



European Medicines Agency

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Annual report of the European Medicines Agency 2005

Adopted by the Management Board on 9 March 2006

The annual report for 2005 is presented to the Management Board by the Executive Director in accordance with Article 64(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. It is forwarded to the European Parliament, Council, Commission and Member States. A 'Summary of the annual report of the European Medicines Agency 2005' will be made available in all official EU languages.

In accordance with the EMEA Financial Regulation, the Agency is required to publish an analysis and assessment of the authorising officer's annual activity report together with its annual report. The Agency will publish the required analysis and assessment for 2005 on its website once it has been adopted by the Management Board.

Previous annual reports and other reference documents are available from the EMEA website:

www.emea.eu.int

This report covers activities of the EMEA in 2005. Chapter 1 sets out the activities of the EMEA within the European system. It includes the work of the Agency's Management Board, its partnership with national competent authorities and European institutions, and other general aspects of the EMEA, including transparency and the Agency's international activities.

The operational and technical work of the EMEA is reported in Chapter 2 on medicines for human use, Chapter 3 on veterinary medicines and Chapter 4 on inspection activities. Implementation of the EU telematics strategy, administration and other support activities are described in Chapters 5 and 6.

The report also summarises the operation of the decentralised (mutual recognition) procedure in accordance with Article 38(1) of Council Directive 2001/83/EC on the Community code relating to medicinal products for human use as amended by Directive 2004/27/EC and Article 42(1) of Council Directive 2001/82/EC as amended by Directive 2004/28/EC.

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EMEA MISSION STATEMENT

The EMEA's Mission Statement is, in the context of a continuing globalisation, to protect and promote public and animal health by

developing efficient and transparent procedures to allow rapid access by users to safe and effective innovative medicines and to generic and non-prescription medicines through a single European marketing authorisation,

controlling the safety of medicines for humans and animals, in particular through a pharmacovigilance network and the establishment of safe limits for residues in food-producing animals,

facilitating innovation and stimulating research, hence contributing to the competitiveness of EU-based pharmaceutical industry, and

mobilising and coordinating scientific resources from throughout the EU to provide high-quality evaluation of medicinal products, to advise on research and development programmes, to perform inspections for ensuring fundamental GxP¹ provisions are consistently achieved, and to provide useful and clear information to users and healthcare professionals.

Routes for authorisation of medicinal products in the European system:

- The centralised procedure is compulsory for all medicinal products for human and animal use derived from biotechnology processes. The same applies to all human medicines intended for the treatment of HIV/AIDS, cancer, diabetes, neurodegenerative disorders and for all designated orphan medicines intended for the treatment of rare diseases. Similarly, all veterinary medicines intended for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals have to go through the centralised procedure. For medicinal products that do not fall under any of the above-mentioned categories companies can submit an application for a centralised marketing authorisation to the EMEA, provided the medicinal product constitutes a significant therapeutic, scientific or technical innovation or the product is in any other respect in the interest of patient or animal health.

Applications are submitted directly to the EMEA. At the conclusion of the scientific evaluation, undertaken in 210 days within the Agency, the opinion of the scientific committee is transmitted to the European Commission to be transformed into a single market authorisation valid throughout the whole European Union.

- The decentralised procedure and the mutual recognition procedure apply to the majority of conventional medicinal products. Both procedures are based upon the principle of recognition of national authorisations. They provides for the extension of marketing authorisations granted by one Member State to one or more other Member States identified by the applicant. Where the original national authorisation cannot be recognised, the points in dispute are submitted to the EMEA for arbitration. The opinion of the scientific committee is transmitted to the European Commission.

The European Commission adopts its decision with the assistance of a standing committee composed of representatives of the Member States.

¹ GXP means 'good clinical practice' (GCP), 'good manufacturing practice' (GMP) and 'good laboratory practice' (GLP) collectively.

FOREWORD BY THE CHAIRMAN OF THE MANAGEMENT BOARD

Professor Hannes Wahlroos

The 11th year of operation of the European Medicines Agency (EMA) was eventful. The reform of EU pharmaceutical legislation, implementation of the EMA's Road Map to 2010 and dealing with pharmacovigilance issues required alertness, steadfastness and commitment to the important task of promoting public health.

The results presented in this Annual Report prove that the EMA ably faced up to its many challenges in 2005. On behalf of the Management Board, therefore, I would like to thank the personnel of the EMA for their important input in promoting European regulation in the field of pharmaceuticals. I would also like to thank the secretariat of the Management Board for their constructive and outstanding collaboration throughout the year. In addition, I would like to thank the Member States' competent authorities, which, together with the EMA, form the core regulatory network for medicinal products. This close-knit network has been strengthened in recent years. In years to come, the EMA will need further top-quality expertise and will be increasingly reliant on the Member States and their authorities to offer this.

Ultimate responsibility for the Agency's operational work rests with the Executive Director. Thomas Lönngren was unanimously appointed by the Management Board to serve in this demanding post for another five-year period, from 2006 to 2010. It is a pleasure for me, at this point, to congratulate him and wish him every success in his further term of office.

On behalf of the Management Board, I would like to emphasise a couple of events that took place last year. An important step forward was made in improving the usability of data relating to the safety of medicines. By the end of the year, the majority of the Member States' authorities were submitting their adverse drug reaction reports electronically to the Agency. This development will greatly enhance the ability of the EMA to evaluate the safety of medicines.

The membership of the Management Board finally reached its full complement during the year under review, as new representatives of patients' organisations and doctors' and veterinarians' associations appointed by the Council of Ministers joined in the work. I am confident that, as a result, the broadened outlook of the Management Board will have a favourable impact on our work.

The EMA will assume an active role in precautionary measures against pandemic influenza. The measures already taken to expedite the assessment procedures for vaccines and conventional medicines have been welcomed and are necessary. The information updates published on the EMA website relating to these issues have been acclaimed as extremely useful.

The Management Board has been closely following the progress of the European innovation and technology platform, especially in the area of veterinary medicines. The Agency is involved in the steering group of the platform, and there are therefore good opportunities to influence and improve the development and availability of veterinary medicines.

At the end of 2005, the European Commission set up the Pharmaceutical Forum, a discussion platform for topics like pricing and reimbursement of medicines, relative effectiveness of medicinal products and drug information in Europe. The EMA will be involved in the issues of relative effectiveness and provision of information to patients.

The Year 2005 was a very promising beginning for the second decade of the EMA.

INTRODUCTION BY THE EXECUTIVE DIRECTOR

Thomas Lönngren

As anticipated, 2005 was quite an extraordinary year for the European Medicines Agency.

It began with celebrations to mark an important milestone in the history of the EMEA: its tenth anniversary. The generous birthday tributes paid to the Agency by so many of its partners and stakeholders were a welcome endorsement of its efforts to maintain and further develop an effective regulatory environment for medicines in the EU.

Now, with a decade of very solid progress behind it, and a good long-term plan in place to guide its forward evolution, the Agency is in better shape than ever to pursue its mission for the protection and promotion of health in Europe.

Those ten years of continuous growth and consolidation gave the Agency the experience and confidence it needed to meet the greatest challenge it has had to face so far: the full entry into force of the revised EU pharmaceutical legislation, in November 2005.

Thanks to the excellent planning and preparations put in place during the run-up to that date, the Agency was able to successfully implement all relevant provisions and guidelines stemming from the new legislation.

As a result, the Agency was immediately able to embrace its new responsibilities and begin offering an extended range of services in support of European efforts to bring innovative new medicines to the market. Achievements of particular note include:

- the successful launch of the Agency's SME Office, which provides specific assistance to the smaller companies that are so often at the cutting edge of medicinal technologies development;
- the implementation of procedures for greater (and in some cases free) provision of early-stage scientific advice to companies developing 'breakthrough' medicines;
- the introduction of new measures to accelerate the assessment of medicines that are of critical importance to public health.

While the Agency devoted great energy in 2005 to setting up these and other initiatives under its extended mandate, it also focused on improving its core scientific activities, particularly in the area of pharmacovigilance, which resulted in more efficient and effective practices for safeguarding the quality, safety and efficacy of authorised medicinal products.

Improvements to scientific and other business practices helped the Agency to deliver very good performance results for the year. The overall volume of pre- and post-authorisation applications received was high, but the Agency was able to handle its tasks successfully. The Agency also made significant contributions to wider European public-health activities, most notably with regard to pandemic-influenza preparedness, and the preparation of new legislation on medicines for children and advanced therapies.

All of these achievements in 2005 would not have been possible without the dedicated cooperation and support the Agency received from the European Parliament, the European Commission, the national medicines authorities and all of the Agency's partners throughout Europe, all of whom I thank for their invaluable help. I am particularly grateful for the excellent participation of our partners from the new Member States, in what was the first full year of operation in a European Union of 25 nations.

Lastly, I extend my wholehearted thanks to all EMEA staff, whose tireless efforts throughout this challenging year resulted in such a positive outcome for the Agency. I know I can rely on your continuing commitment as we bring the EMEA forward into its second decade.

1 EMEA IN THE EUROPEAN SYSTEM

1.1 EMEA – celebrating 10 years

The European Medicines Agency began the year 2005 with celebrations to mark its 10th anniversary, the highlight of which was a scientific conference held in London, in March. Approval for the Agency's achievements during its first ten years was expressed in speeches from European Parliament Vice-President Dagmar Roth-Behrendt, Luxembourg's Health Minister Mars Di Bartolomeo (representing the Council Presidency) and European Commission Vice-President Günter Verheugen, among other distinguished invitees.

A history of the Agency's creation and evolution was recounted in a commemorative book published for the occasion, 'Celebrating Ten Years – Portrait of the European Medicines Agency'.

Besides this symbolic milestone, 2005 was a defining year for the Agency in two other respects: it was the first full year of operation within the European Union of 25 Member States; and it saw the full entry into force of the revised EU pharmaceutical legislation.

A contributing element to the EMEA's good state of preparedness in 2005 was the establishment of its 'Road Map to 2010' long-term strategy. This should help to ensure that the Agency, together with its partners in the EU medicines network, will be equally prepared to face the challenges of the foreseeable future.

1.2 Implementation of the revised legislation

On 20 November 2005, the Agency welcomed the full entry into force of Regulation (EC) No 726/2004², which heralds a more robust, modern and effective regulatory framework for pharmaceuticals in Europe. The new legal basis puts the Agency in a stronger position to fulfil its public and animal health mandate. It enables the Agency to strike the right balance between encouraging research and development of new medicines and strengthening their surveillance, giving patients access to much-needed new, safe and innovative medicines.

The Regulation also gives the EMEA important new responsibilities, in particular for the provision of better information about medicines to patients, consumers and healthcare professionals, and for strengthening the provision of scientific advice to companies. It significantly extends the scope of the centralised procedure for medicines for human use, giving the Agency responsibility for the evaluation and supervision of:

- Biotechnology medicines
- New medicines for the treatment of HIV/AIDS
- New medicines for the treatment of cancer
- New medicines for the treatment of diabetes
- New medicines for the treatment of neurodegenerative disorders
- Designated orphan medicinal products.

The scope of medicines for which the centralised procedure is optional has been broadened to allow for certain circumstances of expected benefit to public health, and now also includes self-medication products and generic medicines.

² OJ L 136, 30.04.2004, p. 1.
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In the area of veterinary medicines, the Agency is responsible for all medicinal products derived from biotechnology or intended primarily for use as performance enhancers to promote growth of or to increase yield from treated animals. The centralised procedure is optional for immunological veterinary medicines for animal diseases that are subject to Community prophylactic measures.

The Regulation introduces, under specific conditions, new accelerated assessment and conditional-marketing authorisation procedures, which help to ensure that patients have timely access to innovative medicines. At the same time, it provides new tools for strengthened protection of public health. These include risk-management plans, the collection of specific pharmacovigilance data from targeted groups of patients, and new possibilities for pharmacovigilance inspections and inspection of active substances.

A new fee regulation came into force by the end of 2005. It modified the Agency's fee rules to take into account the new marketing authorisation procedures and other new provisions of the revised legislation.

During 2005, the Agency provided guidance in preparation for the entry into force of the revised legislation. This included drawing up guidelines for the new procedures, as well as contributing to the update of existing guidance documents, for both human and veterinary medicines, such as the good manufacturing practice (GMP) guide and the Notice to Applicants.

The successful implementation of the new pharmaceutical legislation was thanks to the joint efforts of the EMEA, its scientific committees and their working parties, the national competent authorities and the European Commission, as well as interested parties, who provided valuable feedback during the public consultation on guidelines and procedures.

1.3 Implementation of the Road Map

In the beginning of 2005, the Agency published its long-term strategy, the 'European Medicines Agency Road Map to 2010: Preparing the Ground for the Future'. The strategy aims to contribute to better protection and promotion of public and animal health, to improve the regulatory environment for medicinal products, and to stimulate innovation, research and development in the EU.

Road Map actions implemented during 2005 included:

- Strengthening the quality-assurance system of scientific assessments: The Committee for Medicinal Products for Human Use (CHMP) adopted a procedure for pilot peer reviews during the initial assessment phase of marketing authorisation applications. In addition, the Agency prepared for the introduction of an internal peer-review process to improve scientific consistency in the provision of scientific advice and protocol assistance.
- Supporting applicants in the development of new therapeutic approaches and technologies: A pilot procedure was established to facilitate the evaluation of whether emerging approaches can be considered as medicinal products and thus have access to the centralised procedure. A 'think tank' group was established to consider innovative methods for drug development and to assess hurdles that may be encountered by pharmaceutical companies researching or developing such methods.
- Strengthening the Agency's interaction with European industry associations representing the innovative, generic and self-medication industries: Contacts with industry associations were maintained through the organisation of, and participation in, meetings, information days and conferences.
- Strengthening interaction with the Agency's stakeholders: Following the publication in early 2005 of final recommendations from the EMEA/CHMP Working Group with Patients' and Consumers' Organisations, the Agency started implementation of a first set of recommendations relating to: transparency and dissemination of information; product information; pharmacovigilance; and interaction between the Agency and patients' organisations.

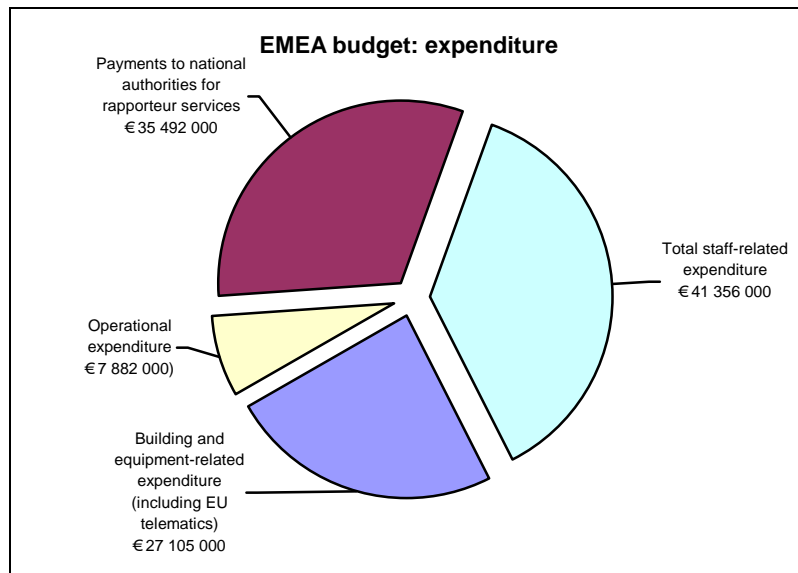
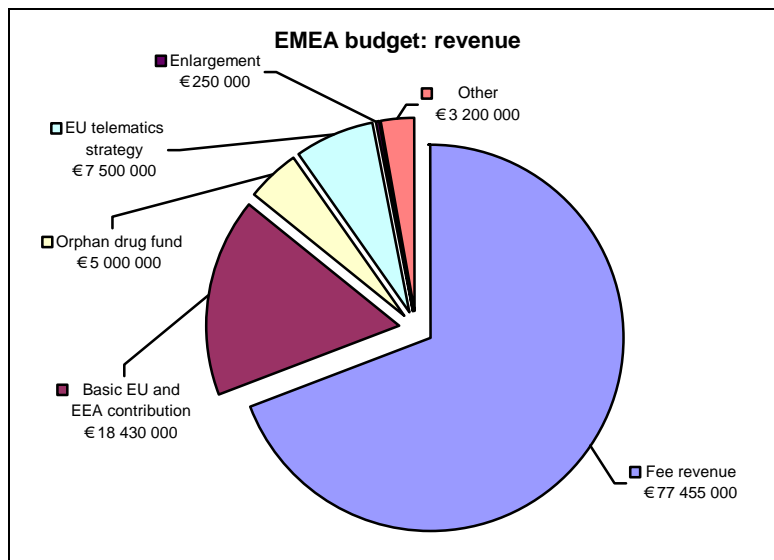
- Developing a European Risk Management Strategy (ERMS) for safer medicines: The EMEA Risk Management Strategy was further developed with national competent authorities in the context of the ERMS. An action plan to further progress the ERMS and a rolling 2-year work plan were agreed upon and published in 2005.
- Addressing antimicrobial resistance: The Committee for Medicinal Products for Veterinary Use (CVMP) made good progress on developing a new strategy on risk management and risk assessment for antimicrobials. The focus of the strategy will be on risk assessment for new antimicrobials, promotion of prudent use of antimicrobials through adequate guidance in the product literature, and support to international activities in this field, e.g. by the World Health Organization (WHO), the World Organisation for Animal Health (OIE) or the Codex Alimentarius. From the beginning of 2005 onwards, the Committee's Scientific Advisory Group on Antimicrobials (SAGAM) was systematically involved in the risk assessment of centralised marketing authorisation applications for new antimicrobials.
- Ensuring adequacy of environmental risk assessment: The CVMP and its Environmental Risk Assessment Working Party (ERAWP) developed guidance to help applicants prepare the environmental risk assessment part of marketing authorisation applications. A full environmental risk assessment for all veterinary marketing authorisation applications is a new legal requirement.

1.4 Management Board

The EMEA Management Board met four times in 2005, under chairman Hannes Wahlroos, from Finland, and vice-chairman Jytte Lyngvig, from Denmark. The full composition is provided in Annex 1.

In 2005, the Management Board:

- Welcomed two representatives of patients', one representative of doctors' and one representative for veterinarians' organisations as members of the Board
- Welcomed observers from Bulgaria and Romania
- Reappointed Thomas Lönngren as Executive Director of the EMEA
- Extended the pilot scheme for the provision of free scientific advice to developers of veterinary medicines intended for minor uses and minor species
- Adopted criteria for the involvement of patients' and consumers' organisations in EMEA activities
- Endorsed a framework on interaction with patients' and consumers' organisations
- Adopted strengthened rules on the handling of conflicts of interest of committee members and experts
- Introduced revised fee implementing rules providing, in particular, for graduations in the fee levels payable for certain new types of applications
- Approved a total budget of EUR 111,935,000 for 2005 (a 12% increase compared to the previous year), together with an establishment plan bringing the Agency's total number of temporary-agent posts to 379.



1.5 *Managing the Agency*

Management and internal-control systems are part of EMEA corporate governance and are consolidated in an integrated management system at the EMEA. The Agency continuously improves its processes and interfaces with partners in the European network.

- The annual management review was conducted to ensure that management tools are effective and suitable in relation to the Agency's needs.
- A self-assessment in the context of the EU benchmarking system was conducted in order to improve the EMEA management system.
- The Agency's internal audit function carried out 14 audits in 2005. This included contributions to the self-assessment exercise and a first review of the Agency's internal control standards.
- A corporate risk-management system, the Agency-wide risk-management system (ARMS), was launched to help the Agency systematically analyse risks in relation to its main activities.
- The provisional Audit Advisory Committee (AAC), established in 2004, held four meetings in 2005. Two tenders were organised to select the external members for the new 2006 Audit

Advisory Committee; an internal selection procedure to select staff representatives for the AAC was conducted.

There were several changes to the Agency's internal management structure.

- A new sector for medical information was created.
- Dr David Mackay was appointed as new Head of Unit for veterinary medicines following a recruitment competition. He succeeds Dr Peter Jones, who left the Agency in September 2005.
- A new Head of Sector for safety and efficacy of medicines was recruited by a competition procedure. Dr Xavier Luria took up his position at the EMEA in December 2005.
- The EMEA SME office was launched in December 2005.

1.6 Support to small and medium-sized enterprises

An important new task of the revised legislation is the provision of assistance to small and medium-sized enterprises (SMEs) involved in the development of pharmaceuticals in the European Union.

With the aim of promoting innovation and the development of new medicinal products by micro, small and medium-sized enterprises, the Agency launched the 'SME Office', dedicated to addressing the particular needs of smaller companies, following the entry into force of the new SME Regulation³ to implement provisions relating to incentives for SMEs in the new EU pharmaceutical legislation.

The SME Office has the sole remit of offering assistance to SMEs. The SME Office aims to facilitate communication with SMEs through dedicated personnel within the Agency who respond to practical or procedural enquiries, monitor applications, and organise workshops and training sessions for SMEs.

The incentives offered by the SME Regulation apply equally to the human and veterinary sectors, and include:

- Administrative and procedural assistance from the SME Office at the Agency
- Fee reductions for scientific advice, inspections and (for veterinary medicines) establishment of maximum residue limits
- Fee exemptions for certain administrative services of the EMEA
- Deferral of the fee payable for an application for marketing authorisation or related inspection
- Conditional fee exemption where scientific advice is followed and a marketing authorisation application is not successful
- Assistance with translations of the product-information documents submitted in the application for a marketing authorisation.

A survey of SMEs was carried out in 2005 to understand their specific needs and expectations, and a first meeting with SME stakeholder organisations was held to discuss the results.

The EMEA received the first requests for SME status following the entry into force of the SME Regulation, and processed them.

³ Commission Regulation (EC) No 2049/2005, OJ L329, 16.12.2005, p. 4.

1.7 Information and communication

In addition to its tasks relating to the review and supervision of medicines, the EMEA has a major role, reinforced by the new pharmaceutical legislation, in the provision of information to patients and healthcare professionals. A new Medical Information sector became fully operational in September 2005 and assumed responsibilities for interaction with patients' and healthcare professionals' organisations and for activities associated with the provision of product-related information.

Working through the EMEA/CHMP Working Group with Patients' and Consumers' Organisations (the platform for the Agency's interaction with patients and consumers), a set of recommendations was published in March 2005 relating to: transparency and dissemination of information; product information; pharmacovigilance; and interaction between the EMEA and patients' organisations. The recommendations were the outcome of an extensive external consultation exercise with the Agency's partners and stakeholders. Some of the recommendations were implemented in 2005, including one for new product-information templates which allow better information to be provided for patients and which are tested for readability.

The EMEA Management Board adopted criteria in September 2005 for the participation of patients' or consumers' organisations in EMEA activities. In order to allow the development of these activities within a broader and more structured environment, the Management Board adopted, in December 2005, a 'Framework of Interaction' between the EMEA and patients' and consumers' organisations.

The new pharmaceutical legislation also gives the Agency new tasks to improve product-related information. These include the publication of a summary of the European public assessment report (EPAR) in a manner that is easily understandable to the public, the publication of withdrawals of marketing authorisation applications prior to an opinion, and the publication of refusals of marketing authorisations.

To further improve the management of translations, the Management Board adopted a revised EMEA translation policy in September 2005. This policy put in place a framework for the checking of translations of product information by the national competent authorities, and set up a financial compensation scheme. Finally, in view of the next phase of EU enlargement, the EMEA completed preparations for pre-accession linguistic check activities for Bulgaria and Romania, to be launched in January 2006.

Another major initiative to provide more information on medicinal products at the EMEA is the creation of a public database on all medicines approved in the European Union. The Agency made progress in developing this database in 2005; it will be gradually implemented over a number of years.

An important aspect of information and communication is the provision of safety-related information to patients and healthcare professionals. A number of 'Dear Doctor Letters' were agreed by the CHMP, in addition to public statements. Question-and-answer documents were prepared systematically for all major safety issues involving centrally authorised products. A new initiative in 2005 was the publication of summaries of certain post-authorisation opinions, namely opinions on extension of indications and on the addition of new contra-indications or warnings.

Following a period of external consultation with stakeholders, the Agency finalised and published a procedure for the development of pharmaceutical guidelines and related documents, proposing a consistent and transparent approach to their development, consultation and publication.

The Agency remained committed to maintaining constant dialogue with the media. More than 60 press releases were published, two press conferences were held and a dedicated press office function ensured follow-up to enquiries.

Several new sections were introduced to the EMEA website. A dedicated section on the new pharmaceutical legislation provided access for interested parties to documents under consultation. At the launch of the SME Office, a new web section went live, providing relevant information about new rules for SME incentives in one convenient location. A new web section for patients' and consumers' groups describes the Agency's activities in this field.

A website evaluation questionnaire provided valuable feedback from users of the EMEA website. Comments received will help the Agency to address the needs of users when changes are made to the website in the future.

1.8 European medicines network

The EMEA operates in partnership with the national competent authorities for human and veterinary medicinal products in the Member States and the EEA-EFTA countries Iceland, Liechtenstein and Norway. The authorities make scientific resources available in the form of a network of more than 3,500 European experts who assist the Agency in performing its scientific tasks.

EMEA payment to national competent authorities totalled EUR 35,492,000, representing some 32% of the Agency's total budget in 2005. These payments are made in return for scientific services provided under contract to the EMEA.

The EMEA participated in all meetings of the heads of national competent authorities in 2005 to assist in the identification of resource needs arising from the revised legislation and scientific advances.

Important contributions to further strengthen the Agency's networking model were made in the following areas:

- An action plan to further progress the European Risk Management Strategy (ERMS) for human medicinal products at the level of the EMEA and the national competent authorities was published.
- The European Surveillance Strategy (ESS), which focuses on improved cooperation between all EU competent authorities and the EMEA in the field of pharmacovigilance for veterinary medicinal products, was revived, with the EMEA Secretariat now as a partner.
- Scientific conferences, workshops and training sessions were held in order to share competencies and strengthen cooperation among the network of European experts. Topics included environmental risk assessment, evaluation of plasma and vaccine-antigen master files, viral safety of medicines, non-clinical testing, statistical methodology, clinical-trial designs, consumer safety in relation to veterinary medicines, and issues relating to pharmacovigilance/risk management.
- Further progress was made on the development and implementation of an EU benchmarking system. The aim of the Benchmarking of European Medicines Agencies (BEMA) initiative is to share and compare best practices between all competent authorities in the European Union, which ultimately contributes to increasing quality, scientific and regulatory consistency in the European medicines network.

1.9 Enlargement

During 2005, representatives from Bulgaria and Romania started participating as observers in EMEA activities. Their participation was supported by the PHARE multi-beneficiary programme. The programme assists national competent authorities in accession countries to align their standards and practices with those in the European Union. This will allow for a smooth transition to full participation in the work of the Agency's scientific committees and working parties upon accession on 1 January 2007.

The EMEA regularly exchanged information with the medicines regulatory authorities in Bulgaria and Romania under the terms of the 'simplified procedure'. This relates to opinions on safety variations, extensions, annual re-assessments and renewal applications adopted by the CHMP for centrally authorised products listed in the EMEA simplified procedure database, as well as to opinions on any provisional changes to the product information introduced in the context of urgent safety restriction procedures.

1.10 *Interaction with EU institutions and other Agencies*

The EMEA cooperates closely with other scientific and regulatory institutions and agencies in the public health arena at European Union level.

- The EMEA continued its interaction with the European Parliament. A delegation of the Parliament's Committee on the Environment, Public Health and Food Safety visited the Agency in October 2005. In addition, the Executive Director answered questions from Committee members during his annual hearing, in November 2005.
- The EMEA worked closely with the Directorate-General for Enterprise and Industry on the implementation of the revised pharmaceutical legislation, as well as on the development of legislation relating to paediatric medicines, advanced therapies and the provision of information to the public.
- The EMEA cooperated with the Directorate-General for Health and Consumer Protection on issues such as rare diseases, blood products, human tissues, nanotechnology medicines and pandemic influenza, as well as on residue control in relation to veterinary medicines and environmental risk assessment.
- The EMEA and its scientific committees actively cooperated with the Directorate-General for Research on the preparation of the 7th Framework Programme for research, technological development and demonstration activities (2007 to 2013). Contributions were made to the Innovative Medicines Initiative (IMI), the development of the European Technology Platform on Global Animal Health (ETPGAH), and the establishment of priorities for rare diseases.
- In the field of emerging technologies, the EMEA, together with the Directorate-General for Enterprise and Industry, worked with the Interservice group chaired by the Directorate-General for Research on issues relating to the implementation of pharmacogenetic testing in the EU. A dialogue was also initiated with the newly reconstituted European Group on Ethics, on topics such as nanotechnology medicines and stem-cell therapies.
- Contacts were established with the European Centre for the Validation of Alternative Methods (ECVAM) of the Joint Research Centre (JRC), regarding initiatives to use alternative methods to animal testing in medicinal-product development.
- The EMEA actively contributed to the EU-wide initiative to improve cooperation between scientific committees and panels of Community bodies involved in risk assessment. The aim is to share information and expertise, in order to avoid divergent opinions between the committees or panels.
- Contact was established with the new European Centre for Disease Prevention and Control (ECDC), addressing areas of common interest, in particular relating to pandemic-influenza preparedness.
- Cooperation with the European Food Safety Authority (EFSA) was strengthened, focussing on issues such as the establishment of maximum residue levels (MRLs) for substances used both as veterinary medicines and feed additives, risk-assessment approaches and antimicrobial resistance.
- Cooperation with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) continued in 2005 in relation to the illicit use of new psychoactive substances.

