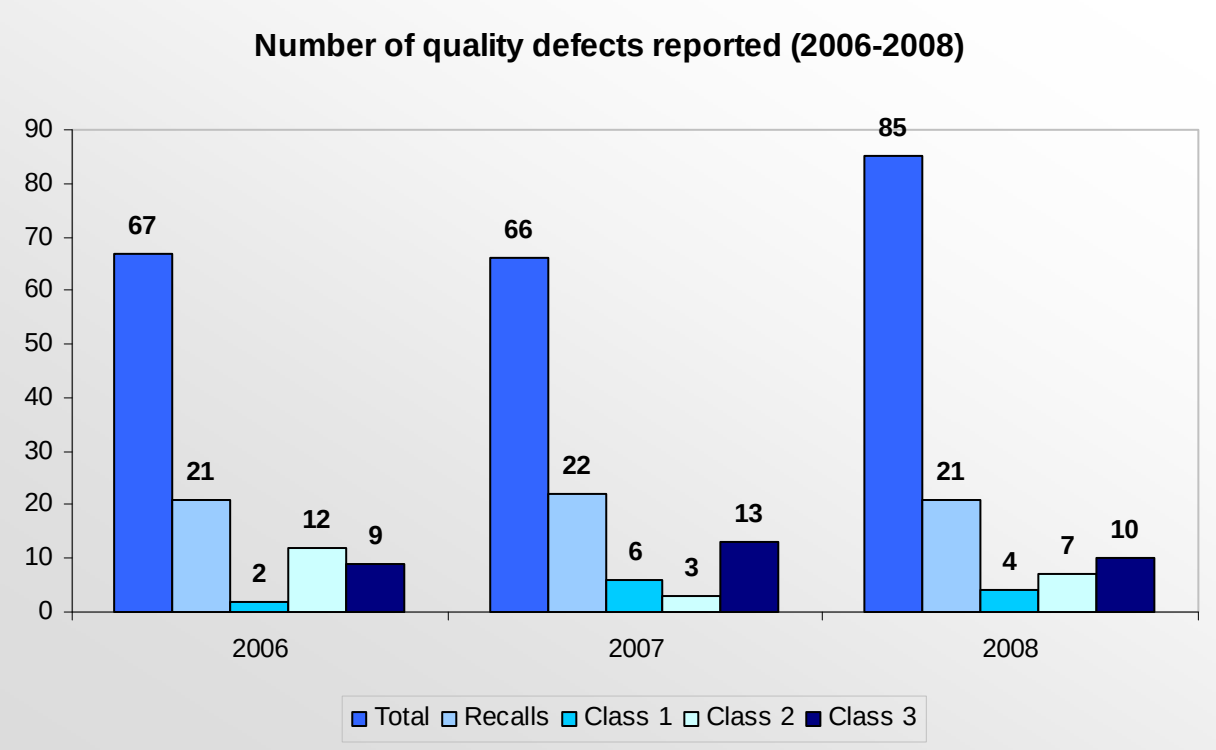


Performance indicators

Performance indicator	Target	Outcome at end of 2008
Management of inspections within legislative timelines	100% of applications	100%

Product defects and deviations

- Coordination work on quality defects increased significantly in 2008. The EMEA received around 25% more suspected quality defect reports than in previous years, although the number of recalls was similar.
- 85 suspected defect reports were successfully coordinated, 21 of which led to recalls. Four recalls were class 1, seven recalls were class 2 and ten recalls were class 3.
- One of the class 1 product defect procedures coordinated by the EMEA was the result of contamination of medicines containing or derived from heparin with oversulphated chondroitin sulphate (OSCS, a contaminant).
- The remaining class 1 recalls included one recall due to product stability issues, one recall due to defective vials leading to a lack of sterility assurance, and one recall due to illegal diversion from a third country.
- There were two deviation procedures arising from GMP non-compliance at the site of manufacture of the medicinal product.



Specific objectives in 2008

- Work to finalise the outstanding GMP annexes stemming from the 2004 legislative review progressed, with a number of final drafts (herbal medicinal products, medical gases, manufacturing of active substances, etc.) being transmitted to the European Commission.
- Significant work to strengthen pharmacovigilance inspections was accomplished. Procedures and a policy relating to pharmacovigilance inspections for centrally authorised human medicinal products were developed, and a routine programme for pharmacovigilance inspections was established.
- To improve cooperation in the European medicines network, an ad hoc pharmacovigilance inspectors working group was set up. This reflects the increasing significance of EU cooperation on pharmacovigilance inspections and its importance for the supervision of the role of the marketing authorisation holders.
- The cooperation and communication in the network was successfully coordinated by the EMEA during the heparin quality-defect situation.
- GCP and GMP requirements for advanced therapy medicinal products (ATMPs) were prepared and submitted to the European Commission for public consultation.
- The EMEA participated in international initiatives to rationalise the use of global inspection resources. A pilot project was started between the EMEA, the FDA and the Australian Therapeutic Goods Administration, for international collaboration on GMP inspections of active pharmaceutical ingredient (API) manufacturers. One joint collaborative inspection with the FDA was carried out.
- Emphasis was placed on GCP inspections in third countries, in order to ensure care of ethical and GCP standards in clinical trials performed in non-EU countries as part of initial marketing authorisation applications. The EMEA prepared a strategy paper on the acceptance of clinical trials conducted in third countries in marketing authorisation applications through the centralised procedure (published in early 2009), and established a working group to develop actions in this area. In the same context, GCP inspectors from a number of Latin American and African countries, and from the United States FDA, joined the GCP Inspectors Working Group training meeting in October 2008.

GMDP, GCP, GLP and ad hoc Pharmacovigilance Inspectors Working Groups and Joint CHMP/CVMP Quality Working Party

- To continue developing cooperation between inspection and assessment functions, a number of joint meetings between the GMDP (good manufacturing and distribution practice) Inspectors Working Group (IWG) and the BWP and QWP took place, groups of GCP and pharmacovigilance inspectors and assessors were set up, and guidance and procedures relating to GCP inspections were developed.
- To develop a coordinated approach to serious GMP non-compliance, a relevant guideline was finalised by the GMDP IWG, following consultation and a pilot period.
- To improve the process for dealing with minor deviations from the marketing authorisation, revised documents were finalised and submitted to the Heads of Medicines Agencies.
- To continue the introduction of risk management in Community procedures, a risk-based planning procedure was published. Conduct of inspections, however, was postponed until 2009.
- To clarify requirements in the context of bioequivalence studies, the draft revision of a related guideline was reviewed by both the GCP and the GLP 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

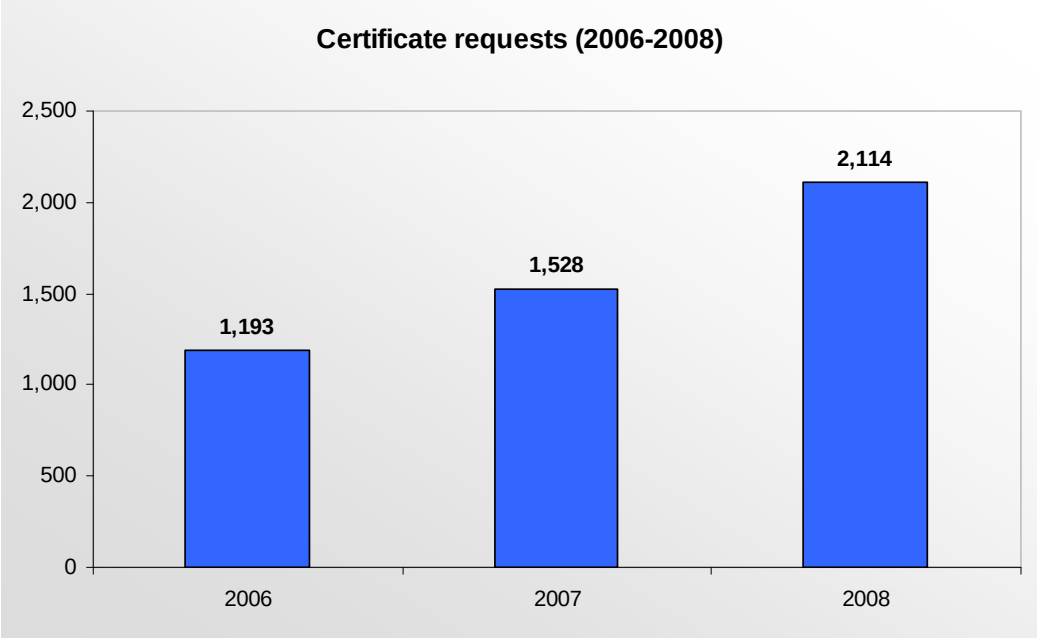
of conformity to specifications for each batch without re-control at import. The EMEA is responsible for implementation and operational aspects of these MRAs. MRAs with Australia, New Zealand, Switzerland, Canada and Japan are currently operational, but with slightly different provisions as to scope and applicability.

- Due to legislative changes in Bulgaria and Romania, the evaluation work in the context of the European Commission-Canada mutual-recognition agreement was delayed.
- As part of the review of the impact of EudraGMP on exchange of information with MRA partners, the Agency prepared a proposal and discussed its implementation with MRA countries.
- Following the adoption of the ICH Q10 on pharmaceutical quality systems in May, discussions with MRA partners to consider the impact of implementing the systems on the equivalency with MRA partners are pending.
- Activities with Japan, Australia and New Zealand did not progress as planned and were characterised by limited interactions. This was due to pending changes in legislation and changes in key contact personnel in those countries.

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 almost 40% relative to 2007.
- To rationalise the certification process, a web-based application has been launched, which takes into account applicants' comments. A meeting to discuss future improvements took place.



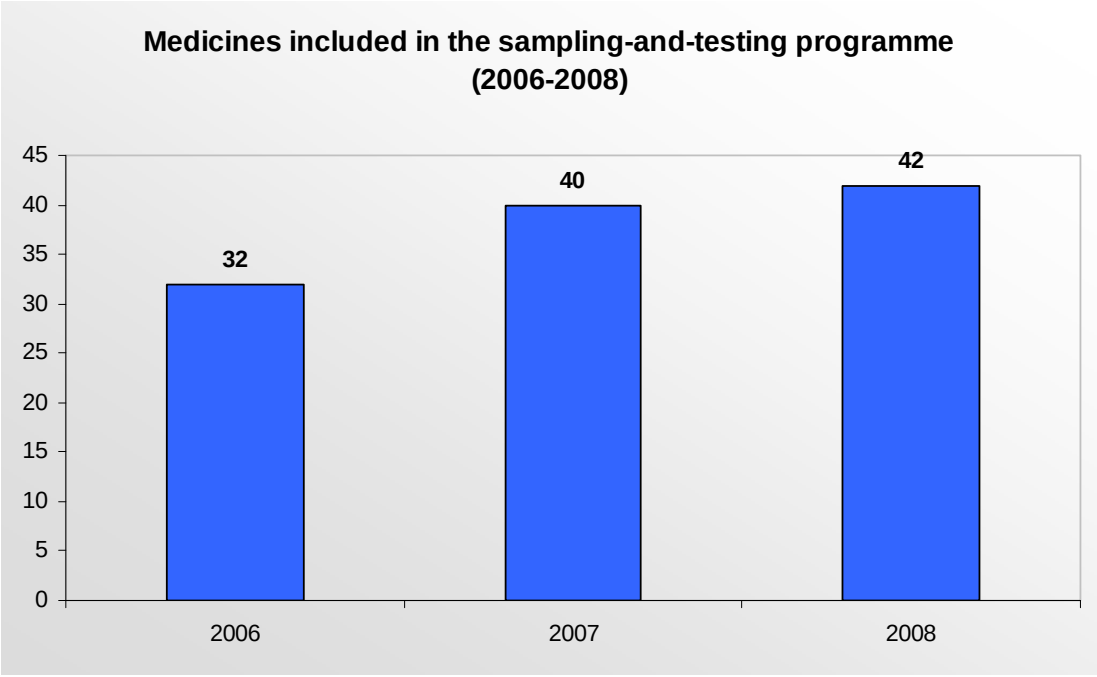
Performance indicators

Performance indicator	Target	Outcome at end of 2008
Percentage of certificates issued to requesting parties within the timeline	90% compliance	95% compliance
Implementation of web-based application	June 2008	July 2008

4.4 Sampling and testing

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

- To progress the risk-based approach to the selection of products for testing, the Committee for Medicinal Products for Human Use endorsed the outline of the risk-based methodology and the detailed work necessary to implement the approach for the 2009 sampling and testing programme was finalised.
- At the request of the CVMP, work was carried out to define a separate methodology for veterinary medicinal products.
- Particularities relating to generic products were included in the risk-based approach. In addition, and in consultation with the European Association of Euro-Pharmaceutical Companies (EAEPC), a strategy was developed to include parallel distributed products in the 2009 sampling and testing programme.



4.5 Implementation of the Clinical Trials Directives

- To support the further implementation of the Clinical Trials Directives and related legislation, the EMEA released the next version of the clinical trials database (EudraCT). The improved database now includes functionality to support supervision of clinical trials by the national competent authorities.
- Preparatory work was undertaken for the future provision of public access to the information held in EudraCT. This included a workshop with representatives of patients' and carers' organisations, healthcare providers, and commercial and non-commercial sponsors. Once the relevant Commission guidelines are published in 2009, the software development can progress.
- GCP inspection procedures and guidelines relating to the preparation and conduct of inspections, communication of findings, etc. were developed to enable harmonisation of procedures and practices, and were published by the European Commission.
- The EMEA provided support to the Clinical Trials Facilitation Group as part of its cooperation activities with Member State competent authorities and the European Commission.

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 the Eudra datawarehouse, EudraVigilance, EudraPharm, EudraCT and improving the project management methodology used at EMEA (RUP@EMEA). During 2008, the EMEA Management Board and the Heads of Medicines Agencies endorsed the EU Telematics Master Plan to 2013.

2008 was the sixth year of implementation of the EU telematics projects by the Agency.

The table below provides an overview of the development of major systems in 2008.

System or process	2008 milestones
EudraPharm	*Complete EudraPharm to Tandem Group specifications* Completed: ▪ Two versions of EudraPharm were released into production and the third version was released into testing at the end of the year. The formal development project was closed and the system transferred into maintenance mode. Change requests have been recorded for resolution by the maintenance team in accordance with stakeholders' prioritisation decisions. The system in production contains data relating to centrally authorised products and benefits from a multilingual interface. Deviations: ▪ Iteration 16 (not yet completed): Extension of data model to include all fields for product information; Display requested EudraCT data (part 1 of 2); Completion of download and export of data (part 2 of 2). ▪ Iteration 17 (not yet completed): Completion of display requested EudraCT data (part 2 of 2); Creation of required paediatrics 'section' as per 726/2004.
EudraVigilance	*Continue development of EudraVigilance to deliver requested functionality within the resource constraints* Completed: ▪ As regards medicinal products for human use, the plan proposed the delivery of the Phase IIa validation exercise, followed by a technical migration that would include (a) upgrade of database software; and (b) migration to the next version of the business intelligence software. Work was then scheduled to begin on the next stage, Phase IIb enhancements. The Phase IIa validation exercise was completed on time. The objectives were to deliver a version of the EudraVigilance Data Warehouse and Analysis System (EVDAS) that is highly available, is reliable from a data consistency perspective, performs well, and includes defined functionality for analysis and signal detection. In addition, a report on the technical feasibility and cost analysis for the implementation of the EudraVigilance Data Access Policy was requested. Work on Phase IIb was initiated in line with the planning agreed at the

	EudraVigilance Steering Committee mid-year. ▪ As regards medicinal products for veterinary use, the plan proposed the delivery of two iterations over the period, which was achieved. Deviations: ▪ Scope of phase IIb was adjusted following review mid-year. Some functionality was deferred and the construction of the tools necessary to support data cleansing activities was brought forward into phase IIb.
Eudra DataWarehouse	*Completion of implementation of the Eudra Data warehouse* Completed: ▪ The third iteration of the Eudra Data Warehouse was made available and the fourth iteration entered user acceptance testing at the end of 2008. These releases provide data analysis functionality on information pertaining to medicinal products for veterinary use to EMEA and NCA staff. Specification work on project 196 was undertaken, leading to a detailed proposal for an implementation contract being available from the proposed vendor at the end of 2008. Project 196 is aimed at bringing forward the integration of the data warehousing and business intelligence functionalities into the data warehouse. In addition, work began towards the end of the year on the reporting requirements of EudraCT via a data warehouse and business intelligence tools. Deviations: ▪ The objectives of providing datawarehousing and reporting for veterinary medicines was largely achieved. A parallel approach to providing reporting functionality for EudraCT was adopted, instead of the sequential approach described in the plan.
EudraCT Paediatrics Database	*Completion of extension of EudraCT to comply with Paediatrics Regulation* Completed: ▪ The EudraCT system is being taken forward on the basis of amalgamated requirements from the Clinical Trials Facilitation Group and those mandated by the Paediatrics Regulation. The plan foresaw two major releases during the period (versions 5 and 6), together with two technical releases in between the two. Version 5 was released in January 2008 as planned, and provided the planned functionality in respect of alerts, the export of data and notification of intention to use a EudraCT number for third-country clinical trials. Version 5.1, which was a technical release with no new business functionality, was released in May 2008. ▪ Version 6 was released towards the end of 2008. It included technical work associated with restructuring the database and migrating the user management tool to EMEA's standard database application. Deviations: ▪ Implementation of the requirements of the Paediatrics Regulation were delayed as a consequence of the guideline not being finalised. Version 7 was delayed into 2009 following late delivery of Version 6 for technical reasons.
Project success criteria and maintenance of quality standards	*Use of RUP@EMEA*

	Completed: ▪ Project to assess current implementation and to implement improved version is ongoing. At the end of the year, the project had completed inception and the vision of the methodology had been delivered. The second iteration, delivering templates for the planning, monitoring and reporting of projects was underway, on course for delivery in the first months of 2009. *Process improvement activities to RUP@EMEA* Completed: ▪ More formal meetings on 'lessons learned', following project closure. ▪ Harmonisation of risk register, such that the Telematics risk register and the unit register are one and the same in the Telematics area. *Quality control activities through internal and external audits* Completed: ▪ Planned number of external quality audits carried out. ▪ Progress achieved on implementation of improvement plans arising out of external audit Opportunities for Improvement (OFIs).
PIM (Product Information Management)	*Formal business and functional analysis to define the PIM system for extension to decentralised and mutual-recognition procedures* Completed: ▪ Final draft documentation on processes and requirements subject to final disposition of architectural issues in respect of a small number of national competent authorities in place. Deviations: ▪ Emphasis on this work reduced pending (a) resolution of the outstanding architectural issues and (b) successful emergence of the system for centralised products from pilot to full production.

Operations

Operational support was put in place to complement the investment in systems and infrastructure over the past five 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.

- The Agency meeting-document management application, EMEA MD, which provides a paperless working environment for delegates, was moved into production in 2008 and supported several key EMEA business meetings, including major committee meetings.
- The deployment of a fully functioning backup and restore system took place in 2008. This ensures that the archiving and back-up of data is of the highest standard, and enables the maintenance of a high level of security and confidentiality of all data held on EMEA systems.
- A new Service Desk system to improve levels of incident problem resolution and the tracking of issues — thus improving the overall quality of IT services to the Agency — was deployed.
- 'Dashboard' reporting and monitoring systems in order to observe status of critical systems and applications and improve their overall service availability were deployed in 2008.

Performance indicator	Target	Outcome at end of 2008
Availability of EU Telematics services (excluding planned maintenance downtime)	98%	99.56%
Response time to 80% of EU Telematics IT Service Desk requests	4 hours	3.78 hours
Response time to 15% of EU Telematics IT Service Desk requests	2 days	2.3 days
Availability of EudraNet services (excluding local NCA downtime)	99%	98.87%
Response time to 80% of EudraNet and EudraLink IT Service-Desk requests	3 hours	2.34 hours
Response time to 15% of EudraNet and EudraLink IT Service Desk requests	1.5 days	1.3 days