1.11 *Interaction with international partners*

The Agency contributes to, and participates in, a number of multilateral forums, and has close relations with a number of non-EU competent authorities.

The Agency remained a committed participant in the two international cooperation activities on harmonisation of technical requirements for the registration of human and veterinary pharmaceuticals (ICH and VICH respectively) in 2005.

The EMEA worked closely with the World Health Organization (WHO) on matters such as consultations on good distribution and manufacturing practice related guidelines, international non-proprietary names (INNs) and pandemic-influenza preparedness. The EMEA supported and contributed to the Innovative Medicines Project hosted by the WHO. Antimicrobial resistance is the main priority of this project, and the EMEA acts as observer in the newly created REACT (Action on Antibiotic Resistance) network.

A new area of cooperation with the WHO is a new procedure introduced by the revised pharmaceutical legislation which gives the CHMP the possibility to adopt opinions, in the context of cooperation with the WHO, for medicinal products intended exclusively for markets outside the Community. More information about the new procedure is available in Chapter 2.

The Agency also participated in international activities of the Codex Alimentarius and the World Organisation for Animal Health (OIE). For the latter, this was in regard to the establishment of criteria for critically important antimicrobials for veterinary use.

Within the framework of the activities of the Council of Europe, the EMEA contributed to discussions on counterfeits, and participated at meetings of the European Pharmacopoeial Commission and associated scientific groups.

Bilateral relations with non-EU competent authorities

A number of new initiatives were conducted in the context of the confidentiality arrangements between the European Commission and the EMEA and the United States Food and Drug Administration (US FDA):

- The pilot phase of the parallel scientific advice procedure took place in 2005, and 4 procedures were completed. The outcome of the pilot was considered positive and the procedure will be continued in 2006.
- In the field of oncology, information was regularly exchanged on scientific advice and issues relating to conditional marketing authorisation, regulatory considerations, ongoing clinical and non-clinical reviews, and encouraging collaboration with oncology professional societies.
- Regular interaction between the EMEA and the US FDA took place, prior to the release of information into the public domain, in the field of emerging safety issues for centrally processed/authorised medicines and medicines subject to a referral at the level of the CHMP. There was also exchange of information regarding pharmacovigilance issues with veterinary medicinal products.
- The two agencies cooperated regularly on issues in emerging areas such as pharmacogenomics, pharmacogenetics and gene-therapy products.
- Regular exchanges on good manufacturing practice (GMP) and good clinical practice (GCP) inspection-related matters took place.

In addition to its cooperation with the US FDA, the Agency also cooperated with non-EU competent authorities in Australia, Canada, Japan and Switzerland, on issues such as the safety of medicines, herbal medicines, the quality of inhalation products, and inspections.

Experts from regulatory authorities in Jordan, Turkey, Saudi Arabia and the United States visited the Agency, and delegations from the Japanese and Chinese authorities were welcomed too.

2 MEDICINES FOR HUMAN USE

2.1 Orphan medicines

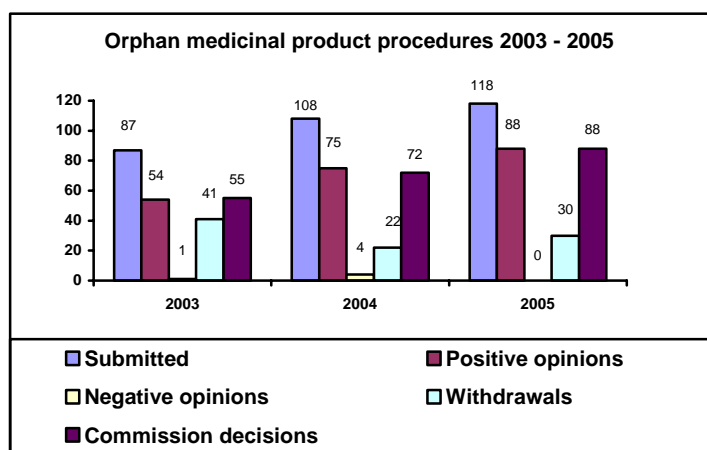
Medicines for rare disorders, so-called orphan medicinal products, are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting no more than five in 10,000 people in the European Union.

Applications for designation of orphan medicines are reviewed by the EMEA through the Committee for Orphan Medicinal Products (COMP). The composition of the Committee is given in Annex 4.

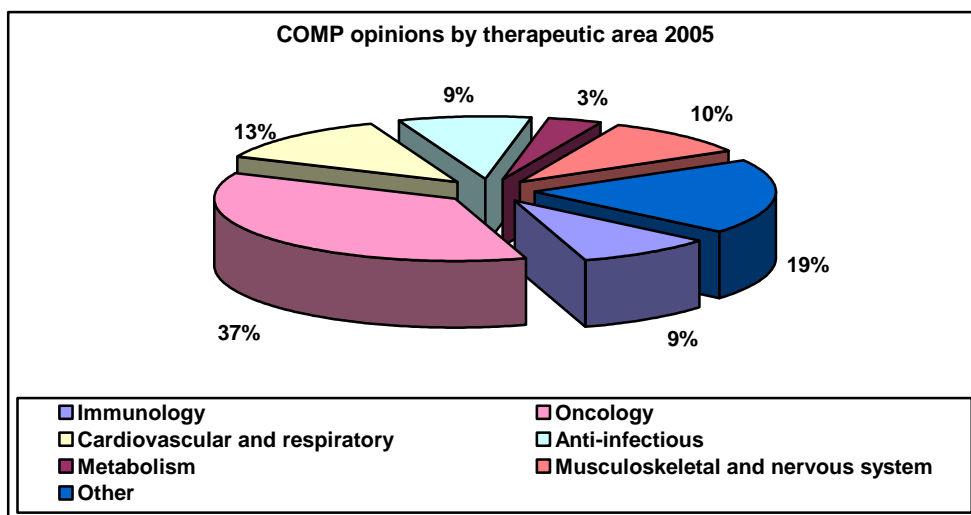
The EMEA's Committee for Orphan Medicinal Products (COMP) produced a 5-year report to the European Commission on the public health benefits obtained since implementation of the legislation on orphan medicinal products.

Orphan designation

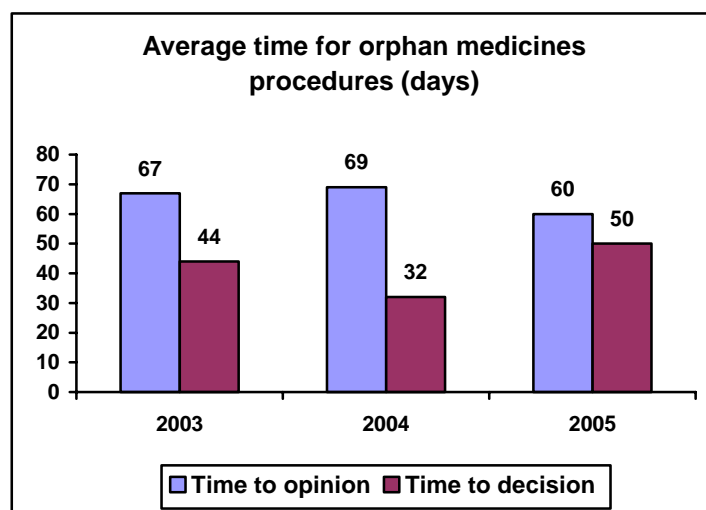
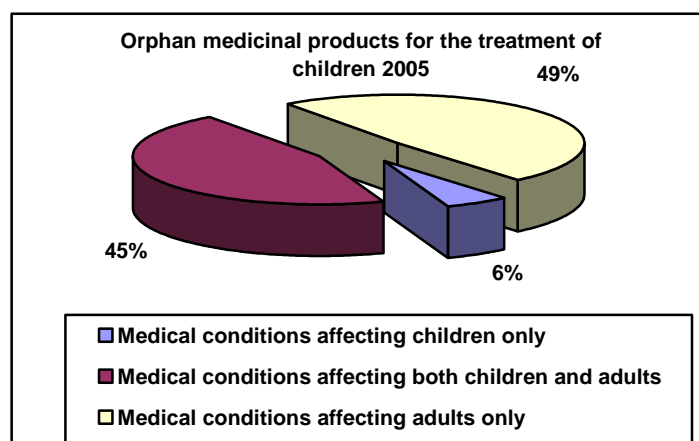
The COMP adopted 88 positive opinions on designation of orphan medicines in 2005, the highest number since the entry into force of the EU legislation in 2000. No negative opinions were adopted. An increase in sponsors seeking pre-submission assistance and guidance was observed.



The designations were for products in a wide range of therapeutic areas, with the largest number of designations for the treatment of cancer patients (oncology).



As the EU institutions progressed their discussions in 2005 on new EU legislation on medicines for children, over half of the designation opinions in 2005 were for conditions that affect children.



All orphan designation procedures were handled in less than 90 days, the time limit set by the legislation.

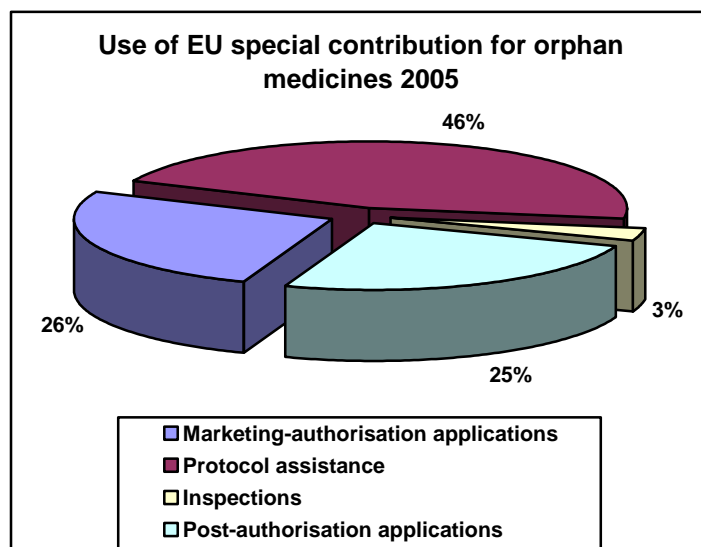
A list of all orphan medicinal products designated in 2005 is provided in Annex 11.

Special financial support from the EU budget

Each year the European Parliament and Council allocate a special contribution from the EU budget to allow the EMEA to offer financial incentives to sponsors of orphan medicinal products.

Initially, € 3.7 million were granted for 2005. The contribution was later increased to € 6.84 million.

The special EU contribution is used to reduce or altogether waive fees payable to the EMEA. The policy in 2005 was to grant 100% waivers for requests for protocol assistance and a 50% reduction for all other types of application fees.



2.2 Scientific advice and protocol assistance

Scientific advice is a priority area for the EMEA. It is aimed at companies developing new medicines, with the dual benefit of helping research companies in their development programme and contribute to speed up access to the market for innovative medicines.

The Agency provides advice on specific questions relating to the quality, safety or efficacy of medicinal products. These questions typically arise during the research and development phase. In the case of sponsors developing designated orphan medicinal products, the scientific advice provided by the Agency is referred to as protocol assistance and is offered free of charge.

A new strategy for providing scientific advice

The revised EU pharmaceutical legislation gives the Agency a greater mandate to provide scientific advice, and gives the Executive Director direct responsibility for establishing efficient structures for its provision — particularly with regard to advice for the development of new therapies.

Working together with the CHMP, Scientific Advice Working Party and interested parties, the Executive Director proposed a new strategy and procedure in 2005, which will be implemented in 2006.

The strategy includes earlier and more frequent involvement of experts particularly on rare diseases and new therapies. Broader advice e.g. on non-product related issues will now be offered, and, in parallel, workshops and think-tank meetings will create opportunities for increased awareness and dialogue with specific experts.

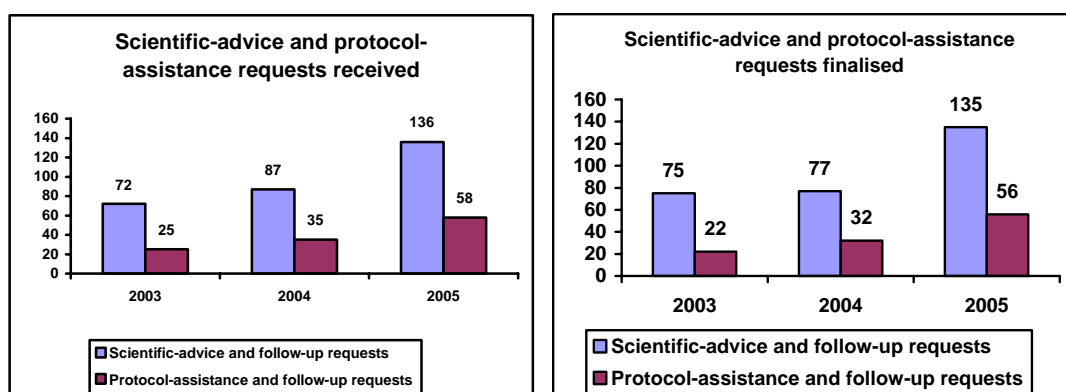
New methodologies for small clinical trials (rare diseases and paediatrics) will be encouraged with the new guideline that was released for consultation in 2005.

Scientific advice and orphan medicines

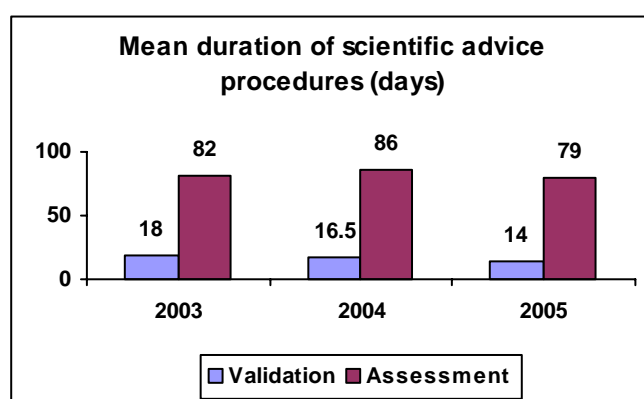
Efforts were made in 2005 to improve coordination between the COMP and the Scientific Advice Working Party in areas that are relevant to the provision of protocol assistance for designated orphan medicinal products. The aim is to increase the awareness of sponsors about protocol assistance so they can benefit from the procedure after designation.

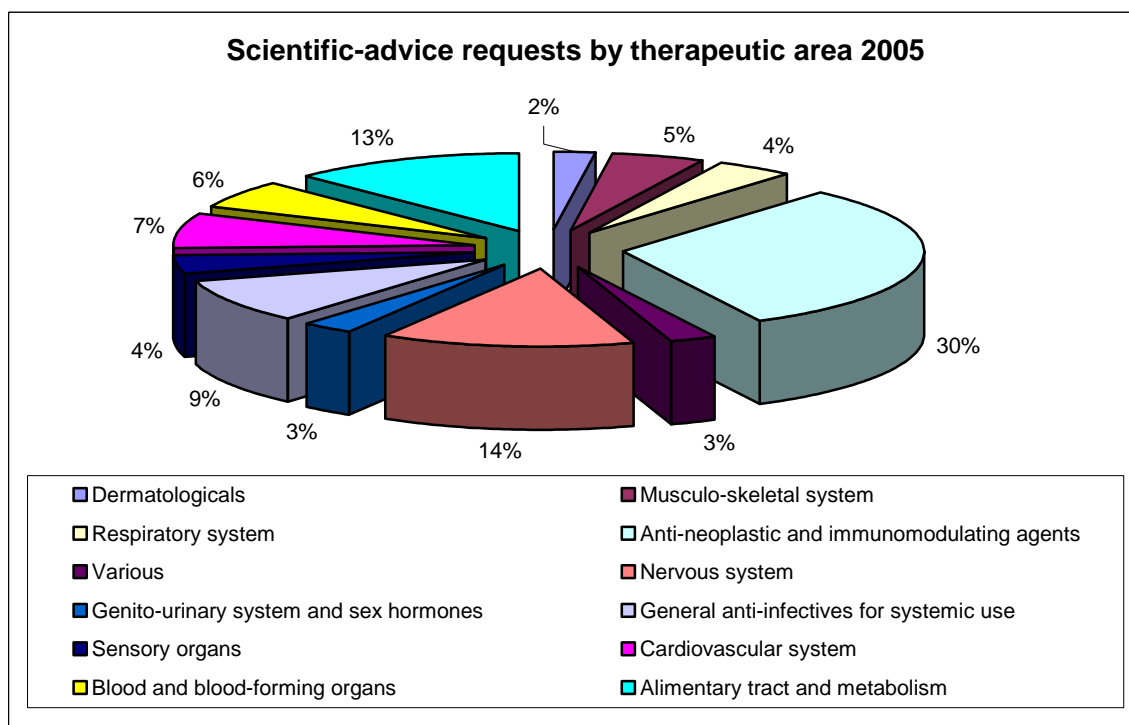
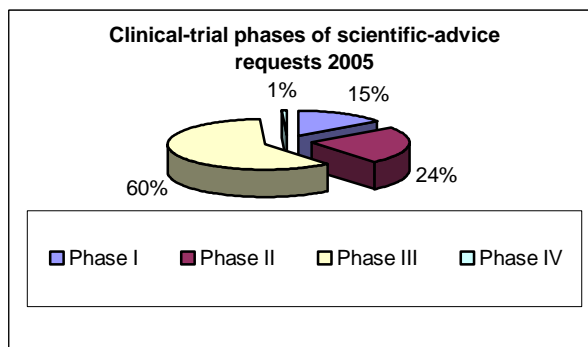
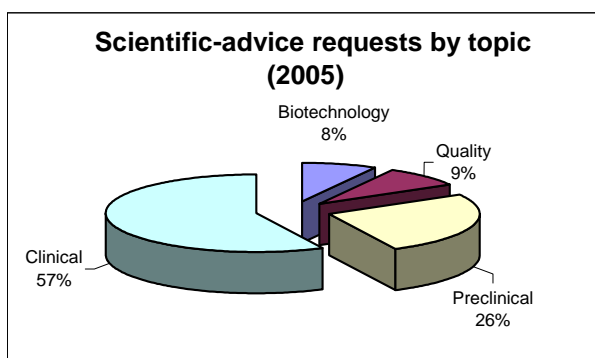
Major increase in requests for scientific advice

There was a substantial increase in the number of requests for scientific advice and protocol assistance in 2005. The number of requests for scientific advice and protocol assistance increased by 60% compared to levels in 2004.



Some streamlining of the scientific advice procedure meant that, despite the increase in requests, the Agency was able to deliver more and faster scientific advice in 2005 than in previous years.





Impact of Scientific Advice

The Agency continuously monitors and analyses the impact of scientific advice on the outcome of applications for marketing authorisations.

The proportion of marketing authorisation applications preceded by scientific advice is growing but still stood at 30% (11 out of 31) for applications submitted in 2004, the majority of which (30) came to an opinion in 2005.

Eight of the 23 (35%) positive outcomes of applications submitted in 2004, which came to an opinion in 2005, were preceded by scientific advice. There is an association between prior scientific advice and success of marketing authorisation applications. Of the 139 applications with an outcome that have been submitted to the Agency since 2001, 40 of the 104 with a positive opinion (38.4%) received scientific advice. In contrast, 7 of the 35 applications that were either withdrawn or had a negative opinion (20%) were preceded by scientific advice. There are several reasons that account for a negative opinion on applications preceded by scientific advice. Applications may encounter major objections from the CHMP on the design of studies, small or no clinical effect, and major safety concerns. There could also be failure to request scientific advice on relevant methodological aspects, failure to follow advice given, and cases where the benefit-risk balance is judged to be negative even if based on methodologically sound data.

Pilot project for parallel scientific advice from the EMEA and the US FDA

A pilot project for parallel scientific advice from the EMEA and the US FDA started in January 2005.

Parallel advice, which can be requested either by companies themselves or by either of the Agencies, has the following advantages

- Increased dialogue between Agencies and sponsor from the beginning of the product life cycle
- Product development can be optimised by avoiding unnecessary replication of testing or unnecessarily divergent testing methodologies
- Allows additional critical issues to be identified and shared simultaneously by both agencies
- Streamlines development of, and facilitates access to, medicinal products (particularly orphan drugs and products eligible for accelerated review)
- Where advice differs, sponsors have a clearer understanding of the agencies' perspectives and the background of any divergence.

Four parallel scientific advice procedures were finalised in 2005. These included products for the treatment of cancer, prevention of transplant rejection and treatment of endometriosis. A further 4 procedures were still underway at the end of the year, relating to products for the treatment of cancer, an anti-infective and a product used in the treatment of neurodegenerative disorders.

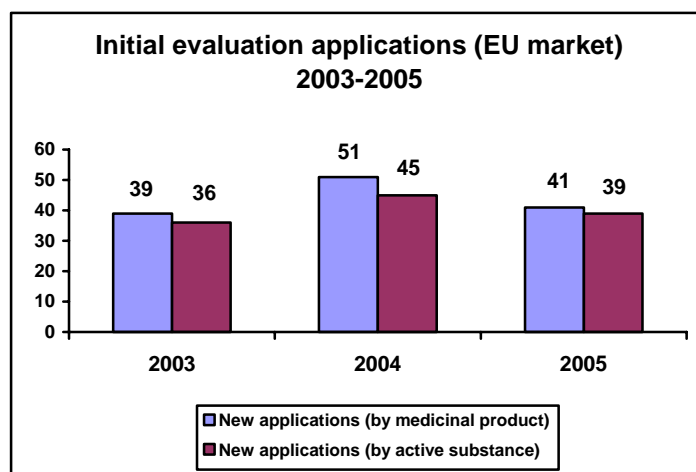
2.3 Initial evaluation

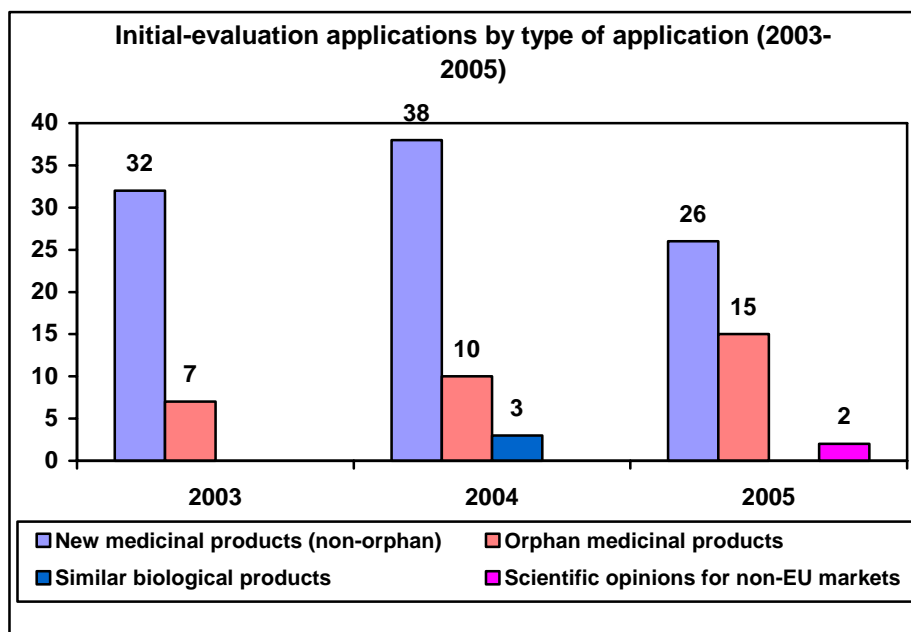
Applications for new medicines are reviewed by the Agency through the Committee for Medicinal Products for Human Use (CHMP). The Committee assesses the quality, safety and efficacy of a medicine and, based on an overall balance of the benefits and risks of the medicine, gives its opinion on whether or not the European Commission should grant a Community-wide marketing authorisation.

The composition of the Committee is given in Annex 2.

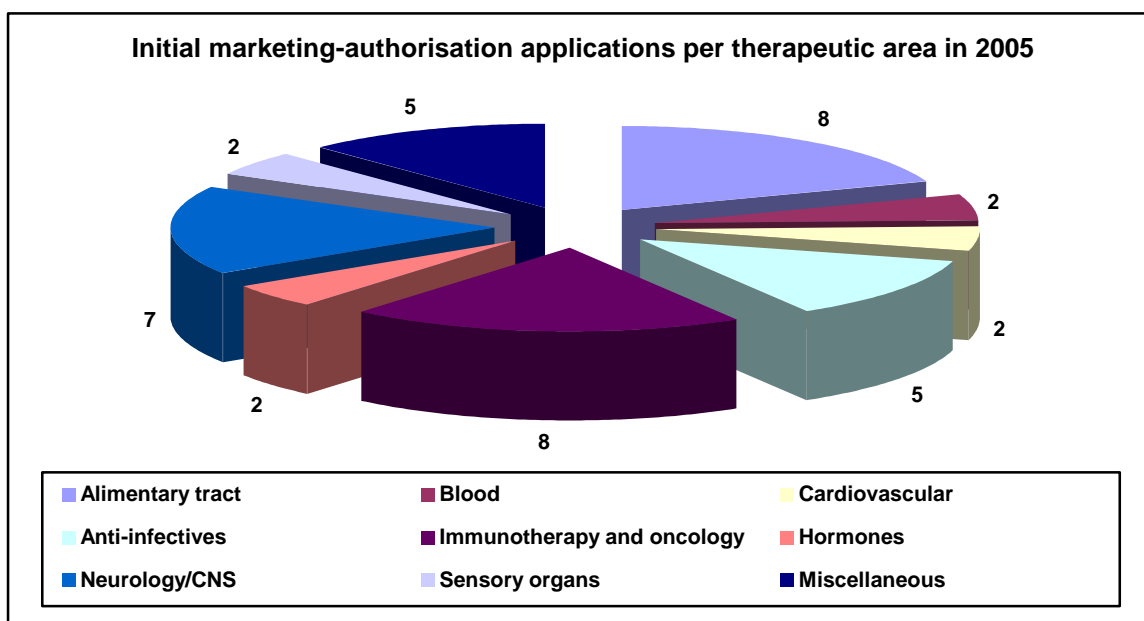
New applications in 2005

The overall number of applications in 2005 was below initial forecasts, possibly related to uncertainty within industry concerning the implementation and consequences of the revised pharmaceutical legislation. However the number of applications for authorisation of designated orphan medicines remained strong, exceeding initial forecasts.

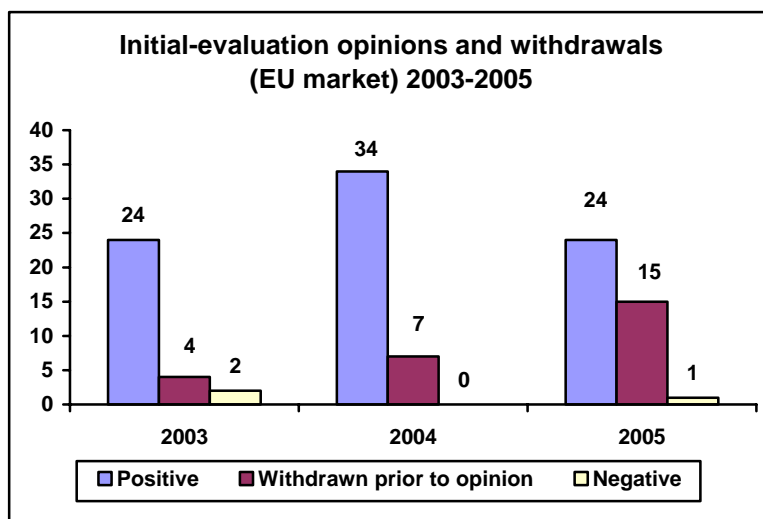




Applications for new medicines were across a wide range of therapeutic areas, with medicines for the treatment of cancer, central nervous system and the alimentary tract making up over half of all applications.



The CHMP adopted 24 positive opinions and one negative opinion in 2005 on products intended for the European market. A further 15 applications were withdrawn prior to opinion.