6. SUPPORT ACTIVITIES

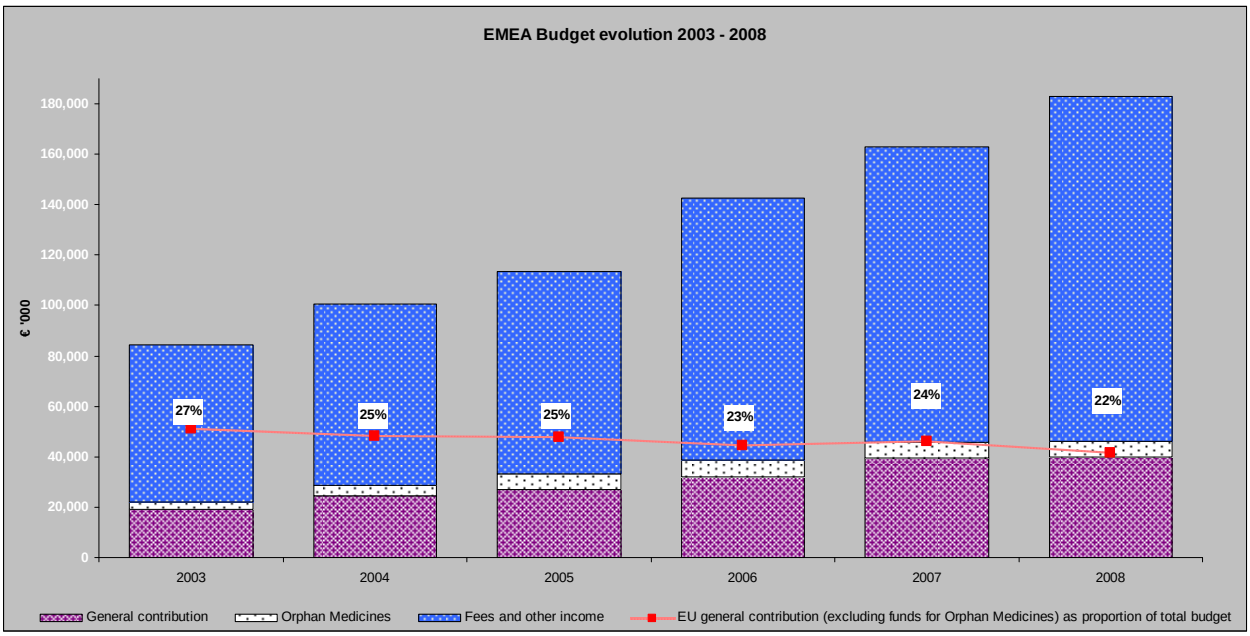
6.1 Administration

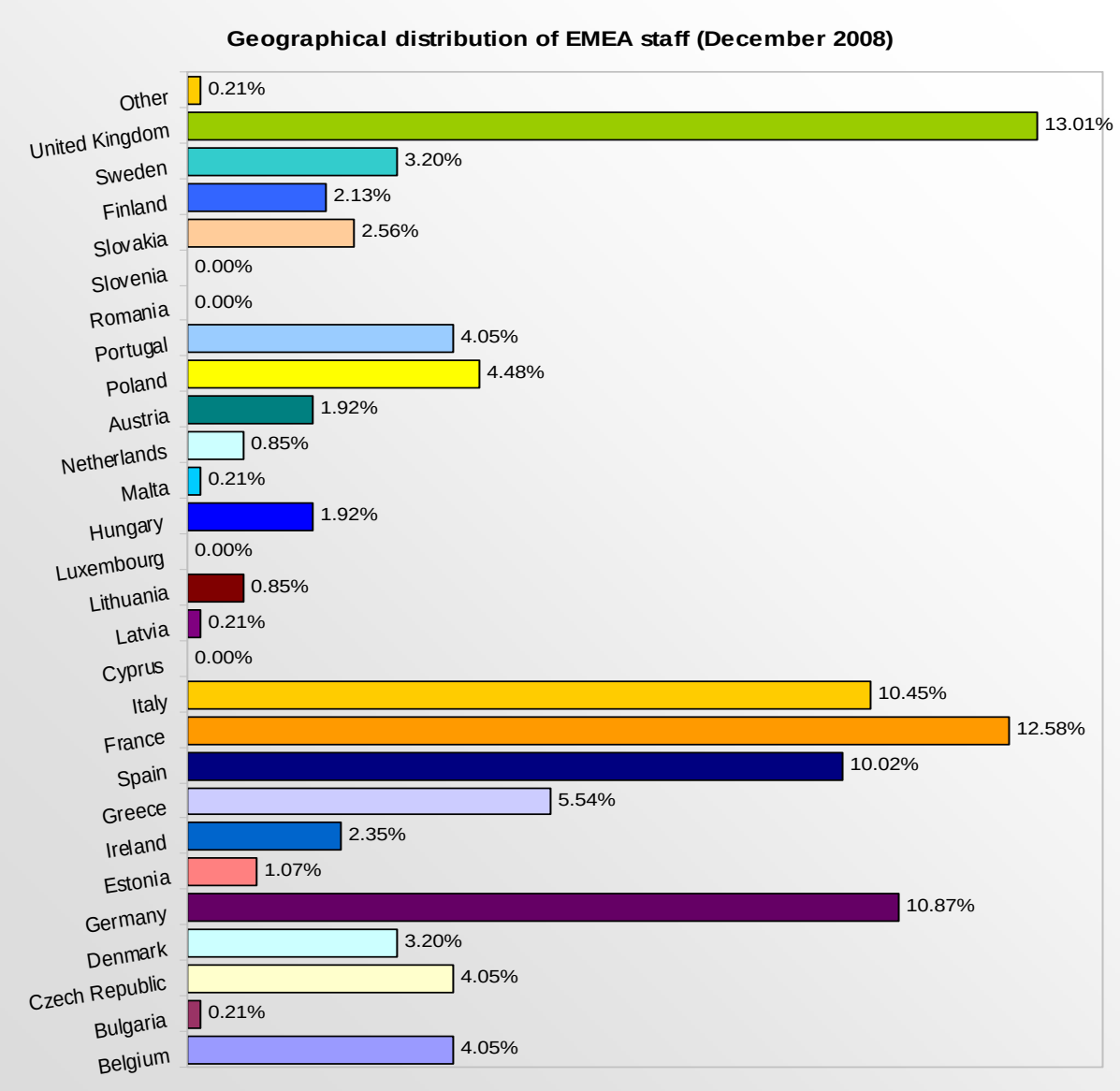
Administration tasks include: managing revenue, expenditure and accounts according to existing rules and regulations; recruiting, managing and administering staff and seconded personnel; providing and running the necessary infrastructure services for effective functioning of the Agency. To manage these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

Personnel and budget

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

- The Agency's total budget in 2008 was €182,895,000.
- The number of staff employed at the EMEA was 469, plus 155 seconded national experts, contract agents, trainees and interim staff.
- Thirty-five 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 3,810.
- Following the completion of a procurement procedure, a new training provider was selected for language and personal-development training, and training participants expressed their satisfaction with the training provided to date.
- A scientific-competence training programme was also introduced.
- Two specific training courses for financial actors were provided.
- Support for the introduction of an enterprise-resource-management system continued as planned; preparatory work for financial and human-resources modules were conducted.
- A 360-degree performance-evaluation system for managers was piloted, and a related public-procurement exercise was completed.


EMEA Budget evolution 2003 - 2008
€ '000
180,000
160,000
140,000
120,000
100,000
80,000
60,000
40,000
20,000
0
27%
25%
25%
23%
24%
22%
2003
2004
2005
2006
2007
2008
General contribution
Orphan Medicines
Fees and other income
EU general contribution (excluding funds for Orphan Medicines) as proportion of total budget


Geographical distribution of EMEA staff (December 2008)
Other 0.21%
United Kingdom 13.01%
Sweden 3.20%
Finland 2.13%
Slovakia 2.56%
Slovenia 0.00%
Romania 0.00%
Portugal 4.05%
Poland 4.48%
Austria 1.92%
Netherlands 0.85%
Malta 0.21%
Hungary 1.92%
Luxembourg 0.00%
Lithuania 0.85%
Latvia 0.21%
Cyprus 0.00%
Italy 10.45%
France 12.58%
Spain 10.02%
Greece 5.54%
Ireland 2.35%
Estonia 1.07%
Germany 10.87%
Denmark 3.20%
Czech Republic 4.05%
Bulgaria 0.21%
Belgium 4.05%

	2006 (final)	2007 (final)	2008 (final)
Workload			
Total staff	395[1] + 100[2]	423[1] + 124[2]	469[1] + 155[2]
EMEA budget	€136,138,676	€163,113,000	€182,895,000
Selection procedures	49	29	35
Mission claims	1,059	922	961
Salary payments	4,791	6,003	6,632
Staff mobility	446	486	567

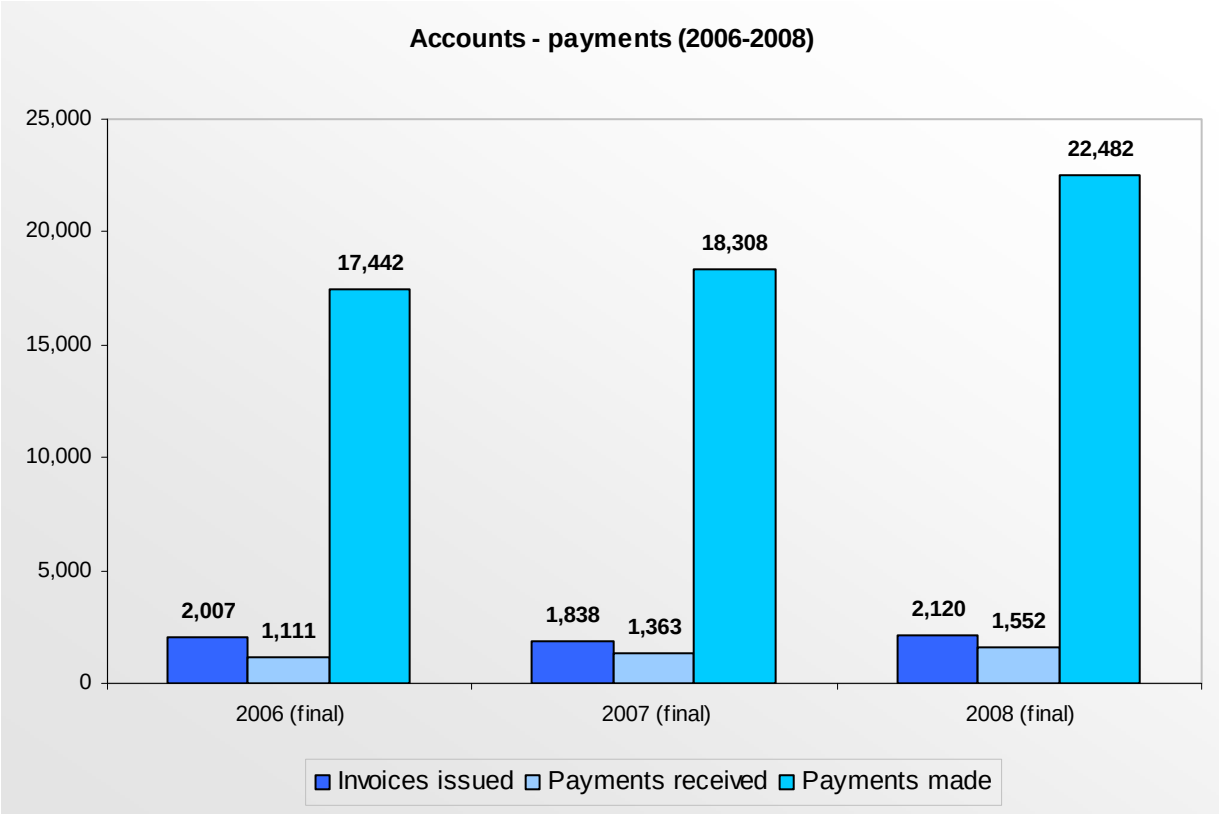
[1] Establishment plan minus vacancy rate.

[2] Number of interims, trainees, national experts and contract agents.

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.

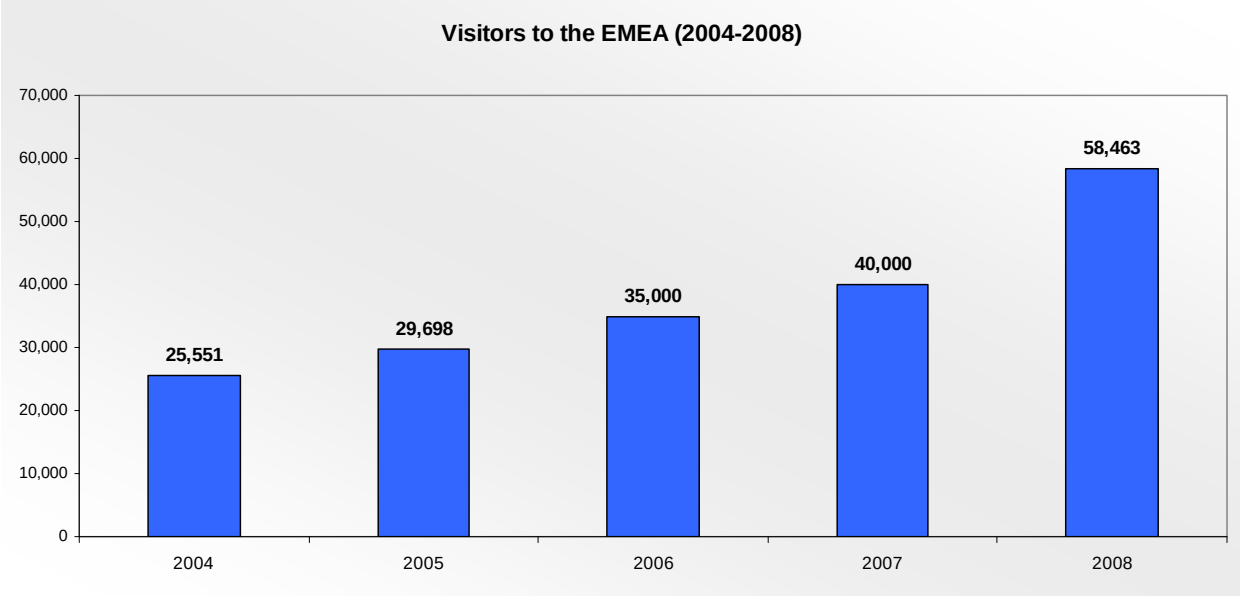
- All bank accounts are reconciled to date. Financial accounts are up to date, and all financial reporting and legal dates were complied with.
- An updated version of the financial accounts reporting package was introduced in the second quarter of 2008.
- A 'blueprint' phase for a new integrated accounting system (SAP) was begun in December 2008.



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, providing 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 catering facilities, and the financial management of 30 budget lines.

- A satisfactory performance was achieved in all main infrastructure-related areas in 2008.
- Public procurement exercises for legal services and property consultancy were successfully run, and contracts were signed with new contractors for these services.
- A contract for refurbishment of the first floor and refit of part of the fourth floor of the Agency's premises was awarded.
- An exercise to rehearse the business-continuity arrangements of the Agency's support services was successfully completed.
- Training and guidance was provided to staff involved in procurement, contract-management and e-facilities.
- The number of visitors to the EMEA (made up largely of delegates for meetings and conferences) increased by 46%.



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.

- A very good performance was recorded in most areas of the verification service's activities.

- The development and enhancement of verification procedures continued to be a priority for the Agency in 2008.
- The quality of controls for both decentralised and centralised bodies was improved significantly.
- The low volume of financial transactions can be explained by a rationalisation of hotel-invoices management, which drastically reduced the number of individual payments.

Workload/Performance Indicators

	2006 (final)	2007 (final)	2008 (final)
Transactions checked[1]	27,150	30,400	30,430
Decentralised verification[2]	26%	41%	56%
Meeting reimbursements	*24%*	*35%*	*32%*
Fee revenue & expenditure	*N/A*	*5%*	*24%*
Administrative expenditure	*2%*	*1%*	*0%*

[1] Corresponding to the number of financial transactions checked by the centralised verifying officer.

[2] Corresponding to the percentage of low-risk transactions 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 2008 through direct partnering with business units, in order to develop and implement a range of critical applications.

- The IT Disaster Recovery (DR) solution was significantly strengthened in 2008 with the commissioning of the DR infrastructure. Core business applications were tested at the DR site in Q3 2008. Integrated with the DR project was the successful replacement of the back-up system, which now provides the service levels required to support full back-up and restore workload predicted for 2009.
- Development of specific applications and databases as required by legislation and defined by the business were completed in 2008. For example, the first phase of the Pharmacovigilance Tracking System (PTS) was successfully deployed.
- The deployment of virtual meeting technologies using Adobe Connect and Vitero took place in 2008.
- The IT Sector made progress with the deployment of a new Service Desk system in 2008, which will be extended to incorporate a range of ITIL business processes in 2009.
- A range of critical applications, such as the new version of SIAMED II and EMEA Resource Planning (ERP, which will replace SI2), were initiated.
- Continual improvements to the Data Centre Management and Enterprise Management services will ensure that all systems are operated to high standards of availability and reliability, in conformity with ITIL best practice.
- Final draft documentation on processes and requirements for the EMEA's web content management system was completed, in preparation for the WCMS build and launch of a new Agency website in 2009.
- Development of Unified Telecommunications Environment based around telephony, video-conferencing and integration with current IT systems commenced in 2008. This also includes extending virtual meetings solutions in line with specific meeting requirements.

- The capacity of IT office space for consultants was heavily increased during 2008, enabling improved management of large development teams.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Availability of corporate services (excluding planned maintenance downtime)	98%	99.63%[1]
Response time to 80% of corporate IT Service Desk requests	2 hours	1.78 hours
Response time to 15% of corporate IT Service Desk requests	1 day	1.2 days
Percentage of systems 'down-time'	2%	0.78%
Percentage of user satisfaction	95%	Not yet measured[2]
Delivery of IT projects against plan and budget	95%	On target[3]
Effective transition to production/operation	95%	On target[3]

[1] This is an estimation based on downtime over 12 months; substantially improved statistics will be available in 2009 following the introduction of the INFRA Service Desk system.

[2] Will be available from 2009 as part of new Service Desk facilities.

[3] More detail on projects' progress against plan will be available when Microsoft Project Server 2007 is fully deployed and used for managing all projects in 2009.

6.3 Meetings and conferences at the EMEA

The EMEA ensures efficient support for meetings it organises, 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 2008 (550) was less than in previous years.
- The number of delegates coming to the Agency stood at 8,000 in 2008.
- The Agency successfully implemented the new reimbursement rules.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Delegates' satisfaction regarding travel and accommodation bookings	95%	On target
Assistance and satisfaction of interested parties (EMEA, delegates, national authorities, suppliers)	95%	On target

Reimbursement of expenses within 2 weeks after the meeting ends	80%	On target
Percentage of payments checked within 48 hours	95%	On target
Provision of monthly budgetary reports and payment breakdown	100%	On target
Satisfaction with management of enlargement programmes	95%	On target

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. For the sector involved, this means: ensuring best practice in document and records management; ensuring best practice in the areas of access to information and documents; providing staff with the most effective access to internal and external information needed to perform their professional duties; verifying the accuracy of translations (excluding medical product information); verifying the quality of documents (excluding content) and organising their publication; organising and supporting Agency exhibitions.

- Further progress on the development and implementation of an electronic records-management system was made with the approval of the EMEA records-management policy in 2008.
- The EMEA received a total of 124 requests for access to documents (of which 31 were refused), compared to 89 (of which 33 were refused) in 2007.
- The EMEA received a total of 4,069 requests for information, compared to 3,477 in 2007.
- A total of 36,345 pages (603 jobs) were translated, compared to 32,268 pages (581 jobs) in 2007.

Performance indicators

Performance indicator	Target	Outcome at end of 2008
Percentage of external requests for documents processed within established timelines	100%	100%
Percentage of external requests for information processed within established timelines	95%	Data not yet available
Percentage of translations processed within established timelines	100%	100%
Percentage of internal library requests for information processed and received within established timelines	90%	Not yet measured
Percentage of published material processed and delivered within established timelines	95%	95%
Percentage of exhibition material processed and delivered within established timelines	100%	100%

ANNEXES

Annex 1 Members of the Management Board

Chair: Pat O'MAHONY
EMEA contact: Martin HARVEY ALLCHURCH

Members

European Parliament	Giuseppe NISTICÓ, Björn LEMMER (*Substitute:* Jozef HOLOMÁŇ)
European Commission	Heinz ZOUREK, Isabel de la MATA[2] (*Alternates:* Georgette LALIS, Bernard MERKEL)
Belgium	Xavier DE CUYPER (*Alternate:* André LHOIR)
Bulgaria	Emil IVANOV HRISTOV (*Alternate:* Meri BORISLAVOVA PEYTCHEVA)
Czech Republic	Lenka BALÁŽOVÁ (*Alternate:* Jiří BUREŠ)
Denmark	Jytte LYNGVIG (*Alternate:* Paul SCHÜDER)
Germany	Walter SCHWERDTFEGER (*Alternate:* Hans-Peter HOFMANN)
Estonia	Kristin RAUDSEPP (*Alternate:* Alar IRS)
Ireland	Pat O'MAHONY (*Alternate:* Rita PURCELL)
Greece	Vassilis KONTOZAMANIS[3] (*Alternate:* Athina LINOU[4])
Spain	Cristina AVENDAÑO-SOLÀ (*Alternate:* Laura Franqueza GARCÍA[5])
France	Jean MARIMBERT (*Alternate:* Pascale BRIAND)
Italy	Guido RASI[6] (*Alternate:* Silvia FABIANI)
Cyprus	Panayiota KOKKINOU (*Alternate:* George ANTONIOU)
Latvia	Inguna ADOVICA (*Alternate:* Dace ĶIKUTE)
Lithuania	Mindaugas BŪTA[7] (*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	Elżbieta WOJTASIK[8] (*Alternate:* Jacek SPLAWINSKI)
Portugal	Vasco A J MARIA (*Alternate:* Fernando d'ALMEIDA BERNARDO[9])
Romania	Magdalena BADULESCU (*Alternate:* Rodica BADESCU)
Slovenia	Martina CVELBAR (*Alternate:* Vesna KOBLAR)
Slovakia	Ján MAZÁG (*Alternate:* Dagmar STARÁ)
Finland	Marja-Liisa PATARNEN (*Alternate:* Pekka JÄRVINEN)
Sweden	Christina ÅKERMAN[10] (*Alternate:* Anders BROSTRÖM)
United Kingdom	Kent WOODS (*Alternate:* Steve DEAN)
Representatives of patients' organisations	Mary BAKER, Mike O'DONOVAN[11]

[2] Replaced Andrzej RYŚ as of October 2008
[3] Replaced Dimitrios VAGIONAS as of June 2008
[4] Replaced Catherine MORAITI as of June 2008
[5] Replaced Teresa PAGES as of October 2008
[6] Replaced Nello MARTINI as of October 2008
[7] Replaced Aurelija KULČICKIENĖ-GUTIENĖ as of October 2008
[8] Replaced Piotr BLASZCZYK as of June 2008
[9] Replaced Hélder MOTA FILIPE as of October 2008
[10] Replaced Gunar ALVÁN as of October 2008
[11] Replaced Jean GEORGES as of December 2008

Representative of doctors' organisations	Lisette TIDDENS-ENGWIRDA *(vice-chair)*
Representative of veterinarians' organisations	Henk VAARKAMP[12]

Observers

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

[12] Member as of December 2008

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

Chair: Eric ABADIE
EMEA contact: Anthony HUMPHREYS

Members

- George AISLAITNER (Greece)[1]
  Alternate Catherine MORAITI [2]
- Viorel Robert ANCUCEANU (Romania)
  Alternate: Raluca CIRSTEA [3]
- John Joseph BORG (Malta)
  Alternate: Patricia VELLA BONANNO
- János BORVENDÉG (Hungary)
  Alternate: Agnes GYURASICS
- Gonzalo CALVO ROJAS (Spain)
  Alternate: Concepcion PRIETO YERRO
- Pierre DEMOLIS (France)
  Alternate: Philipe LECHAT
- Harald ENZMANN (Germany)
  Alternate: Karl BROICH
- Jacqueline GENOUX-HAMES (Luxembourg)
  Alternate: nomination awaited[4]
- Robert James HEMMINGS[5] (United Kingdom) *(co-opted)*
- Ian HUDSON (United Kingdom)
  Alternate: Rafe SUVARNA[6]
- Alar IRS (Estonia)
  Alternate: Irja LUTSAR[7]
- Arthur ISSEYEGH (Cyprus)
  Alternate: Panayiota KOKKINOU
- Jaana KALLIO [8] (Finland)
  Alternate: Outi LAPATTO-REINILUOTO[9]
- Metoda LIPNIK-STANGELJ (Slovenia)
  Alternate: Nevenka TRSINAR[10]
- David LYONS (Ireland)
  Alternate: Patrick SALMON
- Romaldas MAČIULAITIS (Lithuania)
  Alternate: Rugile PILVINIENE [11]
- Ján MAZÁG (Slovakia)
  Alternate: nomination awaited[12]
- Pieter NEELS (Belgium)
  Alternate: Bruno FLAMION
- Giuseppe NISTICÒ (Italy)
  Alternate: Antonio ADDIS[13]
- Sif ORMARSDÓTTIR (Iceland)
  Alternate: Magnús JÓHANNSSON
- Ingemar PERSSON (Sweden) *(co-opted)*
- Michał PIROŻYŃSKI (Poland)
  Alternate: Piotr SIEDLECKI
- Andrea LASLOP (Austria)[14]
  Alternate: Hans WINKLER[15]
- Juris POKROTNIEKS (Latvia)
  Alternate: Natalja KARPOVA[16]
- Jean-Louis ROBERT (Luxembourg) *(co-opted)*
- Sol RUIZ[17] (Spain) *(co-opted)*

[1] Replaced Nikolaos DRAKOULIS as of May 2008 meeting.
[2] Replaced Chryssoula NTAOUSANI (who in turn replaced George AISLAITNER in May 2008 meeting) as of November 2008 meeting.
[3] Replaced Victoria SUBTIRICA as of December 2008 meeting.
[4] Nomination awaited.
[5] Elected as Co-opted member from March 2008.
[6] Replaced Matthew THATCHER (who in turn replaced Julia DUNNE in September 2007) as of February 2008 meeting.
[7] Replaced Raul KIIVET as of January 2007 meeting.
[8] Replaced Pirjo LAITINEN-PARKONNEN as of December 2008 meeting.
[9] Replaced Pirjo LAITINEN-PARKONNEN (as alternate) as of October 2007 meeting.
[10] Replaced Maja LUŠIN (who in turn replaced Barbara RAZINGER-MIHOVEC in May 2007) as of October 2007 meeting).
[11] Replaced Donatas STAKIŠAITIS as of May 2008 meeting.
[12] Karol KRALINKSY, Alternate member as of November 2007 meeting, resigned as of September 2008.
[13] Replaced Pasqualino ROSSI as of July 2008 meeting.
[14] Replaced Heribert PITTNER as of January 2009 meeting.
[15] Replaced Andrea LASLOP as of January 2009 meeting, who in turn replaced Josef SUKO as of May 2007 meeting.
[16] Replaced Indulis PURVINŠ as of May 2007 meeting.