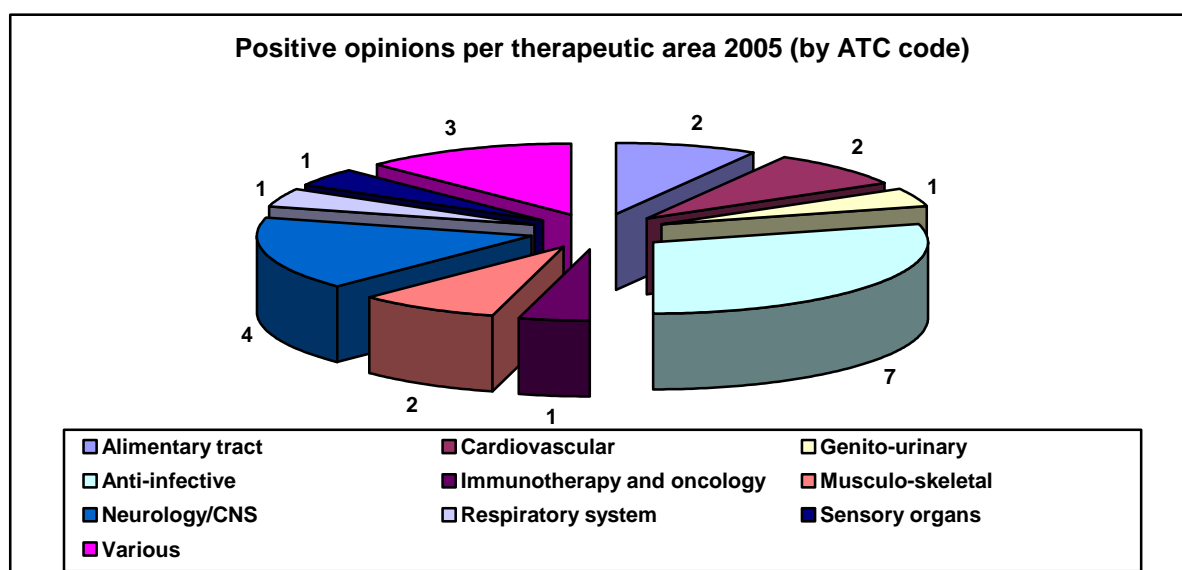


Public health impact of opinions in 2005

Of the medicinal products intended for the European market for which a positive opinion was adopted:

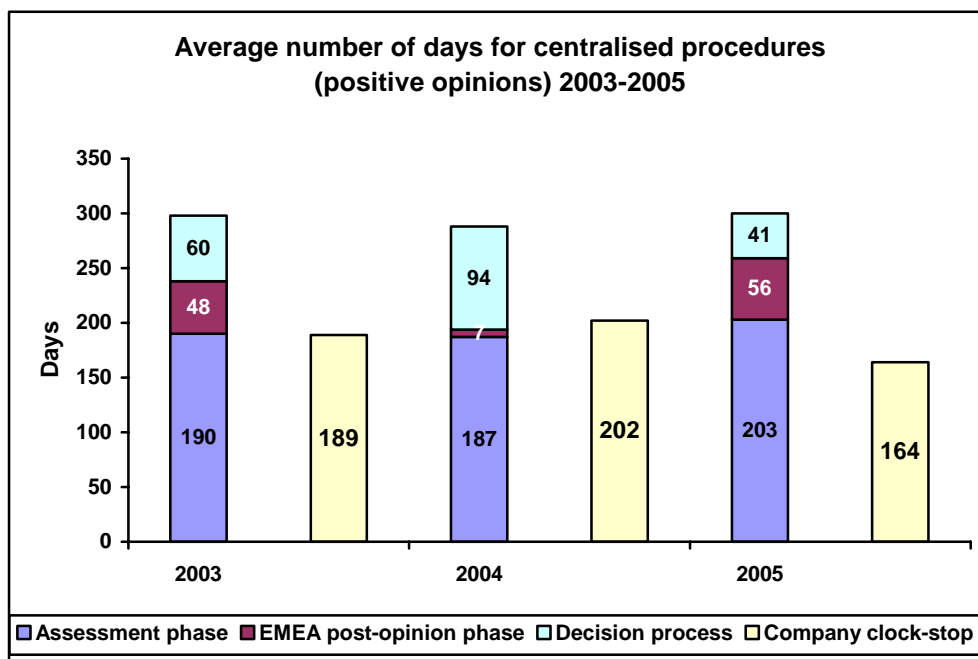
- 2 are for use in cancer therapy, including the treatment of lung cancer — one of the highest causes of cancer-related deaths in the EU
- 7 are anti-infectives, of which 2 are for the treatment of HIV and AIDS
- 4 are for the treatment of metabolic disorders, of which one offers a new route of administration for diabetes patients by allowing insulin to be delivered via the lungs
- 5 are for the treatment of diseases of the central nervous system and sensory organs
- 6 are for the diagnosis or treatment of cardiovascular or pulmonary diseases.

Of these 24 products, 3 are designated orphan products intended for the treatment of narcolepsy, pulmonary arterial hypertension or mucopolysaccharidosis.



The CHMP also gave its first scientific opinions in the context of cooperation with the World Health Organization (WHO) on medicines intended exclusively for use in countries outside of the EU. The opinions concerned 2 medicinal products for the treatment of HIV.

Timelines for opinions



Overall the average active review time increased slightly in 2005 but overall remained within the regulatory timeline of 210 days for the assessment phase. The EMEA post-opinion phase in 2005 is similar to that in 2003. The difference in timelines compared to 2004 is due to a procedural change coupled with the decision process effective only in that year.

Plasma master files and vaccine antigen master files

Nine applications were received for certification or re-certification of plasma master files (PMFs). Certification continues to be a valuable procedure for the evaluation of such files: it has improved the efficiency of the European system by handling requests centrally rather than through the 25 Member States individually.

No applications were received for certification of vaccine antigen master files.

Preparation for new types of applications

The revised pharmaceutical legislation opens the way for new types of applications to be made to the Agency.

- *Similar biological medicinal products:* An overarching guideline on similar biological medicines was finalised in November 2005. Together with this key document, a further 6 draft guidelines on specific types of products were released for consultation in the first half of the year. As part of the consultation process, a major public conference was organised in December 2005 with the participation of industry, regulators, academia, healthcare professionals and patients. The new CHMP Working Party on Similar Biological Medicinal Products was established in 2005.

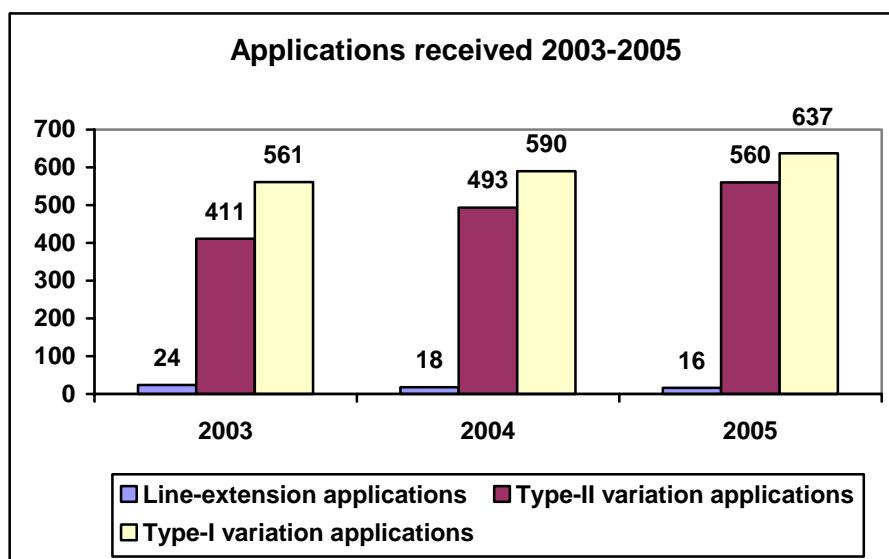
- *Generic medicines:* Detailed guidance was published and existing guidance updated in 2005 concerning all aspects relating to the submission to the EMEA and assessment by the CHMP of generic medicines.
- *Compassionate use:* A guideline was drafted in preparation for the submission of any request by Member States for CHMP opinions.
- *Self-medication medicines:* Amendments were proposed in 2005 to existing Commission guidance on the supply of non-prescription medicines, in particular relating to use of the centralised procedure for self-medication medicines. A reflection paper to highlight patients' benefits in this new area was issued. A number of meetings were held with companies ahead of possible future applications.

2.4 Post-authorisation activities

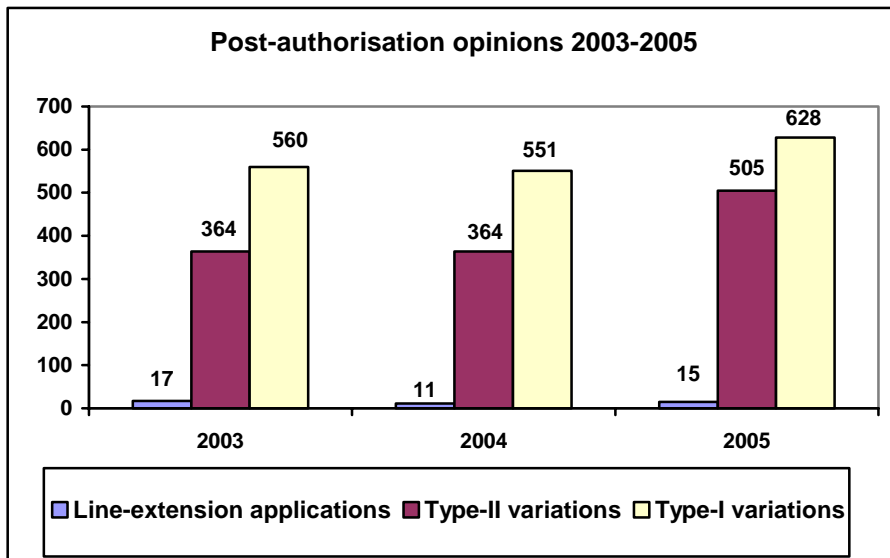
Changes to the terms of marketing authorisations are made frequently during the life of a medicine. These changes, known as variations, often relate to addition of new treatment options, the introduction of warnings or contraindications or changes in the way the product is manufactured. All variations, whether minor (type IA and type IB) or major (type II), require formal approval often involving a decision of the European Commission.

Variations in 2005

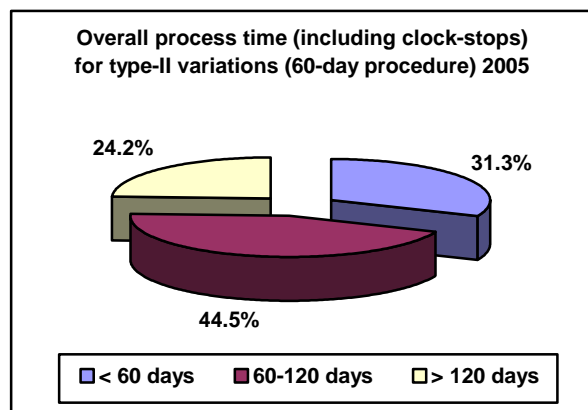
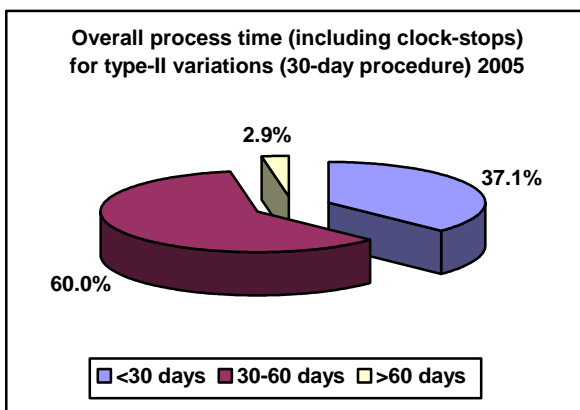
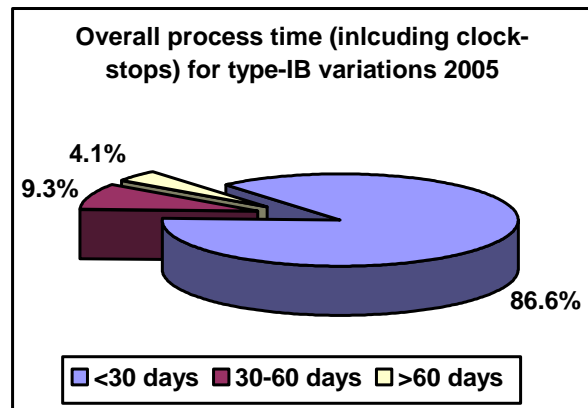
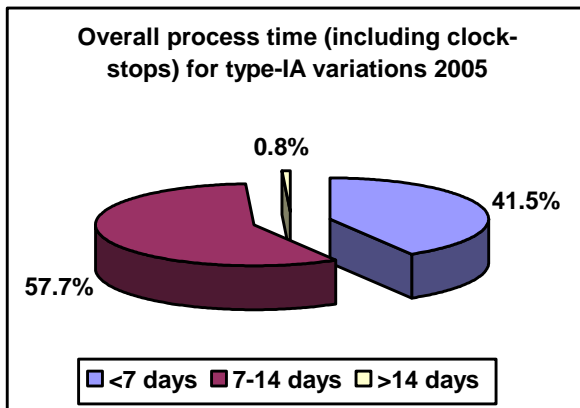
The number of applications for variations to marketing authorisations increased once again in 2005. A total of 1,213 applications were received, which represents a 10% increase compared to 2004.

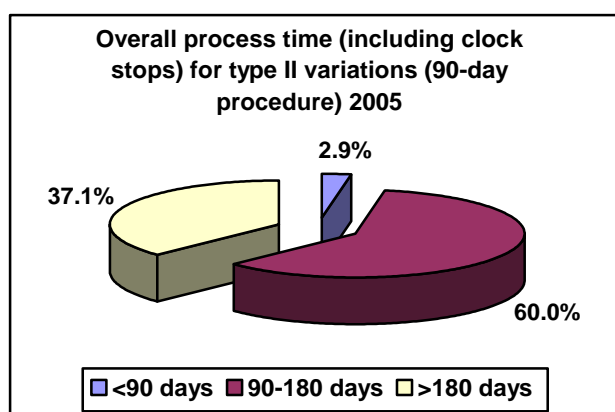


There was a similar increase in the number of post-authorisation opinions adopted, particularly those for type-II variations. More than 1,000 final notifications for type-I variations, opinions on type-II variations (50% relating to safety and efficacy, and 50% relating to quality changes) and line extensions were adopted in 2005.



The evaluation timeframes of the variations handled in 2005 are displayed below. These encompass both the active review time and the clock-stops.





Public health impact of post-authorisation activities

- *New indications:* A total of 28 extensions of indications were introduced, a large number of which related to new treatment options for previously approved medicines in the area of cancer. There were also new indications in the area of diabetes, cardiovascular, neurodegenerative and rheumatoid diseases.
- *Contra-indications and warnings:* A total of 5 new contra-indications were introduced for 11 medicinal products used in the fields of HIV, immunosuppression, osteoporosis and metabolic diseases. In addition there were 74 type-II variations relating to special warnings and precautions for use. Several class-labelling procedures were performed for HIV products. A class-labelling procedure was also conducted in relation to the use of epoetins in cancer patients, and another one in relation to dental, periodontal and psychiatric disorders possibly associated with the use of peginterferon alfa.
- *Extensions of use for children:* 4 products had their use extended to include the treatment of children. The medicines involved are an antiviral for the prevention of influenza, an antibacterial for a range of infections, an anti-epileptic and a product used in the treatment of leukaemia.

2.5 Safety of medicines

Major safety reviews

The Agency dealt with a number of major safety issues in 2005, involving both centrally and non-centrally authorised medicines for human use, including:

- Conclusion of the safety review of COX-2 inhibitors
- Safety review of non-steroidal anti-inflammatory drugs (NSAIDs)
- Safety review of the selective serotonin reuptake inhibitor (SSRI) class of antidepressants
- Suspension of a centrally authorised hexavalent vaccine due to concerns over the level of long-term protection offered by one of its components
- Initiation of a safety review for dermatological medicinal products containing tacrolimus or pimecrolimus, following concerns of potential cancer risks to patients
- Initiation of a review of mifepristone-containing medicinal products (Mifegyne) due to safety and efficacy concerns.

One trend seen in 2005 was the increased use of ‘pre-referral procedures’. This type of procedure, for which a framework was established in 2003, allows the CHMP to look at safety concerns during a preliminary review in order to determine whether regulatory action is necessary. The review of NSAIDs was a prominent example of such a procedure in 2005.

Rapid updating of product information

The Agency completed 6 urgent safety restrictions (USRs) in 2005, all relating to the cardiovascular safety of COX-2 inhibitors.

A USR is a 24-hour procedure used to rapidly change the product information provided to prescribers and users of a medicine.

Risk management strategy

An action plan to further progress the European risk management strategy (ERMS) was published in May 2005, covering a number of key aspects including:

- Implementation of additional tools provided by the revised EU pharmaceutical legislation for monitoring the safety of medicines
- Initiatives in the areas of risk detection, risk assessment, risk minimisation and risk communication
- Strengthening the EU pharmacovigilance system to make the best use of the scientific resources and expertise available at EU level.

A special group (ERMS facilitation group) was set up to oversee the delivery of these key objectives through the development of a rolling work plan for 2005-2007. The group will provide progress reports to the EMEA Management Board and to the group of heads of national medicines agencies.

Risk management plans

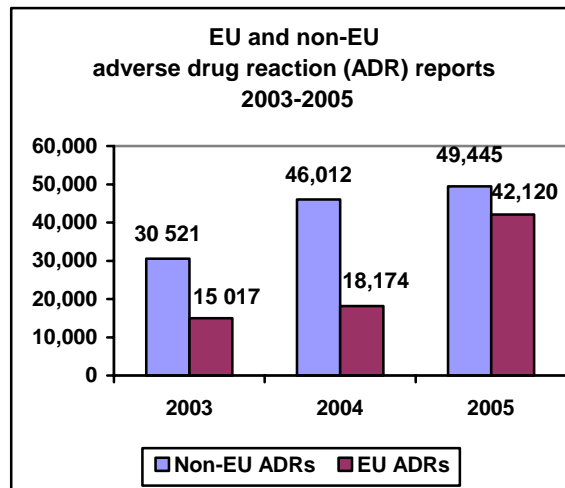
As part of the revised pharmaceutical legislation, all new applications for marketing authorisation and applications for major changes to existing authorisations must be accompanied by a risk management plan. Work began in 2005 on implementing this new provision, which will require plans to identify any known or potential risks associated with the medicinal product concerned. The plans will allow the proactive implementation of risk minimisation measures and other pharmacovigilance activities.

Pharmacovigilance

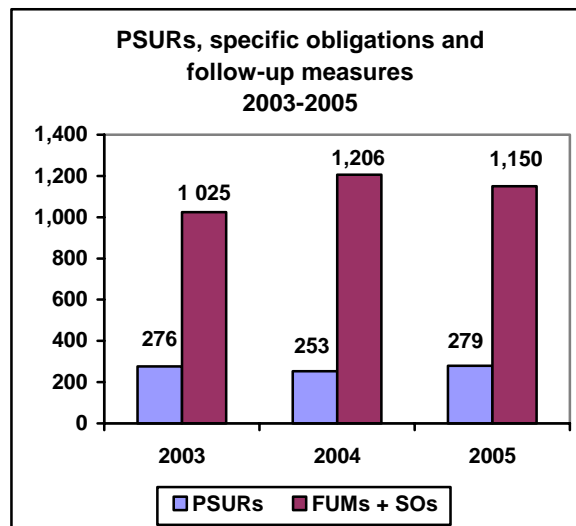
Pharmacovigilance is the process of continuous monitoring of medicinal products on the market. Its aim is to identify and report any potential safety issues relating to medicines and to prevent adverse drug reactions. The collection and exchange of such information between marketing authorisation holders, sponsors of clinical trials and regulators allows rapid and appropriate responses to be made in order to afford the best protection to users of medicinal products.

Adverse reaction reporting

Electronic reporting into the EudraVigilance database became mandatory in November 2005. The number of adverse drug reaction (ADR) reports for centrally authorised medicinal products received by the EMEA in 2005 was significantly greater than in previous years.



The Agency continued to handle a heavy workload relating to periodic safety update reports, specific obligations and follow-up measures in 2005.



Working together with the European Commission, the EMEA developed transitional measures on implementing the revised pharmaceutical legislation for handling periodic safety update reports for products approved before 20 November 2005.

Progress with EudraVigilance

Good progress was made with the implementation of EudraVigilance in 2005, with 23 national competent authorities and 105 marketing authorisation holders reporting electronically to the EudraVigilance Post-Authorisation Module (EVPm). These stakeholders reported electronically a total of 144,786 individual case safety reports (ICSRs) originating from within and outside the EU. Thereof, 73,198 ICSRs were received electronically for centrally authorised products corresponding to 80% of the total adverse reaction reports received for centrally authorised products in 2005 as reflected in the table above.

In addition, 67 sponsors conducting clinical trials within the European Economic Area (EEA) were reporting suspected unexpected serious adverse reactions (SUSARs) to the EudraVigilance Clinical Trial Module (EVCTM). A total of 34,352 ICSRs relating to SUSARs were received.

The retroactive electronic population of EudraVigilance also progressed in 2005, with the transmission of 32,842 ICSRs. At the end of 2005, EudraVigilance contained 524,782 ICSRs, corresponding to 203,844 individual cases.

Mandatory electronic reporting was introduced by the revised EU pharmaceutical legislation in November 2005 and the EMEA was active in ensuring speedy implementation by Member States authorities and marketing authorisation holders.

- The Agency organised several meetings with national competent authorities and marketing authorisation holders to facilitate their implementation of electronic reporting. In addition, a total of 45 EudraVigilance training courses were held for national competent authorities, marketing authorisation holders and commercial and non-commercial sponsors.
- An ad hoc working group established in 2004 issued recommendations to look at policy, compliance and regulatory aspects relating to EudraVigilance. The Heads of Medicines Agencies and the EMEA Management Board subsequently adopted the recommendations.
- The Agency established a EudraVigilance Steering Committee, which defines policies of implementation and access to EudraVigilance, and a EudraVigilance Expert Working Group, addressing all practical and operational aspects of implementation involving all stakeholders.

Strengthened procedures for detection of pharmacovigilance signals

The EMEA put in place procedures to reinforce detection of pharmacovigilance signals for centrally authorised products during 2005, allowing the Agency to take appropriate action earlier. A total of 880 suspected signals, concerning 87 products, were detected and investigated. When appropriate, further follow-up was undertaken to inform the Rapporteur and to assess the need for the collection of additional data from the marketing authorisation holders or the amendment of the product information via a type-II variation.

2.6 Arbitration and Community referrals

Arbitration procedures (either under Article 29 of Directive 2001/83/EC or Article 6(12) and 6(13) of Commission Regulation (EC) No 1084/2003) are initiated because of disagreement between Member States in the framework of the mutual recognition procedure.

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

Referral procedures under Articles 31, 36 and 37 of Directive 2001/83/EC are mainly initiated in cases involving the interests of the Community or concerns relating to the protection of public health.

Arbitrations and referrals finalised

The CHMP adopted opinions on six arbitration referrals. Five cases were referred to the CHMP by national competent authorities under Article 29(2) of Directive 2001/83/EC, and one under Article 6(12) of Commission Regulation (EC) No 1084/2003, on the grounds that the divergences identified could not be resolved through the mutual recognition procedure.

The main triggers for the arbitrations were:

- Divergence on dosage recommendations (in the case of rosuvastatin)
- Divergence on recommendations for the duration of treatment (in the case of ropinirole)
- Divergence on various aspects of the information provided in the summary of product characteristics and of the bioequivalence data (in the cases of lansoprazole and of ethinylestradiol and levonorgestrel)
- Divergence on indications (in the case of perindopril)

The CHMP adopted opinions in two class review referrals, under Article 31:

- Review of SSRIs (serotonin-selective reuptake inhibitors)/SNRIs (serotonin-norepinephrine reuptake inhibitors) in children and adolescents
- Review of COX-2 inhibitor medicines, mainly in relation to concerns over cardiovascular events and serious skin reactions.

At the time of adoption of the CHMP opinions for these procedures, the EMEA released advice to healthcare professionals and patients in the form of question and answer documents accompanying EMEA public statements. In addition, the full CHMP scientific conclusions and product information were made publicly available by the EMEA upon finalisation of the procedures by the European Commission.

Arbitrations and referrals started

New procedures under Article 29(2):

- One procedure for a ceftriaxone-containing medicinal product (Ceftriaxone Tyrol 1g and 2g)
- Five procedures for generic medicinal products containing lanzoprazole
- One procedure for a nifedipine-containing medicinal product (Nifedipine Pharmamatch retard 30 and 60 mg)

New procedures under Article 30:

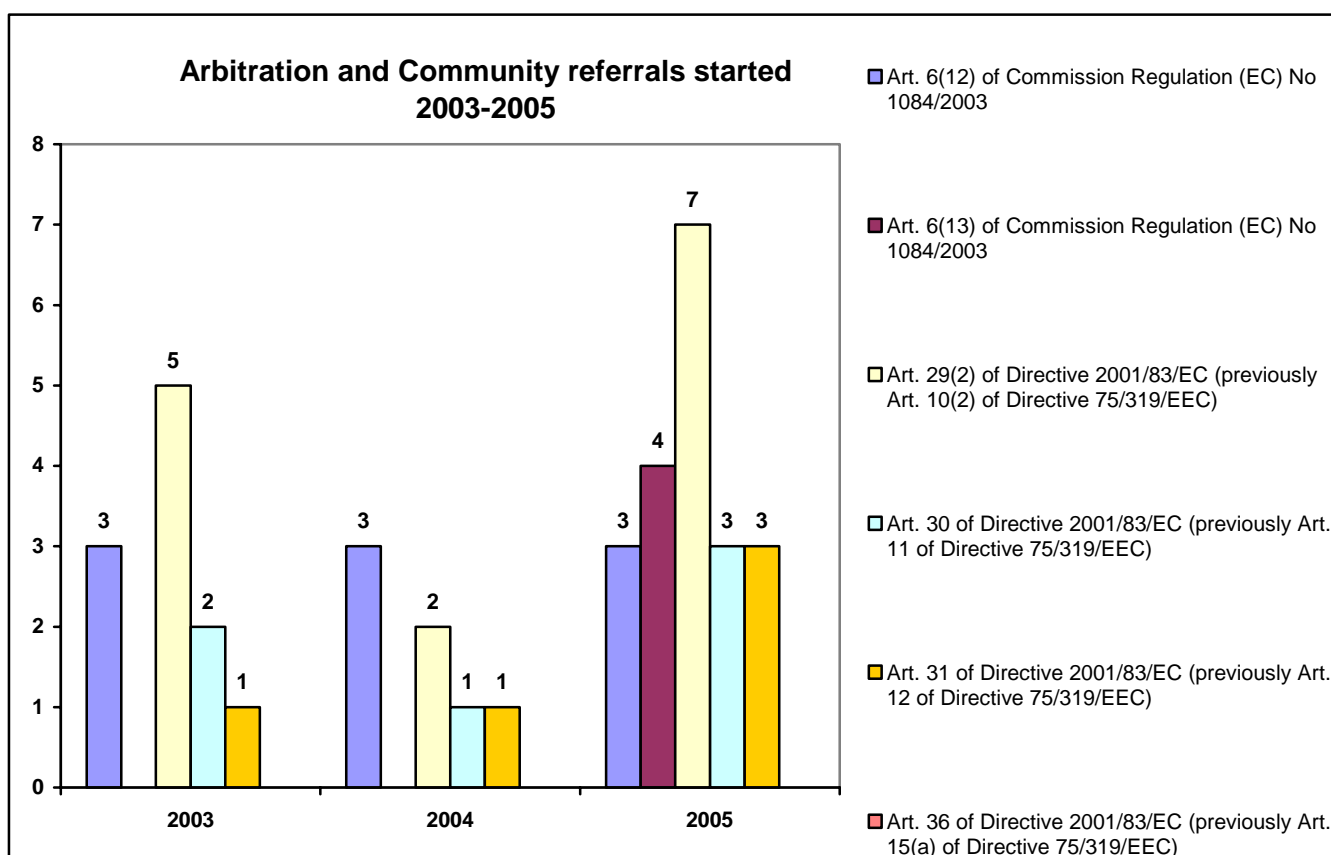
- One procedure for an attenuated yellow fever vaccine (Stamaril)
- One Procedure for a lanzoprazole-containing medicinal product (Agopton)
- One procedure for a tacrolimus-containing medicinal product (Prograf/Prograft)

Two new referral procedures under Article 31 were initiated:

- Review of dermatological medicinal products containing pimecrolimus, following concerns of potential cancer risks to patients
- Review of mifepristone-containing medicinal products (Mifegyne) due to safety and efficacy concerns

Three arbitration procedures under Article 6(12) and four procedures under Article 6(13) were also started. All these procedures were triggered due to disagreement between Member States or disagreement between marketing authorisation holders and Member States in the framework of applications for extensions of the therapeutic indications of medicinal products authorised through the mutual-recognition procedure.

No referral procedures were triggered under Articles 36 or 37 during 2005.



2.7 Herbal medicines

The year 2005 was the first full year of operation of the Committee on Herbal Medicinal Products (HMPC), following its inaugural meeting in September 2004.

The HMPC met six times in 2005 and concentrated on the full implementation of Community legislation in relation to its operation. The Committee focused on work to establish the necessary procedures for conducting its business. This included:

- Finalisation of the structure of the Community list and the template for Community herbal monographs
- Revision of existing quality guidelines, in coordination with the CHMP and CVMP, and good manufacturing practice (GMP) guidelines in cooperation with the GMP inspectors' group
- Organisation of training sessions for EU assessors
- Development of guidelines on clinical safety and efficacy aspects.