- Tomas SALMONSON (Sweden) *(vice-chair)*[18]
  Alternate: Bengt LJUNGBERG
- Christian SCHNEIDER[19] (Germany) *(co-opted)*
- Beatriz SILVA LIMA (Portugal)
  Alternate: Cristina SAMPAIO
- 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[20]
- Martin VOTAVA[21] (Czech Republic)
  Alternate: Ondřej SLANAŘ[22]

[17] Elected as Co-opted member from September 2007.
[18] Vice-chair as of June 2007 meeting.
[19] Co-opted member from September 2007.
[20] Replaced Frits LEKKERKERKER as of June 2007 meeting.
[21] Replaced Milan ŠMÍD as of May 2007 meeting.
[22] Alternate member as of May 2007 meeting.

Working parties, ad hoc groups and scientific advisory groups

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

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

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

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

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

Vaccine Working Party
Chair: Michael PFLEIDERER[1]
EMEA contact: John PURVES

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

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

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

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

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

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

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

Working Party on Cell-based Products
Chair: Paula SALMIKANGAS
EMEA contact: John PURVES

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

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

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

Ad Hoc Working Party on Similar Biological (Biosimilar) Medicinal Products
Chair: Christian SCHNEIDER
EMEA contact: Marisa PAPALUCA AMATI

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

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

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

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

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

[1] Replaced Daniel BRASSEUR as of May 2008 meeting.

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

Chair: Gérard MOULIN (Vice-Chair: Anja HOLM)
EMEA contact: David MACKAY

Members

- Gabriel BEECHINOR (Ireland)
  Alternate: David MURPHY
- Rory BREATHNACH (Ireland) *(co-opted)*
- Jiří BUREŠ (Czech Republic)
  Alternate: Alfred HERA
- Peter EKSTRÖM (Sweden) *(co-opted)*
- Christian FRIIS (Denmark) *(co-opted)*
- Irmeli HAPPONEN (Finland)
  Alternate: Kristina LEHMANN [1]
- Judita HEDEROVÁ (Slovakia)
  Alternate: Eva CHOBOTOVA
- Anja HOLM (Denmark) *(vice-chairman)*
  Alternate: Ellen-Margrethe VESTERGAARD
- Tonje HØY (Norway)
  Alternate: Hanne BERGENDAHL
- Damyan ILIEV[2] (Bulgaria)
  Alternate: Ilian GETCHEV
- Laimis JODKONIS (Lithuania)
  Alternate: Juozas JOKIMAS
- Charalambos KAKOYIANNIS (Cyprus)
  Alternate: Ioanna TALIOTI
- Ruth KEARSLEY (United Kingdom)
  Alternate: Anna-Maria BRADY [3]
- Boris KOLAR (Slovenia) *(co-opted)*
- Ioannis MALEMIS (Greece)
  Alternate: Georgios BATZIAS
- Kenneth MIFSUD (Malta)
  Alternate: Joseph VELLA
- Consuelo Rubio MONTEJANO[4] (Spain)
  Alternate: Gema CORTEZ[5]
- Manfred MOOS[6] (Germany)
  Alternate: Cornelia IBRAHIM[7]

[1] Replaced Tita-Maria Muhonen in March 2008.
[2] Replaced Pascal Zhelyazkov in October 2008.
[3] Replaced Martin Ilott in June 2008.
[4] Replaced Christina Munos Madero in December 2008.
[5] Replaced Consuelo Rubio Montejano in December 2008.
[6] Replaced Reinhard Kroker in May 2008.

- Paul MÕTSKÜLA[8] (Estonia)
  Alternate: Helen MAHLA
- Eugen OBERMAYR (Austria)
  Alternate: Jean-Pierre BINDER
- Jean-Claude ROUBY (France)
  Alternate: Michael HOLZHAUSER-ALBERTI
- Halldór RUNÓLFSSON[9] (Iceland)
  Alternate: Johann LENHARDSSON[10]
- G Johan SCHEFFERLIE (Netherlands)
- Wilhelm SCHLUMBOHM (Germany) *(co-opted)*
- Valda SEJANE (Latvia)
- Tibor SOÓS (Hungary)
  Alternate: Gábor KULCSÁR
- Stane SRČIČ (Slovenia)
  Alternate: Katarina STRAUS
- Lollita Sanda Camelia TABAN (Romania)
  Alternate: Simona STURZU
- Maria TOLLIS (Italy)
  Alternate: Virgilio DONINI
- Karolina TÖRNEKE (Sweden)
  Alternate: Henrik HOLST
- Bruno URBAIN (Belgium)
  Alternate: Frédéric DESCAMPS
- Selene VEIGA[11] (Portugal)
  Alternate: Berta Maria Fernandes
- Marc WIRTOR (Luxembourg)
  Alternate: Maurice HOLPER
- Franciszek ŻMUDZIŃSKI (Poland)

Working parties, ad hoc groups and scientific advisory groups

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

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

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

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

[7] Replaced Manfred Moos in May 2008.
[8] Replaced Birgit Aasmäe in July 2008.
[9] Replaced Sigurður Örn Hansson in May 2008.
[10] Replaced Halldór Runólfsson in February 2008.
[11] Replaced Mario Helena Ponte in August 2008.

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

Joint CHMP/CVMP Quality Working Party
Chair: Jean-Louis ROBERT
EMEA contact: David COCKBURN/ Fergus SWEENEY

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: Jordi LLINARES-GARCIA

Members

- Björn BEERMANN (Sweden)
- Brigitte BLÖCHL-DAUM (Austria)
- János BORVENDÉG[1] (EMEA representative)
- Heidrun BOSCH-TRABERG (Denmark)
- Mariana TODOROVA[2] (Bulgaria)
- Birthe BYSKOV HOLM (patients' organisation representative) *(vice-chair)*
- Yann LE CAM (patients' organisation representative)
- Albert CILIA VINCENTI (Malta)
- Ana CORRÊA NUNES (Portugal)
- Bożenna DEMBOWSKA-BAGIŃSKA (Poland)
- Judit EGGENHOFER (Hungary)
- Rembert ELBERS (Germany)
- Marie Pauline EVERS (patients' organisation representative)
- Lars GRAMSTAD (Norway)
- 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)
- Patrick SALMON (Ireland)
- Miranda SIOUTI (Greece)
- Bruno SEPODES[3] (EMEA representative)
- Domenica TARUSCIO (Italy)
- Sigurður B. THORSTEINSSON (Iceland)
- Vallo TILLMANN (Estonia)
- Josep TORRENT-FARNELL (Spain)
- Albertha VOORDOUW (the Netherlands)
- Agnis ZVAIGZNE[4] (Latvia)

[1] Nominated by the European Commission in July 2008.
[2] Replaced Vessela BOUDINOVA as of December 2008 meeting.
[3] Nominated by the European Commission in July 2008.
[4] Replaced Evija GULBE as of June 2008 meeting.

Ad hoc group

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
- Everaldo ATTARD[1] (Malta)
  Alternate: Gabriel MICALLEF[2]
- Mariette BACKES-LIES (Luxembourg)
  Alternate: Jacqueline GENOUX-HAMES
- Steffen BAGER (Denmark)
  Alternate: Kristine HVOLBY
- Zsuzsanna BIRÓ-SÁNDOR (Hungary)
  Alternate: Nóra Piroska FÜLÖP
- Ioanna CHINOU (Greece) *(vice-chair)*
  Alternate: Eleni SKALTSA
- Per CLAESON (Sweden)
  Alternate: Ubonwan CLAESON
- Marisa DELBÒ (Italy)
  Alternate: Monica CAPASSO
- Nadia GRIGORAS[3] (Romania)
  Alternate: Robert ANCUCEANU
- Marie HEROUTOVÁ (Czech Republic)
  Alternate: Helena LÁTALOVÁ
- Dace KALKE[4] (Latvia)
  Alternate: Vita GULEVSKA[5]
- Artūras KAŽEMEKAITIS (Lithuania)
  Alternate: Kristina RAMANAUSKIENĖ
- Thorbjörg KJARTANDSDÓTTIR (Iceland)
  Alternate: Vilborg HALLDORSDOTTIR[6]
- Werner KNÖSS[7] (Germany)
  Alternate: Jacqueline KOCH[8]
- Samo KREFT (Slovenia)
  Alternate: Barbara RAZINGER-MIHOVEC
- Gloria GARCÍA LORENTE (Spain)
  Alternate: Adela NÚÑEZ VELÁZQUEZ
- Steinar MADSEN (Norway)
  Alternate: Gro FOSSUM
- Ana Paula MARTINS (Portugal)
  Alternate: Maria Helena PINTO FERREIRA[9]
- Heidi NEEF (Belgium)
  Alternate: Arnold J VLIETINCK
- Cora NESTOR (Ireland)
  Alternate: Sinead HARRINGTON
- Stefan NIKOLOV (Bulgaria)
  Alternate: Elena MUSTAKEROVA
- Peter POTÚČEK (Slovakia)
  Alternate: Milan NAGY
- Heribert PITTNER (Austria)
  Alternate: Reinhard LÄNGER
- Michal RÓŻAŃSKI (Poland)
  Alternate: Iwona DROZDZ-JABLOŃSKA
- Antoine SAWAYA (France)
  Alternate: Jacqueline VIGUET POUPELLOZ
- Anneli TÖRRÖNEN (Finland)
  Alternate: Sari KOSKI
- Panayiotis TRIANTAFYLLIS (Cyprus)
  Alternate: Maria STAVROU
- Emiel VAN GALEN (Netherlands)
  Alternate: Burt H KROES
- Marje ZERNANT (Estonia)
  Alternate: Ain RAAL

[1] Replaced Caroline ATTARD as of November 2008 meeting.
[2] Replaced Everaldo ATTARD as of November 2008 meeting.
[3] Replaced Maria NICULESCU as of May 2008 meeting.
[4] Replaced Dailonis PAKALNS as of March 2008 meeting.
[5] Replaced Dace KALKE as of July 2008 meeting.
[6] Replaced Sesselja ÓMARSDOTTIR as of July 2008 meeting.
[7] Member as of January 2008 meeting.
[8] Replaced Werner KNÖSS as of January 2008 meeting.
[9] Alternate member until September 2008 meeting.

Co-opted members

- Gioacchino CALAPAI[1] (Italy)
- Gert LAEKEMAN (Belgium)
- Olavi PELKONEN (Finland)
- Maria Helena PINTO FERREIRA[2] (Portugal)
- Kurt WIDHALM (Austria)

Observers

- Melanie BALD (EDQM)
- Michael WIERER (EDQM)
- Josipa CVEK (Croatia)
- Ivan KOSALEC (Croatia)
- Merjem HADZIHAMZA[3] (The Former Yugoslav Republic of Macedonia)
- Rajna KOSTOSKA[4] (The Former Yugoslav Republic of Macedonia)
- Oyku MUMCU ARISAN[5] (Turkey)
- Hanefi OZBEK[6] (Turkey)
- Mehtap VAREL (Turkey)

Working parties and ad hoc 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
EMEA contact: Anthony HUMPHREYS

[1] Co-opted member as of July 2008 meeting.
[2] Co-opted member as of September 2008 meeting.
[3] Observer as of March 2008 meeting.
[4] Observer as of March 2008 meeting.
[5] Replaced Yasemin SAZAK as of September 2008 meeting.
[6] Replaced Meral GÜNDOĞAN as of July 2008 meeting.

Annex 6 Members of the Paediatric Committee

Chair: Daniel BRASSEUR
EMEA contact: Agnès SAINT RAYMOND

Members

- Jean-Pierre ABOULKER (Health professional)
  Alternate: Alexandra COMPAGNUCCI
- Annagrazia ALTAVILLA (Patient organisation)
  Alternate: Dominique GIOCANTI
- Robert ANCUCEANU (CHMP, Romania)
  Alternate: Raluca CIRSTEA (CHMP)[1]
- Fernando de ANDRÉS TRELLES (Spain)
  Alternate: Maria Jesús FERNÁNDES CORTIZO
- Dina APELE-FREIMANE (Latvia)
  Alternate: Ilze BĀRENE
- Carine de BEAUFORT (Luxembourg)
  Alternate: pending
- John Joseph BORG (Malta)
  Alternate: Herbert LENICKER
- Adriana CECI (Health professional)
  Alternate: Paolo PAOLUCCI
- Kevin CONNOLLY (Ireland)
  Alternate: Yvonne LOONEY
- Hugo DEVLIEGER (Belgium)
  Alternate: Jacqueline CARLEER[2]
- Helena FONSECA (Portugal)
  Alternate: Cristina TRINDADE
- Marta GRANSTRÖM (Sweden)
  Alternate: Viveca Lena ODLIND[3]
- Margarita GUIZOVA (Bulgaria)
  Alternate: Dobrin KONSTANTINOV
- Agnes GYURASICS (Hungary)[4]
  Alternate: Tamás MACHAY
- Alar IRS (CHMP, Estonia)
  Alternate: Irja LUTSAR
- Janez JAZBEC (Slovenia)
  Alternate: pending
- Pirjo LAITINEN-PARKKONEN (Finland)[5]
  Alternate: Ann Marie KAUKONEN [6]
- Romaldas MAČIULAITIS (CHMP, Lithuania)
  Alternate: Rugile PILVINIENE (CHMP)[7]
- Christoph MALE (Austria)
  Alternate: Karl-Heinz HUEMER[8]
- Jan MAZAG (CHMP, Slovakia)
  Alternate: pending[9]
- Dirk MENTZER (Germany)
  Alternate: Birka LEHMANN
- Marek MIGDAL (Poland)
  Alternate: pending[10]
- Hubert MOTTL (Czech Republic)
  Alternate: Peter SZITANYI
- Michal ODERMARSKY (Patient organisation)
  Alternate: Milena STEVANOVIC
- Marianne ORHOLM (Denmark)
  Alternate: Karen TORNØE
- Gylfi OSKARSSON (Iceland)
  Alternate: pending
- Gérard PONS (France) *Vice Chair*
  Alternate: Sophie FORNAIRON
- Paolo ROSSI (Italy)
  Alternate: Francesca ROCCHI
- Tsveta SCHYNS-LIHARSKA (Patient organisation)
  Alternate: Karen AIACH
- Alexandra SOLDATOU (Greece) [11]
  Alternate: Angeliki ROBOTI
- Johannes TAMINIAU (The Netherlands)
  Alternate: Hendrik van den BERG

[1] Replaced Victoria Subtirica, December 2008.
[2] Replaced Christophe Lahorte, April 2008.
[3] Replaced Marie Johannesson, May 2008.
[4] Replaced Lajos Kosa, September 2008.
[5] Replaced Maria Virkki, September 2008.
[6] Replaced Jaana Joensuu, October 2008.
[7] Replaced Donatas Stakisaitis, May 2008.
[8] Replaced Doris Tschabitscher, September 2008.
[9] To replace Karol Kralinsky, June 2008.
[10] To replace Mietczyslaw Litwin, April 2008.
[11] Replaced Christos Kattamis, October 2008.

- Andreas TELOUDES (Cyprus)[12]
  Alternate: Stefanos CHRISTODOULOU
- Matthew THATCHER (United Kingdom)[13]
  Alternate: Timothy CHAMBERS [14]
- Siri WANG (Norway)
  Alternate: Ingvild AALØKEN
- Pending[15] (Health professional)
  Alternate: Pending[16]

[12] Replaced Eleni Tofaridou, April 2008.
[13] Replaced Ian Hudson, September 2008.
[14] Replaced Matthew Thatcher, August 2008.
[15] To replace David Spenser, August 2008.
[16] To replace Alan Smyth, August 2008.

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
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BULGARIA

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CZECH REPUBLIC

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DENMARK

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GERMANY

Johannes LÖWER
Präsident
Bundesamt für Sera und Impfstoffe
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Reinhard KURTH
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ESTONIA

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GREECE

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SPAIN

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FRANCE

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Annex 8 EMEA budget summaries 2006-2008

The summarised comparative budget statements for 2007 to 2009 are as follows:

		2007[1]		2008[2]		2009 DB[3]	
		€ '000	%	€ '000	%	€ '000	%
	Revenue						
100	Fees	111,753	*67.61*	126,318	*69.07*	138,966	*73.65*
200	General EU contribution	39,750	*24.05*	39,997	*21.87*	36,390	*19.29*
201	Special EU contribution for orphan medicinal products	4,892	*2.96*	6,000	*3.28*	5,500	*2.91*
300	Contribution from EEA	789	*0.48*	956	*0.52*	888	*0.47*
600	Community programmes	583	*0.35*	600	*0.33*	300	*0.16*
500+ 900	Other	7,522	*4.55*	9,024	*4.93*	6,645	*3.52*
TOTAL REVENUE		**165,289**	*100.00*	**182,895**	*100.00*	**188,689**	*100.00*

Expenditure							
Staff							
11	Staff in active employment	46,252	*29.07*	53,911	*29.48*	56,661	*30.03*
13	Mission expenses	583	*0.37*	819	*0.45*	789	*0.42*
14	Socio-medical infrastructure	345	*0.22*	603	*0.33*	550	*0.29*
15	Exchange of civil servants and experts	1,182	*0.74*	2,112	*1.15*	4,350	*2.31*
16	Social welfare	47	*0.03*	105	*0.06*	105	*0.06*
17	Entertainment and representation expenses	36	*0.02*	38	*0.02*	38	*0.02*
18	Staff insurances	1,427	*0.90*	1,657	*0.91*	1,867	*0.99*
	Total Title 1	*49,871*	*31.34*	*59,245*	*32.39*	*64,360*	*34.11*
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	15,562	*9.78*	19,468	*10.64*	17,081	*9.05*
21	Expenditure on data processing	25,146	*15.80*	26,685	*14.59*	22,099	*11.71*
22	Movable property and associated costs	2,539	*1.60*	2,132	*1.17*	2,854	*1.51*
23	Other administrative expenditure	682	*0.43*	896	*0.49*	946	*0.50*
24	Postage and communications	767	*0.48*	1,048	*0.57*	978	*0.52*
25	Expenditure on formal and other meetings	62	*0.04*	79	*0.04*	90	*0.05*
	Total Title 2	*44,758*	*28.13*	*50,308*	*27.51*	*44,048*	*23.34*
Operational expenditure							
300	Meetings	7,144	*4.49*	7,746	*4.24*	8.939	*4.74*
301	Evaluations	53,490	*33.61*	60,406	*33.03*	66,419	*35.20*
302	Translation	3,182	*2.00*	4,001	*2.19*	4.245	*2.25*
303	Studies and consultants	81	*0.05*	90	*0.05*	80	*0.04*
304	Publications	69	*0.04*	499	*0.27*	298	*0.16*
305	Community programmes	531	*0.33*	600	*0.33*	300	*0.16*
	Total Title 3	*64,497*	*40.53*	*73,342*	*40.10*	*80,281*	*42.55*
TOTAL EXPENDITURE		**159,126**	*100.00*	**182,895**	*100.00*	**188,689**	*100.00*

[1] Appropriation/Budget 2007 as per final accounts.
[2] Appropriation/Budget 2008 as of 31 December 2008 (incl. AB 02-2008).
[3] Appropriation/Budget DB 2009 as presented to the Management Board on 11 December 2008.

Annex 9 EMEA establishment plan

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

Annex 10 CHMP opinions in 2008 on medicinal products for human use

CHMP positive opinions in 2008 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
▪ Effentora ▪ fentanyl citrate	Cephalon U.K.	▪ N02AB03 ▪ Management of breakthrough pain in patients receiving maintenance opioid therapy for chronic cancer pain	▪ 21.03.2007 ▪ 24.01.2008 ▪ 204 days ▪ 105 days	▪ 04.03.2008 ▪ 04.04.2008 ▪ 09.04.2008 ▪ OJ C 132 of 30.05.2008, p. 4
▪ Pradaxa ▪ dabigatran etexilate	Boehringer Ingelheim International	▪ B01AE07 ▪ Prevention of venous thromboembolic events in patients who have undergone total hip or knee replacement surgery.	▪ 21.02.2007 ▪ 24.01.2008 ▪ 205 days ▪ 132 days	▪ 29.01.2008 ▪ 18.03.2008 ▪ 20.03.2008 ▪ OJ C 104 of 25.04.2008, p. 7
▪ PrePandrix ▪ influenza vaccine H5N1	GlaxoSmithKline Biologicals S.A.	▪ J07BB02 ▪ Active immunisation against H5N1 subtype of Influenza A virus	▪ 24.01.2007 ▪ 21.02.2008 ▪ 189 days ▪ 204 days	▪ 10.04.2008 ▪ 20.05.2008 ▪ 22.05.2008 ▪ OJ C 164 of 27.06.2008, p. 6
▪ Adenuric ▪ febuxostat	Ipsen Limited	▪ M04AA03 ▪ Treatment of hyperuricaemia in conditions where urate deposition has already occurred	▪ 27.09.2006 ▪ 21.02.2008 ▪ 188 days ▪ 324 days	▪ 26.02.2008 ▪ 21.04.2008 ▪ 23.04.2008 ▪ OJ C 132 of 30.05.2008, p. 4
▪ Mycamine ▪ micafungin sodium	Astellas Pharma GmbH	▪ J02AX05 ▪ Prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia for 10 or more days	▪ 24.05.2006 ▪ 21.02.2008 ▪ 203 days ▪ 435 days	▪ 27.02.2008 ▪ 25.04.2008 ▪ 29.04.2008 ▪ OJ C 132 of 30.05.2008, p. 4
▪ Pandemrix ▪ H5N1 split antigen influenza vaccine	GlaxoSmithKlineBiologicals S.A.	▪ J07BB02 ▪ Prophylaxis of influenza in an officialy declared pandemic situation	▪ 21.02.2007 ▪ 21.02.2008 ▪ 161 days ▪ 204 days	▪ 10.04.2008 ▪ 20.05.2008 ▪ 22.05.2008 ▪ OJ C 164 of 27.06.2008, p. 6

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
▪ Privigen ▪ human normal immunoglobulin	ZLB Behring AG	▪ J06BA02 ▪ Replacement therapy in immunodeficiency and for immunomodulation in immune-mediated diseases	▪ 21.02.2007 ▪ 21.02.2008 ▪ 188 days ▪ 177 days	▪ 25.02.2008 ▪ 25.04.2008 ▪ 29.04.2008 ▪ OJ C 132 of 30.05.2008, p. 4
▪ Extavia ▪ interferon beta-1b	Novartis Europharm Limited	▪ L03AB08 ▪ Treatment of patients with a single demyelinating event with an active inflammatory process, patients with relapsing-remitting multiple sclerosis, secondary progressive multiple sclerosis	▪ 14.10.2007 ▪ 19.03.2008 ▪ 77 days ▪ 80 days	▪ 28.03.2008 ▪ 20.05.2008 ▪ 22.05.2008 ▪ OJ C 164 of 27.06.2008, p. 6
▪ Tredaptive ▪ nicotinic acid laropiprant	Merck Sharp and Dohme	▪ C10AD52 ▪ Treatment of combined mixed dyslipidaemia and primary hypercholesterol-aemia	▪ 20.07.2007 ▪ 24.04.2008 ▪ 202 days ▪ 77 days	▪ 28.04.2008 ▪ 03.07.2008 ▪ 07.07.2008 ▪ OJ C 220 of 29.08.2008, p. 5
▪ Clopidogrel Winthrop ▪ clopidogrel	Sanofi Aventis Bristol-Myes Squibb SNC	▪ B01AC04 ▪ Prevention of atherothrombotic events	▪ 24.02.2008 ▪ 24.04.2008 ▪ 60 days ▪ 0 days	▪ 21.05.2008 ▪ 16.07.2008 ▪ 18.07.2008 ▪ OJ C 220 of 29.08.2008, p. 6
▪ Clopidogrel BMS ▪ clopidogrel	Bristol Myers Squibb Pharma EEIG	▪ B01AC04 ▪ Prevention of atherothrombotic events	▪ 24.02.2008 ▪ 24.04.2008 ▪ 60 days ▪ 0 days	▪ 21.05.2008 ▪ 16.07.2008 ▪ 18.07.2008 ▪ OJ C 220 of 29.08.2008, p. 6
▪ Efficib ▪ sitagliptin metformin	Merck Sharp & Dohme	▪ A10BD07 ▪ Glycaemic control in type 2 diabetes mellitus in combination with metformin and/or a sulfonylurea	▪ 23.05.2007 ▪ 24.04.2008 ▪ 120 days ▪ 133 days	▪ 27.05.2008 ▪ 16.07.2008 ▪ 18.07.2008 ▪ OJ C 220 of 29.08.2008, p. 6
▪ Trevaclyn ▪ nicotinic acid laropiprant	Merck Sharp & Dohme Limited	▪ C10AD52 ▪ Treatment of combined mixed dyslipidaemia and primary hypercholesterol-aemia	▪ 20.07.2007 ▪ 24.04.2008 ▪ 176 days ▪ 77 days	▪ 28.04.2008 ▪ 03.07.2008 ▪ 07.07.2008 ▪ OJ C 220 of 29.08.2008, 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
▪ Relistor ▪ methylnaltrexone bromide	Wyeth Europa Ltd.	▪ A06AH01 ▪ Treatment of opioid - induced constipation	▪ 23.05.2007 ▪ 24.04.2008 ▪ 204 days ▪ 133 days	▪ 30.04.2008 ▪ 02.07.2008 ▪ 04.07.2008 ▪ OJ C 220 of 29.08.2008, p. 5
▪ Pelzont ▪ nicotinic acid laropiprant	Merck Sharp & Dohme Limited	▪ C10AD52 ▪ Treatment of combined mixed dyslipidaemia and primary hypercholesterol-aemia	▪ 20.07.2007 ▪ 24.04.2008 ▪ 176 days ▪ 77 days	▪ 28.04.2008 ▪ 03.07.2008 ▪ 07.07.2008 ▪ OJ C 220 of 29.08.2008, p. 5
▪ Janumet ▪ sitagliptin metformin	Merck Sharp & Dohme Limited	▪ A10BD07 ▪ Treatment of type 2 diabetes also combined with a sulfonylurea	▪ 23.05.2007 ▪ 24.04.2008 ▪ 207 days ▪ 133 days	▪ 27.05.2008 ▪ 16.07.2008 ▪ 18.07.2008 ▪ OJ C 220 of 29.08.2008, p. 6
▪ Velmetia ▪ sitagliptin metformin	Merck Sharp & Dohme Limited	▪ A10BD07 ▪ Treatment of type 2 diabetes also cmobined with a sulfonylurea	▪ 23.05.2007 ▪ 24.04.2008 ▪ 204 days ▪ 133 days	▪ 27.05.2008 ▪ 16.07.2008 ▪ 18.07.2008 ▪ OJ C 220 of 29.08.2008, p. 6
▪ Ranexa ▪ ranolazine	CV Therapeutics Europe Limited	▪ C01EB18 ▪ Symptomatic treatment of patients with stable angina pectoris who are inadequately controlled or intolerant to first-line antianginal therapies	▪ 27.12.2006 ▪ 24.04.2008 ▪ 177 days ▪ 307 days	▪ 30.04.2008 ▪ 09.07.2008 ▪ 14.07.2008 ▪ OJ C 220 of 29.08.2008, p. 5
▪ Doribax ▪ doripenem monohydrate	Janssen-Cigla International NV	▪ J01DH04 ▪ Treatment of nosocomial pneumonia, complicated intra-abdominal and urinary tract infections	▪ 20.07.2007 ▪ 30.05.2008 ▪ 0 days ▪ 0 days	▪ 26.06.2008 ▪ 25.07.2008 ▪ 29.07.2008 ▪ OJ C 220 of 29.08.2008, p. 6
▪ Bridion ▪ sugammadex	N.V. Organon	▪ V03AB35 ▪ Reversal of neromuscular block induced by rocuronium or vecuronium	▪ 20.07.2007 ▪ 30.05.2008 ▪ 0 days ▪ 0 days	▪ 27.06.2008 ▪ 25.07.2008 ▪ 29.07.2008 ▪ OJ C 220 of 29.08.2008, p. 6
▪ Intelence ▪ etravirine	Janseen-Cilag	▪ J05AG04 ▪ Treatment of human immunodeficiency virus type 1 infection in patients treated with other antiretroviral products	▪ 15.08.2007 ▪ 26.06.2008 ▪ 178 days ▪ 138 days	▪ 24.07.2008 ▪ 28.08.2008 ▪ 01.09.2008 ▪ OJ C 245 of 26.09.2008, p. 15

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
▪ Vimpat ▪ lacosamide	Schwarz Pharma AG	▪ NO3AX18 ▪ Adjunctive therapy for partial-onset seizures with or without secondary generalisation	▪ 23.05.2007 ▪ 26.06.2008 ▪ 209 days ▪ 191 days	▪ 02.07.2008 ▪ 29.08.2008 ▪ 02.09.2008 ▪ OJ C 245 of 26.09.2008, p. 15
▪ Duloxetine Boehringer Ingelheim ▪ duloxetine	Boehringer Ingelheim International GmbH	▪ N06AX21 ▪ Treatment of moderate to severe stress urinary incontinence in women and of diabetic peripheral neuropathic pain	▪ 30.03.2008 ▪ 24.07.2008 ▪ 89 days ▪ 27 days	▪ 20.08.2008 ▪ 08.10.2008 ▪ 10.10.2008 ▪ OJ C 305 of 28.11.2008, p. 3
▪ Tadalafil Lily ▪ tadalafil	Eli Lilly Nederland B.V.	▪ G04BE08 ▪ Treatment of erectile dysfunction	▪ 28.05.2008 ▪ 24.07.2008 ▪ 57 days ▪ 0 days	▪ 20.08.2008 ▪ 01.10.2008 ▪ 03.10.2008 ▪ OJ C 305 of 28.11.2008, p. 3
▪ Evicel ▪ human fibrinogen.human thrombin	OMRIX Biopharmaceuticals S.A.	▪ Not yet assigned ▪ Improvement of heamostasis in surgery where standard surgical techniques are insufficient and as suture support for haemostasis in vascular surgery	▪ 15.08.2007 ▪ 24.07.2008 ▪ 207 days ▪ 137 days	▪ 20.08.2008 ▪ 06.10.2008 ▪ 09.10.2008 ▪ OJ C 305 of 28.11.2008, p. 3
▪ Prepandemic influenza vaccine ▪ split viron, inactivated, adjuvanted (h5n1)	GlaxoSmithKline Biologicals s.a.	▪ J07BB02 ▪ Active immunisation against H5N1 subtype of Influenza A virus	▪ 28.05.2008 ▪ 24.07.2008 ▪ 57 days ▪ 0 days	▪ 04.08.2008 ▪ 26.09.2008 ▪ 30.09.2008 ▪ OJ C 276 of 31.10.2008, p. 2
▪ Fluticasone furoate GSK ▪ fluticasone furoate	Glaxo Group Ltd.	▪ R01AD12 ▪ Treatment of symptoms of allergic rhinitis	▪ 28.05.2008 ▪ 24.07.2008 ▪ 57 days ▪ 0 days	▪ 08.09.2009 ▪ 06.10.2008 ▪ 08.10.2008 ▪ OJ C 305 of 28.11.2008, p. 3
▪ Xarelto ▪ rivaroxaban	Bayer Health Care	▪ B01AX06 ▪ Prevention of venous thromboembolism in patients undergoing hip or knee replacement surgery.	▪ 23.11.2007 ▪ 24.07.2008 ▪ 181 days ▪ 63 days	▪ 03.09.2008 ▪ 30.09.2008 ▪ 02.10.2008 ▪ OJ C 276 of 31.10.2008, p. 2
▪ Azarga ▪ brinzolamide timolol	Alcon Laboratories Limited	▪ SO1ED51 ▪ Decrease of intraocular pressure in open-angle glaucoma or ocular hypertension	▪ 26.12.2007 ▪ 25.09.2008 ▪ 177 days ▪ 97 days	▪ 07.10.2008 ▪ 25.11.2008 ▪ 27.11.2008 ▪ OJ C 330 of 30.12.2008, p. 6

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
▪ Jalra ▪ vildagliptin	Novartis Europharm Ltd	▪ A10BH02 ▪ Treatment of type 2 diabetes mellitus in combination with other anti-diabetic products	▪ 27.07.2008 ▪ 25.09.2008 ▪ 60 days ▪ 0 days	▪ 23.10.2008 ▪ 19.11.2008 ▪ 21.11.2008 ▪ OJ C 330 of 30.12.2008, p. 6
▪ Xiliarx ▪ vildagliptin	Novartis Europharm Ltd	▪ A10BH02 ▪ Treatment of type 2 diabetes mellitus in combination with other anti-diabetic products	▪ 27.07.2008 ▪ 25.09.2008 ▪ 60 days ▪ 0 days	▪ 24.10.2008 ▪ 19.11.2008 ▪ 21.11.2008 ▪ OJ C 330 of 30.12.2008, p. 6
▪ Vildagliptin metformin hydrochloride Novartis ▪ vildagliptin metformin hydrochloride	Novartis Europharm Ltd	▪ A10BD08 ▪ Treatment of type 2 diabetes mellitus in patients treated with metformin alone or with metformin and vildagliptin as separate tablets	▪ 27.07.2008 ▪ 25.09.2008 ▪ 60 days ▪ 0 days	▪ 06.10.2008 ▪ 01.12.2008 ▪ 03.12.2008 ▪
▪ Zomarist ▪ vildagliptin metformin hydrochloride	Novartis Europharm Ltd	▪ A10BD08 ▪ Treatment of type 2 diabetes mellitus in patients treated with metformin alone or with metformin and vildagliptin as separate tablets	▪ 27.07.2008 ▪ 25.09.2008 ▪ 60 days ▪ 0 days	▪ 06.10.2008 ▪ 01.12.2008 ▪ 03.12.2008 ▪
▪ Zypadhera ▪ olanzapine pamoate	Eli Lilly Nederland B.V.	▪ N05AH03 ▪ Maintenance treatment of schizophrenia	▪ 20.07.2007 ▪ 25.09.2008 ▪ 198 days ▪ 235 days	▪ 02.10.2008 ▪ 19.11.2008 ▪ 21.11.2008 ▪ OJ C 330 of 30.12.2008, p. 12
▪ Lunivia ▪ eszopiclone	Sepracor Pharmaceuticals, Ltd.	▪ N05CF04 ▪ Treatment of insomnia	▪ 15.08.2007 ▪ 23.10.2008 ▪ 205 days ▪ 230 days	▪ ▪ ▪ ▪
▪ Opgenra ▪ eptotermin alfa	Stryker Biotech	▪ M05BC02 ▪ Indicated for posterolateral lumbar spinal fusion in adult patients with spondylolisthesis where autograft has failed or is contra-indicated	▪ 21.02.2007 ▪ 23.10.2008 ▪ 202 days ▪ 289 days	▪ ▪ ▪ ▪
▪ Stelara ▪ ustekinumab	Janssen-Cilag International NV.	▪ L04AC05 ▪ Treatment of plaque psoriasis in patients who have received other systemic therapies	▪ 26.12.2007 ▪ 20.11.2008 ▪ 204 days ▪ 123 days	▪ 17.12.2008 ▪ 16.01.2008 ▪ 19.01.2008 ▪

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
▪ Thymanax ▪ agomelatine	Les Laboratoires Servier	▪ N06AX22 ▪ Treatment of major depressive episodes	▪ 27.09.2007 ▪ 20.11.2008 ▪ 203 days ▪ 217 days	▪ 06.01.2009 ▪ ▪ ▪
▪ Rasilez HCT ▪ aliskiren hemifumarate hydrochloro-thiazide	Novartis Europharm	▪ C09XA52 ▪ Treatment of essential hypertension	▪ 26.12.2007 ▪ 20.11.2008 ▪ 195 days ▪ 135 days	▪ 28.11.2008 ▪ 16.01.2009 ▪ 19.01.2009 ▪
▪ Valdoxan ▪ agomelatine	Les Laboratoires Servier	▪ N06AX22 ▪ Treatment of major depressive episodes	▪ 27.09.2007 ▪ 20.11.2008 ▪ 203 days ▪ 217 days	▪ 06.01.2009 ▪ ▪ ▪
▪ RoActemra ▪ tocilizumab	Roche Registration Limited	▪ L04AC07 ▪ Treatment of moderate to severe active rheumatoid arthritis in patients previously treated with other products	▪ 26.12.2007 ▪ 20.11.2008 ▪ 205 days ▪ 125 days	▪ 01.12.2008 ▪ 16.01.2009 ▪ 20.01.2009 ▪
▪ Zevtera ▪ ceftobiprole medocaril	Janssen-Cigla International NV	▪ J01DI01 ▪ Treatment of complicated skin and soft tissue infections	▪ 20.07.2007 ▪ 20.11.2008 ▪ 175 days ▪ 314 days	▪ ▪ ▪ ▪
▪ Fablyn ▪ lasofoxifene	Pfizer Limited	▪ Not yet assigned ▪ Treatment of osteoporosis in postmenopausal women at increased risk of fracture	▪ 30.01.2008 ▪ 18.12.2008 ▪ 203 days ▪ 120 days	▪ 05.01.2009 ▪ ▪ ▪
▪ Celvapan ▪ A Vietnam 1203 2004 adb A indonesia 05 2005	Baxter AG	▪ J07BB02 ▪ Prophylaxis of H5N1 influenza in an officially declared pandemic situation.	▪ 27.02.2008 ▪ 18.12.2008 ▪ 205 days ▪ 90 days	▪ 12.01.2009 ▪ ▪ ▪
▪ Efient ▪ prasugrel	Eli Lilly and Company Limited	▪ Not yet assigned ▪ Prevention of atherothrombotic events in patients with acute coronary syndrome undergoing percutaneous coronary intervention	▪ 27.02.2008 ▪ 18.12.2008 ▪ 204 days ▪ 91 days	▪ 05.01.2009 ▪ ▪ ▪
▪ Firmagon ▪ degarelix	Ferring Pharmaceuticals A.S	▪ L02BX02 ▪ Treatment of adult male patients with advanced hormone-dependent prostate cancer	▪ 26.03.2008 ▪ 18.12.2008 ▪ 195 days ▪ 72 days	▪ 16.01.2009 ▪ ▪ ▪

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
▪ Intanza ▪ split viron inactivated	Sanofi Pasteur MSD	▪ J07BB02 ▪ Prophylaxis of influenza in adults	▪ 26.12.2007 ▪ 18.12.2008 ▪ 205 days ▪ 153 days	▪ 05.01.2009 ▪ ▪ ▪
▪ Idflu ▪ split influenza virus, inactivated	Sanofi Pasteur SA	▪ J07BB02 ▪ Prophylaxis of influenza in adults	▪ 26.12.2007 ▪ 18.12.2008 ▪ 205 days ▪ 153 days	▪ 16.01.2009 ▪ ▪ ▪

CHMP positive opinions in 2008 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
▪ Thalidomide Pharmion ▪ thalidomide	Pharmion Ltd.	▪ L04AX02 ▪ Treatment, in combination with melphalan, of patients with untreated multiple myeloma	▪ 21.02.2007 ▪ 24.01.2008 ▪ 177 days ▪ 160 days	▪ 10.03.2008 ▪ 16.04.2008 ▪ 18.04.2008 ▪ OJ C 132 of 30.05.2008, p. 4
▪ Volibris ▪ ambrisentan	Glaxo Group Limited U.K.	▪ CO2KX02 ▪ Treatment of paitents with pulmonary arterial hypertension classified as WHO classs II and III	▪ 21.03.2007 ▪ 21.02.2008 ▪ 205 days ▪ 132 days	▪ 19.03.2008 ▪ 21.04.2008 ▪ 24.04.2008 ▪ OJ C 132 of 30.05.2008, p. 4
▪ Ceplene ▪ histamine dihydochloride	EpiCept GmbH	▪ L03AX14 ▪ Indicated for maintenance of remission in adult patients with acute myeloid leukaemia to prolong the duration of leukaemia-free survival	▪ 25.10.2006 ▪ 19.03.2008 ▪ 202 days ▪ 309 days	▪ 05.09.2008 ▪ 07.10.2008 ▪ 09.10.2008 ▪ OJ C 305 of 28.11.2008, p. 3
▪ Firazyr ▪ icatibant acetate	Jerini AG	▪ C01EB19 ▪ Treatment of hereditary angioedema	▪ 15.08.2007 ▪ 24.04.2008 ▪ 204 days ▪ 49 days	▪ 27.05.2008 ▪ 11.07.2008 ▪ 15.07.2008 ▪ OJ C 220 of 29.08.2008, p. 6
▪ Kuvan ▪ sapropterin dihydrochloride	Merck KGaA	▪ A16AX07 ▪ Treatment of hyperphenylalanin-aemia in patients with phenyl-ketonuria or tetrahydrobiopterin deficiency	▪ 23.11.2007 ▪ 25.09.2008 ▪ 200 days ▪ 107 days	▪ 05.11.2008 ▪ 02.12.2008 ▪ 04.12.2008 ▪

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
▪ Vidaza ▪ azacitidine	Pharmion Ltd	▪ L01BC07 ▪ Treatment of patients with myelodysplastic syndromes not eligible for haematopoietic stem cell transplantation	▪ 30.01.2008 ▪ 23.10.2008 ▪ 198 days ▪ 69 days	▪ 19.11.2008 ▪ 17.12.2008 ▪ 22.12.2008 ▪
▪ Nplate ▪ romiplostim	Amgen Europe B.V.	▪ B02BX04 ▪ Treatment of adult chronic immune (idiopathic) thrombocytopenia purpura in splenectomised patients refractory to other treatments and non-splenectomised patients where surgery is contra-indicated	▪ 21.11.2007 ▪ 20.11.2008 ▪ 203 days ▪ 162 days	▪ 16.12.2008 ▪ ▪ ▪
▪ Ixiaro (previously Japanese Encephalitis Vaccine) ▪ attenuated strain SA_{14}-14-2 grown in Vero cells	Intercell AG	▪ J07BA02 ▪ Active immunization against Japanese encephalitis	▪ 30.01.2008 ▪ 18.12.2008 ▪ 204 days ▪ 119 days	▪ 20.01.2009 ▪ ▪ ▪
▪ Mepact ▪ mifamurtide	IDM SA	▪ L03AX15 ▪ Treatment of high-grade resectable non-metastatic osteosarcoma after macroscopically complete surgical resection	▪ 22.11.2006 ▪ 18.12.2008 ▪ 205 days ▪ 552 days	▪ 06.01.2009 ▪ ▪ ▪

CHMP positive opinions in 2008 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
▪ Tevagrastim ▪ filgrastim	Teva Pharmaceuticals Europe B.V.	▪ L03AA02 ▪ Reduction in duration of neutropenia and incidence of febrile neutropenia in patients treated with established cytotoxic chemotheraphy	▪ 21.02.2007 ▪ 21.02.2008 ▪ 209 days ▪ 156 days	▪ 31.07.2008 ▪ 15.09.2008 ▪ 17.09.2008 ▪ OJ C 276 of 31.10.2008, 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
▪ Biograstim ▪ filgrastim	Ribosepharm GmbH	▪ LO3AA02 ▪ Reduction in duration of neutropenia and incidence of febrile neutropenia in patients treated with established cytotoxic chemotheraphy	▪ 21.02.2007 ▪ 21.02.2008 ▪ 209 days ▪ 156 days	▪ 31.07.2008 ▪ 15.09.2008 ▪ 17.09.2008 ▪ OJ C 276 of 31.10.2008, p. 2
▪ Filgrastim ratiopharm ▪ filgrastim	Ratiopharm GmbH	▪ LO3AA02 ▪ Reduction in duration of neutropenia and incidence of febrile neutropenia in patients treated with established cytotoxic chemotheraphy	▪ 21.02.2007 ▪ 21.02.2008 ▪ 209 days ▪ 156 days	▪ 31.07.2008 ▪ 15.09.2008 ▪ 17.09.2008 ▪ OJ C 276 of 31.10.2008, p. 2
▪ Ratiograstim ▪ filgrastim	Ratiopharm GmbH	▪ LO3AA02 ▪ Reduction in duration of neutropenia and incidence of febrile neutropenia in patients treated with established cytotoxic chemotheraphy	▪ 21.02.2007 ▪ 21.02.2008 ▪ 209 days ▪ 156 days	▪ 31.07.2008 ▪ 15.09.2008 ▪ 17.09.2008 ▪ OJ C 276 of 31.10.2008, p. 2
▪ Filgrastim Sandoz ▪ filgrastim	Sandoz GmbH	▪ L03AA02 ▪ Reduction in duration of neutropenia and incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy	▪ 27.09.2007 ▪ 20.11.2008 ▪ 204 days ▪ 216 days	▪ 18.12.2008
▪ Filgrastim hexal ▪ Filgrastim	Hexal Biotech Forschungs GmbH	▪ L03AA02 ▪ Reduction in duration of neutropenia and incidence of febrile neutropenia in patients treated with established cytotoxic chemotherapy	▪ 27.09.2007 ▪ 20.11.2008 ▪ 204 days ▪ 216 days	▪ 18.12.2008 ▪ ▪ ▪