Community herbal monographs

A Community herbal monograph comprises the HMPC's scientific opinion on a given herbal medicinal product, based on its evaluation of available scientific data (well-established use) or on the historic use of that product in the European Community (traditional use). The Committee released for public consultation the first draft Community herbal monographs, covering well-established and/or traditional use, for:

- Valerian root
- Psyllium seed
- Linseed
- Ispaghula husk
- Ispaghula seed.

Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

Herbal medicinal products entered into the Community list fulfil certain criteria, such as having been in medicinal use for a sufficiently long time, and are considered not to be harmful under normal conditions of use. The Committee released for public consultation draft entries to the ‘Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products’ for:

- Valerian root
- Linseed.

The Community herbal monographs and entries to the Community list, as well as HMPC guidelines and working documents adopted or released for consultation in 2005, are listed in Annexes 12a and 12b of this annual report.

2.8 Management and organisation of EMEA scientific committees for human medicines

Three EMEA scientific committees are responsible for formulating opinions on medicinal products – the Committee for Medicinal Products for Human Use (CHMP); the Committee for Orphan Medicinal Products (COMP); the Committee for Herbal Medicinal Products (HMPC).

The work of the Committees is supported by a number of working parties, composed of European experts selected from a list maintained by the EMEA.

The working parties are involved, according to their area of responsibility, in the development and revision of guidelines and in the provision of recommendations and advice on medicinal products for which applications are made for orphan drug designation, scientific advice, protocol assistance, marketing authorisation or post-authorisation activities.

Committee for Medicinal Products for Human Use (CHMP)

The Committee held 11 plenary meetings in 2005.

By the end of 2005, the following standing and temporary working parties, scientific advisory groups and other working groups supported the work of the CHMP:

Standing working parties

- Scientific Advice Working Party (SAWP)
- Biologics Working Party (BWP)
- Blood Products Working Party (BPWP)
- Cell-based Products Working Party (CPWP)

- Efficacy Working Party (EWP)
- Gene Therapy Working Party (GTWP)
- Joint CHMP/CVMP Quality Working Party (QWP)
- Pharmacogenetics Working Party (PgWP)
- Pharmacovigilance Working Party (PhVWP)
- Safety Working Party (SWP)
- Vaccine Working Party (VWP)

Temporary working parties

- Paediatric Working Party (PEG)
- Similar Biological (Biosimilar) Medicinal Products Working Party (BMWP)

Scientific advisory groups

- Scientific Advisory Group on Anti-infectives
- Scientific Advisory Group on Cardiovascular Issues
- Scientific Advisory Group on Central Nervous System
- Scientific Advisory Group on Diabetes/Endocrinology
- Scientific Advisory Group on Diagnostics
- Scientific Advisory Group on HIV/Viral Diseases
- Scientific Advisory Group on Oncology

Other working groups of the CHMP

- CHMP/EMA Implementation Task Force
- Invented Name Review Group (NRG)
- EMA/CHMP Working Group with Patients' and Consumers' Organisations (WGPO)
- Working Group on Quality Review of Documents (QRD)

Committee for Orphan Medicinal Products (COMP)

The COMP met 11 times in 2005.

Two working groups assisted the Committee in its work.

- Ad hoc Biotechnology Working Group
- COMP Working Group with Interested Parties

Committee on Herbal Medicinal Products (HMPC)

The HMPC met 6 times in its first full year in operation. It is supported by the following working groups:

- Organisational Matters Drafting Group
- Quality Drafting Group
- Safety & Efficacy Drafting Group

All working documents adopted by the Committees can be found in Annex 13.

2.9 Contribution to EU public health strategies

Pandemic influenza preparedness

The Agency released the 'EMEA pandemic influenza crisis management plan for the evaluation and maintenance of pandemic influenza vaccines and antivirals' for consultation in 2005.

Incentives, including fee waivers for scientific advice, were introduced in 2005 to encourage companies to use the core-dossier approach – a novel concept, which allows for completion of the evaluation and approval of an application based on a mock-up vaccine (with an influenza virus strain similar to the pandemic strain) before the outbreak of a pandemic. The CHMP also committed itself to accelerating the scientific evaluation of applications for scientific advice and marketing authorisation for pandemic influenza vaccine core dossiers.

The first submission of a core dossier was made in December 2005, and discussions on a number of other submissions were under way at the year's end.

In addition to its activities relating to development of a pandemic influenza vaccine, the EMEA also looked at antivirals and issued guidelines in October 2005 on the use of these medicines in the event of a pandemic.

Medicines for paediatric use

Preparatory work for implementation of the future regulation on medicinal products for paediatric use was initiated in conjunction with the CHMP Paediatric Working Party. In addition, the EMEA set up an initiative reminding all marketing authorisation holders of their obligation to submit existing data not yet submitted to the competent authorities, in particular data relating to paediatric use of authorised medicines. This initiative was designed to run in parallel to a similar one initiated by Member States through the Mutual Recognition Facilitation Group.

Advanced therapies

The Agency contributed to the development of a proposed regulation on advanced therapies. It provided support to the European Commission with the technical requirements for such products, and will continue to do so as necessary during the Council and European Parliament consultation process.

2.10 Reinforcing scientific consistency

Establishment of scientific advisory groups

In addition to the scientific advisory groups established in 2004 for the evaluation of oncology, anti-infective and diagnostic medicinal products, four new groups were created in 2005 to cover the remaining three therapeutic areas for which the centralised procedure is mandatory, i.e. diabetes (and endocrinology), neurodegenerative diseases (and other central nervous system conditions) and HIV (and viral diseases). Preparations were also made for a new group with expertise on cardiovascular diseases.

Their main task is to provide independent recommendations on scientific aspects, particularly clinical aspects, of products under evaluation by the CHMP (whether pre- or post-authorisation), or on any other scientific issue relevant to the work of the Committee. Members of scientific advisory groups are independent experts from academia and university hospitals, and represent various schools of medical thinking in the EU.

Strengthening the concept of lifecycle management and scientific consistency

Several initiatives were undertaken to reinforce regulatory and scientific consistency and continuity throughout the lifecycle of a medicinal product – from the early stages of scientific advice over the pre-submission, submission and initial evaluation stages through to the post-authorisation phase.

The CHMP adopted a pilot procedure for a peer review during the initial phase of the assessment of a marketing authorisation application to contribute to the quality assurance of the list of questions intended for the applicant.

In addition, the new framework for scientific advice and protocol assistance will further involve the CHMP by formalising their contribution to peer review before final adoption of the advice letter to maximise the clarity and ensure consistency in the provision of scientific advice. This will involve reviewers from the Scientific Advice Working Party, CHMP and COMP, in addition to the EMEA Secretariat.

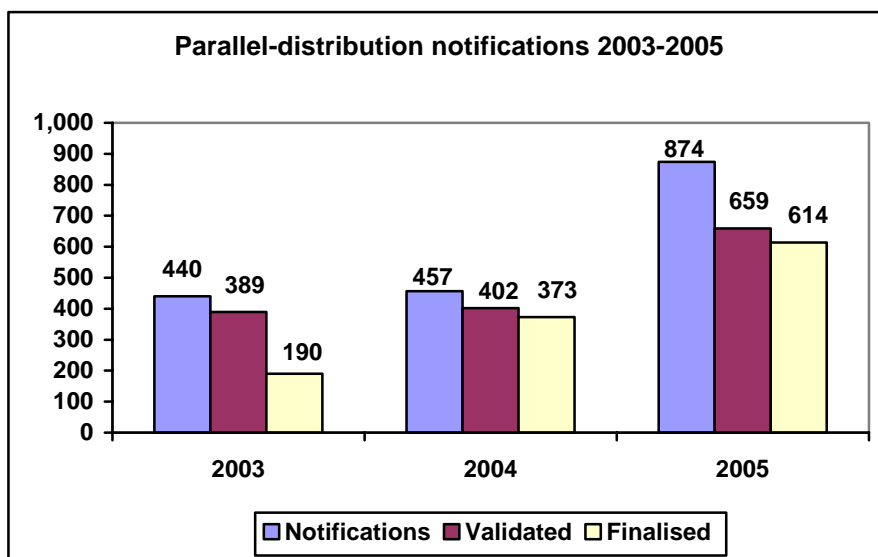
Improving internal procedures to ensure high-quality functioning of core activities

Increasing the cost-efficiency of resources to address the increasing workload and responsibilities of the Agency is a priority. The EMEA started looking at internal processes with a view to increasing the efficiency of existing resources. Procedural simplifications were introduced by producing guidelines on all aspects of the revised pharmaceutical legislation, to avoid discrepancies and the need for case-by-case procedure management.

2.11 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. A parallel distributor may market products placed on the market in one Member State in any other part of the Community, independently 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.

Implementation of the revised pharmaceutical legislation, which makes notification to the EMEA mandatory, led to a doubling of parallel distribution notifications made to the EMEA in 2005. In addition to these notifications, the Agency received over 1,000 notifications of changes.



Because of this unexpected important increase in workload, delays in the procedure were encountered during 2005, but, due to a temporary increase in staff and improved efficiency of the process, the delays were partially reduced by the end of the year. The Agency organised a tracking project with the European Association of Euro-Pharmaceutical Companies in order to identify areas for improvement. Following the project, corrective actions were implemented and the efficiency of the process was further improved.

The EMEA also updated the post-authorisation guidance for parallel distribution, reflecting the experience gained in 2004.

2.12 Mutual Recognition Facilitation Group / Coordination Group for Mutual Recognition and Decentralised Procedures–Human

Websites:

Heads of Medicines Agencies–Human: <http://heads.medagencies.com/>

European product index: <http://mri.medagencies.com/prodidx/>

EMEA/CMD(h) secretariat e-mail: mrp@emea.eu.int

The Mutual Recognition Facilitation Group (MRFG), which coordinated and facilitated the operation of the mutual recognition procedure over the past ten years, held its final meeting in October 2005.

In November 2005, the MRFG was replaced by the ‘Coordination Group for Mutual Recognition and Decentralised Procedures–Human’, or ‘CMD(h)’. The new group was set up under the revised EU pharmaceutical legislation to examine any question relating to the marketing of a medicinal product in two or more Member States, in accordance with the mutual recognition procedure (MRP) or the new decentralised procedure (DCP).

The MRFG met nine times in 2005. Mrs Truus Janse-de Hoog chaired the meetings on behalf of the Luxembourg presidency, in the first half of 2005, and Ms Shirley Norton during the UK presidency, in the second half of the year, until the final meeting of the MRFG in October 2005. Two informal meetings were held in 2005, in Luxembourg and in Dorking, UK. Mrs Truus Janse-de Hoog was elected Chairperson of the CMD(h) for a term of three years. The Vice-Chair was Ms. Shirley Norton for the duration of the term of the UK presidency of the Council of the European Union.

The MRFG worked in close collaboration with the EMEA on the development of guidance for the authorisation and supervision of medicinal products for human use in line with the provisions of the

new EU pharmaceutical legislation. Preparations for implementation of the new pharmaceutical legislation and arrangements for the new CMD(h) were permanent items on the agenda of the MRFG meetings.

A number of MRFG/CMD(h) subgroups meetings were held during 2005. The subgroup on the communication tracking system (CTS), which is in charge of the MRP tracking system, further developed the system to enable the tracking of the DCP. An updated version of the CTS software was deployed to all Member States on 1 November 2005.

The Joint MRFG/QRD Working Group on Patient information, set up to consider the new legal requirements for patient information organised a workshop to discuss the structure and content of package leaflets in different Member States, in order to develop a harmonised view regarding the assessment of the package leaflet in the MRP/DCP.

The Joint Pharmacovigilance Working Party/ MRFG Working Group met 3 times in 2005, twice with Interested Parties mainly to discuss the synchronisation of PSUR submissions and the PSUR work-sharing project.

In view of the role of the Coordination group to lay down a list of medicinal products for which a harmonised SPC should be drawn up, in accordance with Article 30(2) of Directive 2001/83/EC, as amended, a Sub-Group with representatives from the CMD(h), CHMP, the EMEA and the European Commission was set up.

Press releases with statistics and adopted documents were published monthly on the Heads of Medicines Agencies website. Statistical information on applications under the MRP and the new DCP was provided by the EMEA and presented in the monthly MRFG/CMD(h) press releases.

From 30 October 2005 until the end of 2005, 10 procedures were referred to the CMD(h) in accordance with Article 29(1) of Directive 2001/83/EC, as amended.

	Total submitted in 2005*	Under evaluation in 2005*	Ended positively in 2005*	Referrals to CHMP in 2005	Referrals to CMD(h) in 2005
Applications under MRP	826	137	954	2	10
Applications under DCP	31	9	N/A	N/A	N/A
Type-IA variations	4681	404	4044	N/A	N/A
Type-IB variations	2299	372	1944	0	N/A
Type-II variations	2050	855	1509	7	N/A

*The numbers include multiple procedures as stated at 31 December 2005.

A 'Summary of MRFG/CMD(h) Activities in 2005' is available on the Heads of Medicines Agencies–Human website.

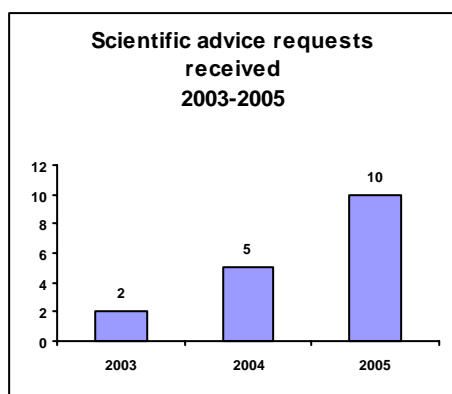
3 VETERINARY MEDICINES

3.1 *Scientific advice*

Scientific advice is a priority area for the EMEA. It is aimed at companies developing new medicines, with the benefit of helping improve the availability of medicinal products and the competitiveness of European-based research companies and helping speed access to market for innovative medicines.

The Agency provides advice on specific questions relating to the quality, safety or efficacy of medicinal products. These questions typically arise during the research and development phase.

Scientific advice activity increased significantly in 2005: 10 requests for scientific advice were received (1 more than the forecast), compared to the 5 received in 2004.



The average time required to finalise procedures for provision of scientific advice in 2005 was 46 days.

Free scientific advice for minor uses and minor species

In September 2005, the EMEA Management Board extended the pilot scheme for free scientific advice for veterinary medicines for minor uses and minor species (MUMS). The scheme is part of the Agency's strategy to improve the availability of such medicines.

Two scientific advice requests received in 2005 were eligible for free advice under the provisions of this programme for minor uses and minor species. One of these concerned an intended application for establishing maximum residue limits for a substance to be used in bees and in trout. The second application concerned residue studies and the clinical development of a product to be used for rabbits.

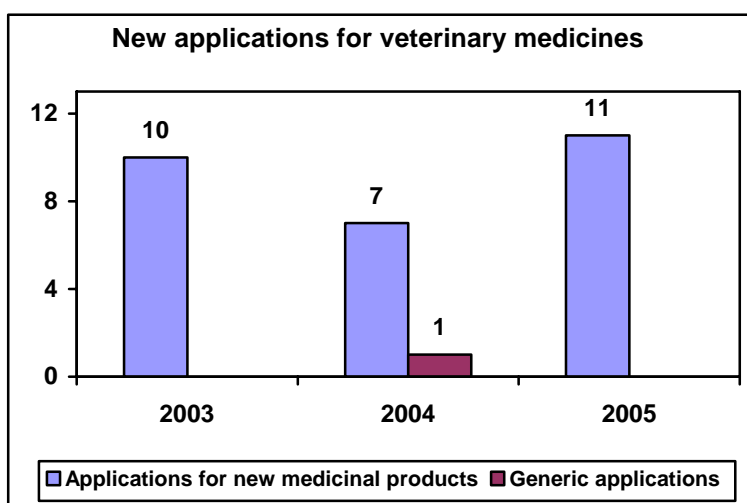
3.2 *Initial evaluation*

The EMEA promotes public and animal health by reviewing new applications for authorisation of medicinal products in a timely and efficient manner, thus contributing to the provision of new and safe treatment options.

An initial evaluation is conducted by the EMEA to assess the quality, safety and efficacy of every new veterinary product that is subject to the Community or centralised procedure. Following this initial evaluation, the Committee for Medicinal Products for Veterinary Use (CVMP) adopts an opinion on whether the product should receive a marketing authorisation.

Level of applications

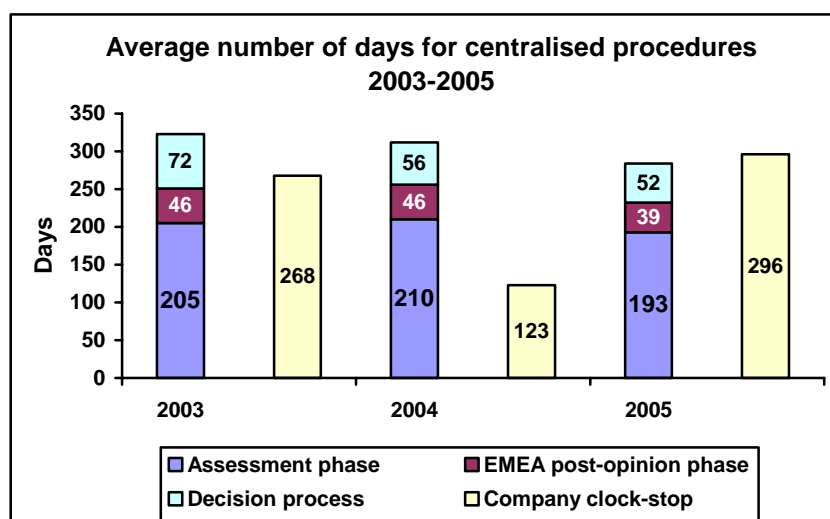
Eleven initial marketing authorisation applications were received, 10 of which were for pharmaceuticals and 1 for an immunological. The majority of applications concerned medicinal products for single, companion-animal species (dogs or cats only); 1 was for dogs, cats and horses; 1 was for use in food-producing animals (pigs).



In 2005, the CVMP adopted a total of 5 positive opinions for initial marketing authorisation applications. There were no negative opinions. One application was withdrawn prior to opinion.

Among the 5 positive opinions were:

- 1 for a third-generation cephalosporin used to treat bacterial infections in pigs
- 1 for a novel combination endoparasiticide to treat roundworms and tapeworms in cats
- 3 vaccines for horses, against equine influenza and tetanus.



All initial evaluations were carried out within the 210 days regulatory time limit. For those new applications for which the Commission delivered a decision in 2005, the average CVMP assessment time was 193 days — a significant improvement on the average of 210 days in 2004.

Details of the opinion are given in Annex 10.

Improving the quality and consistency of scientific assessments

Significant progress was made on establishing a scientific memory database for centrally authorised veterinary medicinal products. The project is designed to underpin the quality and consistency of the CVMP's scientific assessments of centrally authorised products.

The database will help to classify the major objections against a marketing authorisation application which arise during the evaluation — typically at day 120, when the list of questions is adopted, and at day 180, when the list of outstanding issues is adopted. The expected benefit of the database is that it strengthens the risk/benefit analysis during the authorisation process.

3.3 Availability of veterinary medicines

The EMEA continued efforts to address the shortage of essential medicines to the veterinary practitioner particularly for minor uses and minor species (MUMS), focusing in particular on the implementation of recommendations of the position paper regarding availability of products for minor uses and minor species.

The CVMP launched a public consultation for a number of guidelines proposing the adaptation of data requirements for the testing of veterinary medicines for minor uses and minor species regarding quality, safety, including maximum residue limits (MRLs), and efficacy, while ensuring public health. Finalisation of the guidelines is expected in the second quarter of 2006.

In the context of the pilot scheme to provide free scientific advice to companies willing to develop medicines for minor uses and minor species, industry confirmed their interest in the scheme. Only few requests for free scientific advice have been made since the scheme was introduced in October 2003. The scheme will only become fully operational once the guidelines on adaptation of data requirements become available.

Another initiative aimed in particular at encouraging the development of medicines for minor species in the important livestock sector is the extrapolation of MRLs from major to minor species. The CVMP continued to extrapolate MRLs upon requests from companies in 2005 for substances essential for therapy in minor species. The extrapolations are carried out without specific applications or payment of fees, provided the criteria detailed in the relevant CVMP guideline are met, thus ensuring consumer safety.

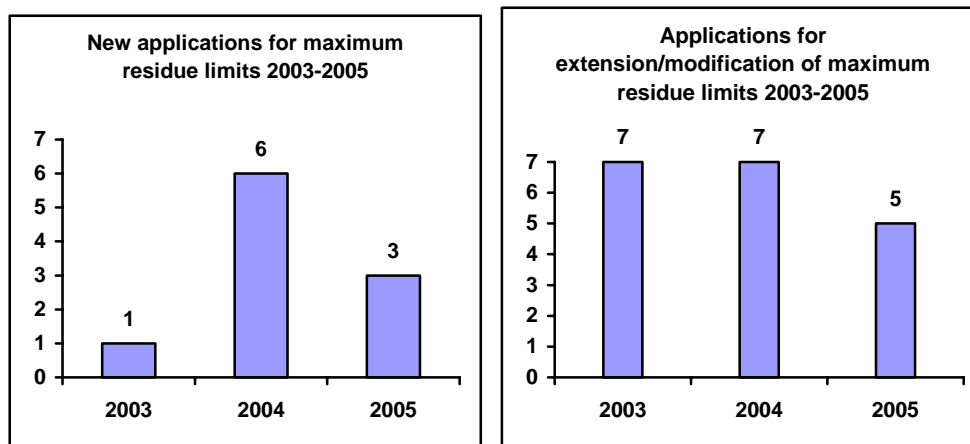
The CVMP, in consultation with the Federation of Veterinarians in Europe, prepared a proposal for a list of essential substances for the treatment of horses following the request from the European Commission. The list was submitted to the Commission in May 2005 to serve as basis for a list of essential substances, which is provided for by the new legislation. Once adopted products containing the substances on the list can be used by veterinarians for the treatment of horses under the conditions of the 'cascade principle', provided a minimum 6-month withdrawal period is applied.

3.4 Maximum residue limits

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

In 2005, the EMEA received and validated 3 new applications for MRLs — 4 less than the 7 forecast.

This small number of new MRL applications indicates that there is currently less interest among veterinary pharmaceutical companies for developing medicines for food-producing animals than there is for developing new drugs for companion animals.



Five applications for extension or modification of MRLs were submitted in 2005. This represents a shortfall of 4 in the 9 that were forecast, and a slight deviation from the previous years' steady trend. The decrease may be due to the fact that, in some cases, it is now possible to extend MRLs to further species without formal applications, provided the criteria for MRL extrapolations are met.

The CVMP gave 3 positive opinions for the establishment of MRLs and 8 opinions for the extension of existing MRLs to other species. 4 of these 8 were opinions to establish final MRLs following the previous establishment of provisional MRLs. In addition, the CVMP gave 3 opinions for the extrapolation of existing MRLs to further species, in line with its policy on availability of veterinary medicines.

The Committee carried out all first scientific assessments for MRL applications in less than 120 days – the maximum provided for by the legislation. In the four cases where provisional MRLs had been established before, the assessment of the additional data to establish final MRLs was carried out within 90 days.

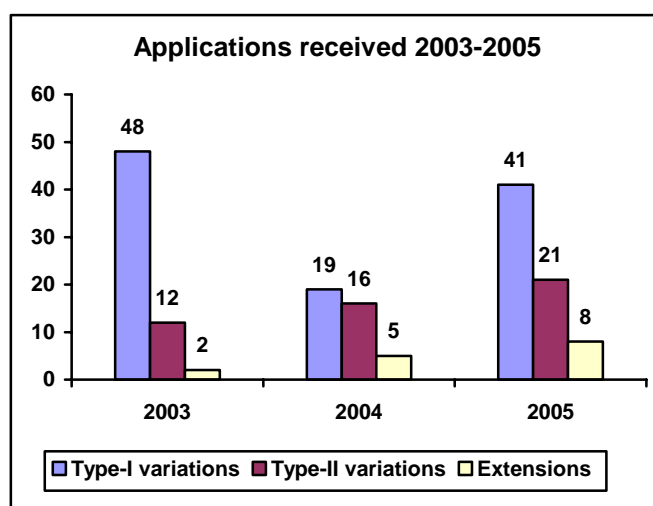
See Annex 10 for a detailed list of opinions adopted.

3.5 *Post-authorisation activities*

Changes to the terms of marketing authorisations are made frequently during the life of a medicine. Marketing authorisation holders may want to change the manufacturing process, alter or improve the medicinal product, or introduce additional warnings and contraindications. These changes, known as variations, require formal approval often involving a decision of the European Commission.

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

A greater number of applications for variations to marketing authorisations were received in 2005 than in the previous year, which is a consequence of the increased number of centrally authorised products available.



A total of 41 type-I variation applications were received, relating to 14 type-IA and 27 type-IB variations.

Twenty-one applications received related to the more complex type-II variations. Of these, 14 applications were for immunologicals, and concerned quality changes; 7 were for pharmaceuticals, with 4 concerning clinical changes and 3 concerning quality changes.

Eight applications for extension of a marketing authorisation were received: 6 related to pharmaceuticals and 2 to immunologicals. While the majority of these concerned new pharmaceutical forms, 2 concerned new target species.

Evaluation of variation applications was conducted within the regulatory time limits.

3.6 Pharmacovigilance and maintenance activities

Pharmacovigilance is the process of continuous monitoring of veterinary medicinal products on the market. Its aim is to identify and report any potential safety issues relating to these medicines. Procedures are in place for the collection and reporting of all suspected adverse reactions and other safety related data. This ensures that appropriate responses be made in order to afford the best protection to users of medicinal products.

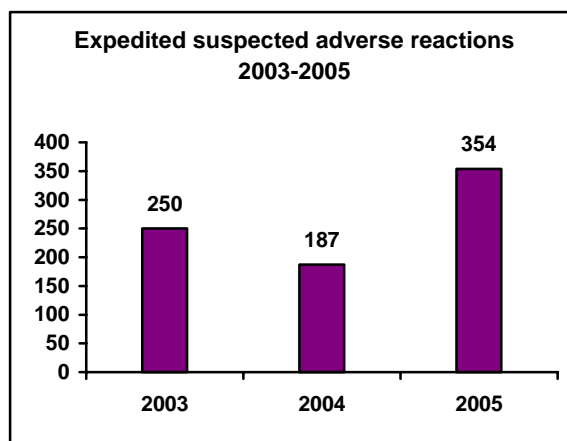
The related activities include the assessments of suspected serious reaction reports and periodic safety update reports as well as other maintenance activities such as follow-up measures, specific obligations, annual re-assessments (annual reports) and renewal applications.

Annual reports (re-assessment reports prepared in cooperation with rapporteur and co-rapporteur, and adopted by the CVMP) were prepared for 42 products in 2005.

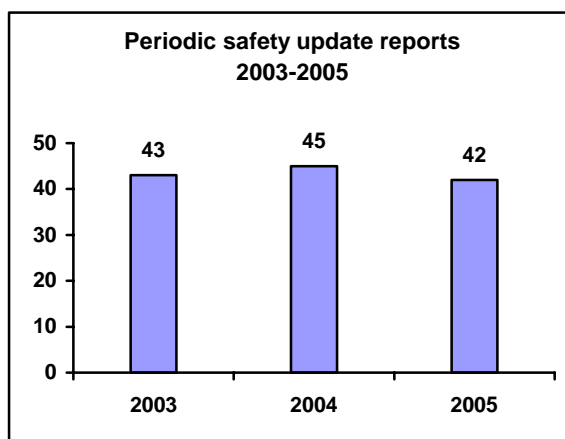
In 2005, the EMEA received a total of 354 expedited spontaneous reports of suspected serious adverse reactions to centrally authorised veterinary medicines in animals or humans. This number includes reports originating in the EU and in countries outside the EU, such as the United States.

Of these, 305 reports related to suspected adverse reactions in animals, with a single report relating to one or more animals. Suspected adverse reactions in dogs and cats were most frequently reported. Only 32 reports related to food-producing animals. Altogether, 238 deaths in animals were reported.

Adverse reactions in human beings following exposure to a veterinary medicinal product were reported in 49 cases during 2005, none of which resulted in fatality.



The considerable increase in spontaneous reporting compared to previous years is partly the result of promotion activities encouraging veterinarians to report suspected drug reactions. Another contributing factor to the relatively high number is the good progress made with electronic reporting to the EudraVigilance Veterinary database.



Forty-two periodic safety update reports (PSURs) were received and reviewed by the CVMP. The PSURs were generally received in a good format and in a timely manner. In one case, the CVMP recommended changes to the product literature, following an in-depth review of the product's safety.