CHMP positive opinions in 2008 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
▪ Oprymea ▪ pramipexole	Krka D.D.	▪ N04BC05 ▪ Treatment of signs and symptoms of idiopathic Parkinson's disease	▪ 21.11.2007 ▪ 26.06.2008 ▪ 177 days ▪ 41 days	▪ 28.07.2008 ▪ 12.09.2008 ▪ 15.09.2008 ▪ OJ C 276 of 31.10.2008, 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
▪ Irbesartan krka ▪ irbesartan hydrochloride	Krka d.d. Nove Mesto	▪ C09CA04 ▪ Treatment of essential hypertension and of renal disease in patients with hypertension and type 2 diabetes mellitus	▪ 26.12.2007 ▪ 24.07.2008 ▪ 177 days ▪ 34 days	▪ 02.10.2008 ▪ 01.12.2008 ▪ 03.12.2008
▪ Olanzapine Mylan ▪ olanzapine	Generics (UK) limited	▪ N05AH03 ▪ Treatment of schizophrenia and of moderate to severe manic episode; prevention of recurrence in patients with bipolar disorder	▪ 26.12.2007 ▪ 24.07.2008 ▪ 177 days ▪ 34 days	▪ 20.08.2008 ▪ 07.10.2008 ▪ 09.10.2008 ▪ OJ C 305 of 28.11.2008, p. 3
▪ Pramipexole Teva ▪ pramipexole	Teva Pharma GmbH	▪ N04BC05 ▪ Treatment of signs and symptoms of idiopathic Parkinson's disease	▪ 21.11.2007 ▪ 23.10.2008 ▪ 196 days ▪ 141 days	▪ 29.10.2008 ▪ 18.12.2008 ▪ 23.12.2008

CHMP negative opinions in 2008 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
▪ Lenalidomide - Celgene Europe ▪ lenalidomide	Celgene Europe	▪ L04AX04 ▪ Treatment of patients with transfusion-dependent anemia due to low or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality	▪ 28.09.2005 ▪ 24.01.2008 ▪ 176 days ▪ 672 days	
▪ Ramelteon ▪ ramelteon	Takeda Global Research & Development Centre	▪ N05CH02 ▪ Short or long term treatment of patients with insomnia	▪ 21.03.2007 ▪ 30.05.2008 ▪ 210 days ▪ 225 days	
▪ Sovrima ▪ idebenone	Santhera AG	▪ N06BX13 ▪ Treatment of Friedreich's ataxia	▪ 15.08.2007 ▪ 24.07.2008 ▪ 203 days ▪ 141 days	
▪ Ixempra ▪ ixapebilone	Bristol-Myers Squib EEIG	▪ L01DC04 ▪ Treatment of metastatic or locally advanced breast cancer	▪ 25.10.2007 ▪ 20.11.2008 ▪ 203 days ▪ 189 days	

Centralised applications for medicinal products for human use – withdrawals in 2008 prior to opinion

▪ **Product** ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Date of withdrawel ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Pristiqs ▪ desvenlafaxine succinate monohydrate	Wyeth Europe Ltd	▪ N06AX23 ▪ Treatment of vasomotor symptoms associated with menopause	▪ 25.10.2006 ▪ 10.03.2008 ▪ 193 days ▪ 309 days	▪
▪ Orbec ▪ beclomethasone dipropionate	Voisin Consulting S.A.R.L	▪ Not yet assigned ▪ Treatment of gastro-intestinal graft-versus-host disease	▪ 22.11.2006 ▪ 22.05.2008 ▪ 205 days ▪ 342 days	▪
▪ Duoplavin ▪ clopidogrel hydrogen sulphate acetylsalicylic acid	Sanofi Pharma Bristol Myers Squibb SNC	▪ B01AC04 ▪ Prevention of atherothrombotic events in patients suffering from acute coronary syndrome	▪ 20.06.2007 ▪ 22.05.2008 ▪ 205 days ▪ 132 days	▪
▪ DuoCover ▪ clopidogrel hydrogen sulphate acetylsalicylic acid	Bristol Myers Squibb Pharma EEIG	▪ B01AC04 ▪ Prevention of atherothrombotic events in patients suffering from acute coronary syndrome	▪ 20.06.2007 ▪ 22.05.2008 ▪ 205 days ▪ 132 days	▪
▪ Aquilda ▪ satavaptan	Sanofi Aventis	▪ Not yet assigned ▪ Management of delusional hyponatremia	▪ 20.06.2007 ▪ 23.05.2008 ▪ 117 days ▪ 221 days	▪
▪ Aflunov ▪ H5N1 surface antigen	Novartis Vaccines and Diagnostics S.r.l.	▪ J07BB02 ▪ Prophylaxis of avian influenza in adults	▪ 22.11.2006 ▪ 13.06.2008 ▪ 190 days ▪ 379 days	▪
▪ Spanidin ▪ gusperimus trihydrochloride	Euro Nippon Kayaku GmbH	▪ L04AA15 ▪ Therapy in refractory Wegener's granulomatosis, unresolved by standard treatment	▪ 27.12.2006 ▪ 17.06.2008 ▪ 194 days ▪ 334 days	▪
▪ Orplatna ▪ satraplatin	Pharmion Ltd	▪ L01XA04 ▪ Treatment of patients with hormone refractory prostate cancer who have failed or are ineligible for docetaxel therapy	▪ 20.07.2007 ▪ 01.08.2008 ▪ 172 days ▪ 206 days	▪
▪ Exulett ▪ dalbavancin	Pfizer Limited	▪ Not yet assigned ▪ Treatment of complicated skin and soft tissue infections	▪ 15.08.2007 ▪ 09.09.2008 ▪ 174 days ▪ 217 days	▪

▪ **Product** ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ ATC code ▪ Summary of indication	**EMEA.CHMP** ▪ Validation ▪ Date of withdrawel ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Lacosamide Pain Schwarz Pharma ▪ lacosamide	Schwarz Pharma AG	▪ N03AX18 ▪ Treatment of neuropathic pain associated with diabetic peripheral neuropathy in adults	▪ 25.08.2007 ▪ 25.09.2008 ▪ 176 dyas ▪ 231 days	▪
▪ Ellefore ▪ desvenlafaxine	Wyeth Europe Limited	▪ N06AX23 ▪ Treatment of major depressive disorder	▪ 25.10.2007 ▪ 13.10.2008 ▪ 166 days ▪ 188 days	▪
▪ Vibactiv ▪ televancin	Astellas Pharma Europe B.V.	▪ Not yet assigned ▪ Treatment of complicated skin and skin structure infections in adults	▪ 23.05.2007 ▪ 21.10.2008 ▪ 201 days ▪ 316 days	▪
▪ Vekacia ▪ ciclosporine	Novagali Pharma SA	▪ L04AA01 ▪ Treatment of vernal kerato-conjunctivitis	▪ 15.08.2007 ▪ 14.11.2008 ▪ 168 days ▪ 289 days	▪
▪ Theraloc ▪ nimotuzumab	Oncoscience AG	▪ Not yet assigned ▪ Treatment of children and adolescents with relapsed high-grade brain glioma	▪ 25.10.2007 ▪ 01.12.2008 ▪ 173 days ▪ 230 days	▪
▪ Advexin ▪ contusugene ladenovec	Gendux AB	▪ Not yet assigned ▪ Treatment of Li-Fraumeni cancer	▪ 26.12.2007 ▪ 17.12.2008 ▪ 174 days ▪ 183 days	▪

Annex 11 CVMP opinions in 2008 on medicinal products for veterinary use

Centralised applications for medicinal products for veterinary use – Positive opinions

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ Target species ▪ Summary of indication	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Reconcile ▪ fluoxetine (as fluoxetine HCl)	Elanco	▪ Dogs ▪ Behavioural problems	▪ 15/05/2007 ▪ 16/04/2008 ▪ 210 ▪ 127	▪ 30/05/2008 ▪ 08/07/2008 ▪ 16/07/2008 ▪ OJ C 220/15
▪ Posatex ▪ orbifloxacin, mometasone furoate and posaconazole	Schering Plough Animal Health	▪ Dogs ▪ Treatment of acute and recurrent otitis externa	▪ 17/10/2006 ▪ 15/04/2008 ▪ 210 ▪ 334	▪ 21/04/2008 ▪ 23/06/2008 ▪ 25/06/2008 ▪ OJ C 188/14
▪ Equioxx ▪ firocoxib	Mérial	▪ Horse ▪ Alleviation of pain and inflammation	▪ 19/03/2008 ▪ 14/05/2008 ▪ 55 ▪ 0	▪ 28/03/2008 ▪ 25/06/2008 ▪ 27/06/2008 ▪ OJ C 188/14
▪ Zactran ▪ gamithromycin	Mérial	▪ Cattle ▪ Respiratory disease	▪ 13/03/2007 ▪ 14/05/2008 ▪ 204 ▪ 204	▪ 09/06/2008 ▪ 24/07/2008 ▪ 28/07/2008 ▪ OJ C 220/15
▪ Trocoxil ▪ mavacoxib	Pfizer	▪ Dogs ▪ Treatment of pain and inflammation associated with degenerative joint disease	▪ 15/05/2007 ▪ 16/07/2008 ▪ 204 ▪ 226	▪ 13/08/2008 ▪ 09/09/2008 ▪ 11/09/2008 ▪ OJ C 276
▪ Easotic ▪ hydrocortisone aceponate, miconazole nitrate, gentamicin sulphate	Virbac S.A	▪ Dogs ▪ Treatment of otitis externa (QS02CA)	▪ 15/01/2008 ▪ 17/9/2008 ▪ 210 ▪ 36	▪ 23/10/2008 ▪ 17/11/2008
▪ Duvaxyn WNV ▪ inactivated West Nile Virus	Fort Dodge Animal Health	▪ Horses and ponies ▪ Vaccine to aid in prevention of West Nile Virus (QI05AA)	▪ 14/08/2007 ▪ 17/09/2008 ▪ 210 ▪ 190	▪ 23/10/2008 ▪ 21/11/2008
▪ Masivet ▪ masitinib	AB Science	▪ Dogs ▪ Mast cell tumours	▪ 13/03/2007 ▪ 18/09/2008 ▪ 182 ▪ 246	▪ 17/10/2008 ▪ 17/11/2008
▪ Onsior ▪ robenacoxib	Novartis	▪ Cats and dogs ▪ Painkiller	▪ 13/03/2007 ▪ 15/10/2008 ▪ 210 ▪ 371	▪ 20/10/2008 ▪ 16/12/2008 ▪ ▪ OJ C 375

Centralised applications for medicinal products for veterinary use – withdrawals in 2008 prior to opinion

Product ▪ Brand name ▪ INN	**Marketing authorisation holder**	**Therapeutic area** ▪ Target species ▪ Summary of indication	**EMEA/CVMP** ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	**European Commission** ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Kexxtone ▪ avilamycin	Elanco	▪ Rabbits ▪ Enteritis due to Cl. perfringens	▪ 15/05/2008 ▪ - ▪ 120 ▪ 362	

CVMP positive opinions in 2008 on establishment of MRLs 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
▪ Lectin	▪ Porcine	▪ 18/10/2007 ▪ 16/01/2008 ▪ 90 days ▪ 0 days	▪
▪ Monepantel	▪ Ovine, caprine	▪ 15/12/2008 ▪ 12/11/2008 ▪ 120 ▪ 151	▪

CVMP negative opinions in 2008 on establishment of MRLs 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
▪ Isoeugenol	▪ Atlantic salmon	▪ 18/01/2007 ▪ 16/10//2008 ▪ 179 days ▪ 458	▪

Annex 12 COMP opinions in 2008 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
Recombinant human monoclonal antibody to human IL-1beta of the IgG1/K class	Novartis Europharm Ltd - UK	Treatment of systemic-onset juvenile idiopathic arthritis	▪ 20/04/2007 ▪ 09/11/2007 ▪ 10/01/2008 ▪ 62 days	▪ 21/01/2008 ▪ 04/02/2008
Lumiliximab	Biogen Idec Ltd - UK	Treatment of chronic lymphocytic leukaemia	▪ 20/09/2007 ▪ 15/10/2007 ▪ 10/01/2008 ▪ 87 days	▪ 21/01/2008 ▪ 04/02/2008
Tretazicar	Morvus Technology Ltd - UK	Treatment of visceral leishmaniasis	▪ 27/09/2007 ▪ 15/10/2007 ▪ 10/01/2008 ▪ 87 days	▪ 21/01/2008 ▪ 04/02/2008
Heterologous human adult liver-derived stem cells	Prof Etienne Sokal - Belgium	Treatment of ornithine transcarbamylase deficiency	▪ 24/10/2007 ▪ 09/11/2007 ▪ 10/01/2008 ▪ 62 days	▪ 21/01/2008 ▪ 04/02/2008
Autologous urothelial and smooth muscle cells	Choice Pharma Ltd - UK	Treatment of spina bifida	▪ 20/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 17/03/2008
Chimeric antibody to mesothelin	Chiltern International Ltd - UK	Treatment of pancreatic cancer	▪ 20/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 17/03/2008
Recombinant human monoclonal antibody against transforming growth factor beta-1, 2 and 3	Genzyme BV - The Netherlands	Treatment of idiopathic pulmonary fibrosis	▪ 25/10/2007 ▪ 09/11/2007 ▪ 06/02/2008 ▪ 89 days	▪ 25/02/2008 ▪ 01/04/2008
Ammonium tetrathiomolybdate	JJGConsultancy Ltd - UK	Treatment of Wilson's disease	▪ 22/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 01/04/2008
Humanised monoclonal antibody to the folate receptor alpha	Chiltern International Ltd - UK	Treatment of ovarian cancer	▪ 20/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 01/04/2008

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Filgrastim	Sygnis Bioscience GmbH & Co. KG - Germany	Treatment of amyotrophic lateral sclerosis	▪ 24/10/2007 ▪ 09/11/2007 ▪ 06/02/2008 ▪ 89 days	▪ 25/02/2008 ▪ 01/04/2008
Ascorbic acid	Murigenetics SAS - France	Treatment of Charcot-Marie-Tooth disease type 1A	▪ 03/10/2007 ▪ 09/11/2007 ▪ 06/02/2008 ▪ 89 days	▪ 25/02/2008 ▪ 01/04/2008
Allogeneic human umbilical cord tissue-derived cells	Centocor, B.V. - The Netherlands	Treatment of retinitis pigmentosa	▪ 25/10/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 01/04/2008
Amrubicin hydrochloride	Celgene Europe Ltd - UK	Treatment of small cell lung cancer	▪ 20/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 02/04/2008
Omigapil maleate	Santhera Pharmaceuticals (Deutschland) GmbH - Germany	Treatment of congenital muscular dystrophy with collagen VI deficiency (Ullrich Syndrome and Bethlem Myopathy)	▪ 25/10/2007 ▪ 07/12/2007 ▪ 04/03/2008 ▪ 88 days	▪ 28/03/2008 ▪ 08/05/2008
Omigapil maleate	Santhera Pharmaceuticals (Deutschland) AG - Germany	Treatment of congenital muscular dystrophy with merosin (laminin alpha 2) deficiency	▪ 25/10/2007 ▪ 07/12/2007 ▪ 04/03/2008 ▪ 88 days	▪ 28/03/2008 ▪ 08/05/2008
Ribonucleotide reductase R2 specific phosphorothioate oligonucleotide	Dr Ulrich Granzer - Germany	Treatment of acute myeloid leukaemia	▪ 13/12/2007 ▪ 11/01/2008 ▪ 04/03/2008 ▪ 53 days	▪ 28/03/2008 ▪ 08/05/2008
Sarsasapogenin	Phytopharm plc - UK	Treatment of amyotrophic lateral sclerosis	▪ 19/12/2007 ▪ 11/01/2008 ▪ 04/03/2008 ▪ 53 days	▪ 28/03/2008 ▪ 08/05/2008
[Nle4, D-Phe7]-alfa-melanocyte stimulating hormone	Clinuvel UK Ltd - UK	Treatment of congenital erythropoietic porphyria	▪ 20/11/2007 ▪ 07/12/2007 ▪ 04/03/2008/ ▪ 88 days	▪ 28/03/2008 ▪ 08/05/2008
[Nle4, D-Phe7]-alfa-melanocyte stimulating hormone	Clinuvel UK Ltd - UK	Treatment of erythropoietic protoporphyria	▪ 20/11/2007 ▪ 07/12/2007 ▪ 04/03/2008 ▪ 88 days	▪ 28/03/2008 ▪ 08/05/2008

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
NGR-human Tumour Necrosis Factor	MolMed S.p.A. - Italy	Treatment of malignant mesothelioma	▪ 31/01/2008 ▪ 15/02/2008 ▪ 08/04/2008 ▪ 53 days	▪ 23/04/2008 ▪ 03/06/2008
Recombinant fusion protein of circulary-permuted IL-4 and pseudomonas exotoxin A, [IL-4(38-37)-PE38KDEL]	Gregory Fryer Associates Ltd - UK	Treatment of glioma	▪ 31/01/2008 15/02/2008 08/04/2008 ▪ 53 days	▪ 23/04/2008 ▪ 03/06/2008
Nimotuzumab	Oncoscience AG - Germany	Treatment of pancreatic cancer	▪ 31/01/2008 ▪ 15/02/2008 ▪ 08/04/2008 ▪ 53 days	▪ 23/04/2008 ▪ 03/06/2008
Alpha-1 proteinase inhibitor (for inhalation use)	Talecris Biotherapeutics GmbH - Germany	Treatment of congenital alpha-1 antitrypsin deficiency	▪ 30/01/2008 ▪ 15/02/2008 ▪ 08/04/2008 ▪ 53 days	▪ 23/04/2008 ▪ 03/06/2008
Anti-von Willebrand Aptamer	FGK Representative Service GmbH - Germany	Treatment of thrombotic thrombocytopenic purpura	▪ 18/12/2007 ▪ 11/01/2008 ▪ 08/04/2008 ▪ 88 days	▪ 23/04/2008 ▪ 03/06/2008
Carfilzomib	Nexus Onclology Ltd. - UK	Treatment of multiple myeloma	▪ 18/12/2007 ▪ 15/02/2008 ▪ 08/04/2008 ▪ 53 days	▪ 23/04/2008 ▪ 03/06/2008
Pegylated recombinant factor VIIa	Novo Nordisk A/S - Denmark	Treatment of haemophilia B	▪ 18/12/2007 ▪ 15/02/2008 ▪ 08/04/2008 ▪ 53 days	▪ 23/04/2008 ▪ 03/06/2008
Pegylated recombinant factor VIIa	Novo Nordisk A/S - Denmark	Treatment of haemophilia A	▪ 18/12/2007 ▪ 15/02/2008 ▪ 08/04/2008/ ▪ 53 days	▪ 23/04/2008 ▪ 04/06/2008
Vincristine sulphate liposomes	QuadraMed Ltd - UK	Treatment of acute lymphoblastic leukaemia	▪ 30/01/2008 ▪ 15/02/2008 ▪ 14/05/2008 ▪ 89 days	▪ 28/05/2008 ▪ 08/07/2008
N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide	Voisin Consulting S.A.R.L. - France	Treatment of cystic fibrosis	▪ 27/02/2008 ▪ 14/03/2008 ▪ 14/05/2008 ▪ 61 days	▪ 28/05/2008 ▪ 08/07/2008

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Sapacitabine	Cyclacel Ltd - UK	Treatment of myelodysplastic syndrome	▪ 28/02/2008 ▪ 14/03/2008 ▪ 14/05/2008 ▪ 61 days	▪ 28/05/2008 ▪ 08/07/2008
Beraprost sodium	Lung Rx Ltd - UK	Treatment of pulmonary arterial hypertension	▪ 28/02/2008 ▪ 14/03/2008 ▪ 14/05/2008 ▪ 61 days	▪ 28/05/2008 ▪ 10/07/2008
Sapacitabine	Cyclacel Ltd - UK	Treatment of acute myeloid leukaemia	▪ 28/02/2008 ▪ 14/03/2008 ▪ 14/05/2008 ▪ 61 days	▪ 28/05/2008 ▪ 10/07/2008
Recombinant derivative of C3 transferase	Triskel EU Services - UK	Treatment of traumatic spinal cord injury	▪ 27/02/2008 ▪ 14/03/2008 ▪ 11/06/2008 ▪ 89 days	▪ 14/07/2008 ▪ 05/09/2008
Topotecan hydrochloride (liposomal)	Dr Matthias Luz - Germany	Treatment of glioma	▪ 26/03/2008 ▪ 11/04/2008 ▪ 11/06/2008 ▪ 61 days	▪ 27/06/2008 ▪ 05/09/2008
Donor lymphocyte preparation depleted of functional alloreactive T-cells	Kiadis Pharma Netherlands B.V - The Netherlands	Prevention of Graft-versus-Host Disease	▪ 18/12/2007 ▪ 11/04/2008 ▪ 11/06/2008 ▪ 61 days	▪ 27/06/2008 ▪ 05/09/2008
(-)-(2R)-3-(2-hydroxymethylindanyl-4-oxy)-phenyl-4,4,4-trifluorobutane-1-sulfonate	KeyNeurotek Pharmaceuticals AG - Germany	Treatment of moderate and severe closed traumatic brain injury	▪ 15/02/2007 ▪ 14/03/2008 ▪ 11/06/2008 ▪ 89 days	▪ 27/06/2008 ▪ 05/09/2008
Bosentan	Actelion Registration Ltd - UK	Treatment of idiopathic pulmonary fibrosis	▪ 27/03/2008 ▪ 11/04/2008 ▪ 11/06/2008 ▪ 61 days	▪ 27/06/2008 ▪ 05/09/2008
Recombinant human minibody against complement component C5	Adienne S.r.l - Italy	Treatment of atypical haemolytic uraemic syndrome (aHUS) associated with an inherited abnormality of the complement system	▪ 06/05/2008 ▪ 13/06/2008 ▪ 09/07/2008 ▪ 26 days	▪ 25/07/2008 ▪ 22/09/2008
N'-(5-chloro-2-hydroxy-3-methylbenzylidene)-2,4-dihydroxybenzhydrazide	Innate Pharmaceuticals AB - Sweden	Treatment of partial deep dermal and full thickness burn wounds	▪ 27/03/2008 ▪ 11/04/2008 ▪ 09/07/2008 ▪ 89 days	▪ 25/07/2008 ▪ 22/09/2008

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Recombinant human CXCL8 mutant	ProtAffin Biotechnologie AG - Austria	Prevention of delayed graft function after solid organ transplantation	▪ 27/03/2008 ▪ 11/04/2008 ▪ 09/07/2008 ▪ 89 days	▪ 25/07/2008 ▪ 22/09/2008
Drotrecogin alfa (activated)	Drugrecure Aps - Denmark	Treatment of acute respiratory distress syndrome	▪ 08/12/2006 ▪ 13/06/2008 ▪ 09/07/2008 ▪ 26 days	▪ 25/07/2008 ▪ 22/09/2008
Miltefosine	ExperGen Drug Development GmbH - Austria	Treatment of cutaneous T-cell lymphoma	▪ 29/04/2008 ▪ 13/06/2008 ▪ 09/07/2008 ▪ 26 days	▪ 25/07/2008 ▪ 22/09/2008
Pegylated L-asparaginase	Enzon (UK) Ltd - UK	Treatment of acute lymphoblastic leukaemia	▪ 02/05/2008 ▪ 13/06/2008 ▪ 09/07/2008 ▪ 26 days	▪ 25/07/2008 ▪ 22/09/2008
Levofloxacin hemihydrate	Mpex London Ltd - UK	Treatment of cystic fibrosis	▪ 27/03/2008 ▪ 11/04/2008 ▪ 09/07/2008 ▪ 89 days	▪ 25/07/2008 ▪ 23/09/2008
Avian polyclonal IgY antibody against Pseudomonas aeruginosa	Immunsystem I.M.S. AB - Sweden	Treatment of cystic fibrosis	▪ 02/05/2008 ▪ 13/06/2008 ▪ 09/07/2008 ▪ 26 days	▪ 25/07/2008 ▪ 23/09/2008
Carglumic acid	Orphan Europe SARL - France	Treatment of propionic acidaemia	▪ 25/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Adeno-associated viral vector containing the human alpha-sarcoglycan gene	Généthon - France	Treatment of alpha-sarcoglycanopathy	▪ 25/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Filgrastim	Sygnis Bioscience GmbH & Co. KG - Germany	Treatment of spinal cord injury	▪ 25/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Autologous urothelial and smooth muscle cells	Choice Pharma Ltd - UK	Treatment of spinal cord injury	▪ 24/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
(R)-3-(4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl)-3-cyclopentylpropanenitrile phosphate	Incyte Corporation Ltd - UK	Treatment of chronic idiopathic myelofibrosis	▪ 23/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Carglumic acid	Orphan Europe SARL - France	Treatment of isovaleric acidaemia	▪ 25/10/2007 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Ofatumumab	Glaxo Group Ltd - UK	Treatment of chronic lymphocytic leukaemia	▪ 26/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Carglumic acid	Orphan Europe SARL - France	Treatment of methylmalonic acidaemia	▪ 25/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Recombinant human heparan-N-sulfatase	Shire Pharmaceutical Development Ltd - UK	Treatment of mucopolysaccharidosis, type IIIA (Sanfilippo A syndrome)	▪ 26/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Ex vivo expanded autologous human corneal epithelium containing stem cells	Chiesi Farmaceutici S.P.A. - Italy	Treatment of corneal lesions, with associated corneal (limbal) stem cell deficiency, due to ocular burns	▪ 27/03/2008 ▪ 13/06/2008 ▪ 10/09/2008 ▪ 89 days	▪ 29/09/2008 ▪ 07/11/2008
Cysteamine hydrochloride	Orphan Europe SARL - France	Treatment of cystinosis	▪ 10/06/2008 ▪ 11/07/2008 ▪ 10/09/2008 ▪ 61 days	▪ 29/09/2008 ▪ 07/11/2008
Monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E	Seattle Genetics UK, Ltd - UK	Treatment of anaplastic large cell lymphoma	▪ 24/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ Decision awaited
Daunorubicin (liposomal)	Diatos S.A. - France	Treatment of acute myeloid leukaemia	▪ 26/06/2008 ▪ 11/07/2008 ▪ 08/10/2008 ▪ 89 days	▪ 30/10/2008 ▪ 03/12/2008
Gadodiamide (liposomal)	Dr Matthias Luz - Germany	Treatment of glioma	▪ 06/05/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 03/12/2008

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Cenersen	EleosInc Ltd - UK	Treatment of chronic lymphocytic leukaemia	▪ 30/06/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 03/12/2008
N2'-Deacetyl-N2'-[4-methyl-4-(oxobuthyldithio)-1-oxopentyl]-maytansine-chimerized anti-CD138 IgG4 monoclonal antibody	Biotest AG - Germany	Treatment of multiple myeloma	▪ 23/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 03/12/2008
Recombinant human ADAMTS-13	Baxter AG - Austria	Treatment of thrombotic thrombocytopenic purpura	▪ 18/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 03/12/2008
Recombinant human tissue non-specific alkaline phosphatase - Fc - deca-aspartate fusion protein	Europa Rx Ltd - UK	Treatment of hypophosphatasia	▪ 24/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 03/12/2008
Palifosfamide	Ziopharm Oncology Ltd - UK	Treatment of soft tissue sarcoma	▪ 25/06/2008 ▪ 11/07/2008 ▪ 08/10/2008 ▪ 89 days	▪ 30/10/2008 ▪ 03/12/2008
Murine anti-CD22 antibody variable region fused to truncated Pseudomonas exotoxin 38	MedImmune Ltd - UK	Treatment of hairy cell leukaemia	▪ 23/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 04/12/2008
RNA, [P-deoxy-P-(dimethylamino)] (2',3'-dideoxy-2',3'-imino-2',3'-seco) (2'a→5') (C-m5U-C-C-A-A-C-A-m5U-C-A-A-G-G-A-A-G-A-m5U-G-G-C-A-m5U-m5U-m5U-C-m5U-A-G), P-[4-[[2-[2-(2-hydroxyethoxy)ethoxy]ethoxy]carbonyl]-1-piperazinyl] N,N dimethylaminophosphonamidate	AVI BioPharma International Ltd - UK	Treatment of Duchenne muscular dystrophy	▪ 25/06/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 03/12/2008
5-(ethylsulfonyl)-2-(naphthalen-2-yl)benzo[d]oxazole	Summit (Oxford) Ltd - UK	Treatment of Duchenne muscular dystrophy	▪ 23/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 04/12/2008

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Yttrium (^{90}Y) edotreotide	Molecular Insight Ltd - UK	Treatment of gastro-entero-pancreatic neuroendocrine tumours	▪ 21/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 04/12/2008
Monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E	Seattle Genetics UK, Ltd - UK	Treatment of Hodgkin lymphoma	▪ 24/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ Decision awaited
2-[[3-({4-[(5-{2-[(3-Fluorophenyl)amino]-2-oxoethyl}-1H-pyrazol-3-yl)amino]-quinazolin-7-yl}oxy)propyl](ethyl) amino]ethyl dihydrogen phosphate trihydrate	AstraZeneca AB - Sweden	Treatment of acute myeloid leukaemia	▪ 23/07/2008 ▪ 08/08/2008 ▪ 08/10/2008 ▪ 61 days	▪ 30/10/2008 ▪ 04/12/2008
Recombinant human monoclonal antibody to human Nogo-A protein of the IgG4/kappa class	Novartis Europharm Ltd - UK	Treatment of spinal cord injury	▪ 22/07/2008 ▪ 12/09/2008 ▪ 05/11/2008	▪ Decision awaited
Exon 44 specific phosphorothioate oligonucleotide	Prosensa Therapeutics B.V. - The Netherlands	Treatment of Duchenne muscular dystrophy	▪ 26/08/2008 ▪ 12/09/2008 ▪ 05/11/2008	▪ Decision awaited
Recombinant human minibody against complement component C5 fused with RGD-motif	Adienne S.r.l - Italy	Prevention of the ischaemia/reperfusion injury associated with solid organ transplantation	▪ 25/06/2008 ▪ 12/09/2008 ▪ 05/11/2008	▪ Decision awaited
Milatuzumab	Immunomedics GmbH - Germany	Treatment of multiple myeloma	▪ 30/06/2008 ▪ 08/08/2008 ▪ 05/11/2008	▪ Decision awaited
Pralatrexate	European Medical Advisory Services Ltd - UK	Treatment of non-papillary transitional cell carcinoma of the urinary bladder	▪ 24/07/2008 ▪ 12/09/2008 ▪ 05/11/2008	▪ Decision awaited
2,3,4,5 tetrahydro-2,8-dimethyl-5-[2-(6-methyl-3-pyridinyl)ethyl]-1H-pyrido[4,3-b]indole dihydrochloride	Innovative Drug European Associates Ltd - UK	Treatment of Huntington's disease	▪ 24/07/2008 ▪ 08/08/2008 ▪ 05/11/2008	▪ Decision awaited
Human anti-intercellular adhesion molecule-1 monoclonal antibody	BioInvent International AB - Sweden	Treatment of multiple myeloma	▪ 25/07/2008 ▪ 12/09/2008 ▪ 05/11/2008	▪ Decision awaited
Recombinant human residue 41 glutamic acid to glutamine variant of Interferon-alfa-2b	Creabilis Therapeutics S.p.A. - Italy	Treatment of Behçet's Disease	▪ 23/07/2008 ▪ 08/08/2008 ▪ 05/11/2008	▪ Decision awaited

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Exon 51 specific phosphorothioate oligonucleotide	Prosensa Therapeutics B.V. - The Netherlands	Treatment of Duchenne muscular dystrophy	▪ 26/08/2008 ▪ 12/09/2008 ▪ 05/11/2008	▪ Decision awaited
Milatuzumab	Immunomedics GmbH - Germany	Treatment of chronic lymphocytic leukaemia	▪ 21/07/2008 ▪ 08/08/2008 ▪ 05/11/2008	▪ Decision awaited
Recombinant human proinsulin (Proinsulin)	ProRetina Therapeutics S.L. - Spain	Treatment of retinitis pigmentosa	▪ 25/09/2008/ ▪ 13/10/2008 ▪ 10/12/2008	▪ Decision awaited
Adeno-associated viral vector serotype 5 containing the human ABCA4 gene	Fondazione Telethon - Italy	Treatment of Stargardt's disease	▪ 29/08/2008/ ▪ 13/10/2008 ▪ 10/12/2008	▪ Decision awaited
Type I native bovine skin collagen	arGentis Autoimmune Europe Limited - UK	Treatment of systemic sclerosis	▪ 28/08/2008/ ▪ 12/09/2008 ▪ 10/12/2008	▪ Decision awaited
Cyclopropane-1,1-dicarboxylic acid [4-(6,7-dimethoxy-quinolin-4-yloxy)-phenyl]-amide (4-fluoro-phenyl)-amide, (L)-malate salt	PPD Global Ltd - UK	Treatment of medullary thyroid carcinoma	▪ 26/09/2008/ ▪ 13/10/2008 ▪ 10/12/2008	▪ Decision awaited
Yttrium (90Y)-DOTA-radiolabelled humanized monoclonal antibody against	Immunomedics GmbH - Germany	Treatment of pancreatic cancer	▪ 26/08/2008/ ▪ 13/10/2008 ▪ 10/12/2008	▪ Decision awaited
Recombinant human hepatocarcinoma-intestine-pancreas / pancreatic associated protein	Alfact Innovation SAS - France	Treatment of acute liver failure	▪ 29/08/2008/ ▪ 12/09/2008 ▪ 10/12/2008	▪ Decision awaited
Recombinant human monoclonal antibody to human IL-1beta of the IgG1/K class	Novartis Europharm Ltd - UK	Treatment of systemic-onset juvenile idiopathic arthritis	▪ 20/04/2007 ▪ 09/11/2007 ▪ 10/01/2008 ▪ 62 days	▪ 21/01/2008 ▪ 04/02/2008
Lumiliximab	Biogen Idec Ltd - UK	Treatment of chronic lymphocytic leukaemia	▪ 20/09/2007 ▪ 15/10/2007 ▪ 10/01/2008 ▪ 87 days	▪ 21/01/2008 ▪ 04/02/2008
Tretazicar	Morvus Technology Ltd - UK	Treatment of visceral leishmaniasis	▪ 27/09/2007 ▪ 15/10/2007 ▪ 10/01/2008 ▪ 87 days	▪ 21/01/2008 ▪ 04/02/2008

Product INN	Sponsor	Summary of indication	EMEA/COMP ▪ Submission ▪ Start date ▪ Opinion ▪ Active time	European Commission ▪ Opinion received ▪ Date of decision
Heterologous human adult liver-derived stem cells	Prof Etienne Sokal - Belgium	Treatment of ornithine transcarbamylase deficiency	▪ 24/10/2007 ▪ 09/11/2007 ▪ 10/01/2008 ▪ 62 days	▪ 21/01/2008 ▪ 04/02/2008
Autologous urothelial and smooth muscle cells	Choice Pharma Ltd - UK	Treatment of spina bifida	▪ 20/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 17/03/2008
Chimeric antibody to mesothelin	Chiltern International Ltd - UK	Treatment of pancreatic cancer	▪ 20/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 17/03/2008
Recombinant human monoclonal antibody against transforming growth factor beta-1, 2 and 3	Genzyme BV - The Netherlands	Treatment of idiopathic pulmonary fibrosis	▪ 25/10/2007 ▪ 09/11/2007 ▪ 06/02/2008 ▪ 89 days	▪ 25/02/2008 ▪ 01/04/2008
Ammonium tetrathiomolybdate	JJGConsultancy Ltd - UK	Treatment of Wilson's disease	▪ 22/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 01/04/2008
Humanised monoclonal antibody to the folate receptor alpha	Chiltern International Ltd - UK	Treatment of ovarian cancer	▪ 20/11/2007 ▪ 07/12/2007 ▪ 06/02/2008 ▪ 61 days	▪ 25/02/2008 ▪ 01/04/2008
Filgrastim	Sygnis Bioscience GmbH & Co. KG - Germany	Treatment of amyotrophic lateral sclerosis	▪ 24/10/2007 ▪ 09/11/2007 ▪ 06/02/2008 ▪ 89 days	▪ 25/02/2008 ▪ 01/04/2008

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
4-[[[4-(4-Chlorophenoxy)phenyl]sulfonyl]-methyl]tetrahydro-N-hydroxy-2H-pyran-4-carboxamide	Anthony William Fox - UK	Prevention of graft rejection after liver transplantation	▪ 25/03/2008 ▪ 13/06/2008 ▪ 10/09/2008	▪ Decision awaited

Annex 13 HMPC Community herbal monographs

Reference number	Document title	Status
EMEA/HMPC/179281/2007	Community herbal monograph on Calendulae flos	Adopted March 2008
EMEA/HMPC/104945/2006	Community herbal monograph on Echinaceae purpureae herba	Adopted March 2008
EMEA/HMPC/260019/2006	Community herbal monograph on Betulae folium	Adopted May 2008
EMEA/HMPC/244569/2006	Community herbal monograph on Eleutherococci radix	Adopted May 2008
EMEA/HMPC/513617/2006	Community herbal monograph on Lupuli flos	Adopted May 2008
EMEA/HMPC/394894/2007	Community herbal monograph on Equiseti herba	Adopted July 2008
EMEA/HMPC/354177/2007	Community herbal monograph on Meliloti herba	Adopted July 2008
EMEA/HMPC/283166/2007	Community herbal monograph on Sambuci flos	Adopted July 2008
EMEA/HMPC/170261/2006	Community herbal monograph on Urticae herba	Adopted July 2008
EMEA/HMPC/395213/2007	Community herbal monograph on Verbasci flos	Adopted July 2008
EMEA/HMPC/368600/2007	Community herbal monograph on Avenae fructus	Adopted September 2008
EMEA/HMPC/202966/2007	Community herbal monograph on Avenae herba	Adopted September 2008
EMEA/HMPC/193909/2007	Community herbal monograph on Menthae piperitae folium	Adopted September 2008
EMEA/HMPC/261938/2007	Community herbal monograph on Rusci aculeati rhizoma	Adopted September 2008
EMEA/HMPC/285758/2007	Community herbal monograph on Solidaginis virgaureae herba	Adopted September 2008
EMEA/HMPC/251323/2006	Community herbal monograph on Harpagophyti radix	Released for public consultation January 2008 Adopted November 2008
EMEA/HMPC/600668/2007	Community herbal monograph on Polypodii rhizoma	Released for public consultation May 2008 Adopted November 2008
EMEA/HMPC/591648/2007	Community herbal monograph on Boldi folium	Released for public consultation May 2008
EMEA/HMPC/508015/2007	Community herbal monograph on Urticae folium	Released for public consultation May 2008
EMEA/HMPC/98717/2008	Community herbal monograph on Althaeae radix	Released for public consultation July 2008
EMEA/HMPC/105536/2008	Community herbal monograph on Centaurii herba	Released for public consultation July 2008

Reference number	Document title	Status
EMEA/HMPC/225319/2008	Community herbal monograph on Hippocastani semen	Released for public consultation September 2008
EMEA/HMPC/114586/2008	Community herbal monograph on Hamamelidis folium	Released for public consultation September 2008
EMEA/HMPC/332350/2008	Community herbal monograph on Echinaceae pallidae radix	Released for public consultation September 2008
EMEA/HMPC/101304/2008	Community herbal monograph on Hyperici herba	Released for public consultation November 2008
EMEA/HMPC/234463/2008	Community herbal monograph on Absinthii herba	Released for public consultation November 2008
EMEA/HMPC/114583/2008	Community herbal monograph on Hamamelidis cortex	Released for public consultation November 2008
EMEA/HMPC/114584/2008	Community herbal monograph on Hamamelidis folium et cortex aut ramunculus destillatum	Released for public consultation November 2008
EMEA/HMPC/456845/2008	Community herbal monograph on Curcumae longae rhizoma	Released for public consultation November 2008

Annex 14 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/297757/2006	Community list entry on Anisi fructus	Adopted January 2008
EMEA/HMPC/179283/2007	Community list entry on Calendulae flos	Adopted March 2008
EMEA/HMPC/189629/2007	Community list entry on Echinaceae purpureae herba	Adopted May 2008
EMEA/HMPC/83756/2007	Community list entry on Eleutherococci radix	Adopted May 2008
EMEA/HMPC/189245/2008	Community list entry on Menthae piperitae aetheroleum	Released for public consultation May 2008 Adopted November 2008
Reference number	Document title	Status

Annex 15 PDCO opinions and EMEA decisions on paediatric investigation plans and waivers in 2008