Safety review of COX-2 inhibitors

Following safety concerns raised over COX-2 inhibitor medicines for human use, the CVMP, supported by its Pharmacovigilance Working Party (PhVWP-V), investigated the safety of COX-2 inhibitor medicines for veterinary use. On the basis of the data reviewed, the Committee concluded that no regulatory action was required with respect to veterinary COX-2 medicines in relation to cardiovascular and gastrointestinal safety or skin reactions.

Improving veterinary pharmacovigilance

Pharmacovigilance in the veterinary sector was a top priority for the EMEA in 2005. A number of important actions were carried out, aimed at improving electronic reporting of post-authorisation safety information, improving the exchange of safety information within the EU, and ensuring adequate surveillance and harmonised action.

To implement changes introduced by the revised EU pharmaceutical legislation, the Agency updated its pharmacovigilance guidance notes to the veterinary pharmaceutical industry, the Member States and health professionals.

The CVMP prepared a simple guide on veterinary pharmacovigilance, targeted primarily at veterinarians, in order to encourage reporting of adverse drug reactions.

The Agency also developed guidelines and concept papers designed to improve the consistency of safety data assessments.

Considerable progress was made on establishing internationally agreed pharmacovigilance reporting requirements under VICH (the trilateral EU-Japan-USA programme aimed at harmonising technical requirements for veterinary product registration). Further, detailed guidance is currently being developed.

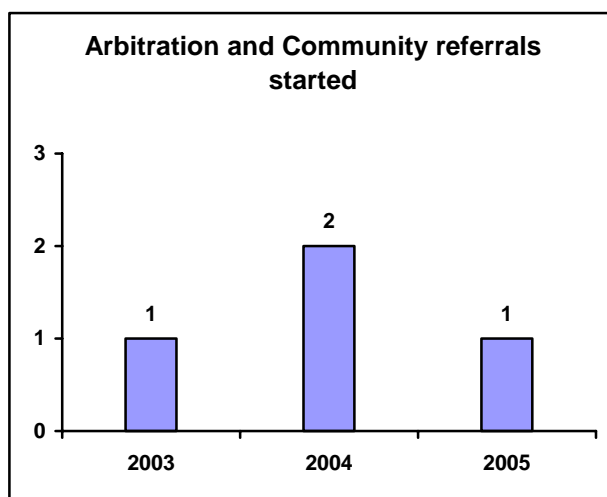
Good progress with EudraVigilance Veterinary

By the end of 2005, the majority of EU Member States were reporting electronically to the EudraVigilance Veterinary database, launched in October 2004; the remaining Member States are set to follow suit shortly.

Electronic reporting of adverse reactions is now mandatory. In 2005, the Agency discussed implementation plans for electronic reporting with major partners in the veterinary pharmaceutical industry. To address the specific needs of smaller companies, an additional, simple electronic reporting form was developed for use at the Member State level by smaller marketing authorisation holders.

3.7 Arbitration and Community referrals

Arbitration procedures are initiated because of disagreement between Member States in the framework of the mutual recognition procedure (Article 33 of Directive 2001/82/EC). Referrals are initiated either in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by the 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).



In 2005, one referral was received; no arbitration was submitted. A total of 9 such procedures were forecast for 2005.

The high forecast was based on the expectation that more arbitrations would arise through the mutual recognition procedure after the 2004 enlargement of the EU, given that it would be more difficult to achieve consensus among the increased number of Member States, and that more Article 34 referrals would ensue following the entry into force of the new legal provisions on harmonisation of the summary of product characteristics (SPC) information.

The one referral submitted concerned the product Suramox 15% (amoxicilin). The referral was submitted following a mutual recognition procedure and subsequent withdrawal of the application in some Member States due to concerns regarding the withdrawal period for the product in cattle and pigs.

In 2005, the CVMP also reconsidered its previous opinion on the referral procedure for Micotil 300 (tilmicosin), initiated in 2004 to investigate concerns regarding user safety following an accidental human fatality resulting from use of this product during the treatment of animals. Following the receipt of new safety information, the European Commission requested the CVMP to review its previous opinion. Confirming its previous opinion, the CVMP concluded that the benefits of Micotil, under appropriate conditions of use, outweigh the potential risk to the user. It recommended, however, in order to mitigate such risk, that additional precautions and warnings be included on the summary of product characteristics and the package leaflet. The amended opinion provides expanded guidance on advisable treatment in the case of accidental human injection.

3.8 *Management and organisation of the Committee for Medicinal Products for Veterinary Use*

The Committee for Medicinal Products for Veterinary Use is responsible for formulating the Agency's opinions on any matter in relation to veterinary medicinal products.

The work of the Committees is supported by a number of working parties, composed of European experts selected from a list maintained by the EMEA.

The working parties are involved, according to their area of responsibility, in the development and revision of guidelines and in the provision of recommendations and advice on medicinal products for which applications are made for orphan drug designation, scientific advice, protocol assistance, marketing authorisation or post-authorisation activities.

The Committee held 11 plenary meetings in 2005. The following standing and temporary working parties and scientific advisory groups assisted the Committee in its work:

- Scientific Advice Working Party (SAWP-V)
- Efficacy Working Party (EWP-V)
- Immunologicals Working Party (IWP)
- Joint CHMP/CVMP Quality Working Party (QWP)
- Pharmacovigilance Working Party (PhVWP-V)
- Safety Working Party (SWP-V)
- Environmental Risk Assessment (ERAWP) (temporary working party)
- Scientific Advisory Group on Antimicrobials (SAGAM)

3.9 **Veterinary Mutual Recognition Facilitation Group / Coordination Group for Mutual Recognition and Decentralised Procedures—Veterinary**

Useful website:

Heads of Medicines Agencies—Veterinary

<http://www.hevra.org/>

The Veterinary Mutual Recognition Facilitation Group (VMRFG) met on a monthly basis until October 2005. For the first six months, the meetings were chaired by the Netherlands, acting on behalf of the Luxembourg EU Presidency. From July to October, the meetings were chaired by the United Kingdom. Two informal meetings were held: one in Oslo, Norway, and one in Windsor, UK.

Following the entry into force of the revised EU pharmaceutical legislation, the VMRFG was transformed into the Coordination Group for Mutual Recognition and Decentralised Procedures—Veterinary, or CMD(v), at the end of October. The group now has a formal basis.

Dr Esther Werner was elected as the chairperson for a term of 3 years. The role of the vice-chair will rotate with the EU Presidency. CMD(v) drafted its rules of procedure as well as various best-practice guides (BPGs) and standard operating procedures (SOPs). Two subgroups were set up to advise on the management of BPGs and SOPs, and to discuss and recommend changes to the Notice to Applicants.

A further sub-group with representatives from the CMD(v), an observer of the Commission and the EMEA for secretarial support was created to lay down a list of veterinary medicinal products for which a harmonised SPC should be drawn up.

Eighty-eight products started the mutual recognition procedure (MRP) and 95 procedures were finalised. For 2 applications, no agreement could be reached within the legal timeframe. In accordance with Article 33 of Directive 2001/82/EC as amended, these were referred to CMD(v) for further consideration. Another product was referred to the CVMP on the grounds of Community interest (Article 35 of the Directive). More information on this procedure is provided in chapter 3.7.

Applications	Received	Finalised	CMD(v) referral	CVMP referral
MRP	88	95	4	1

The revised legislation introduced a further route for obtaining of a marketing authorisation within the Community: the decentralised procedure. By the end of 2005, the number of applications received for this procedure was 10.

Four meetings were held with IFAH-Europe and the European Group for Generic Veterinary Products (EGGVP) to discuss industry issues on MRP and other topics. The joint IFAH-Europe and VMRFG survey on MRP, conducted during 2004, was completed.

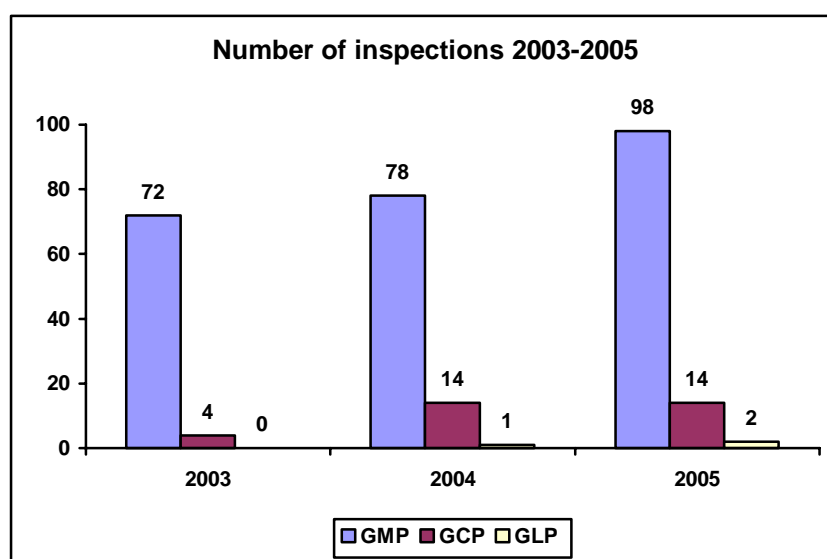
The EMEA provided full secretariat and administrative support to VMRFG and CMD(v).

4 INSPECTIONS

4.1 GMP, GCP, GLP inspections

The EMEA continues to support all 25 Member States on good manufacturing practice (GMP), good clinical practice (GCP) and pharmacovigilance inspections, through the work of the ad hoc GMP and GCP inspectors meetings on harmonisation of procedures and interpretation of related requirements. Discussions on resource implications, management and prioritisation were a significant part of the work of these groups in 2005.

The EMEA coordinated and managed requests for 98 GMP and plasma master file inspections, 14 GCP and pharmacovigilance inspections, and 2 good laboratory practice (GLP) inspections during 2005, representing a total increase of 23% relative to 2004. By August 2005, 500 GMP inspections had been completed since the start of the operation of the centralised procedure. All inspections were completed within the legal timeframes and to the standards required by the Agency's quality management system.



Implementation of the Clinical Trials Directive for human medicines

The EMEA continued to support the Commission and the Member States with the implementation of Directive 2001/20/EC on clinical trials, through: activities of the ad hoc meetings of GCP and GMP inspection services; participation in working groups of the Commission; support to the Heads of Medicines Agencies' Clinical Trials Facilitation Group; support to the Commission and Member States on developing and updating guidance on various aspects of clinical trials; and facilitating harmonisation of inspection practices through the activities of the above-mentioned GCP and GMP meetings.

Product defects and deviations

Marketing authorisation holders are required to notify the EMEA of any defect or abnormal restriction of a centrally authorised medicinal product that could result in a recall.

As expected, the workload in dealing with product defects and deviations increased, mainly due to the greater number of centrally authorised products on the market and a growing awareness of industry's responsibilities to keep the EMEA informed.

The EMEA received 65 quality defect reports concerning human medicinal products and 3 quality defect reports for veterinary medicinal products. Twenty-two of these defect reports resulted in a product recall (20 related to human medicinal products and 2 related to veterinary medicinal products); the remainder were classified as minor.

Two out of the 22 recalls were classified as 'Class 1' recalls, i.e. relating to defects which are potentially life-threatening or could cause serious risks to health. Six recalls were 'Class 2' recalls, i.e. relating to defects which could cause illness or mistreatment. The majority of recalls (14) were classified as 'Class 3' recalls, which are not associated with serious public health hazards.

Meetings and other activities

The EMEA organised and chaired 4 meetings each for the Ad hoc GMP and GCP Inspectors Groups in 2005. These two groups contribute to the harmonisation of inspection-related procedures across the EU and develop guidance documents. The ad hoc GMP inspectors are also responsible for overseeing the implementation of the EudraGMP database on manufacturing authorisations and GMP certificates, on which major developmental work took place in 2005.

The Agency also provided secretarial support to the Joint CHMP/CVMP Quality Working Party (QWP), which continued its work on development of EU quality guidelines, provision of support to ICH and VICH, and cooperation with the European Directorate for the Quality of Medicines (EDQM).

One joint meeting of the QWP and ad hoc GMP inspectors group took place, building on cooperation between assessors and inspectors on quality related matters. A joint meeting of GMP and GCP inspectors also served to identify some areas for future work on Annex 13 to the GMP guide concerning manufacture of clinical trial materials.

Activities in the context of the joint audit programme for GMP inspectorates

In the context of the joint audit programme for GMP inspectorates, the EMEA coordinated activities designed to ensure consistent quality standards and harmonised approaches.

The Compliance Group, a subgroup of the GMP Inspection Services Group, met 4 times in 2005. The group revised the joint audit programme documentation and procedures, and established an audit schedule for all GMP inspectorates in the Member States, Iceland, Liechtenstein and Norway. The first training session for auditors was held at the EMEA in October 2005.

EMEA PAT (Process Analytical Technologies) team

The EMEA PAT team continued to meet to review the implications of PAT with a view to ensuring that the European regulatory framework and the authorities are prepared to conduct thorough and effective evaluations of PAT-based submissions. PAT is a system for designing, analysing and controlling manufacturing through the timely measurement (i.e. during processing) of critical quality and performance attributes of raw and in-process materials and processes, with the goal of ensuring final product quality (= identifying and mentoring factors that affect product quality). The PAT team held 4 meetings in 2005 and heard presentations from 3 industry groups, as well as participating in 2 site visits. A question and answer document aimed at clarifying certain provisions was prepared and published.

4.2 Mutual recognition agreements

Good progress was made on the harmonisation of operational aspects of all EC mutual recognition agreements (MRAs). All MRA partners agreed to share annual reporting on GMP with each other as part of the maintenance programme. MRA partners have been closely involved in the changes to the EU GMP requirements to ensure ongoing equivalency. Work to include further product types under the scope of the MRA with Japan had to be postponed until 2006.

In the context of the EC-Canada mutual recognition agreement, the preparatory evaluation work performed by EU competent authorities on all new Member State GMP authorities was completed. Most new Member States were visited in 2004, and Latvia, Lithuania, Poland and Slovenia were visited in 2005. However, reporting and follow-up to some of these visits is still ongoing. Canada commenced the evaluation of Czech Republic and Hungary in 2005 and is currently preparing for the evaluations of Cyprus, Malta and Slovak Republic in 2006.

Mutual recognition agreement (MRA) implementation status and coverage:		
MRA	Implementation status	Coverage
European Community – Australia	Human medicinal products: 1 January 1999 Veterinary medicinal products: 1 June 2001	Human and veterinary medicinal products Official batch release excluded
European Community – Canada	Operational since 1 February 2003 Assessment of new member states ongoing	Human and veterinary medicinal products Veterinary immunologicals and vaccines excluded
European Community – Japan	Operational since 29 May 2004	Human medicinal products only Currently excludes sterile and biological medicinal products, active substances, investigational medicinal products, medicinal gases Official batch release excluded
European Community – New Zealand	Human medicinal products: 1 January 1999 Veterinary medicinal products: 1 June 2002	Human and veterinary medicinal products Official batch release excluded
European Community – Switzerland	1 June 2002	Human and veterinary medicinal products and recognition of official batch control of biologicals (human)
European Community – United States	Not in operation. Transitional period ended. No decision on formal extension of the transitional period has been taken	Human and veterinary medicinal products Official batch release excluded

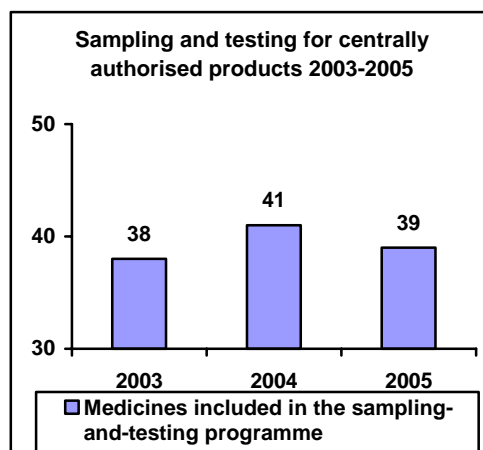
4.3 Sampling and testing

The objectives of the sampling and testing programme are to supervise the quality of centrally authorised medicinal products placed on the market, and to check compliance of these with their authorised specifications.

Sampling from the market in different countries is carried out by national inspectorates, and testing is performed by Official Medicines Control Laboratories coordinated through the EDQM. A selection of centrally authorised products is included in each annual programme.

Thirty-nine medicinal products were included within the scope of the 2005 programme of sampling and testing of centrally authorised products. The majority of results show that the products were of high quality and complied with their specifications. Results requiring further investigation were found in 8 of the 39 products.

None of these concerned out-of-specification results. The investigations revealed some regulatory and scientific discrepancies, which were mainly addressed through amendment of the testing documentation by the marketing authorisation holders concerned.

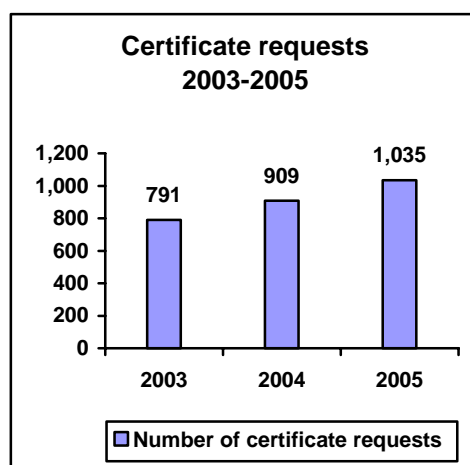


Major progress was made in improving the Sampling and Testing Programme. Revised objectives and descriptions of the programme were published and communication and reporting was made more transparent by publishing annual reports of the outcome of the testing results and a list of all centrally authorised products tested. Work on drafting a risk-based approach to the selection of products and parameters to be tested was also initiated during 2005.

4.4 Certificates of a medicinal product

The EMEA issues certificates of medicinal products to confirm the marketing authorisation status of products that have been authorised through the centralised procedure, or of products for which a centralised marketing authorisation application has been submitted to the EMEA. The purpose of this EMEA certification scheme is to support the work of health authorities outside the European Union, in particular those in developing countries.

The number of issued certificates continued to increase, and certificate number 100,000 was issued (for an AIDS product) in August 2005. Despite the increasing number of requests, the average issuing time has remained within procedural limits. This has been achieved by rationalisation of human resources and further process automation.



Legalisation of EMEA certificates by the European Commission Representation in the United Kingdom stopped on 1 November 2005. When the Agency was created, in 1995, it was requested that EMEA certificates be legalised by the European Commission because health authorities in countries outside the EU were unfamiliar with the activities of the Agency at that time. Now that the EMEA has been in operation for more than 10 years, and further to consultation with interested parties, legalisation by the Commission is now considered superfluous. The EMEA developed an action plan to cooperation and communication between involved parties in order to facilitate this change.

5 EU TELEMATICS STRATEGY AND INFORMATION TECHNOLOGY

Various initiatives are currently underway to implement the EU telematics Strategy drawn up by the Member States, the European Commission and the EMEA. Their objective is to support and facilitate the operation of procedures established in accordance with European policy and legislation in the field of pharmaceuticals, whilst also increasing their efficiency and transparency.

EU telematics and EMEA internal systems are backed by dedicated support and maintenance systems and services, which ensure high levels of availability, security and confidentiality.

Providing high-quality EU telematics services

New services and improvements to the corporate and EU telematics infrastructure were introduced in 2005. Management systems which monitor EU telematics and corporate systems are now in place, and are used to maintain high levels of service, in conjunction with the EMEA helpdesk and support services. These management systems have the added advantage of providing users in the EMEA and the national competent authorities with updated application-performance information. A good example of these services is provided by EudraNet, the network that interlinks the more than 40 national competent authorities, the Commission and the EMEA, where administrators are provided with real-time information on the status of the network in a form that highlights key indicators with colour coding and graphics.

EU telematics projects were taken forward to put in place the modifications to systems and services necessary to implement the new legislation.

- Community database for medicinal products: The first production version of the community database was delivered in line with the planned specifications and made available to the regulatory community. It presents key data relating to medicinal products authorised via the centralised procedure and has multiple-field search functionality that allows searching by product name, active substance etc.
- EudraVigilance: First production versions of the EudraVigilance datawarehouse and pharmacointelligence tools were delivered for testing. These tools enable safety data received electronically and stored in the database to be reorganised for more sophisticated searching and analysed against complex criteria to highlight potential trends for further investigation in the context of the assurance of product safety.
- Product information management: The first production version of the product information management (PIM) review system for regulatory authorities and the first production version of the PIM light authoring tool for applicants were ready, enabling formal delivery very early in 2006. PIM enables the management and exchange of product information (summary of product characteristics, package leaflet and labelling) by all parties involved in the evaluation process for the centralised procedure. Product information is structured into reusable parts and exchanged by electronic means. For regulatory authorities, the information is held in a single location and worked on from geographical locations all over the European Union.
- EudraCT: Work on the completion of phase 2a of EudraCT, the European Clinical Trials registration database, was delayed due to unforeseen difficulties with the final steps of the upgrade to version 3.0.0. Phase 2a incorporates a system that alerts Member State competent authorities to certain events, including interruptions or early terminations of clinical trials for safety reasons, or because of lack of efficacy of the substance undergoing the trial. The system is also adapted for the new application form for clinical trials in the European Union.
- EudraGMP: Work on the development of this system, the Community database of manufacturing authorisations and of certificates of good manufacturing practice, began. An initial prototype was demonstrated to the responsible implementation group in December.

Corporate IT projects

In 2005, the EMEA operated a large number of IT systems and developed a programme of projects. The monitoring systems the EMEA has introduced provide improved performance-management capability. The key corporate development projects in 2005 include:

- The new Eudra Common Directory (ECD): The directory, which is based on industry-standard LDAP (Lightweight Directory Access Protocol, a set of protocols for accessing information directories), went into full production in February, providing a central repository for contact information on persons and organisations that have business relations with the Agency.
- The new module of Meetings Management System (MMS III) went into production in June, allowing meeting organisers to streamline the process of inviting over 6 000 delegates a year to meetings at the EMEA.
- The new Experts database, with information on over 3 800 experts nominated by national competent authorities, was ready for user-acceptance testing at the end of 2005.
- Work started in 2005 on SIAMED II, the Agency's tracking system for medicinal products, to migrate this core business application to the new J2EE/Oracle platform.

Videoconferencing technology

Given the increase in meetings, the Agency is considering new and innovative ways of applying technological solutions to conducting meetings, including promoting greater use of videoconferencing and web streaming. The EMEA piloted a number of projects in 2005 concerning electronic provision of documentation for meetings and use of alternative technologies for electronic meetings.

Improving business continuity

An integral part of the EMEA's overall business-continuity arrangements are those necessary to recover IT systems in the event of disasters. In 2005, a range of IT contingency measures were implemented. A four-phase plan was also formulated for the development and implementation of remote off-site disaster-recovery facilities for the EMEA in such events. The first phase of this plan was contracted in 2005.

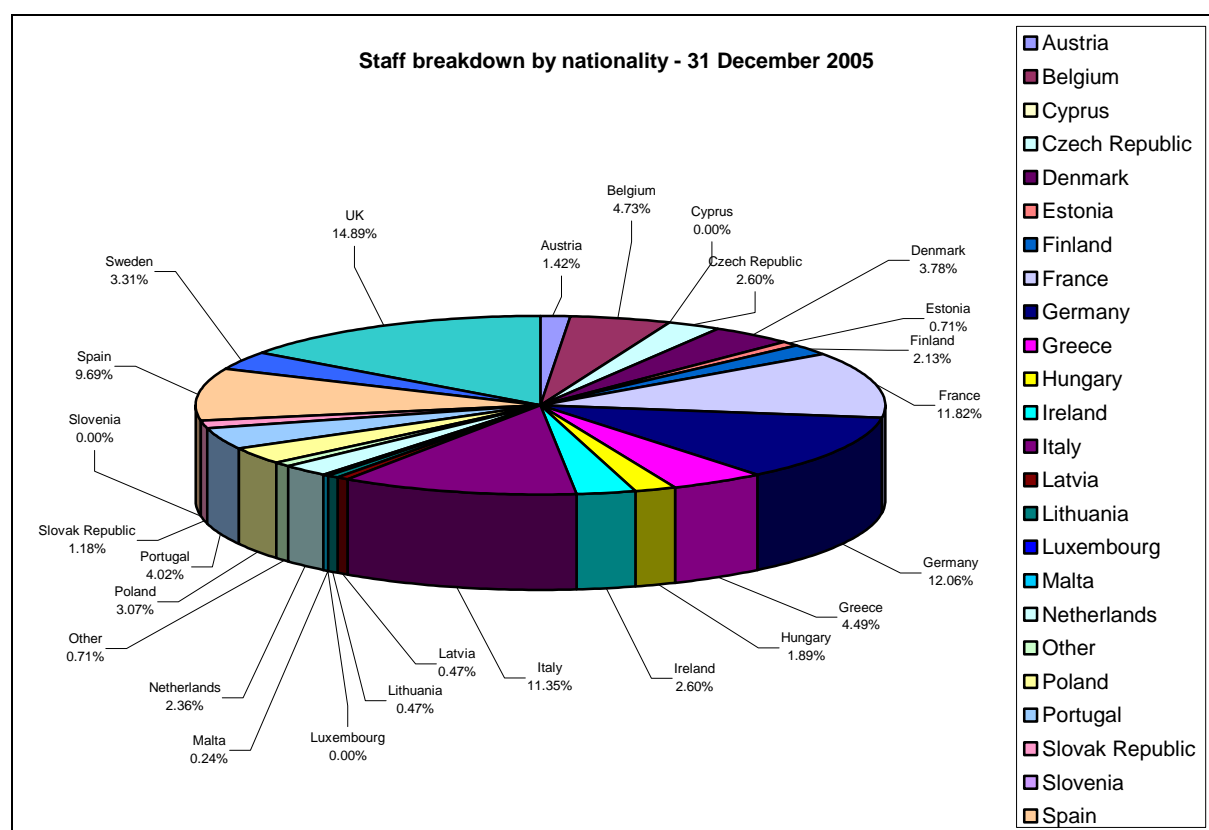
6 SUPPORT SERVICES

6.1 Personnel and budget

Activities in this area relate to a number of functions, including managing and administering staff and seconded personnel, conducting recruitment procedures, and managing revenue and expenditure.

Following the entry into force of new 'Regulations and Rules applicable to officials and other servants of the European Communities', the EMEA prepared a series of implementing rules for adoption by the Management Board.

Taking into account the greater scientific role of the Agency, stemming from the revised EU pharmaceutical legislation and the Road Map, the Agency started the implementation of training profiles for all EMEA staff. The training profiles aim for a continuous system of competence development and help to identify outstanding training needs.



Regular budget-monitoring reports were prepared during 2005, with one amending budget submitted to, and approved by, the Management Board.

The activity-based budgeting system was further enhanced by the introduction of a template, which will provide for a more streamlined process of data collection across the Agency.

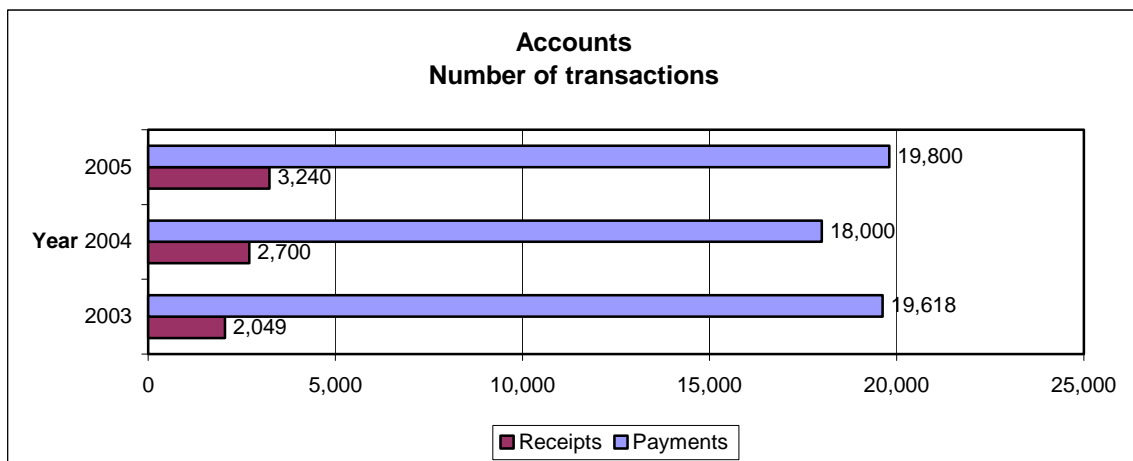
6.2 Accounts

The account sector maintains the accounts, makes payments and collects revenue in accordance with the procedures laid down in the Financial Regulation. It manages the cash resources of the Agency, maintains the Agency's relationship with its banks, and provides accurate and timely financial information to management.

Important projects for 2005 included:

- Consolidation of an asset management software system
- Implementation of a new fee invoicing system: As required by the new fee regulation the EMEA changed, on December 1, 2005, its method of collecting fee income from the previous upfront payment scheme to an invoicing system.
- Coordination of the interagency 'Common Support Service' (CSS) group: The EMEA chaired the Interagency Common Support Service in 2005. The CSS is a forum for exchange of experiences between EU agencies on common accounting and other administrative systems.