Product INN/ Invented Name	**Applicant**	**Therapeutic Area**	**PIP (P) / PIP Modification (PM) / Full Waiver (W)**	**PDCO** ▪ Start date ▪ Opinion	**EMEA Decision**
Corifollitropin alfa	N.V. Organon	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 31/07/2008 ▪ 12/12/2008	P/131/2008 19/12/2008
Travoprost / brinzolamide	Alcon Laboratories (UK) Limited	Ophthalmology	P	▪ 25/092008 ▪ 14/11/2008	P/130/2008 23/12/2008
Pirfenidone	InterMune, Inc.	Pneumology/ Allergology	W	▪ 25/09/2008 ▪ 14/11/2008	P/129/2008 23/12/2008
Eprotirome	KaroBio AB	Endocrinology/ metabolism	W	▪ 25/09/2008 ▪ 14/11/2008	P/128/2008 23/12/2008
Telaprevir	Tibotec BVBA	Infectious Diseases	P	▪ 08/05/2008 ▪ 14/11/2008	P/127/2008 23/12/2008
Voclosporin	Lux Biosciences GmbH	Ophthalmology	P	▪ 14/02/2008 ▪ 14/11/2008	P/126/2008 23/12/2008
Fingolimod hydrochloride	Novartis Europharm Limited	Neurology	P	▪ 20/12/2007 ▪ 14/11/2008	P/125/2008 05/12/2008
Everolimus (Certican and associated names)	Novartis Europharm Limited	Oncology	P	▪ 13/03/2008 ▪ 17/10/2008	P/124/2008 05/12/2008
Clopidogrel (Iscover)	Sanofi Pharma Bristol-Myers Squibb SNC	Cardiovascular diseases	PM	▪ 25/09/2008 ▪ 17/10/2008	P/123/2008 05/12/2008
Clopidogrel (Plavix)	Bristol-Myers Squibb Pharma EEIG	Cardiovascular diseases	PM	▪ 25/09/2008 ▪ 17/10/2008	P/122/2008 05/12/2008
Treprostinil (Remodulin and associated names)	United Therapeutics Europe Ltd	Cardiovascular diseases	P	▪ 05/06/2008 ▪ 14/11/2008	P/121/2008 01/12/2008
Omega-3-acid (ethyl esters of eicosapentaenoic acid (EPA) / docosahexaenoic acid (DHA) / simvastatin	Sigma-Tau SpA	Metabolism	W	▪ 27/08/2008 ▪ 17/10/2008	P/120/2008 01/12/2008
Alipogene tiparvovec	Amsterdam Molecular	Cardiovascular diseases	P	▪ 05/06/2008 ▪ 17/10/2008	P/119/2008 01/12/2008
Diphenhydramine hydrochloride	Wyeth Consumer Healthcare	Pain	W	▪ 08/05/2008 ▪ 17/10/2008	P/118/2008 01/12/2008
Sitagliptin phosphate monohydrate / metformin hydrochloride (Efficib)	Merck Sharp and Dohme (Europe), Inc.	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 13/03/2008 ▪ 17/10/2008	P/117/2008 01/12/2008
Sitagliptin phosphate monohydrate / metformin hydrochloride (Velmetia)	Merck Sharp and Dohme (Europe), Inc.	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 13/03/2008 ▪ 17/10/2008	P/116/2008 01/12/2008
Human normal immunoglobulin	LFB Biotechnologies	Immunology/ rheumatology/ transplantation	P	▪ 13/03/2008 ▪ 17/10/2008	P/115/2008 01/12/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Sitagliptin phosphate monohydrate / metformin hydrochloride (Janumet)	Merck Sharp and Dohme (Europe), Inc.	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 13/03/2008 ▪ 17/10/2008	P/114/2008 01/12/2008
Tigecycline (Tygacil)	Wyeth Europa Limited	Infectious diseases	P	▪ 13/03/2008 ▪ 17/10/2008	P/113/2008 01/12/2008
3-(1H-indol-3-yl)-4-(2-(4-methyl-1-Perazinyl)-4-quinazolinyl)-1H-pyrrole-2,5-dione acetate(1:1)	Novartis Europharm Limited	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 20/12/2007 ▪ 17/10/2008	P/112/2008 01/12/2008
Telbivudine (Sebivo)	Novartis Europharm Limited	Gastroenterology, Hepatology	P	▪ 22/11/2007 ▪ 17/10/2008	P/111/2008 01/12/2008
TGp1PTH1-34 L-Asparaginyl-L-glutaminyl-L-glutamyl-L-glutaminyl-L-valy1-L-seryl-L-prolyl-L-leucyl-L-tyrosyl-L-lysil-L-asparaginyl-L-arginyl-L-seryl-L-valyl-L-seryl-L-glutamyl-L-isoleucyl-L-glutaminyl-L-leucyl-L-methionyl-L-histidyl-L-asparaginyl-L-leucyl-L-glycyl-L-lysyl-L-histidyl-L-leucyl-L-asparaginyl-L-seryl-L-methionyl-L-glutamyl-L-arginyl-L-valyl-L-glutamyl-L-tryptophanyl-L-leucyl-L-arginyl-L-lysyl-L-lysyl-L-leucyl-L-glutamyl-L-asparty-L-valyl-L-histidyl-L-asparaginyl-L-phenylalanine-, acetate salt	Kuros Biosurgery International AG	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 25/10/2007 ▪ 17/10/2008	P/110/2008 01/12/2008
Maraviroc (Celsentri)	Pfizer Limited	Infectious diseases	P	▪ 30/08/2007 ▪ 17/10/2008	P/109/2008 01/12/2008
Purified diphtheria toxoid, Purified tetanus toxoid, Five component acellular pertussis [Purified Pertussis Toxoid (PT), Purified Filamentous Haemagglutinin (FHA), Purified Fimbriae Types 2 and 3 (FIM), and Purified Pertactin (PRN)], Inactivated poliomyelitis vaccine (Vero) – Type 1 (Mahoney), Type 2 (MEF-1) and Type 3 (Saukett), Purified polyribosylribitol phosphate capsular polysaccharide of Haemophilus influenzae type b covalently bound to Tetanus protein (PRP-T) (PEDIACEL)	Sanofi Pasteur MSD SNC	Vaccines	P	▪ 01/07/2008 ▪ 14/11/2008	P/108/2008 26/11/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Skimmed cow's milk powder	DBV Technologies	Immunology/ rheumatology/ transplantation	P	▪ 10/04/2008 ▪ 14/11/2008	P/107/2008 28/11/2008
Perflubutane	Nycomed Danmark ApS	Diagnostics	W	▪ 10/04/2008 ▪ 14/11/2008	P/106/2008 28/11/2008
Liraglutide	Novo Nordisk A/S	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 14/02/2008 ▪ 14/11/2008	P/105/2008 28/11/2008
Vicriviroc maleate	Schering-Plough Europe	Infectious diseases	P	▪ 16/01/2008 ▪ 14/11/2008	P/104/2008 01/12/2008
Meningococcal group A oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MenACRM), Meningococcal group C oligosaccharides conjugated to Corynebacterium diphtheriae CRMI97 protein (MenCCRM), Meningococcal group W-135 oligosaccharides conjugated to Corynebacterium diphtheriae CRMl97 protein (MenWCRM), Meningococcal group Y oligosaccharides conjugated to Corynebacterium diphtheriae CRMI97 protein (MenYCRM)	Novartis Vaccines and Diagnostics S.r.l.	Vaccines	P	▪ 15/10/2008 ▪ 17/10/2008	P/103/2008 03/11/2008
Lenalidomide	Celgene Europe Limited	Oncology	W	▪ 27/08/2008 ▪ 17/10/2008	P/102/2008 06/11/2008
Influenza Virus Type A, H3N2 Influenza Virus Type A, H1N1 Influenza Virus Type B	MedImmune, LLC	Vaccines	W	▪ 05/06/2008 ▪ 17/10/2008	P/101/2008 03/11/2008
Nomegestrol acetate / 17 beta – estradiol	NV Organon	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 10/04/2008 ▪ 19/09/2008	P/100/2008 03/11/2008
Belatacept	Bristol-Myers Squibb International Corporation	Immunology/ rheumatology/ transplantation	P	▪ 13/03/2008 ▪ 19/09/2008	P/99/2008 03/11/2008
Dienogest	Bayer Schering Pharma AG	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 13/03/2008 ▪ 19/09/2008	P/98/2008 03/11/2008
Aprepitant	Merck Sharp & Dohme Ltd.	Oncology	P	▪ 13/03/2008 ▪ 19/09/2008	P/97/2008 03/11/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Paracetamol	Baxter World Trade SA/NV	Pain	P	▪ 14/02/2008 ▪ 17/10/2008	P/96/2008 03/11/2008
Ipilimumab	Bristol-Myers Squibb International Corporation	Oncology	P	▪ 13/03/2008 ▪ 19/09/2008	P/95/2008 03/11/2008
Vandetanib	AstraZeneca AB	Oncology	P	▪ 16/01/2008 ▪ 19/09/2008	P/94/2008 03/11/2008
Nalfurafine hydrochloride	Toray International U.K. Limited	Dermatology	W	▪ 08/05/2008 ▪ 19/09/2008	P/93/2008 22/10/2008
Peginterferon alfa-2b	Schering-Plough Europe	Gastroenterology/ Hepatology	P	▪ 31/07/2008 ▪ 29/08/2008	P/92/2008 14/10/2008
Chimeric Murine-Human Anti Interleukin 6 Monoclonal Antibody	Centocor B.V.	Oncology	W	▪ 01/07/2008 ▪ 29/08/2008	P/91/2008 14/10/2008
Catridecacog	Novo Nordisk A/S	Haematology-Hemostaseology	P	▪ 13/03/2008 ▪ 29/08/2008	P/90/2008 14/10/2008
Denosumab	Amgen Europe B.V.	Endocrinology/ gynaecology/ fertility/ metabolism Immunology– Rheumatology-Transplantation	P	▪ 13/03/2008 ▪ 29/08/2008	P/89/2008 14/10/2008
Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains: A/Solomon Islands/3/2006 (H1N1) like strain (A/Solomon Islands/3/2006, IVR-145) A/Wisconsin/67/2005 (H3N2) like strain (A/Wisconsin/67/2005, NYMC X161B) B/Malaysia/2506/2004 like strain (B/Malaysia/2506/2004	Bristol-Myers Squibb Pharma EEIG	Vaccine	P	▪ 16/01/2008 ▪ 29/08/2008	P/88/2008 14/10/2008
Abatacept	Bristol-Myers Squibb Pharma EEIG	Immunology rheumatology/ transplantation	P	▪ 14/02/2008 ▪ 29/08/2008	P/87/2008 14/10/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Alanine, Arginine, Aspartic acid, Cysteine Glutamic acid, Glycine, Histidine, Isoleucine, Leucine, Lysine monohydrate, Methionine, Ornithine hydrochloride, Phenylalanine, Proline, Serine, Taurine, Threonine, Tryptophan, Tyrosine, Valine, Sodium chloride, Potassium acetate, Calcium chloride dihydrate, Magnesium acetate tetrahydrate, Sodium glycerophosphate, hydrated, Glucose monohydrate, Olive oil, refined, Soya-bean oil, refined	Baxter World Trade SA/NV	Nutrition	P	▪ 16/01/2008 ▪ 29/08/2008	P/86/2008 14/10/2008
Mometasone furoate / Formoterol fumarate dihydrate	Novartis Europharm Limited	Pneumology	P	▪ 25/10/2007 ▪ 29/08/2008	P/85/2008 14/10/2008
Valsartan (Diovan and associated names)	Novartis Europharm Limited	Cardiovascular diseases	P	▪ 01/08/2007 ▪ 29/08/2008	P/84/2008 14/10/2008
Eltrombopag Olamine	GlaxoSmithKline Trading Services Limited	Haematology-Haemostaseology	P	▪ 13/03/2008 ▪ 19/09/2008	P/83/2008 14/10/2008
Bevacizumab	Roche Registration Ltd	Oncology	P	▪ 27/08/2008 ▪ 19/09/2008	P/82/2008 01/10/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
13 valent pneumococcal polysaccharide conjugate vaccine: Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate	Wyeth Lederle Vaccines SA	Vaccines	PM	▪ 31/07/2008 ▪ 29/08/2008	P/81/2008 29/09/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Naproxen / Esomeprazole magnesium trihydrate	AstraZeneca AB	Immunology–Rheumatology-Transplantation	W	▪ 01/07/2008 ▪ 29/08/2008	P/80/2008 19/09/2008
Lidocaine / prilocaine	Plethora Solutions Limited	Uronephrology	W	▪ 01/07/2008 ▪ 29/08/2008	P/79/2008 15/09/2008
Bortezomib	Janssen-Cilag International NV	Oncology	W	▪ 05/06/2008 ▪ 31/07/2008	P/78/2008 14/09/2008
Retigabine	Valeant Pharmaceuticals Ltd.	Neurology	P	▪ 16/01/2008 ▪ 31/07/2008	P/77/2008 12/09/2008
Dabigatran etexilate	Boehringer Ingelheim International GmbH	Haematology-Haemostaseology	P	▪ 20/12/2007 ▪ 31/07/2008	P/76/2008 14/09/2008
Pramipexole dihydrochloride monohydrate (Mirapexin)	Boehringer Ingelheim International GmbH	Neurology	P	▪ 22/11/2007 ▪ 31/07/2008	P/75/2008 12/09/2008
Pramipexole dihydrochloride monohydrate (Sifrol)	Boehringer Ingelheim International GmbH	Neurology	P	▪ 22/11/2007 ▪ 31/07/2008	P/74/2008 12/09/2008
Ezetimibe / simvastatin (INEGY and associated names)	MSD-SP Limited	Endocrinology/ gynaecology/ fertility/ metabolism	P	▪ 02/08/2007 ▪ 31/07/2008	P/73/2008 14/09/2008
Nicotinic acid /simvastatin / laropiprant	Merck Sharp and Dohme (Europe), Inc.	Endocrinology and Metabolism	P	▪ 05/06/2008 ▪ 31/07/2008	P/72/2008 20/08/2008
Nicotinic acid / simvastatin / laropiprant	Merck Sharp and Dohme (Europe), Inc.	Endocrinology and Metabolism	P	▪ 05/06/2008 ▪ 31/07/2008	P/71/2008 20/08/2008
Nicotinic acid / simvastatin / laropiprant	Merck Sharp and Dohme (Europe), Inc.	Endocrinology and Metabolism	P	▪ 22/11/2007 ▪ 31/07/2008	P/70/2008 20/08/2008
Eplivanserin hemifumarate	sanofi-aventis recherche & dévelopment	Psychiatry	P	▪ 16/01/2008 ▪ 04/07/2008	P/69/2008 11/08/2008
Dexamethasone	Allergan Pharmaceuticals Ireland	Ophthalmology	W	▪ 08/05/2008 ▪ 04/07/2008	P/68/2008 15/08/2008
Everolimus	Novartis Europharm Ltd	Oncology	W	▪ 05/05/2008 ▪ 04/07/2008	P/67/2008 15/08/2008
Aciclovir / Hydrocortisone	Medivir AB	Infectious diseases	P	▪ 20/12/2007 ▪ 04/07/2008	P/66/2008 15/08/2008
Balaglitazone	Rheoscience A/S	Endocrinology and metabolism	W	▪ 20/12/2007 ▪ 04/07/2008	P/65/2008 15/08/2008
Peginterferon alfa-2b	Schering-Plough Europe	Gastroenterology Hepatology	W	▪ 22/11/2007 ▪ 04/07/2008	P/64/2008 15/08/2008
Ribavirin	Schering-Plough Europe	Gastroenterology Hepatology	W	▪ 22/11/2007 ▪ 04/07/2008	P/63/2008 15/08/2008
Thrombin alfa (recombinant)	Bayer HealthCare AG	Haematology-Hemostaseology	W	▪ 13/03/2008 ▪ 31/07/2008	P/62/2008 14/08/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Tiotropium bromide, monohydrate	Boehringer Ingelheim International GmbH	Pneumology	P	▪ 30/08/2007 ▪ 04/07/2008	P/61/2008 15/08/2008
Ezetimibe	MSD-SP Limited	Endocrinology	P	▪ 01/08/2007 ▪ 14/03/2008	P/59/2008 20/07/2008
Amlodipine besylate / Valsartan / Hydrochlorothiazide	Novartis Europharm Ltd.	Cardiology	W	▪ 10/04/2008 ▪ 04/06/2008	P/58/2008 20/07/2008
Epoetin theta (recombinant human erythropoietin)	Ratiopharm GmbH	Haematology	W	▪ 10/04/2008 ▪ 04/06/2008	P/57/2008 20/07/2008
Epoetin theta (recombinant human erythropoietin)	Ratiopharm GmbH	Haematology	W	▪ 10/04/2008 ▪ 04/06/2008	P/56/2008 20/07/2008
Epoetin theta (recombinant human erythropoietin)	CT Arzneimittel GmbH	Haematology	W	▪ 10/04/2008 ▪ 04/06/2008	P/55/2008 20/07/2008
Glucosamine hydrochloride / chondroitin sulfate	Bioiberica S.A.	Rheumatology	W	▪ 10/04/2008 ▪ 04/06/2008	P/54/2008 20/07/2008
Atorvastatin calcium trihydrate	Pfizer Limited	Metabolism	P	▪ 22/11/2007 ▪ 04/06/2008	P/53/2008 20/07/2008
Mepolizumab	Glaxo Group Limited	Gastroenterology Immunology	P	▪ 22/11/2007 ▪ 04/06/2008	P/52/2008 20/07/2008
Zoledronic acid anhydrous	Novartis Europharm Limited	Metabolism	P	▪ 25/10/2007 ▪ 04/06/2008	P/51/2008 20/07/2008
Rabeprazole sodium	Eisai Limited	Gastroenterology Hepatology	P	▪ 25/10/2007 ▪ 04/06/2008	P/50/2008 20/07/2008
Darunavir ethanolate	Janssen-Cilag International NV	Infectious diseases	P	▪ 25/10/2007 ▪ 04/06/2008	P/49/2008 20/07/2008
Tapentadol hydrochloride	Grünenthal GmbH	Neurology	P	▪ 13/06/2008 ▪ 31/07/2008	P/48/2008 11/08/2008
Nicotinic acid / laropiprant	Merck Sharp and Dohme (Europe), Inc.	Metabolism	P	▪ 22/11/2007 ▪ 04/06/2008	P/46/2008 23/06/2008
Nicotinic acid / laropiprant	Merck Sharp and Dohme (Europe), Inc.	Metabolism	P	▪ 22/11/2007 ▪ 04/06/2008	P/45/2008 23/06/2008
Nicotinic acid / laropiprant	Merck Sharp and Dohme (Europe), Inc.	Metabolism	P	▪ 22/11/2007 ▪ 04/06/2008	P/44/2008 23/06/2008
Vernakalant hydrochloride	Cardiome UK Limited	Cardiology	W	▪ 10/04/2008 ▪ 08/05/2008	P/43/2008 24/06/2008
Dutasteride tamsulosin hydrochloride	Glaxo Group Ltd	Urology	W	▪ 10/04/2008 ▪ 08/05/2008	P/42/2008 24/06/2008
Elocalcitol	BioXell SpA	Urology	W	▪ 10/04/2008 ▪ 08/05/2008	P/41/2008 24/06/2008
AP214 Acetate (Acetyl-(Lys)6-α-MSH, acetate	Action Pharma A/S	Nephrology	W	▪ 13/03/2008 ▪ 08/05/2008	P/40/2008 24/06/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Taranabant	Merck Sharp & Dohme (Europe) Inc	Endocrinology and metabolism	P	▪ 22/11/2007 ▪ 08/05/2008	P/39/2008 24/06/2008
Pitavastatin calcium	Kowa Pharmaceutical Europe Co. Ltd	Endocrinology and metabolism	P	▪ 25/10/2007 ▪ 08/05/2008	P/38/2008 24/06/2008
Pitavastatin calcium	Kowa Pharmaceutical Europe Co. Ltd	Endocrinology and metabolism	P	▪ 05/10/2007 ▪ 08/05/2008	P/37/2008 24/06/2008
Pitavastatin calcium	Kowa Pharmaceutical Europe Co. Ltd	Endocrinology and metabolism	P	▪ 25/10/2007 ▪ 08/05/2008	P/36/2008 24/06/2008
Pitavastatin calcium	Kowa Pharmaceutical Europe Co. Ltd	Endocrinology and metabolism	P	▪ 25/10/2007 ▪ 08/05/2008	P/35/2008 24/06/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Valent pneumococcal polysaccharide conjugate vaccine: Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate	Wyeth Lederle Vaccines S.A.	Vaccines	P	▪ 27/09/2007 ▪ 08/05/2008	P/34/2008 24/06/2008
Tifacogin	Novartis Europharm Limited	Infectious diseases	P	▪ 30/08/2007 ▪ 08/05/2008	P/33/2008 24/06/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Zoledronic acid	Novartis Europharm Limited	Endocrinology and metabolism	P	▪ 30/08/2007 ▪ 08/05/2008	P/32/2008 24/06/2008
Dalbavancin	Pfizer Limited	Infectious diseases	P	▪ 08/05/2008 ▪ 04/06/2008	P/31/2008 19/06/2008
Caspofungin acetate (Cancidas)	Merck Sharp & Dohme (Europe) Ltd	Infectious diseases	PM	▪ 06/05/2008 ▪ 08/05/2008	P/30/2008 23/05/2008
Arzoxifene	Eli Lilly and Company Ltd	Oncology	W	▪ 14/02/2008 ▪ 11/04/2008	P/29/2008 23/05/2008
Adenovirus-mediated Herpes simplex virus-thymidine kinase gene	Ark Therapeutics Ltd	Oncology	P	▪ 14/02/2008 ▪ 11/04/2008	P/28/2008 23/05/2008
Recombinant human monoclonal antibody to human IL-1beta of the IgG/K class	Novartis Europharm Limited	Immunology	P	▪ 30/08/2007 ▪ 11/04/2008	P/27/2008 23/05/2008
Clopidogrel (Iscover)	Bristol-Myers Squibb Pharma EEIG	Cardiology	P	▪ 27/09/2007 ▪ 11/04/2008	P/26/2008 23/05/2008
Clopidogrel (Plavix)	Sanofi Pharma Bristol-Myers Squibb SNC	Cardiology	P	▪ 27/09/2007 ▪ 11/04/2008	P/25/2008 23/05/2008
N-Acetyl-L-Cysteine (corresponds to L-Cysteine), L-Alanine, L-Alanyl-L-Glutamine (corresponds to to L-Alanine and L-Glutamine), L-Arginine, Glycine, Glycyl-L-Tyrosine (corresponds to Glycine and L-Tyrosine), L-Histidine, L-Isoleucine, L-Leucine, L-Lysine acetate (corresponds to L-Lysine), L-Methionine, L-Phenylalanine, L-Proline, L-Serine, Taurine, L-Threonine, L-Tryptophan, L-Valine	Fresenius Kabi Deutschland GmbH	Nutrition	P	▪ 25/10/2007 ▪ 11/04/2008	P/24/2008 23/05/2008
Albumin interferon alfa-2b	Novartis Europharm Limited	Hepatology	P	▪ 30/08/2007 ▪ 11/04/2008	P/23/2008 23/05/2008
Docetaxel (Taxotere)	Aventis Pharma SA	Oncology	P	▪ 30/08/2007 ▪ 15/02/2008	P/22/2008 16/05/2008
Roflumilast	Nycomed GmbH	Pneumology	W	▪ 16/01/2008 ▪ 14/03/2008	P/21/2008 28/04/2008
Flibanserin	Boehringer Ingelheim GmbH	Gynaecology	W	▪ 17/01/2008 ▪ 14/03/2008	P/20/2008 28/04/2008

Product INN/ Invented Name	Applicant	Therapeutic Area	PIP (P) / PIP Modification (PM) / Full Waiver (W)	PDCO ▪ Start date ▪ Opinion	EMEA Decision
Meningococcal groups A, C, W-135 and Y oligosaccharides conjugated to Corynebacterium diphtheriae CRM197 protein (MenA-CRM, MenC-CRM, MenW-CRM, MenY-CRM)	Novartis Vaccines and Diagnostics S.r.l.	Vaccines	P	▪ 25/10/2007 ▪ 13/03/2008	P/19/2008 28/04/2008
Ezetimibe	MSD-SP Limited	Endocrinology	P	▪ 01/08/2007 ▪ 14/03/2008	P/18/2008 28/04/2008
Naproxcinod	NicOx S.A.	Rheumatology	W	▪ 20/12/2007 ▪ 15/02/2008	P/16/2008 31/03/2008
Fosfluridine tidoxil	Heidelberg Pharma AG	Dermatology	W	▪ 20/12/2007 ▪ 15/02/2008	P/15/2008 31/03/2008
Doripenem monohydrate	Johnson & Johnson PRD	Infectious diseases	P	▪ 02/08/2007 ▪ 15/02/2008	P/14/2008 31/03/2008
Paliperidone (Invega)	Janssen Cilag International N.V	Psychiatry	P	▪ 02/08/2007 ▪ 15/02/2008	P/13/2008 31/03/2008
Montelukast sodium (Singulair)	Merck Sharp & Dohme (Europe) Inc.	Pneumology	P	▪ 02/08/2007 ▪ 18/01/2008	P/12/2008 29/02/2008
Latanoprost (Xalatan)	Pfizer Global Research & Development	Ophthalmology	P	▪ 02/08/2007 ▪ 18/01/2008	P/11/2008 29/02/2008
Caspofungin acetate (Cancidas)	Merck Sharp & Dohme (Europe) Inc.	Infections diseases	P	▪ 02/08/2007 ▪ 18/01/2008	P/10/2008 29/02/2008
Losartan potassium (Cozaar and associated names)	Merck Sharp & Dohme (Europe) Inc.	Cardiology	P	▪ 02/08/2007 ▪ 18/01/2008	P/9/2008 29/02/2008
Rosiglitazone maleate	GlaxoSmithKline R&D Limited	Neurology	W	▪ 25/10/2007 ▪ 20/12/2007	P/8/2008 01/02/2008
Recombinant L-Asparaginase	medac Gesellschaft für klinische Spezialpräparate	Oncology	P	▪ 02/08/2007 ▪ 20/12/2007	P/7/2008 01/02/2008
Panobinostat lactate salt	Novartis Europharm Limited	Oncology	W	▪ 25/10/2007 ▪ 20/12/2007	P/6/2008 01/02/2008
Indacaterol maleate / Glycopyrronium bromide	Novartis Europharm Limited	Pneumology	W	▪ 25/10/2007 ▪ 20/12/2007	P/5/2008 01/02/2008
Glycopyrronium bromide	Novartis Europharm Limited	Pneumology	W	▪ 25/10/2007 ▪ 20/12/2007	P/4/2008 01/02/2008
Telmisartan / ramipril	Boehringer Ingelheim International GmbH	Cardiology	W	▪ 25/10/2007 ▪ 20/12/2007	P/3/2008 01/02/2008
Indacaterol maleate	Novartis Europharm Limited	Pneumology	W	▪ 25/10/2007 ▪ 20/12/2007	P/2/2008 01/02/2008
Lasofoxifene tartrate	Pfizer Ltd	Bone diseases	W	▪ 27/09/2007 ▪ 23/11/2007	P/1/2008 01/02/2008