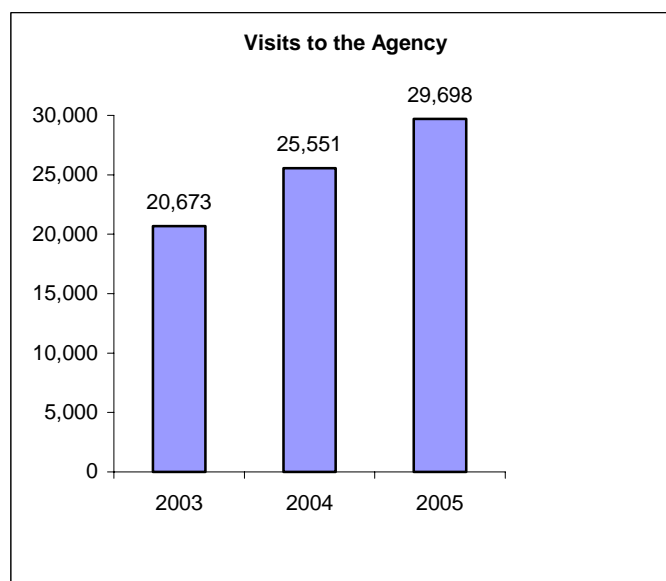
The financial accounts are prepared based on generally accepted accounting principles and are published at the EMEA Website.



6.3 Infrastructure services at the EMEA

Activities in this field relate to the provision and running of the necessary infrastructure services for effective functioning of the Agency, including the management of procurement procedures.

In 2005, the Agency had 29,698 visits. This is a 16% increase compared to the previous year.

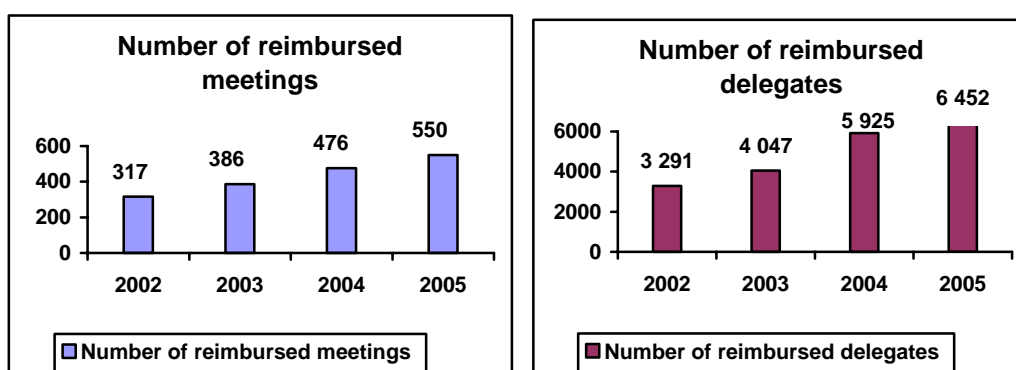


- A business continuity plan for the whole Agency was developed in 2005. A Business Continuity Group has been established to ensure coordination and cooperation throughout the Agency. Business impact assessments for each sector were begun in 2005 and are ongoing.
- Two additional floors of 7 Westferry Circus were acquired during 2005 in order to accommodate more offices and meeting rooms.
- The EMEA put in place new implementing rules reflecting changes introduced by the new consolidated Public Procurement Directive, and published a guidebook for tenderers.
- The EMEA's range of standard procurement contracts was extended in 2005 to include a standard outsourcing contract as well as low-level IT terms and conditions.
- Reception and switchboard duties were outsourced following a call for tender. A contract was awarded for technical assistance for meeting rooms throughout the Agency.

6.4 Meetings and conferences at the EMEA

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

The number of meetings organised by the EMEA increased by 16% and the number of delegates reimbursed increased by 7% in 2005, compared to 2004.



With a view to re-engineering and reinforcing its processes relating to meetings management, phase three of an automated system for streamlining the organisation of meetings processes and conferences was released in 2005. This Meeting Management System enables the automation of many administrative documents, such as invitations, participation lists and reimbursement forms, and the setting up of a tracking system for hotel and travel details.

6.5 EMEA document management and publishing

The year 2005 was the first full year of operation of the rules on access to EMEA documents, adopted by the Management Board in May 2004. Consequently, growing demands from the public and interested parties for access to the documents held by the Agency had procedural and resource implications. Notably, the workload of the Document Management & Publishing sector increased drastically compared to previous years.

Implementation of the electronic document management system remained a priority in the area of document management and publishing, as it is the bedrock for effective document management at the

Agency and for publishing of core business information to the web interface. Further development and implementation of document management, records management and mail registration policies were undertaken in 2005.

	2005	2004	Av per month	% Increase
External requests	3,003	2,535	250	16
Internal requests	4,813	3,662	401	24
Visitors to library	1,383	620	115	55
Translated pages	14,741	4,679	1,228	68
New titles published on Web	5,566	3,640	464	35

ANNEXES

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Annex 1 Members of the Management Board

Chair: Hannes WAHLROOS

EMEA contact: Martin HARVEY ALLCHURCH

Members

European Parliament	Gianmartino BENZI, José-Luis VALVERDE LÓPEZ
European Commission	Horst REICHENBACH ¹ , Fernand SAUER ² (<i>Alternates</i> : Georgette LALIS ³ , Patricia BRUNKO)
Belgium	Johan van CALSTER, André PAUWELS
Czech Republic	Milan ŠMÍD (<i>Alternate</i> : Alfred HERA)
Denmark	Jytte LYNQVIG (<i>vice-chairman</i>) (<i>Alternate</i> : Paul SCHÜDER)
Germany	Walter SCHWERDTFEGER (<i>Alternate</i> : Ilse-Dore SCHÜTT)
Estonia	Kristin RAUDSEPP (<i>Alternate</i> : Alar IRS)
Greece	Dimitrios VAGIONAS (<i>Alternate</i> : Vassilis KONTOZAMANIS)
Spain	Val DIEZ (<i>Alternate</i> : Teresa PAGES ⁴)
France	Philippe DUNETON (<i>Alternate</i> : Jean MARIMBERT)
Ireland	Pat O'MAHONY (<i>Alternate</i> : Joan GILVARRY)
Italy	Nello MARTINI (<i>Alternate</i> : Silvia FABIANI)
Cyprus	Panayiota KOKKINOY (<i>Alternate</i> : Louis PANAYI)
Latvia	(<i>Alternate</i> : Inguna ADOVICA)
Lithuania	Mindaugas PLIESKIS ⁵ (<i>Alternate</i> : Juozas JOKIMAS)
Luxembourg	Mariette BACKES-LIES (<i>Alternate</i> : Claude A HEMMER)
Hungary	Tamás L PAÁL (<i>Alternate</i> : Beatrix HORVÁTH)
Malta	Patricia VELLA BONANNO (<i>Alternate</i> : Kenneth MIFSUD)
Netherlands	Aginus A W KALIS
Austria	Robert SCHLÖGEL (<i>Alternate</i> : Christian KALCHER)
Poland	Piotr BLASZCZYK (<i>Alternate</i> : Jacek SPLAWINSKI)
Portugal	Vasco MARIA ⁶ (<i>Alternate</i> : Helder MOTA FILIPE)
Slovenia	Stanislav PRIMOŽIČ (<i>Alternate</i> : Vesna KOBLAR)
Slovakia	Dagmar STARÁ ⁷
Finland	Hannes Wahlroos (<i>Alternate</i> : Pekka JÄRVINEN)
Sweden	Gunar ALVÁN (<i>Alternate</i> : Anders BROSTRÖM)
United Kingdom	Kent WOODS (<i>Alternate</i> : Steve DEAN)
Representatives of Patients' organisations	Mary BAKER, Jean GEORGES
Representative of doctors' organisations	Lisette TIDDENS-ENGWIRDA
Representative of veterinarians' organisations	Fritz Rupert UNGEMACH

¹ Until March 2005 meeting.

² Until December 2005 meeting.

³ Replaced Paul WEISSENBURG as of March 2005 meeting.

⁴ Replaced José MARTINEZ OLMOS as of December 2005 meeting.

⁵ Replaced Vytautas BASYS as of March 2005 meeting.

⁶ Replaced Rui dos SANTOS IVO as of September 2005 meeting.

⁷ Replaced Ľudevít MARTINEC as of September 2005 meeting.

Observers

Iceland	Ingolf J PETERSEN (Alternate: Rannveig GUNNARSDÓTTIR)
Liechtenstein	Brigitte BATLINER (Alternate: Peter MALIN)
Norway	Gro Ramsten WESENBERG (Alternate: Hans HALSE)
Bulgaria	Emil IVANOV HRISTOV (Alternate: Meri BORISLAVOVA PEYCHEVA)
Romania	Magdalena BADULESCU (Alternate: Rodica BADESCU)

Annex 2

Members of the Committee for Medicinal Products for Human Use (CHMP)

Chair: Daniel BRASSEUR

EMA contact: Anthony HUMPHREYS

Members

- Eric ABADIE (France) (*vice-chairman*)
Alternate: Jean-Hugues TROUVIN
- John Joseph BORG¹ (Malta)
Alternate: Patricia VELLA BONANNO²
- János BORVENDÉG (Hungary)
Alternate: Agnes GYURASICS
- Gonzalo CALVO ROJAS (Spain)
Alternate: Concepcion PRIETO YERRO³
- Nikolaos DRAKOULIS (Greece)
Alternate: Michalis AVGERINOS
- Harald ENZMANN⁴ (Germany)
Alternate: Karl BROICH
- Jacqueline GENOUX-HAMES (Luxembourg)
Alternate: nomination awaited⁵
- Manfred HAASE (Germany) (*co-opted*)
- Ian HUDSON (United Kingdom)
Alternate: Julia DUNNE
- Arthur ISSEYEGH (Cyprus)
Alternate: Panayiota KOKKINO
- Raul KIIVET (Estonia)
Alternate: Alar IRS
- Tapio KUITUNEN⁶ (Finland)
Alternate: Riita TOKOLA
- Pekka KURKI (Finland) (*co-opted*)
- Metoda LIPNIK-ŠTANGELJ (Slovenia)
Alternate: Barbara RAZINGER-MIHOVEC
- David LYONS (Ireland)
Alternate: Patrick SALMON
- Romaldas MAČIULAITIS (Lithuania)
Alternate: Mykolas MAURICAS
- Ján MAZÁG (Slovakia)
Alternate: nomination awaited⁷
- Pieter NEELS (Belgium)
Alternate: Bruno FLAMION
- Giuseppe NISTICÒ (Italy)
Alternate: Pasqualino ROSSI
- Sif ORMARSDÓTTIR (Iceland)
Alternate: Magnús JÓHANNSSON
- Ingemar PERSSON (Sweden) (*co-opted*)
- Michał PIROŻYŃSKI (Poland)
Alternate: Piotr SIEDLECKI
- Heribert PITTNER (Austria)
Alternate: Josef SUKO
- Juris POKROTNIEKS (Latvia)
Alternate: Indulis PURVINŠ
- Jean-Louis ROBERT (Luxembourg)
(co-opted)
- Frances ROTBLAT² (United Kingdom)
(co-opted)
- Tomas SALMONSON (Sweden)
Alternate: Bengt LJUNGBERG⁸
- Beatriz SILVA LIMA (Portugal)
Alternate: Cristina SAMPAIO
- Eva SKOVLUND (Norway)
Alternate: Liv MATHIESEN
- Milan ŠMÍD (Czech Republic)
Alternate: nomination awaited
- Steffen THIRSTRUP (Denmark)
Alternate: Jens ERSBØLL
- Barbara VAN ZWIETEN-BOOT (Netherlands)
Alternate: Frits LEKKERKERKER

¹ Replaced Helen VELLA as alternate in November 2004. He then replaced Patricia VELLA BONANNO as member in April 2005.

² Initially nominated as alternate, Patricia VELLA BONANNO replaced Helen VELLA as member in July 2004. She then replaced John BORG as alternate in April 2005.

³ Replaced Fernando de ANDRES TRELLES as alternate in September 2005.

⁴ Replaced Gottfried KREUTZ as member in November 2005.

⁵ Nomination awaited following appointment of Jean-Louis ROBERT as co-opted member in September 2004.

⁶ Replaced Markku TOIVONEN as member in May 2005.

⁷ Nomination awaited following departure of Leila FARAH in September 2005.

⁸ Replaced Per NILSSON as alternate in May 2005.

Observers

Bulgaria Dimiter TERZIIVANOV NIKOLOV (*Alternate: Ivanka ATANASOVA*)
Romania Rodica BADESCU (*Alternate: Victoria SUBTIRICA*)

Working parties, ad hoc groups and scientific advisory groups

Scientific Advice Working Party

Chair: Bruno FLAMION
EMA contact: Agnès SAINT-RAYMOND

Biologics Working Party

(formerly Biotechnology Working Party)
Chair: Jean-Hugues TROUVIN
EMA contact: John PURVES

Blood Products Working Party

Chair: Manfred HAASE
EMA contact: John PURVES

Cell-based Products Working Party

(formerly *Ad hoc Expert Group on Cell Therapy/Cell Therapy Working Party*)
Chair: Pekka KURKI
EMA contact: John PURVES

Efficacy Working Party

Chair: Barbara VAN ZWIETEN-BOOT
EMA contact: Xavier LURIA

Gene Therapy Working Party

Chair: Klaus CICHUTEK
EMA contact: Marisa PAPALUCA AMATI

Joint CHMP/CVMP Quality Working Party

Chair: Jean-Louis ROBERT
EMA contact: Emer COOKE

Pharmacogenetics Working Party

Chair: Eric ABADIE
EMA contact: Marisa PAPALUCA AMATI

Pharmacovigilance Working Party

Chair: June RAINE
EMA contact: Panos TSINTIS

Safety Working Party

Chair: Beatriz SILVA LIMA
EMA contact: Xavier LURIA

Vaccine Working Party

Chair: Roland DOBBELAER
EMA contact: John PURVES

Paediatric Working Party

Chair: Daniel BRASSEUR
EMA contact: Agnès SAINT-RAYMOND

Working Party on Similar Biological (Biosimilar) Medicinal Products

Chair: Pekka KURKI
EMA contact: Marisa PAPALUCA AMATI

Scientific Advisory Group on Anti-infectives

Chair: To be appointed
EMA contact: Xavier LURIA

Scientific Advisory Group on Cardiovascular Issues

Chair: To be appointed
EMA contact: Xavier LURIA

Scientific Advisory Group on Central Nervous System

Chair: Michael DONAGHY
EMA contact: Xavier LURIA

Scientific Advisory Group on Diabetes/Endocrinology

Chair: To be appointed
EMA contact: Xavier LURIA

Scientific Advisory Group on Diagnostics

Chair: To be appointed
EMA contact: Xavier LURIA

Scientific Advisory Group on HIV/Viral Diseases

Chair: Ian WELLER

EMEA contact: Xavier LURIA

Scientific Advisory Group on Oncology

Chair: Michel MARTY

EMEA contact: Xavier LURIA

CHMP/EMEA Implementation Task Force

Chair: Daniel BRASSEUR

EMEA contact: Anthony HUMPHREYS

Invented Name Review Group

Chair: Zaïde FRIAS

EMEA contact: Zaïde FRIAS

EMEA/CHMP Working Group with Patients' and Consumers' Organisations

Chair: Frits LEKKERKERKER/Isabelle Moulon

EMEA contact: Isabelle MOULON

Working Group on Quality Review of Documents

Chair: Hilde BOONE

EMEA contact: Hilde BOONE

Annex 3 Members of the Committee for Medicinal Products for Veterinary Use (CVMP)

Chair: Gérard MOULIN
EMEA contact: David MACKAY

Members

- Birgit AASMÄE (Estonia)
Alternate: Helen MAHLA
- Gabriel BEECHINOR (Ireland)
Alternate: David MURPHY
- Rory BREATHNACH (Ireland) (*co-opted*)
- Ivo CLAASEN (Netherlands) (*co-opted*)
- Peter EKSTRÖM (Sweden) (*co-opted*)
- Christian FRIIS (Denmark) (*co-opted*)
- Lorenzo FRAILE SAUCE (Spain) (*co-opted*)
- Judita HEDEROVÁ (Slovakia)
- Alfred HERA (Czech Republic)
Alternate: Jiří BUREŠ
- Anja HOLM (Denmark)
Alternate: Lotte Winther
- Tonje HØY (Norway)
Alternate: Hanne BERGENDAHL
- Arvils JAKOVSKIS (Latvia)
Alternate: Valda SEJANE
- Laimis JODKONIS (Lithuania)
Alternate: Juozas JOKIMAS
- Liisa KAARTINEN (Finland)
Alternate: Tita-Maria SAUKKO
- Reinhard KROKER (Germany)
Alternate: Manfred MOOS
- Katarzyna KRZYŻAŃSKA (Poland)
Alternate: Roman LECHOWSKI
- Ioannis MALEMIS (Greece)
Alternate: Orestis PAPADOPOULOS
- Kenneth MIFSUD (Malta)
Alternate: Joseph VELLA
- Cristina MUÑOZ MADERO (Spain)
Alternate: Consuelo Rubio MONTEJANO
- Giorgos NEOPHYTOU (Cyprus)
Alternate: Ioanna TALIDI
- John O'BRIEN (United Kingdom)
Alternate: Martin ILOTT
- Eugen OBERMAYR (Austria)
Alternate: Jean-Pierre BINDER
- Sigurður ÖRN HANSSON (Iceland)
Alternate: Halldór RUNÓLFSSON
- Johannes PETRUS HOOGLAND (Netherlands) (*vice-chairman*)
Alternate: Johan SCHEFFERLIE
- Maria Helena PONTE (Portugal)
Alternate: Leonor Maria MEISEL
- Jean-Claude ROUBY (France)
Alternate: Michael HOLZHAUSER-ALBERTI
- Tibor SOÓS (Hungary)
Alternate: Gábor KULCSÁR
- Stane SRCIC (Slovenia)
Alternate: Blanka EMERSIC
- Karolina TÖRNEKE (Sweden)
Alternate: Henrik HOLST
- Maria TOLLIS (Italy)
Alternate: Virgilio DONINI
- Bruno URBAIN (Belgium)
Alternate: Lionel LAURIER
- Marc WIRTOR (Luxembourg)
Alternate: Maurice HOLPER

Scientific Advice Working Party (SAWP-V)

Chair: Reinhard KROKER

EMEA contact: Jill ASHLEY-SMITH

Immunologicals Working Party (IWP)

Chair: Jean-Claude ROUBY

EMEA contact: Jill ASHLEY-SMITH

**Pharmacovigilance Working Party
(PhVWP-V)**

Chair: Cornelia IBRAHIM

EMEA contact: Kornelia GREIN

Environmental Risk Assessment (ERAWP)

(temporary working party)

Chair: Hans HOOGLAND

EMEA contact: Kornelia GREIN

Efficacy Working Party (EWP-V)

Chair: Michael HOLZHAUSER-ALBERTI

EMEA contact: Jill ASHLEY-SMITH

**Joint CHMP/CVMP Quality Working Party
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Chair: Jean-Louis ROBERT

EMEA contact: Emer COOKE

Safety Working Party (SWP-V)

Chair: Christian FRIIS

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**Scientific Advisory Group on Antimicrobials
(SAGAM)**

Chair: Liisa KAARTINEN

EMEA contact: Kornelia GREIN

Annex 4

Members of the Committee for Orphan Medicinal Products (COMP)

Chair: Josep TORRENT-FARNELL
EMEA contact: Agnès SAINT-RAYMOND

Members

- Eric ABADIE¹ (EMEA representative)
- Fernando DE ANDRÉS-TRELLES² (Spain)
- Gianmartino BENZI (EMEA representative)
- Brigitte BLÖCHL-DAUM³ (Austria)
- Andrew BORG⁴ (Malta)
- Heidrun BOSCH-TRABERG (Denmark)
- Birthe BYSKOV HOLM (patients' organisation representative)
- Yann LE CAM (patients' organisation representative) (*vice-chairman*)
- Ana CORRÊA NUNES⁵ (Portugal)
- Judit EGGENHOFER (Hungary)
- Rembert ELBERS (Germany)
- Lars GRAMSTAD (Norway)
- Emmanuel HÉRON (France)
- Alastair KENT (patients' organisation representative)
- Ioannis KKOLOS (Cyprus)
- Kateřina KUBÁČKOVÁ (Czech Republic)
- Magdaléna KUŽELOVÁ (Slovakia)
- André LHOIR (Belgium)
- David LYONS (EMEA representative)
- Greg MARKEY (United Kingdom)
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- Martin MOŽINA (Slovenia)
- Kristina PAVLOVSKA (Latvia)
- Veijo SAANO (Finland)
- Patrick SALMON (Ireland)
- Harrie J. J. SEEVERENS (The Netherlands)
- George STATHOPOULOS (Greece)
- Domenica TARUSCIO (Italy)
- Sigurður B THORSTEINSSON (Iceland)
- Vallo TILLMANN (Estonia)
- Algirdas UTKUS (Lithuania)
- Kerstin WESTERMARK (Sweden)
- Jolanta WIĘCKOWSKA (Poland)

¹ Resigned in November 2005.

² Replaced José Félix OLALLA MARAÑÓN as of May 2005 meeting.

³ Replaced Bernd JILMA as of July 2005 meeting.

⁴ Replaced Joseph GIGLIO as of November 2005 meeting.

⁵ Replaced José Manuel TOSCANO RICO as of June 2005 meeting.

Ad hoc Biotechnology Working Group

Chair: Harrie SEEVERENS/Jean-Hugues TROUVIN

EMEA contact: Spiros VAMVAKAS

Working Group with Interested Parties

Chair: Yann LE CAM/Agnès SAINT-RAYMOND

EMEA contact: Frida RIVIÈRE

Annex 5 Members of the Committee on Herbal Medicinal Products (HMPC)

Chair: Konstantin KELLER
EMEA contact: Anthony HUMPHREYS

Members

- Linda ANDERSON (United Kingdom)
Alternate: Sue HARRIS
- Mariette BACKES-LIES (Luxembourg)
Alternate: Jacqueline GENOUX-HAMES
- Steffen BAGER (Denmark)
Alternate: Kristine HVOLBY
- Zsuzsanna BIRÓ-SÁNDOR (Hungary)
Alternate: Nomination awaited¹
- Per CLAESON (Sweden)
Alternate: Ubonwan CLAESON
- Christian CUSCHIERI (Malta)
Alternate: Caroline ATTARD
- Dairine DEMPSEY (Ireland)
Alternate: Elaine BRESLIN
- Wojciech DYMOWSKI (Poland)
Alternate: Elżbieta WOJTASIK
- Anneli TÖRRÖNEN² (Finland)
Alternate: Sari KOSKI
- Emiel VAN GALEN (Netherlands)
Alternate: Burt H KROES
- Gloria GARCÍA LORENTE (Spain)
Alternate: Adela VELÁZQUEZ
- Ioanna CHINO³ (Greece)
Alternate: Eleni SKALTSA⁴
- Marie HEROUTOVÁ (Czech Republic)
- Thorbjörg KJARTANDSDÓTTIR (Iceland)
Alternate: Sesselja ÓMARSÐOTTIR⁵
- Gert LAEKEMAN (Belgium) (*co-opted*)
- Audronis LUKOSIUS (Lithuania)
- Steinar MADSEN (Norway)
Alternate: Gro FOSSUM
- Ana Paula MARTINS (Portugal)
Alternate: Maria Helena PINTO FERREIRA
- Samo KREFT⁶ (Slovenia)
Alternate: Barbara RAZINGER-MIHOVEC
- Dailonis PAKALNS (Latvia)
Alternate: Dace KALKE
- Olavi PELKONEN (Finland) (*co-opted*)
- Heribert PITTNER (Austria) (*vice-chairman*)
Alternate: Wolfgang KUBELKA
- Klaus REH (Germany)
Alternate: Christine WERNER
- Marie SAARSOO (Estonia)
Alternate: Ain RAAL
- Dáša SALUGOVÁ⁷ (Slovakia)
Alternate: Pavol MUČAJI⁸
- Antoine SAWAYA (France)
Alternate: Jacqueline VIGUET POUPELLOZ
- Vittorio SILANO (Italy)
Alternate: Marisa DELBÓ
- Panayiotis TRIANTAFYLLIS (Cyprus)
Alternate: Maria STAVROU
- Arnold J VLIETINCK (Belgium)
Alternate: Heidi NEEF
- Ulrike WISSINGER-GRÄFENHAHN (Germany) (*co-opted*)

¹ Nomination awaited following the departure of Gyöngyi BACS who resigned 10 February 2005.

² Replaced Anna-Liisa ENKOVAARA as of September 2005 meeting.

³ Replaced Catherine HARVALA (who resigned in July 2005) as of November 2005 meeting.

⁴ Replaced Foteini TZAVELLA (who resigned in March 2005) as of November 2005 meeting.

⁵ Replaced Kristin INGÓLFSDÓTTIR as of July 2005 meeting.

⁶ Replaced Aleš MLINARIC as of May-June 2005 meeting.

⁷ Replaced Lucia KUROPKOVÁ as of December 2005 meeting. Lucia KUROPKOVÁ replaced Andrea KUPKOVÁ (who resigned in September 2005) as of September 2005 meeting.

⁸ Replaced Ludmila ŠTRBOVÁ as of September 2005 meeting.

Observers

- Ellen PEL (EDQM) (on maternity leave from September 2005)
- Michael WIERER (EDQM)
- Stefan NIKOLOV (Bulgaria)
Alternate: Gerassim KITANOV
- Maria NICULESCU (Romania)
Alternate: Laurentia RUSCAN

Working parties and ad hoc groups

Organisational Matters Drafting Group

Chair: Emiel VAN GALEN

EMEA contact: Anthony HUMPHREYS

Quality Drafting Group

Chair: Dairíne DEMPSEY

EMEA contact: Anthony HUMPHREYS

Safety & Efficacy Drafting Group

Chair: Heribert PITTNER

EMEA contact: Anthony HUMPHREYS

Annex 6 National competent authority partners

Further information on the national competent authorities is also available on the national authorities' Internet sites: <http://heads.medagencies.org/> and <http://www.hevra.org/>

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Annex 7 EMEA budget summaries 2004–2006

The summarised comparative budget statements for 2004 to 2006 are as follows:

	2004 ¹		2005 ²		2006 ³	
	€'000	%	€'000	%	€'000	%
Revenue						
Fees	67,350	67.76	77,455	69.26	83,580	67.65
General EU contribution	17,000	17.11	17,900	16.01	22,000	17.81
Special EU contribution for IT telematics strategy	7,500	7.55	7,500	6.71	8,000	6.48
Special EU contribution for orphan medicinal products	3,985	4.01	5,000	4.47	4,000	3.24
Contribution from EEA	537	0.54	530	0.47	650	0.53
Community programmes	91	0.09	250	0.22	550	0.45
Other	2,922	2.94	3,200	2.86	4,771	3.86
TOTAL REVENUE	99,385	100	111,835	100	123,551	100

Expenditure							
Staff							
11	Staff in active employment	31,774	32.84	37,738	33.74	40,638	32.89
13	Mission expenses	452	0.47	616	0.55	556	0.45
14	Socio-medical infrastructure	281	0.29	447	0.40	485	0.39
15	Exchange of civil servants and experts	750	0.78	1,280	1.14	1,099	0.89
16/17	Social welfare, entertainment and representation expenses	26	0.03	86	0.08	28	0.02
18	Staff insurances	867	0.90	1,189	1.06	1,230	1.00
	<i>Total Title 1</i>	<i>34,150</i>	<i>35.31</i>	<i>41,356</i>	<i>36.98</i>	<i>44,036</i>	<i>35.64</i>
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	8,296	8.58	12,934	11.57	15,071	12.20
21	Expenditure on data processing	13,964	14.43	10,922	9.77	11,642	9.42
22	Movable property and associated costs	627	0.65	1,602	1.43	1,020	0.83
23/25	Other administrative expenditure	568	0.59	917	0.82	833	0.67
24	Postage and communications	423	0.44	730	0.65	800	0.65
	<i>Total Title 2</i>	<i>23,878</i>	<i>24.69</i>	<i>27,105</i>	<i>24.24</i>	<i>29,366</i>	<i>23.77</i>
300	Meetings	5,347	5.53	6,133	5.48	6,731	5.45
301	Evaluations	32,008	33.09	35,492	31.74	39,559	32.02
302	Translation	1,110	1.15	1,064	0.95	2,945	2.38
303	Studies and consultants	80	0.08	180	0.16	170	0.14
304	Publications	141	0.15	255	0.23	194	0.16
305	Community programmes	0	0.00	250	0.22	550	0.45
	<i>Total Title 3</i>	<i>38,686</i>	<i>40.00</i>	<i>43,374</i>	<i>38.78</i>	<i>50,149</i>	<i>40.59</i>
TOTAL EXPENDITURE		96,714	100.00	111,835	100.00	123,551	100.00

¹ Final accounts 2004.

² Appropriation/Budget 2005 as of 31 December 2005.

³ Appropriation/Budget 2006 as adopted by the Management Board on 15 December 2005.

Annex 8
EMEA Establishment Plan

Category & Grade	TEMPORARY POSTS		
	Occupied as per 31.12.04	Authorised for 2005	Authorised for 2006 ⁴
A*16	-	-	1
A*15	1	1	3
A*14	5	7	4
A*13	-	4	4
A*12	32	33	34
A*11	37	32	33
A*10	39	34	34
A*9	-	11	13
A*8	36	32	32
A*7	-	41	43
A*6	-	-	12
A*5	-	-	-
<i>Total grade A</i>	<i>150</i>	<i>195</i>	<i>213</i>
B*11	-	-	-
B*10	6	6	6
B*9	-	-	2
B*8	8	10	10
B*7	11	12	12
B*6	12	12	12
B*5	9	9	9
B*4	-	2	5
B*3	-	8	10
<i>Total grade B</i>	<i>46</i>	<i>59</i>	<i>66</i>
C*7	-	-	2
C*6	19	19	18
C*5	24	23	23
C*4	48	47	47
C*3	6	6	8
C*2	-	2	10
C*1	-	21	30
<i>Total grade C</i>	<i>97</i>	<i>118</i>	<i>138</i>
D*5	-	-	-
D*4	2	2	2
D*3	5	5	5
D*2	-	-	-
<i>Total grade D</i>	<i>7</i>	<i>7</i>	<i>7</i>
Total Staff	300	379	424

⁴ As authorised by the Budgetary Authority and adjusted by the Management Board on 15 December 2005.

Annex 9 CHMP opinions in 2005 on medicinal products for human use

Centralised applications – Positive opinions

Product ▪ Brand name ▪ INN ▪ Part A or B	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
▪ Aclasta ▪ zoledronic acid ▪ Part B	Novartis Europharm Ltd	▪ M05BA08 ▪ Treatment of P.t's disease of the bone.	▪ 17.05.2004 ▪ 20.01.2005 ▪ 181 days ▪ 67 days	▪ 08.03.2005 ▪ 15.04.2005 ▪ 19.04.2005 ▪ OJ C 104, 29.04.2005, p. 15
▪ Duloxetine Lilly ▪ duloxetine ▪ Part B	Eli Lilly Nederland B.V.	▪ N06AX21 ▪ Treatment of diabetic peripheral neuropathic pain in adults.	▪ 17.05.2004 ▪ 17.02.2005 ▪ 180 days ▪ 96 days	▪ 05.04.2005 ▪ ▪ ▪
▪ Fosavance ▪ alendronate sodium-colecalciferol ▪ Part B	Merck Sharp & Dohme Ltd.	▪ Not yet assigned ▪ Treatment of postmenopausal osteoporosis in patients at risk of vitamin D insufficiency.	▪ 18.10.2004 ▪ 26.05.2005 ▪ 182 days ▪ 38 days	▪ 11.07.2005 ▪ 24.08.2005 ▪ 26.08.2005 ▪ OJ C 241, 30.09.2005, p. 1
▪ Tarceva ▪ erlotinib ▪ Part B	Roche Registration Limited	▪ L01XX34 ▪ Treatment of patients with locally advanced or metastatic non-small-cell lung cancer after failure of at least one prior chemotherapy regimen.	▪ 20.09.2004 ▪ 23.06.2005 ▪ 193 days ▪ 83 days	▪ 12.08.2005 ▪ 19.09.2005 ▪ 21.09.2005 ▪ OJ C 268, 28.10.2005, p. 2
▪ Vasovist ▪ gadofosveset trisodium ▪ Part B	Schering AG	▪ Not yet assigned ▪ Contrast-enhanced magnetic resonance angiography for visualization of abdominal or limb vessels in patients with suspected or known vascular disease.	▪ 21.06.2004 ▪ 23.06.2005 ▪ 182 days ▪ 185 days	▪ 23.08.2005 ▪ 03.10.2005 ▪ 05.10.2005 ▪ OJ C 293, 25.11.2005, p. 11
▪ Xyrem [#] ▪ sodium oxybate ▪ Part B	UCB Pharma Ltd	▪ N07XX04 ▪ Treatment of cataplexy in adult patients with narcolepsy.	▪ 29.03.2004 ▪ 23.06.2005 ▪ 198 days ▪ 253 days	▪ 24.08.2005 ▪ 13.10.2005 ▪ 18.10.2005 ▪ OJ C 293, 25.11.2005, p. 11

[#] Denotes an orphan medicinal product designated under Regulation (EC) No 121/2000.

Product ▪ Brand name ▪ INN ▪ Part A or B	Marketing authorisation holder	Therapeutic area ▪ Summary of indication	EMEA/CHMP ▪ Opinion ▪ Active time ▪ Clock stop	European Commission received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Posaconazole SP ▪ posaconazole ▪ Part B	SP Europe	▪ J02AC04 ▪ Treatment of invasive fungal infections: Invasive aspergillosis; Fusariosis, Chromoblastomycosis and mycetoma; Coccidioidomycosis.	▪ 19.07.2004 ▪ 28.07.2005 ▪ 219 days ▪ 154 days	▪ 13.09.2005 ▪ 25.10.2005 ▪ 27.10.2005 ▪ OJ C 293, 25.11.2005, p. 11
▪ Procoralan ▪ ivabradine ▪ Part B	Les Laboratoires Servier	▪ C01EB17 ▪ Treatment of chronic stable angina pectoris.	▪ 17.05.2004 ▪ 28.07.2005 ▪ 211 days ▪ 225 days	▪ 13.09.2005 ▪ 25.10.2005 ▪ 27.10.2005 ▪ OJ C 293, 25.11.2005, p. 11
▪ Kepivance ▪ palifermin ▪ Part A	Amgen Europe B.V.	▪ V03A F08 ▪ Treatment oral mucositis in patients with haematological malignancies receiving myeloablative therapy.	▪ 19.07.2004 ▪ 28.07.2005 ▪ 217 days ▪ 156 days	▪ 12.09.2005 ▪ 25.10.2005 ▪ 27.10.2005 ▪ OJ C 293, 25.11.2005, p. 11
▪ Xolair ▪ omalizumab ▪ Part A	Novartis Europharm Ltd.	▪ R03DX05 ▪ Treatment of severe persistent allergic asthma.	▪ 19.07.2004 ▪ 28.07.2005 ▪ 214 days ▪ 159 days	▪ 13.09.2005 ▪ 25.10.2005 ▪ 27.10.2005 ▪ OJ C 293, 25.11.2005, p. 11
▪ Noxafil ▪ posaconazole ▪ Part B	SP Europe	▪ J02AC04 ▪ Treatment of invasive fungal infections: Invasive aspergillosis; Fusariosis, Chromoblastomycosis and mycetoma; Coccidioidomycosis.	▪ 19.07.2004 ▪ 28.07.2005 ▪ 219 days ▪ 154 days	▪ 13.09.2005 ▪ 25.10.2005 ▪ 27.10.2005 ▪ OJ C 293, 25.11.2005, p. 11
▪ Corlentor ▪ ivabradine ▪ Part B	Les Laboratoires Servier	▪ C01EB17 ▪ Treatment of chronic stable angina pectoris.	▪ 17.05.2004 ▪ 28.07.2005 ▪ 211 days ▪ 225 days	▪ 13.09.2005 ▪ 25.10.2005 ▪ 27.10.2005 ▪ OJ C 293, 25.11.2005, p. 11
▪ Aptivus ▪ tipranavir ▪ Part B	Boehringer Ingelheim	▪ J05AE09 (temporary) ▪ Treatment of HIV-1 infection.	▪ 15.11.2004 ▪ 28.07.2005 ▪ 204 days ▪ 50 days	▪ 13.09.2005 ▪ 25.10.2005 ▪ 27.10.2005 ▪ OJ C 293, 25.11.2005, p. 11
▪ Revatio [#] ▪ sildenafil citrate ▪ Part B	Pfizer Ltd	▪ G04BE03 ▪ Treatment of patients with pulmonary arterial hypertension.	▪ 20.12.2004 ▪ 28.07.2005 ▪ 177 days ▪ 42 days	▪ 26.09.2005 ▪ 28.10.2005 ▪ 04.11.2005 ▪ OJ C 293, 25.11.2005, p. 11

[#] Denotes an orphan medicinal product designated under Regulation (EC) No 121/2000.

Product ▪ Brand name ▪ INN ▪ Part A or B	Marketing authorisation holder	Therapeutic area ▪ Summary of indication	EMEA/CHMP ▪ Opinion ▪ Active time ▪ Clock stop	European Commission received ▪ Date of decision ▪ Notification ▪ Official Journal
▪ Yttriga ▪ yttrium (90Y) chloride ▪ Part B	AEA Technology OSA GmbH	▪ Not yet assigned ▪ Radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide.	▪ 17.05.2004 ▪ 15.09.2005 ▪ 216 days ▪ 207 days	▪ 29.11.2005 ▪ 19.01.2006 ▪ ▪
▪ Naglazyme [#] ▪ galsulfase ▪ Part A	BioMarin Pharmaceutical Inc.	▪ A16AB08 ▪ Long-term enzyme replacement therapy in patients with a confirmed diagnosis of Mucopolysaccharidosis VI	▪ 20.12.2004 ▪ 15.09.2005 ▪ 213 days ▪ 56 days	▪ 22.12.2005 ▪ ▪ ▪
▪ Proquad ▪ Measles, Mumps, Rubella and Varicella virus ▪ Part B	Aventis Pasteur	▪ J07BD54 ▪ Simultaneous vaccination against measles, mumps, rubella and varicella.	▪ 18.10.2004 ▪ 15.09.2005 ▪ 209 days ▪ 123 days	▪ 08.11.2005 ▪ ▪ ▪
▪ Macugen ▪ pegaptanib sodium ▪ Part B	Pfizer Ltd.	▪ S01XA17 (temporary) ▪ Treatment of neovascular (wet) age-related macular degeneration (AMD).	▪ 20.09.2004 ▪ 15.09.2005 ▪ 216 days ▪ 170 days	▪ 23.12.2005 ▪ 31.01.2006 ▪ ▪
▪ Ionsys ▪ fentanyl hydrochloride ▪ Part B	Janssen-Cilag International NV	▪ N02AB03 ▪ Management of acute moderate to severe post-operative pain for use in a hospital setting only	▪ 19.07.2004 ▪ 13.10.2005 ▪ 199 days ▪ 252 days	▪ 19.12.2005 ▪ ▪ ▪
▪ Exubera ▪ insulin human ▪ Part A	Pfizer Ltd	▪ Not yet assigned ▪ Treatment of adult patients with diabetes mellitus	▪ 23.02.2004 ▪ 13.10.2005 ▪ 208 days ▪ 390 days	▪ 20.12.2005 ▪ ▪ ▪
▪ Cubicin ▪ daptomycin ▪ Part B	Chiron Corporation Ltd	▪ Not yet assigned ▪ Indicated for treatment of complicated skin and skin structure infections	▪ 20/12/2004 ▪ 17/11/2005 ▪ 217 days ▪ 115 days	▪ 15.12.2005 ▪ 19.01.2006 ▪ ▪
▪ Kiovig ▪ human normal immunoglobulin (IVIg) ▪ Part B	Baxter AG	▪ J06BA02 ▪ Primary immunodeficiency syndromes, immunomodulation and allogeneic bone marrow transplantation.	▪ 18/10/2004 ▪ 17/11/2005 ▪ 204 days ▪ 191 days	▪ 19.12.2005 ▪ 19.01.2006 ▪ ▪

[#] Denotes an orphan medicinal product designated under Regulation (EC) No 121/2000.

Product	Marketing authorisation holder	Therapeutic area	EMEA/CHMP	European Commission
<ul style="list-style-type: none"> ▪ Brand name ▪ INN ▪ Part A or B 		<ul style="list-style-type: none"> ▪ Summary of indication 	<ul style="list-style-type: none"> ▪ Opinion ▪ Active time ▪ Clock stop 	<ul style="list-style-type: none"> received ▪ Date of decision ▪ Notification ▪ Official Journal
<ul style="list-style-type: none"> ▪ Neupro ▪ rotigotine ▪ Part B 	Schwarz BioSciences GmbH	<ul style="list-style-type: none"> ▪ N04BC09 ▪ Treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa) 	<ul style="list-style-type: none"> ▪ 18.10.2004 ▪ 14.12.2005 ▪ 202 days ▪ 220 days 	<ul style="list-style-type: none"> ▪ ▪ ▪ ▪
<ul style="list-style-type: none"> ▪ Rotarix ▪ Live human rotavirus RIX4414 ▪ Part B 	GlaxoSmithKline Biologicals	<ul style="list-style-type: none"> ▪ J07BH01 ▪ Indicated for the active immunisation of infants from the age of 6 weeks for prevention of gastro-enteritis due to rotavirus infection 	<ul style="list-style-type: none"> ▪ 20/12/2004 ▪ 14/12/2005 ▪ 175 days ▪ 154 days 	<ul style="list-style-type: none"> ▪ 20.01.2006 ▪ ▪ ▪

CHMP Opinions in the Context of cooperation with the World Health Organization (WHO) for the evaluation of medicinal products intended exclusively for markets outside the Community

Product	Marketing authorisation holder	Therapeutic area	EMEA/CHMP
<ul style="list-style-type: none"> ▪ Brand name ▪ INN ▪ Part A or B 		<ul style="list-style-type: none"> ▪ ATC code ▪ Summary of indication 	<ul style="list-style-type: none"> ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop
<ul style="list-style-type: none"> ▪ Lamivudine GSK 150 mg film-coated tablet ▪ lamivudine ▪ Part B 	Glaxo Group Limited	<ul style="list-style-type: none"> ▪ J05AF05 ▪ Treatment in combination of HIV-1 infected adults and children 	<ul style="list-style-type: none"> ▪ 19.09.2005 ▪ 17.11.2005 ▪ 59 days ▪ 0 days
<ul style="list-style-type: none"> ▪ lamivudine/zidovudine GSK film-coated tablet ▪ Lamivudine / zidovudine ▪ Part B 	Glaxo Group Limited	<ul style="list-style-type: none"> ▪ J05AF30 ▪ Treatment in combination of HIV-1 infected adults and adolescents over 12 years of age 	<ul style="list-style-type: none"> ▪ 19.09.2005 ▪ 17.11.2005 ▪ 59 days ▪ 0 days

Centralised applications – Negative opinions

Product <ul style="list-style-type: none"> ▪ Brand name ▪ INN ▪ Part A or B 	Marketing authorisation holder	Therapeutic area <ul style="list-style-type: none"> ▪ ATC code ▪ Summary of indication 	EMEA/CHMP <ul style="list-style-type: none"> ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop 	European Commission <ul style="list-style-type: none"> ▪ Opinion received ▪ Date of decision ▪ Notification ▪ Official Journal
<ul style="list-style-type: none"> ▪ Zelnorm ▪ Tegaserod ▪ Part B 	Novartis Europharm Limited	<ul style="list-style-type: none"> ▪ A03AE02 ▪ Treatment of IBS (abdominal pain and discomfort, bloating and constipation). 	<ul style="list-style-type: none"> ▪ 18/10/2004 ▪ 14/12/2005 ▪ 204 days ▪ 218 days 	<ul style="list-style-type: none"> ▪ ▪ ▪ ▪

No withdrawals prior to opinion (after 20 November 2005)

Annex 10 CVMP opinions in 2005 on medicinal products for veterinary use

Centralised applications – Positive opinions

Product ▪ Brand name ▪ INN ▪ Part A or B	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
▪ Naxcel ▪ Ceftiofur ▪ Part B	Pfizer	▪ Pigs ▪ Respiratory disease	▪ 12.11.2002 ▪ 11.01.2005 ▪ 210 ▪ 506	▪ 15.02.2005 ▪ 19.05.2005 ▪ 24.05.2005 ▪ OJ C 153, 24.06.2005, p.5
▪ Profender ▪ Emodepside ▪ praziquantel ▪ Part B	Bayer Health Care	▪ Cats ▪ Antiparasitic	▪ 16.03.2004 ▪ 18.05.2005f ▪ 204 ▪ 155	▪ 16.06.2005 ▪ 27.07.2005 ▪ 29.07.2005 ▪ OJ C 209, 26.08.2005, p.5
▪ Equilis ▪ Prequenza-Te ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Equine influenza and tetanus	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ 08.07.2005 ▪ 29.07.2005 ▪ OJ C 209, 26.08.2005, p.5
▪ Equilis Prequenza ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Immunity against influenza	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ 08.07.2005 ▪ 29.07.2005 ▪ OJ C 209, 26.08.2005, p.5
▪ Equilis Te ▪ Vaccine ▪ Part B	Intervet	▪ Horses ▪ Immunity against tetanus	▪ 13.01.2004 ▪ 13.04.2005 ▪ 183 ▪ 273	▪ 27.05.2005 ▪ 08.07.2005 ▪ 29.07.2005 ▪ OJ C 209, 26.08.2005, p.5
▪ Metacam 0.5 mg/ml oral suspension for dogs (extension new strength)	Boehringer Ingelheim Vetmedica GmbH	▪ Dogs	▪ 05.08.2004 ▪ 18.05.2005 ▪ 187 ▪ 99	▪ 01.06.2005 ▪ 01.08.2005 ▪ 03.08.2005 ▪ OJ C 241, 30.09.2005, p.4
▪ Novem 5mg/ml (extension to new target species)	Boehringer Ingelheim Vetmedica GmbH	▪ Pigs ▪ Musculoskeletal disorder	▪ 15.03.2005 ▪ 15.06.2005 ▪ 92 ▪ 0 ▪ n/a	▪ 25.08.2005 ▪ 29.08.2005 ▪ OJ C 241, 30.09.2005, p.4

No negative opinions

No withdrawals prior to opinion (since 20 November 2005)

Establishment of maximum residue limits for new substances

Substance INN	Therapeutic area ▪ Target species	EMEA/CVMP ▪ Validation ▪ Opinion ▪ Active time ▪ Clock stop	European Commission ▪ Opinion received ▪ Date of regulation ▪ Official Journal
Phenoxymethylpenicillin (extension)	▪ Poultry	▪ 12.02.2004 ▪ 12.01.2005 ▪ 120 days ▪ 214 days	▪ 02.02.2005 ▪ 08.08.2005 ▪ OJ L 206, 09.08.2005, p.6
Thiamphenicol (extension)	▪ Pigs	▪ 19.06.2003 ▪ 12.01.2005 ▪ 119 days ▪ 453 days	▪ 02.02.2005 ▪ 08.08.2005 ▪ OJ L 206, 09.08.2005, p.7
Phoxim (extension)	▪ Chickens	▪ 17.10.2002 ▪ 12.01.2005 ▪ 180 days ▪ 637 days	▪ 02.02.2005 ▪ 08.08.2005 ▪ OJ L 206, 09.08.2005, p.6
Oxolinic acid (extension)	▪ Cattle (extrapolated to all food-producing species)	▪ 11.09.2003 ▪ 09.02.2005 ▪ 180 days ▪ 516 days	▪ 11.03.2005 ▪ 18.08.2005 ▪ OJ L 214, 19.08.2005, p.5
Acetylisovaleryltylosin (extension)	▪ Poultry	▪ 15.04.2004 ▪ 09.03.2005 ▪ 179 days ▪ 149 days	▪ 06.04.2005 ▪ 19.09.2005 ▪ OJ L 244, 20.09.2005, p.12
Fluazuron	▪ Cattle	▪ 09.12.2004 ▪ 09.03.2005 ▪ 90 days ▪ 0 days	▪ 06.04.2005 ▪ 19.09.2005 ▪ OJ L 244, 20.09.2005, p.12
Firocoxib	▪ Horses	▪ 15.07.2004 ▪ 13.07.2005 ▪ 120 days ▪ 243 days	▪ 02.08.2005 ▪ ... ▪ ...
Piceae turiones recentes extractum (<i>Spruce-tips extract</i>)	▪ All food-producing	▪ 16.01.2004 ▪ 13.07.2005 ▪ 117 days ▪ 426 days	▪ 02.08.2005 ▪ ... ▪ ...
Tosylchloramide Sodium (extension)	▪ Horses	▪ 14.04.2005 ▪ 13.07.2005 ▪ 90 days ▪ 0 days	▪ 02.08.2005 ▪ ... ▪ ...
Toltrazuril (extension)	▪ Calves	▪ 18.03.2004 ▪ 07.09.2005 ▪ 180 days ▪ 358 days	▪ 06.10.2005 ▪ ... ▪ ...
Triclabendazole (extension)	▪ Cattle and sheep	▪ 14.10.2004 ▪ 05.10.2005 ▪ 120 days ▪ 236 days	▪ 04.11.2005 ▪ ... ▪ ...

Annex 11 COMP opinions in 2005 on designation of orphan medicinal products

Positive COMP designation opinions

Product INN	Sponsor	Summary of indication	EMEA/COMP	European Commission
			<ul style="list-style-type: none"> ▪ Submission ▪ Start date ▪ Opinion ▪ Active time 	<ul style="list-style-type: none"> ▪ Opinion received ▪ Date of decision
Titanium dioxide and bisoctrizole	Orfagen - France	Treatment of UV-A and visible light-induced photosensitivity disorders (chronic actinic dermatitis, cutaneous porphyrias, actinic prurigo and solar urticaria)	<ul style="list-style-type: none"> ▪ 23/08/2004 ▪ 18/10/2004 ▪ 13/01/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 03/02/2005 ▪ 03/03/2005
Dimethyl sulfoxide	AOP Orphan Pharmaceuticals AG - Austria	Treatment of severe closed traumatic brain injury	<ul style="list-style-type: none"> ▪ 20/10/2004 ▪ 08/11/2004 ▪ 13/01/2005 ▪ 67 days 	<ul style="list-style-type: none"> ▪ 03/02/2005 ▪ 03/03/2005
Fluocinolone acetonide (prolonged-release intravitreal implant)	Bausch & Lomb (UK) Ltd - UK	Treatment of non-infectious uveitis affecting the posterior segment of the eye	<ul style="list-style-type: none"> ▪ 21/10/2004 ▪ 08/11/2004 ▪ 13/01/2005 ▪ 67 days 	<ul style="list-style-type: none"> ▪ 03/02/2005 ▪ 07/03/2005
Ciclosporin (inhalation use)	Chiron Corporation Ltd - UK	Prevention of graft rejection after lung transplantation	<ul style="list-style-type: none"> ▪ 18/11/2004 ▪ 06/12/2005 ▪ 02/02/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 18/02/2005 ▪ 10/03/2005
Ciclosporin (inhalation use)	Chiron Corporation Ltd - UK	Treatment of graft rejection after lung transplantation	<ul style="list-style-type: none"> ▪ 18/11/2004 ▪ 06/12/2004 ▪ 02/02/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 18/02/2005 ▪ 10/03/2005
(Z)-N-[2-(Diethylamino)ethyl]-5-[(5-fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide (S)-2-hydroxysuccinate	Pfizer Limited - UK	Treatment of malignant gastrointestinal stromal tumours	<ul style="list-style-type: none"> ▪ 20/10/2004 ▪ 06/12/2004 ▪ 02/02/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 18/02/2005 ▪ 10/03/2005
(Z)-N-[2-(Diethylamino)ethyl]-5-[(5-fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide (S)-2-hydroxysuccinate	Pfizer Limited - UK	Treatment of renal cell carcinoma	<ul style="list-style-type: none"> ▪ 20/10/2004 ▪ 06/12/2004 ▪ 02/02/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 18/02/2005 ▪ 10/03/2005
Tipifarnib	Janssen-Cilag International NV - Belgium	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> ▪ 19/11/2004 ▪ 06/12/2004 ▪ 02/02/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 18/02/2005 ▪ 10/03/2005
Cholest-4-en-3-one, oxime	Trophos SA - France	Treatment of 5q spinal muscular atrophy	<ul style="list-style-type: none"> ▪ 15/10/2004/ ▪ 08/11/2004 ▪ 02/02/2005/ ▪ 88 days 	<ul style="list-style-type: none"> ▪ 18/02/2005 ▪ 10/03/2005
Paromomycin sulfate	OneWorld Health - UK	Treatment of visceral leishmaniasis	<ul style="list-style-type: none"> ▪ 17/11/2004 ▪ 06/12/2004 ▪ 03/03/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 15/03/2005 ▪ 11/04/2005

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Ambrisentan	European Medical Advisory Services Limited - UK	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension	<ul style="list-style-type: none"> ▪ 15/12/2004 ▪ 10/01/2005 ▪ 03/03/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 15/03/2005 ▪ 11/04/2005
Estradiol hemihydrate and progesterone	B. Braun Melsungen AG - Germany	Prevention of bronchopulmonary dysplasia in premature neonates of less than 30 weeks of gestational age	<ul style="list-style-type: none"> ▪ 19/11/2004 ▪ 06/12/2004 ▪ 03/03/2005 ▪ 89 days 	<ul style="list-style-type: none"> ▪ 15/03/2005 ▪ 11/04/2005
Histamine dihydrochloride	Maxim Pharmaceuticals Europe Ltd. - UK	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> ▪ 19/11/2004 ▪ 06/12/2004 ▪ 03/03/2005 ▪ 89 days 	<ul style="list-style-type: none"> ▪ 15/03/2005 ▪ 11/04/2005
Autologous tumor-derived gp96 heat shock protein-peptide complex	Antigenics Therapeutics Limited - Ireland	Treatment of renal cell carcinoma	<ul style="list-style-type: none"> ▪ 22/11/2004 ▪ 10/01/2005 ▪ 03/03/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 15/03/2005 ▪ 11/04/2005
Melatonin	ICON Consulting - UK	Treatment of non-24-hour sleep-wake disorders in blind people with no light perception	<ul style="list-style-type: none"> ▪ 14/12/2004 ▪ 10/01/2005 ▪ 03/03/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 15/03/2005 ▪ 11/04/2005
Humanized agonistic anti-CD28 monoclonal antibody	TeGenero AG - Germany	Treatment of B-cell chronic lymphocytic leukaemia	<ul style="list-style-type: none"> ▪ 18/11/2004/ ▪ 06/12/2004 ▪ 03/03/2005/ ▪ 89 days 	<ul style="list-style-type: none"> ▪ 15/03/2005 ▪ 11/04/2005
(3-[5-(2-fluorophenyl)-[1,2,4]oxadiazole-3-yl]-benzoic acid	The Matthews Consultancy Ltd - UK	Treatment of Duchenne muscular dystrophy	<ul style="list-style-type: none"> ▪ 16/12/2004 ▪ 10/01/2005 ▪ 07/04/2005 ▪ 89 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005
Interferon gamma	Mondobiotech Laboratories Anstalt - Liechtenstein	Treatment of idiopathic pulmonary fibrosis	<ul style="list-style-type: none"> ▪ 25/01/2005 ▪ 14/02/2005 ▪ 07/04/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005
Sodium butyrate (rectal use)	Promefarm srl - Italy	Prevention of radiation proctitis	<ul style="list-style-type: none"> ▪ 27/01/2005 ▪ 14/02/2005 ▪ 07/04/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005
Recombinant megakaryopoiesis-stimulating protein	Amgen Europe BV - The Netherlands	Treatment of idiopathic thrombocytopenic purpura	<ul style="list-style-type: none"> ▪ 28/01/2005 ▪ 14/02/2005 ▪ 07/04/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005
Miltefosine	Obwaller Forschungs- und Entwicklungs GmbH - Austria	Treatment of Acanthamoeba keratitis	<ul style="list-style-type: none"> ▪ 28/01/2005 ▪ 14/02/2005 ▪ 07/04/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005
Acadesine	Advanced In Vitro Cell Technologies (Advancell) - Spain	Treatment of B-cell chronic lymphocytic leukaemia	<ul style="list-style-type: none"> ▪ 28/01/2005 ▪ 14/02/2005 ▪ 07/04/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005
(3-[5-(2-fluorophenyl)-[1,2,4]oxadiazole-3-yl]-benzoic acid	The Matthews Consultancy Ltd - UK	Treatment of cystic fibrosis	<ul style="list-style-type: none"> ▪ 16/12/2004 ▪ 10/01/2005 ▪ 07/04/2005 ▪ 89 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005