Annex 16 Guidelines and working documents in 2008

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 2008	Number of concept papers/ guidelines/ documents in progress during 2008	Number of guidelines/ documents adopted during 2008
CHMP Biologics Working Party	57	15	31	13
CHMP Blood Products Working Party	26	3	7	0
CHMP Efficacy Working Party	227	52	63	33
CHMP Gene Therapy Working Party	6	0	8	2
CHMP Pharmacogenomics Working Party	10	4	5	3
CHMP Pharmacovigilance Working Party	25	2	0	17
CHMP Safety Working Party	44	8	15	9
CHMP Scientific Advice Working Party	1	1	1	0
CHMP Similar Biological (Biosimilar) Medicinal Products Working Party	19	1	2	0
CHMP Vaccine Working Party	13	1	5	2
CHMP Working Party on Cell-based Products	3	0	1	1
CHMP Invented Name Review Group	0	1	1	0
EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	9	3	2	4
EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)	3	2	3	0
CHMP Ad-Hoc SmPC Group	1	0	1	1

CHMP guidelines

Working Party/Group	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
CHMP Biologics Working Party	Technical requirements for ATMP (revision of annex I with CPWP and GTWP)
CHMP Efficacy Working Party	Ulcerative colitis (guideline) Medicinal products for the treatment of smoking (guideline) Medicinal products for the treatment of cystic fibrosis (guideline) Medicinal products for the treatment of attention deficit hyperactivity disorder (guideline) Medicinal Products for the treatment of pulmonary arterial hypertension (guideline)
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

Working Party/Group	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
	(guideline) Medicinal products containing genetically modified cells (guideline) Recombinant adeno-associated viral vectors (reflection paper)
CHMP Pharmacovigilance Working Party	Volume 9A Version 2008: Ch I.3 on Risk Management Plans, Ch I.4, I.5 and II.1 regarding biological products inc vaccines Revision 2008 of Volume 9A: Ch 1.7 on Post-Authorisation Safety Studies and various Chapters with clarifications for electronic reporting CHMP Guideline on the Conduct of Pharmacovigilance for Vaccines for Pre- and Post-Exposure Prophylaxis against Infectious Diseases ICH-E2F on Development Safety Update Reports
CHMP Similar Biological (Biosimilar) Medicinal Products Working Party	Epoetins (guideline) Immunogenicity of monoclonal antibodies (annex to guideline)
CHMP Vaccine Working Party	Dossier structure and content for pandemic influenza marketing authorisation application (guideline) Core risk management plan for influenza vaccines prepared from viruses with the potential to cause a pandemic and intended for use outside of the core dossier context (recommendations)
CHMP Working Party on Cell-based Products	Human cell-based medicinal products (guideline)
CHMP Invented Name Review Group	Criteria for NRG objections based on potential risk to confusion with names of suspended or withdrawn/revoked Marketing Authorisations (MA)
EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	Report on the progress of the interaction with Patients' and Consumers' Organisations and analysis of the degree of satisfaction of patients/consumers involved in EMEA activities during 2007 Communication on benefit and risks: patients, consumers and healthcare professionals' expectations Revision of procedure for review of information on products by patients'/consumers' organisations Rules of involvement of members of patients' consumers' and healthcare professionals' organisations in committee-related activities
EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG)	- HCP WG Recommendations and Proposals for Action: Draft released for consultation in June 2008 -Communication on benefit and risks: patients, consumers and healthcare professionals' expectations -Rules of involvement of members of patients' consumers' and healthcare professionals' organisations in committee-related activities
CHMP Ad-Hoc SmPC Group	Proposed revision of the guideline on Summary of Product Characteristics.
Working Party/Group	**Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest**
CHMP Biologics Working Party	Technical requirements for ATMP (revision of annex I with CPWP and GTWP)
CHMP Efficacy Working Party	Ulcerative colitis (guideline) Medicinal products for the treatment of smoking (guideline) Medicinal products for the treatment of cystic fibrosis (guideline) Medicinal products for the treatment of attention deficit hyperactivity disorder (guideline) Medicinal Products for the treatment of pulmonary arterial hypertension (guideline)

Committee for Medicinal Products fro Veterinary Use (CVMP)

CVMP Efficacy Working Party (EWP-V)

Reference number	Document title	Status
EMEA/CVMP/VICH/393388/2006	VICH guideline: GL43 on Target Animal Safety for Pharmaceuticals	Adopted, September 2008

CVMP Immunologicals Working Party (IWP)

Reference number	Document title	Status
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, March 2008 (This guideline has been updated following comments received from IFAH Europe)
EMEA/CVMP/IWP/105504/2007-CONSULTATION	Guideline on the requirements for the replacement of established master seeds (MS) already used in authorised immunological veterinary medicinal products (IVMPs)	Adopted for consultation, March 2008 (End of consultation: September 2008)
EMEA/CVMP/IWP/37267/2008	Concept paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue	Adopted, June 2008
EMEA/CVMP/IWP/123243/2006-Rev.1	Guideline on data requirements for IVMPs intended for minor use or minor species/limited markets	Adopted for consultation (following minor revision), July 2008 (End of consultation: October 2008)
EMEA/CVMP/439633/2007	Clarification note on the requirements for starting materials of biological origin	Adopted, September 2008
EMEA/CVMP/VICH/359665/2005	VICH guideline: GL44 on Target Animal Safety for Veterinary Live and Inactivated Vaccines	Adopted, September 2008
EMEA/CVMP/IWP/220193/2008	Guideline on requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue	Adopted, November 2008

Joint CHMP/CVMP Quality Working Party (QWP)

Reference number	Document title	Status
EMEA/CHMP/CVMP/QWP/28271/2008 – CONSULTATION	Reflection paper on the acceptability of water for injections prepared by reverse osmosis	Adopted for consultation, February 2008
EMEA/CVMP/VICH/581467/2007-CONSULTATION	VICH guideline (GL45) on Quality: Bracketing and Matrixing Designs for Stability Testing of new Veterinary Drug Substances and Medicinal Products	Adopted for consultation, February 2008 (End of consultaion: August 2008)
EMEA/HMPC/CHMP/CVMP/214869/2006	Guideline on the Quality of Combination Herbal Medicinal Products / Traditional Herbal Medicinal Products	Adopted, March 2008

EMEA/CHMP/CVMP/QWP/139037/2008	Question and Answer document on process validation and other quality data requirements	Adopted, June 2008
EMEA/CHMP/CVMP/QWP/136351/2008-CONSULTATION	Concept Paper on the development of a guideline on setting specifications for related impurities in antibiotics	Adopted for consultation, June 2008 (End of consultation: September 2008)
EMEA/CVMP/QWP/846/99-Rev.1	Guideline on Stability Testing: Stability testing of existing active substances and related finished products	Adopted, July 2008
▪ EMEA/CHMP/CVMP/QWP/321287/2008 ▪ EMEA/CHMP/CVMP/QWP/321422/2008 ▪ EMEA/CHMP/CVMP/QWP/321388/2008	Question and Answer documents on: ▪ Glycerol (glycerin) contamination ▪ The harmonised Ph.Eur. General chapter: Uniformity of dosage units (2.9.40) ▪ The calculation of expiry dates	Adopted, July 2008
EMEA/HMPC/CHMP/CVMP/287539/2005-Rev.1	Revised guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products	Adopted for consultation, October 2008 (End of consultation: January 2009)

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference number	Document title	Status
EMEA/CVMP/PhVWP/72829/2007	EMEA public bulletin 2007 on veterinary pharmacovigilance	Adopted, February 2008
EMEA/CVMP/VICH/547/00	VICH guideline (GL24) on Management of Adverse Event Reports	Adopted, March 2008
▪ EMEA/CVMP/413/99-Rev.5 ▪ EMEA/CVMP/891/04-Rev.3 ▪ EMEA/CVMP/553/03-Rev.3	Standard lists used for electronic reporting of suspected adverse reactions: ▪ VEDDRA list of clinical terms for adverse reactions in animals ▪ VEDDRA list of clinical terms for adverse reactions in humans ▪ List of species and breeds	Adopted, July 2008
EMEA/123353/2004-Rev.3	Revised Call for Comments on Standard Lists for EudraVigilance Veterinary	Adopted, July 2008
EMEA/CVMP/PhVWP/288284/2007	Use of VeDDRA Terminology for Reporting Suspected Adverse Reactions in Animals	Adopted, July 2008
EMEA/CVMP/PhVWP/4550/2006	Recommendation on management and assessment of Periodic Safety Update Reports (PSURs) of veterinary medicinal products	Adopted, October 2008

CVMP Safety Working Party (SWP-V)

Reference number	Document title	Status
EMEA/CVMP/27466/2008	Report of the Focus group meeting on user safety guideline	Adopted, March 2008
EMEA/CVMP/SWP/173804/2008-CONSULTATION	Concept paper for the revision of the Guideline on User Safety	Adopted for consultation, April 2008. (End of consultation: May 2008)

EMEA/CVMP/520190/2007-CONSULTATION	Reflection paper on injection site residues: Considerations for risk assessment and residue surveillance	Adopted for consultation, June 2008 (End of consultation: September 2008
EMEA/CVMP/SWP/138366/2008	Reflection paper on the new approach developed by JECFA for exposure and MRL assessment of residues of VMP	Endorsed, June 2008, Revision (inserting an introductory note) endorsed, September 2008
EMEA/CVMP/SWP/95682/2007	Reflection paper on assessment of bioavailability of bound residues in food commodities of animal origin	Adopted, September 2008

CVMP Environmental Risk Assessment Working Party (ERAWP)

Reference number	Document title	Status
EMEA/CVMP/ERA/418282/2005-Rev.1	Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH Guidelines GL6 (Phase I) and GL38 (Phase II)	Adopted, November 2008

CVMP Scientific Advisory Group on Antimicrobials (SAGAM)

Reference number	Document title	Status
EMEA/CVMP/SAGAM/428938/2007	Reflection paper on antimicrobials resistance surveillance as post-marketing authorisation commitment	Adopted, October 2008
EMEA/CVMP/SAGAM/81730/2006-CONSULTATION	Reflection paper on the use of 3rd and 4th generation cephalosporins in food-producing animals in the European Union: development of resistance and impact on human and animal health	Adopted for consultation, February 2008. (End of consultation: August 2008)

CVMP General

Reference number	Document title	Status
EMEA/CVMP/28510/2008-CONSULTATION	Guideline on Dossier Requirements for Anticancer Medicinal Products for Dogs and Cats	Adopted for consultation, January 2008. (End of consultation: July 2008)
EMEA/328/98-Rev.3	Guidline on the acceptability of names for veterinary medicinal products processed through the centralised procedure	Adopted, January 2008
EMEA/410/01-Rev.4	Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products	Adopted, February 2008
EMEA/CVMP/182112/2006	CVMP Reflection Paper regarding the assessment of environmental risks of veterinary medicinal products	Adopted for consultation, March 2008 (End of consultation: June 2008)
EMEA/CVMP/430630/2006 – Rev.1	Reflection paper on Criteria for requiring one additional five-year renewal on pharmacovigilance grounds	Adopted, May 2008 (to become part of Volume 9B, which will be published for consultation shortly)

EMEA/CVMP/PhVWP/430286/2007	Volume 9B of the Rules Governing Medicinal Products in the European Union - Pharmacovigilance for Veterinary Medicinal products	Adopted, September 2008 (for submission to the European Commission)
EMEA/CVMP/248499/2007	Recommendation on the evaluation of the benefit-risk balance of veterinary medicinal products	Adopted for second consultation, October 2008 (End of consultation: January 2009)

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 2008	Number of concept papers/ guidelines/ documents in progress during 2008	Number of guidelines/ documents adopted in 2008
Committee for Orphan Medicinal Products	5	0	1	1

Scientific Committee	Subject of concept papers/guidelines/documents of significant scientific/therapeutic interest
Committee for Orphan Medicinal Products	Elements required to support the medical plausibility and the assumption of significant benefit for orphan medicinal product designation (recommendation)

Committee on Herbal Medicinal Products (HMPC) *

Reference number	Document title	Status
EMEA/HMPC/439705/2006 Rev.3	Template for a Community list entry	Revision adopted March 2008
EMEA/HMPC/107436/2005 Rev.3	Template for a Community herbal monograph	Revision adopted March 2008
EMEA/HMPC/99116/2007	Reflection paper on the adaptogenic concept	Adopted May 2008
EMEA/HMPC/107079/2007	Guideline on the assessment of genotoxicity of herbal substances/preparations	Adopted May 2008
EMEA/HMPC/315413/2008	Concept paper on selection of test materials for genotoxicity testing for traditional herbal medicinal products/herbal medicinal products'	Released for public consultation July 2008
EMEA/HMPC/410043/2008	Mandate, objectives and composition for the HMPC quality drafting group (Q DG)	Adopted September 2008
EMEA/HMPC/451978/2008	Concept paper on the development of a guideline on preparation of herbal teas	Released for public consultation September 2008
EMEA/HMPC/574496/2008	Recommended format for list of references supporting HMPC assessment report	Adopted November 2008
EMEA/HMPC/139800/2004 Rev.2	Committee on Herbal Medicinal Products: Rules of Procedure	Revision adopted November 2008
EMEA/HMPC/85114/2008	Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products used in children	Released for public consultation November 2008

* 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/253629/2007	Reflection paper on markers used for quantitative and qualitative analysis of herbal medicinal products and traditional herbal medicinal products	Released for public consultation January 2008 Adopted July 2008
EMEA/HMPC/CHMP/ CVMP/214869/2006	Guideline on quality of combination herbal medicinal products/traditional herbal medicinal products	Adopted by HMPC January 2008
EMEA/HMPC/CHMP/ CVMP/287539/2005 Rev. 1	Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products	Revision adopted by HMPC July 2008 for release for public consultation
EMEA/HMPC/186645/2008	Reflection paper on level of purification of extracts to be considered as herbal preparations	Released for public consultation November 2008
EMEA/HMPC/531300/2008	Questions & answers on quality issues emerging for herbal medicinal products'	Adopted November 2008

HMPC Organisational Matters Drafting Group

Reference number	Document title	Status
EMEA/HMPC/71049/2007	Guideline on the use of the CTD format in the preparation of a registration application for traditional herbal medicinal products	Adopted January 2008
EMEA/HMPC/326440/2007	Reflection paper on the reasons and timelines for revision of final Community herbal monographs and Community list entries	Released for public consultation March 2008 Adopted September 2008
EMEA/HMPC/328575/2007	Procedure on management of proposals submitted by interested parties for Community list entries or Community herbal monographs	Adopted May 2008
EMEA/HMPC/418902/2005 Rev.1	Assessment report template for the development of Community monographs and for inclusion of herbal substance(s), preparation(s) or combinations thereof in the List	Revision adopted November 2008

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	Public consultation conducted and completed
EMEA/226983/2008	Priority list for studies into off-patent paediatric medicinal products	Updated for call for expressions of interest

Annex 17 Arbitration and Community referrals overview 2008

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	24.01.2008	ribavirin
Article 29(4) of Directive 2001/83/EC	21.02.2008	amlodipine besylate, lisinopril dihydrate
Article 29(4) of Directive 2001/83/EC	19.03.2008	salbutamol
Article 29(4) of Directive 2001/83/EC	19.03.2008	stradiol/norethisterone acetate
Article 29(4) of Directive 2001/83/EC	30.05.2008	salbutamol sulphate
Article 29(4) of Directive 2001/83/EC	25.09.2008	budesonide
Article 29(4) of Directive 2001/83/EC	25.09.2008	loratadine
Article 29(4) of Directive 2001/83/EC	25.09.2008	itraconazole
Article 29(4) of Directive 2001/83/EC	23.10.2008	moxifloxacin hydrochloride
Article 29(4) of Directive 2001/83/EC	23.10.2008	teicoplanin
Article 29(4) of Directive 2001/83/EC	20.11.2008	human hepatitis B immunoglobulins
Article 29(4) of Directive 2001/83/EC	20.11.2008	betahistine dihydrochloride
Article 29(4) of Directive 2001/83/EC	20.11.2008	bleomycine sulphate
Article 29(4) of Directive 2001/83/EC	18.12.2008	ciclosporin
Article 30 of Directive 2001/83/EC	24.01.2008	ramipril
Article 30 of Directive 2001/83/EC	24.01.2008	ramipril and hydrochlorothiazide
Article 30 of Directive 2001/83/EC Article 30 of Directive 2001/83/EC	21.02.2008	amoxicilin / clavulanic acid
Article 30 of Directive 2001/83/EC Article 30 of Directive 2001/83/EC Article 30 of Directive 2001/83/EC Article 30 of Directive 2001/83/EC	26.06.2008	valsartan
Article 30 of Directive 2001/83/EC	30.05.2008	topiramate
Article 30 of Directive 2001/83/EC	18.11.2008	valsartan
Article 30 of Directive 2001/83/EC	24.07.2008	omeprazole
Article 30 of Directive 2001/83/EC	25.09.2008	pantoprazole
Article 30 of Directive 2001/83/EC	23.10.2008	meropenem
Article 30 of Directive 2001/83/EC	20.11.2008	valaciclovir
Article 30 of Directive 2001/83/EC	18.12.2008	famciclovir
Article 31 of Directive 2001/83/EC	24.01.2008	dextropropoxyphene and paracetamol
Article 31 of Directive 2001/83/EC	20.11.2008	gadolinium-containing contrast agents
Article 107 of Directive 2001/83/EC	26.06.2008	moxifloxacin
Article 20 of Council Regulation (EC) No 726/2004	20.11.2008	gadoversetamide
Article 20 of Council Regulation (EC) No 726/2004	20.11.2008	gadofosveset
Article 107 of Directive 2001/83/EC	24.07.2008	moxifloxacin

Procedures finalised

Type of referral	Date of CHMP opinion	International non-proprietary name (INN)
Article 29(4) of Directive 2001/83/EC	21.02.2008	nimesulide
Article 29(4) of Directive 2001/83/EC	21.02.2008	formoterol fumarate
Article 29(4) of Directive 2001/83/EC	19.03.2008	ciclesonide
Article 29(4) of Directive 2001/83/EC	19.03.2008	budesonide
Article 29(4) of Directive 2001/83/EC	19.03.2008	moxifloxacin
Article 29(4) of Directive 2001/83/EC	26.06.2008	stradiol/norethisterone acetate

Type of referral	Date of CHMP opinion	International non-proprietary name (INN)
Article 29(4) of Directive 2001/83/EC	26.06.2008	fentanyl citrate
Article 29(4) of Directive 2001/83/EC	24.07.2008	amlodipine besylate, lisinopril dihydrate
Article 29(4) of Directive 2001/83/EC	24.07.2008	ribavirin
Article 29(4) of Directive 2001/83/EC	20.11.2008	etonogestrel
Article 29(4) of Directive 2001/83/EC	18.12.2008	salbutamol sulphate
Article 29(4) of Directive 2001/83/EC	18.12.2008	bleomycin
Article 29(4) of Directive 2001/83/EC	18.12.2008	human hepatitis B immunoglobulin
Article 30 of Directive 2001/83/EC	24.04.2008	losartan potassium
Article 30 of Directive 2001/83/EC	24.04.2008	losartan potassium/hydrochlorothiazide
Article 30 of Directive 2001/83/EC	24.04.2008	lamotrigin
Article 30 of Directive 2001/83/EC	24.04.2008	montelukast sodium
Article 30 of Directive 2001/83/EC	30.05.2008	cetirizine
Article 30 of Directive 2001/83/EC	26.06.2008	gemcitabine HCI
Article 30 of Directive 2001/83/EC	26.06.2008	mirtazapine
Article 30 of Directive 2001/83/EC	24.07.2008	ciprofloxacin
Article 30 of Directive 2001/83/EC	24.072008	venlafaxine
Article 30 of Directive 2001/83/EC	24.07.2008	risperidone
Article 30 of Directive 2001/83/EC	20.11.2008	valsartan
Article 30 of Directive 2001/83/EC	18.12.2008	ramipril
Article 30 of Directive 2001/83/EC	18.12.2008	ramipril and hydrochlorothiazide
Article 30 of Directive 2001/83/EC	18.12.2008	sertraline
Article 31 of Directive 2001/83/EC	24.07.2008	norfloxacin
Article 31 of Directive 2001/83/EC	26.06.2008	bromocriptine /cabergoline/ dihydroergotamine/lisuride / pergolide
Article 31 of Directive 2001/83/EC	26.06.2008	etoricoxib
Article 6(12) Of Commission Regulation (EC) N. 1084/2003	19.03.2008	moxifloxacin
Article 6(12) Of Commission Regulation (EC) N. 1084/2003	26.06.2008	etoricoxib

Referrals made to the CVMP

Procedures started

Type of referral	Date of CVMP start of procedure	INN
Article 33(4) of Directive 2001/82/EC	16/01/2008	Heparin sodium, levomenthol, hydroxyethyl salicylate
Article 33(4) of Directive 2001/82/EC	13/05/2008	Enrofloxacin
Article 33(4) of Directive 2001/82/EC	13/05/2008	Enrofloxacin
Article 33(4) of Directive 2001/82/EC	13/05/2008	Tylosine tartrate
Article 33(4) of Directive 2001/82/EC	16/09/2008	Amoxicillin and clavulanic acid
Article 33(4) of Directive 2001/82/EC	16/09/2008	Florfenicol
Article 33(4) of Directive 2001/82/EC	16/09/2008	Florfenicol
Article 33(4) of Directive 2001/82/EC	15/10/2008	Strains of Actinobacillus pleuropneumoniae
Article 33(4) of Directive 2001/82/EC	12/11/2008	Tiludronic acid (as disodium salt)
Article 34(1) Directive 2001/82/EC	16/07/2008	Tilmicosin
Article 34(1) Directive 2001/82/EC	16/09/2008	Tilmicosin
Article 34(1) Directive 2001/82/EC	15/10/2008	Tiamutin Fumarate
Article 35 of Directive 2001/82/EC	16/01/2008	Ivermectin

Procedures finalised

Type of referral	Date of CVMP opinion	INN
Article 33(4) of Directive 2001/82/EC	13/02/2008	Heparin sodium, levomenthol, hydroxyethyl salicylate
Article 33(4) of Directive 2001/82/EC	12/12/2008	Tylosine tartrate
Article 33(4) of Directive 2001/82/EC	13/02/2008	Sodium salicylate
Article 35 of Directive 2001/82/EC	15/04/2008 (follow up opinion) 19/06/2008	Amoxicillin

Annex 18 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) 7418 8569 E-mail: pharmacovigilance@emea.europa.eu
For matters relating to pharmacovigilance for medicinal products for veterinary use:	**Fia WESTERHOLM** Direct telephone: (44-20) 7418 8581 E-mail: vet-phv@emea.europa.eu
For product defect and other quality-related matters:	Website: http://www.emea.europa.eu/Inspections/Defectinstruction.html E-mail: qualitydefects@emea.europa.eu Direct telephone: (44-20) 7523 7676 Fax: (44-20) 7418 8590 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) 7418 8575/8463 Fax: (44-20) 7523 7040 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:	Direct telephone: (44-20) 7523 7107 Fax: (44-20) 7418 8595 E-mail: certificate@emea.europa.eu

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) 7418 8552
Fax: (44-20) 7418 8545
E-mail: PMF@emea.europa.eu

For enquiries concerning VAMF certificates:

Ragini SHIVJI
Direct telephone: (44-20) 7418 8698
Fax: (44-20) 7418 8545
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:

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) 7418 8670

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

Press office

Press officers:

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