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(E)-(1S,4S,10S,21R)-7-[(Z)-ethylidene]-4,21-diisopropyl-2-oxa-12,13-dithia-5,8,20,23-tetraazabicyclo[8.7.6]tricycos-16-ene-3,6,9,19,22-pentone	The Matthews Consultancy Ltd - UK	Treatment of cutaneous T-cell lymphoma	<ul style="list-style-type: none"> ▪ 24/01/2005 ▪ 14/02/2005 ▪ 07/04/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005
Bimosiamose disodium	Revotar Biopharmaceuticals AG - Germany	Treatment of acute lung injury	<ul style="list-style-type: none"> ▪ 28/01/2005 ▪ 14/02/2005 ▪ 07/04/2005 ▪ 54 days 	<ul style="list-style-type: none"> ▪ 20/04/2005 ▪ 27/05/2005
Nelarabine	GlaxoSmithKline Research & Development Limited - UK	Treatment of acute lymphoblastic leukaemia	<ul style="list-style-type: none"> ▪ 04/03/2005 ▪ 21/03/2005 ▪ 12/05/2005 ▪ 53 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 16/06/2005
Soluble yeast beta-1,3/1,6- glucan	Biotec Pharmacon ASA - Norway	Prevention of oral mucositis in head and neck cancer patients undergoing radiation therapy	<ul style="list-style-type: none"> ▪ 27/01/2005 ▪ 14/02/2005 ▪ 12/05/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 16/06/2005
H-D-Asp-D-Gln-D-Ser-D-Arg-D-Pro-D-Val-D-Gln-D-Pro-D-Phe-D-Leu-D-Asn-D-Leu-D-Thr-D-Thr-D-Pro-D-Arg-D-Lys-D-Pro-D-Arg-D-Pro-D-Arg-D-Arg-D-Arg-D-Gln-D-Arg-D-Arg-D-Lys-D-Lys-D-Arg-D-Gly-NH ₂	Laboratoires Auris SAS - France	Treatment of acute sensorineural hearing loss (acute acoustic trauma, sudden deafness and surgery induced acoustic trauma)	<ul style="list-style-type: none"> ▪ 04/03/2005 ▪ 21/03/2005 ▪ 12/05/2005 ▪ 53 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 16/06/2005
Human monoclonal antibody against HLA-DR	GPC Biotech AG - Germany	Treatment of Hodgkin's lymphoma	<ul style="list-style-type: none"> ▪ 04/03/2005 ▪ 21/03/2005 ▪ 12/05/2005 ▪ 53 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 16/06/2005
N-(methyl-diazacyclohexyl-methylbenzamide)-azaphenyl-aminothiopyrrole	AB Science - France	Treatment of multiple myeloma	<ul style="list-style-type: none"> ▪ 02/03/2005 ▪ 21/03/2005 ▪ 12/05/2005 ▪ 53 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 20/06/2005
Pegylated arginine deiminase	Dr Francesco Izzo - Italy	Treatment of hepatocellular carcinoma	<ul style="list-style-type: none"> ▪ 17/11/2004 ▪ 21/03/2005 ▪ 12/05/2005 ▪ 53 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 20/06/2005
Bovine bile extract	GMG BioBusiness Ltd - UK	Treatment of pancreatic cancer	<ul style="list-style-type: none"> ▪ 28/01/2005 ▪ 14/02/2005 ▪ 12/05/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 20/06/2005
Humanised antibody fragment (EP-CAM)-truncated Pseudomonas exotoxin A fusion protein	Viventia Biotech (EU) Limited - UK	Treatment of Ep-CAM-positive squamous cell carcinoma of the head and neck	<ul style="list-style-type: none"> ▪ 13/12/2004 ▪ 14/02/2005 ▪ 12/05/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 20/06/2005
4-[3-(methylsulfonyl)phenyl]-1-propylpiperidine x HCl	A Carlsson Research AB - Sweden	Treatment of Huntington's disease	<ul style="list-style-type: none"> ▪ 01/03/2005 ▪ 21/03/2005 ▪ 12/05/2005 ▪ 53 days 	<ul style="list-style-type: none"> ▪ 23/05/2005 ▪ 20/06/2005
Hepatitis C immunoglobulin	Nabi Biopharmaceuticals Europe Ltd - Ireland	Prevention of recurrent hepatitis C virus induced liver disease in liver transplant recipients	<ul style="list-style-type: none"> ▪ 15/12/2004 ▪ 14/02/2005 ▪ 12/05/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 31/05/2005 ▪ 08/07/2005

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Hydrocortisone (modified release tablet)	Prof Richard JM Ross - UK	Treatment of congenital adrenal hyperplasia	<ul style="list-style-type: none"> ▪ 31/03/2005 ▪ 18/04/2005 ▪ 15/06/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 24/06/2005 ▪ 27/07/2005
Adeno-associated viral vector containing a modified U7 snRNA gene	Généthon - France	Treatment of Duchenne muscular dystrophy	<ul style="list-style-type: none"> ▪ 01/04/2005 ▪ 18/04/2005 ▪ 15/06/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 24/06/2005 ▪ 27/07/2005
4-imino-1, 3-diazobicyclo-[3.1.0]-hexan-2-one	ICON Clinical Research (UK) Ltd - UK	Treatment of pancreatic cancer	<ul style="list-style-type: none"> ▪ 01/04/2005 ▪ 18/04/2005 ▪ 15/06/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 24/06/2005 ▪ 27/07/2005
Mifepristone	Laboratoire HRA Pharma - France	Treatment of Cushing's syndrome secondary to ectopic ACTH secretion	<ul style="list-style-type: none"> ▪ 31/03/2005 ▪ 18/04/2005 ▪ 15/06/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 24/06/2005 ▪ 27/07/2005
Nemorubicin hydrochloride	Nerviano Medical Science Srl - Italy	Treatment of hepatocellular carcinoma	<ul style="list-style-type: none"> ▪ 29/03/2005 ▪ 18/04/2005 ▪ 15/06/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 24/06/2005 ▪ 27/07/2005
Autologous CD34+ cells transfected with retroviral vector containing adenosine deaminase gene	Fondazione Telethon - Italy	Treatment of severe combined immunodeficiency (SCID) due to adenosine deaminase (ADA) deficiency	<ul style="list-style-type: none"> ▪ 27/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 04/08/2005 ▪ 26/08/2005
Troxacitabine	GMG BioBusiness Ltd - UK	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> ▪ 27/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Treprostinil diethanolamine (oral use)	United Therapeutics Europe Ltd - UK	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension	<ul style="list-style-type: none"> ▪ 25/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Sapropterin	Dr Gunter Schaub - Germany	Treatment of hyperphenylalaninemia	<ul style="list-style-type: none"> ▪ 19/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Imatinib mesilate	Novartis Europharm Limited - UK	Treatment of dermatofibrosarcoma protuberans	<ul style="list-style-type: none"> ▪ 26/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Imatinib mesilate	Novartis Europharm Limited - UK	Treatment of acute lymphoblastic leukaemia	<ul style="list-style-type: none"> ▪ 26/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Imatinib mesilate	Novartis Europharm Limited - UK	Treatment of mastocytosis	<ul style="list-style-type: none"> ▪ 26/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Chimeric monoclonal antibody to shiga-toxin 1 and 2	Albany Regulatory Consulting Ltd - UK	Treatment of shiga-toxin producing bacterial infection	<ul style="list-style-type: none"> ▪ 20/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 04/08/2005 ▪ 26/08/2005
Human autologous mesenchymal adult stem cells extracted from adipose tissue	Cellerix SL - Spain	Treatment of anal fistula	<ul style="list-style-type: none"> ▪ 31/03/2005 ▪ 18/04/2005 ▪ 13/07/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 04/08/2005 ▪ 26/08/2005

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2-{4-[(5,6-diphenylpyrazin-2-yl)(isopropyl)amino]butoxy}-N-(methylsulfonyl)acetamide	Nippon Shinyaku Co. Ltd - Germany	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension	<ul style="list-style-type: none"> ▪ 26/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
(2S)-2-[(4R)-2-oxo-4-propyltetrahydro-1H-pyrrol-1-yl] butanamide	UCB SA - Belgium	Treatment of progressive myoclonic epilepsies	<ul style="list-style-type: none"> ▪ 27/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
(1R, 2R, 4S)-4-[(2R)-2-[(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R, 27R,34aS)-9,27-dihydroxy-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-1,5,11,28,29-pentaoxo-1,4,5,6,9,10,11,12,13,14,21,22,23,24,25,26,27,28,29,31,32,33,34,tetra-cosahydro-3H-23,27-epoxyprido[2,1-c][1,4]oxazacyclohentrin-3-yl]propyl]-2-methoxy-cyclohexyldimethylphosphinate	Orphix Consulting GmbH - Germany	Treatment of soft tissue sarcoma	<ul style="list-style-type: none"> ▪ 27/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Extract of Sorghum bicolor leaf, Pterocarpus osun stem, Piper guineense seed and Caryophylli flower	Xechem UK Ltd - UK	Treatment of sickle cell disease	<ul style="list-style-type: none"> ▪ 21/03/2005 ▪ 18/04/2005 ▪ 13/07/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 04/08/2005 ▪ 26/08/2005
(1R,2S) 6-bromo-alpha-[2-(dimethylamino)ethyl]-2-methoxy-alpha-(1-naphthyl)-beta-phenyl-3-quinolineethanol	Tibotec Pharmaceuticals Ltd - Ireland	Treatment of tuberculosis	<ul style="list-style-type: none"> ▪ 01/04/2005 ▪ 18/04/2005 ▪ 13/07/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
A mixture of anti-CD3 mAb (SPV-T3a)-ricin A chain fusion protein and anti-CD7 mAb (WT1)-ricin A chain fusion protein	Henogen SA - Belgium	Treatment of graft versus host disease	<ul style="list-style-type: none"> ▪ 27/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Sodium valproate	The Jennifer Trust for Spinal Muscular Atrophy - UK	Treatment of 5q spinal muscular atrophy	<ul style="list-style-type: none"> ▪ 27/05/2005 ▪ 13/06/2005 ▪ 13/07/2005 ▪ 32 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Mecasermin	Tercica Europe Limited - Ireland	Treatment of primary growth hormone insensitivity syndrome	<ul style="list-style-type: none"> ▪ 01/04/2005 ▪ 18/04/2005 ▪ 13/07/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 02/08/2005 ▪ 26/08/2005
Levamisol hydrochloride	ACE Pharmaceuticals BV - The Netherlands	Treatment of nephrotic syndrome	<ul style="list-style-type: none"> ▪ 13/07/2005 ▪ 25/07/05 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
Recombinant microbial lipase	Solvay Pharmaceuticals GmbH - Germany	Treatment of malabsorption due to exocrine pancreatic enzyme insufficiency	<ul style="list-style-type: none"> ▪ 11/07/2005 ▪ 25/07/2005 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005

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(E)-(1S,4S,10S,21R)-7-[(Z)-ethylidene]-4,21-diisopropyl-2-oxa-12,13-dithia-5,8,20,23-tetraazabicyclo[8.7.6]triacos-16-ene-3,6,9,19,22-pentone	The Matthews Consultancy Ltd - UK	Treatment of peripheral T-cell lymphoma (nodal, other extranodal and leukaemic/disseminated)	<ul style="list-style-type: none"> ▪ 04/07/2005 ▪ 25/07/2005 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
Imatinib mesilate	Novartis Europharm Limited - UK	Treatment of chronic eosinophilic leukaemia and the hypereosinophilic syndrome	<ul style="list-style-type: none"> ▪ 26/05/2005 ▪ 13/06/2005 ▪ 19/08/2005 ▪ 67 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
Peptide 144 TGF-beta1-inhibitor (TSLDASIIWAMMQN)	Digna Biotech S.L. - Spain	Treatment of localised scleroderma	<ul style="list-style-type: none"> ▪ 26/05/2005 ▪ 13/06/2005 ▪ 09/09/2005 ▪ 89 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
Peptide 144 TGF-beta1-inhibitor (TSLDASIIWAMMQN)	Digna Biotech S.L. - Spain	Treatment of systemic sclerosis	<ul style="list-style-type: none"> ▪ 26/05/2005 ▪ 13/06/2005 ▪ 09/09/2005 ▪ 89 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
Recombinant modified vaccinia virus Ankara expressing tuberculosis antigen 85A	University of Oxford - UK	Prevention of tuberculosis disease in BCG vaccinated individuals	<ul style="list-style-type: none"> ▪ 22/04/2005 ▪ 13/06/2005 ▪ 09/09/2005 ▪ 89 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
Alfimeprase	QuadraMed Limited - UK	Treatment of acute peripheral arterial occlusion	<ul style="list-style-type: none"> ▪ 11/07/2005 ▪ 25/07/2005 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
(1R, 2R, 4S)-4-[(2R)-2-[(3S,6R,7E,9R,10R,12R,14S,15E,17E,19E,21S,23S,26R, 27R,34aS)-9,27-dihydroxy-10,21-dimethoxy-6,8,12,14,20,26-hexamethyl-1,5,11,28,29-pentaoxo-1,4,5,6,9,10,11,12,13,14,21,22,23,24,25,26,27,28,29,31,32,33,34a-tetra-cosahydro-3H-23,27-epoxy-pyrido[2,1-c][1,4]oxazacyclohept-2-yl]propyl]-2-methoxy-cyclohexyldimethyl-phosphinate	Orphix Consulting GmbH - Germany	Treatment of primary malignant bone tumours	<ul style="list-style-type: none"> ▪ 04/07/2005 ▪ 25/07/2005 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
Oligonucleotide phosphorothioate (TAAACGTTATAACGTTATGACGTCAT), sodium salt	Oligovax - France	Treatment of glioma	<ul style="list-style-type: none"> ▪ 27/04/2005 ▪ 25/07/2005 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 28/10/2005
Tilarginine acetate	Dr Ulrich Granzer - Germany	Treatment of cardiogenic shock	<ul style="list-style-type: none"> ▪ 26/05/2005/ ▪ 13/06/2005 ▪ 09/09/2005/ ▪ 89 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 03/11/2005
Human Staphylococcus aureus immunoglobulin	Nabi Biopharmaceuticals Europe Ltd - Ireland	Treatment of Staphylococcus aureus bacteraemia	<ul style="list-style-type: none"> ▪ 06/07/2005 ▪ 25/07/2005 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 03/11/2005

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Mannitolum	Stricent AB - Sweden	Treatment of cystic fibrosis	<ul style="list-style-type: none"> ▪ 08/07/2005 ▪ 25/07/2005 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 07/11/2005
Bacterial lipase	Nordmark Arzneimittel GmbH & Co. KG - Germany	Treatment of malabsorption due to exocrine pancreatic enzyme insufficiency	<ul style="list-style-type: none"> ▪ 27/05/2005 ▪ 25/07/2005 ▪ 09/09/2005 ▪ 47 days 	<ul style="list-style-type: none"> ▪ 22/09/2005 ▪ 07/11/2005
Eptacog alfa (activated)	DKA Consult ApS - Denmark	Treatment of diffuse alveolar haemorrhage	<ul style="list-style-type: none"> ▪ 22/07/2005 ▪ 15/08/2005 ▪ 24/10/2005 ▪ 71 days 	<ul style="list-style-type: none"> ▪ 14/11/2005 ▪ 14/12/2005
1,2-bis(methylsulphonyl)-1-(2-chloroethyl)-2-[(methylamino)carbonyl]hydrazine	Vion (UK) Limited - UK	Treatment of acute myeloid leukaemia	<ul style="list-style-type: none"> ▪ 01/08/2005 ▪ 15/08/2005 ▪ 24/10/2005 ▪ 71 days 	<ul style="list-style-type: none"> ▪ 14/11/2005 ▪ 14/12/2005
Human Staphylococcus aureus polyclonal immunoglobulin and human Staphylococcus epidermidis polyclonal immunoglobulin	Omnicare Clinical Research - UK	Prevention of late onset sepsis in premature infants of less or equal than 32 weeks of gestational age	<ul style="list-style-type: none"> ▪ 08/07/2005 ▪ 25/07/2005 ▪ 21/10/2005 ▪ 89 days 	<ul style="list-style-type: none"> ▪ 14/11/2005 ▪ 14/12/2005
Human immunoglobulin G1 constant region - human ectodysplasmin-A1 receptor-binding domain fusion protein	Apoxis SA - France	Treatment of X-linked hypohidrotic ectodermal dysplasia (Christ-Siemens-Touraine Syndrome)	<ul style="list-style-type: none"> ▪ 27/07/2005 ▪ 15/08/2005 ▪ 24/10/2005 ▪ 71 days 	<ul style="list-style-type: none"> ▪ 14/11/2005 ▪ 14/12/2005
Dasatinib	Bristol-Myers Squibb Pharma EEIG - UK	Treatment of acute lymphoblastic leukaemia	<ul style="list-style-type: none"> ▪ 25/08/2005 ▪ 12/09/2005 ▪ 10/11/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 23/11/2005 ▪ 23/12/2005
Denufosol tetrasodium	Quintiles Limited - UK	Treatment of cystic fibrosis	<ul style="list-style-type: none"> ▪ 24/08/2005 ▪ 12/09/2005 ▪ 10/11/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 23/11/2005 ▪ 23/12/2005
Brostallicin	Nerviano Medical Science Srl - Italy	Treatment of soft tissue sarcoma	<ul style="list-style-type: none"> ▪ 24/08/2005 ▪ 12/09/2005 ▪ 10/11/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 23/11/2005 ▪ 23/12/2005
Enzastaurin hydrochloride	Eli Lilly Nederland B.V. - The Netherlands	Treatment of glioma	<ul style="list-style-type: none"> ▪ 25/08/2005 ▪ 12/09/2005 ▪ 10/11/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 23/11/2005 ▪ 23/12/2005
Imatinib mesilate	Novartis Europharm Limited - UK	Treatment of myelodysplastic/myeloproliferative diseases	<ul style="list-style-type: none"> ▪ 03/08/2005 ▪ 15/08/2005 ▪ 10/11/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 23/11/2005 ▪ 23/12/2005
Heparin sodium (inhalation use)	Vectura Group plc - UK	Treatment of cystic fibrosis	<ul style="list-style-type: none"> ▪ 04/07/2005 ▪ 15/08/2005 ▪ 10/11/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 23/11/2005 ▪ 23/12/2005
Dasatinib	Bristol-Myers Squibb Pharma EEIG - UK	Treatment of chronic myeloid leukaemia	<ul style="list-style-type: none"> ▪ 25/08/2005 ▪ 12/09/2005 ▪ 10/11/2005 ▪ 60 days 	<ul style="list-style-type: none"> ▪ 23/11/2005 ▪ 23/12/2005
Imexon	ICON Clinical Research (UK) Ltd - UK	Treatment of ovarian cancer	<ul style="list-style-type: none"> ▪ 29/07/2005 ▪ 15/08/2005 ▪ 10/11/2005 ▪ 88 days 	<ul style="list-style-type: none"> ▪ 23/11/2005 ▪ 23/12/2005

Product INN	Sponsor	Summary of indication	EMEA/COMP <ul style="list-style-type: none"> ▪ Submission ▪ Start date ▪ Opinion ▪ Active time 	European Commission <ul style="list-style-type: none"> ▪ Date of decision
E. Coli heat-shock protein 70 with bovine retinal S-antigen	Biotech Tools SA - Belgium	Treatment of autoimmune uveitis	<ul style="list-style-type: none"> ▪ 22/08/2005 ▪ 17/10/2005 ▪ 7/12/2005 ▪ 52 days 	<ul style="list-style-type: none"> ▪ 19/12/2005 ▪ 24/01/2006
Human monoclonal antibody against HLA-DR	GPC Biotech AG - Germany	Treatment of chronic lymphocytic leukaemia	<ul style="list-style-type: none"> ▪ 30/09/2005 ▪ 17/10/2005 ▪ 7/12/2005 ▪ 52 days 	<ul style="list-style-type: none"> ▪ 19/12/2005 ▪ 24/01/2006
Purified inactivated Japanese encephalitis SA14-4-2 virus vaccine	Intercell AG - Austria	Prevention of Japanese encephalitis	<ul style="list-style-type: none"> ▪ 30/09/2005 ▪ 17/10/2005 ▪ 7/12/2005 ▪ 52 days 	<ul style="list-style-type: none"> ▪ 19/12/2005 ▪ 24/01/2006
Lentiviral vector containing the human Wiskott Aldrich syndrome protein gene	Généthon - France	Treatment of Wiskott Aldrich syndrome	<ul style="list-style-type: none"> ▪ 30/09/2005 ▪ 17/10/2005 ▪ 7/12/2005 ▪ 52 days 	<ul style="list-style-type: none"> ▪ 19/12/2005 ▪ 24/01/2006
Vandetanib	AstraZeneca UK Limited - UK	Treatment of medullary thyroid carcinoma	<ul style="list-style-type: none"> ▪ 30/09/2005 ▪ 17/10/2005 ▪ 7/12/2005 ▪ 52 days 	<ul style="list-style-type: none"> ▪ 19/12/2005 ▪ 24/01/2006

Annex 12a

HMPC Community herbal monographs

Title	Reference	Status
Community herbal monograph on ispaghula husk (plantago ovata, tegumentum)	EMEA/HMPC/340857/2005	Draft released for public consultation in September 2005
Community herbal monograph on ispaghula seed (plantago ovata, semen)	EMEA/HMPC/340861/2005	Draft released for public consultation in September 2005
Community herbal monograph on linseed (linum, semen)	EMEA/HMPC/340849/2005	Draft released for public consultation in September 2005
Community herbal monograph on psyllium seed (plantago afra et plantago indica, semen)	EMEA/HMPC/340865/2005	Draft released for public consultation in September 2005
Community herbal monograph on valerian root (valeriana, radix)	EMEA/HMPC/340719/2005	Draft released for public consultation in September 2005

Annex 12b

Entries to the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

Title	Reference	Status
Entry to the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products: linseed (linum, semen)	EMEA/HMPC/340854/2005	Draft released for public consultation in September 2005
Entry to the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products: valerian root (valeriana, radix)	EMEA/HMPC/340779/2005	Draft released for public consultation in September 2005

Annex 13 Guidelines and working documents in 2005

CHMP Biologics Working Party

Reference number	Document title	Status
CPMP/BWP/2458/03	Guideline on Development and Manufacture of Lentiviral Vectors	Adopted in May 2005
EMA/CPMP/4548/03	Guideline on Requirements for Vaccine Antigen Master File (VAMF) Certification	Adopted in April 2005
EMA/BWP/111233/05	EU Recommendations for the Influenza Vaccine Composition for the Season 2005/2006	Adopted in March 2005
EMA/BWP/125/04	Guideline on Epidemiological Data on Blood Transmissible infections	Adopted in January 2005
EMA/CHMP/BWP/298388/05	Guideline on Validation of Immunoassay for the detection of antibody to Human Immunodeficiency Virus (Anti-HIV) in Plasma Pools	Released for consultation in September 2005
EMA/CHMP/BWP/298390/05	Guideline on Validation of Immunoassay for the detection of Hepatitis B Virus Surface Antigen (HBSAG) in Plasma Pools	Released for consultation in September 2005
CHMP/BWP/229472/05	Concept Paper on the Revision of the Note for guidance on Allergen Products (CPMP/BWP/243/96): Production and Quality Issues	Released for consultation in September 2005
EMA/CHMP/BWP/12446/05	Guideline on Potency Labelling for Insulin Analogue containing Products with Particular Reference to the use of "International Units" or "Units"	Released for consultation in April 2005
EMA/CHMP/49348/05	Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Quality Issues	Released for consultation in March 2005
EMA/CHMP/BWP/135148/04	Environmental Risk Assessments for Medicinal products containing, or consisting of, Genetically Modified Organisms (GMOs) (Module 1.6.2)	Released for consultation in January 2005

CHMP Blood Products Working Party

Reference number	Document title	Status
CHMP/BPWG/151426/04	Concept Paper on revision of: Note of Guidance on the Clinical Investigation of Human Normal Immunoglobulin for Intravenous Administration (IVIg)	Released for consultation in March 2005
EMA/CHMP/BPWG/37101/05	Concept Paper on the Revision of Core SPC for Human Plasma Fibrinogen Products	Released for consultation in December 2005
CPMP/BPWG/3726/02	Core SPC for Human Varicella Immunoglobulin for Intramuscular Use	Adopted in July 2005
CPMP/BPWG/3728/02	Core SPC for Human Rabies Immunoglobulin for Intramuscular Use	Adopted in July 2005
CPMP/BPWG/3730/02	Core SPC for Human Tetanus Immunoglobulin for Intramuscular Use	Adopted in July 2005
CPMP/BPWG/3732/02	Core SPC for Human Tick-Borne Encephalitis Immunoglobulin for Intramuscular Use	Adopted in July 2005

Reference number	Document title	Status
CPMP/BPWG/278/02	Guideline on the Core SPC for Human Plasma Derived von Willebrand Factor	Adopted in November 2005
CPMP/BPWG/220/02	Guideline on the Clinical Investigation of Human Plasma Derived von Willebrand Factor Products	Adopted in November 2005
CPMP/BPWG/2231/99	Revision 2, Guideline on the Core SPC for Human Albumin Solution	Adopted in November 2005

CHMP Efficacy Working Party

Reference number	Document title	Status
CHMP/EWP/195220/05	Concept Paper on the Development of a CHMP Guideline on Reporting the Results of Population Pharmacokinetic Analyses	Adopted in June 2005
CHMP/EWP/369963/05	Concept Paper on the Development of a Guideline on the Development of New Products for the Treatment of Tobacco and Alcohol Dependence	Released for consultation in November 2005
CHMP/369929/05	Recommendations on the Need for Revision of the Guideline on Clinical Investigation of Medicinal Products in the Treatment of Alzheimer's Disease (CPMP/EWP/553/95)	Released for consultation in November 2005
CHMP/EWP/369959/05	Recommendations on the Need for Revision of the Guideline on Clinical Investigation of Medicinal Products in the Treatment of Parkinson's Disease (CPMP/EWP/563/95)	Released for consultation in November 2005
CHMP/EWP/340660/05	Recommendations on the Need for Revision of the Guideline on Clinical Investigation of Medicinal Products for Prophylaxis of Intra- and Post-operative Venous Thromboembolic Risk (CPMP/EWP/707/98)	Released for consultation in November 2005
CPMP/EWP/6172/03	Draft Guideline on the Evaluation of Medicinal Products Intended for Treatment of Hepatitis B	Released for consultation in February 2005
CPMP/EWP/4937/03	Draft Guideline on Non-Clinical and Clinical Development of Medicinal Products for the Treatment of Nausea and Vomiting associated with Cancer Chemotherapy	Released for consultation in February 2005
CPMP/EWP/147013/04	Draft Guideline on the Role of Pharmacokinetics in the Development of Medicinal Products in the Paediatric Population	Released for consultation in February 2005
CHMP/EWP/83561/05	Draft Guideline on Clinical Trials in Small Populations	Released for consultation in March 2005
CPMP/EWP/4713/03	Draft Guideline on Clinical Investigation of Medicinal Products for the Treatment of Sepsis	Released for consultation in May 2005
CPMP/EWP/6235/04	Draft Guideline on Clinical Investigation of Medicinal Products for the Prophylaxis of Venous Thromboembolic Risk in Non-Surgical Patients	Released for consultation in May 2005
CPMP/EWP/4891/03	Draft Guideline on Clinical Investigation of Medicinal Products for the Treatment of Ankylosing Spondylitis	Released for consultation in June 2005

Reference number	Document title	Status
CPMP/EWP/438/04	Draft Guideline on Clinical Investigation of Medicinal Products for the Treatment of Psoriatic Arthritis	Released for consultation in June 2005
CPMP/EWP/422/04	Draft Guideline on Clinical Investigation of Medicinal Products for the Treatment of Juvenile Idiopathic Arthritis	Released for consultation in June 2005
CPMP/EWP/234/95 <i>Revision 1</i>	Draft Guideline on Clinical Investigation of Anti-Anginal Medicinal Products in Stable Angina Pectoris	Released for consultation in June 2005
CHMP/EWP/89249/04	Draft Guideline on Clinical Investigation of the Pharmacokinetics of Therapeutic Proteins	Released for consultation in July 2005
CPMP/EWP/561/98	Draft Guideline on Clinical Investigation of Medicinal Products the Treatment of Multiple Sclerosis	Released for consultation in September 2005
CPMP/EWP/504/97	Draft Guideline on Clinical investigation of Medicinal Products in Prevention and Treatment Acute Respiratory Distress Syndrome	Released for consultation in September 2005
CPMP/EWP/552/95 <i>Revision 2</i>	Note for Guidance on Post-Menopausal Osteoporosis in Women	Released for consultation in December 2005
CPMP/EWP/4284/02	Guideline on the Clinical Investigation of Medicinal Products indicated for Generalised Anxiety Disorder	Adopted in January 2005
CPMP/EWP/4280/02	Guideline on the Clinical Investigation of Medicinal Products indicated for the Treatment of Panic Disorder	Adopted in January 2005
CPMP/EWP/4279/02	Guideline on Clinical Investigation of Medicinal Products for the Treatment of Obsessive Compulsive Disorder	Adopted in January 2005
CPMP/EWP/2339/02	Guideline on Evaluation of the Pharmacokinetics of Medicinal Products in Patients with Impaired Hepatic Function	Adopted in February 2005
CHMP/EWP/191583/05	Questions and Answers document on the Clinical Development of Fixed Combinations of Drugs Belonging to Different Therapeutic Classes in the Field of Cardiovascular Treatment and Prevention	Adopted in June 2005
CPMP/EWP/519/98 <i>Revision 1</i>	Guideline on Clinical Investigation of Steroid Contraceptives in Women	Adopted in July 2005
CHMP/EWP/5872/03	Guideline on Data Monitoring Committees	Adopted in July 2005
CPMP/EWP/2158/99	Guideline on the Choice of the Non-Inferiority Margin	Adopted in July 2005
CPMP/EWP/139391/04	Reflection Paper on the regulatory guidance for the use of Health-Related Quality of Life (HRQL) measures in the evaluation of medicinal products	Adopted in July 2005
CPMP/EWP/021/97 <i>Revision 1</i>	Guideline on Clinical Investigation of Medicinal Products for Hormone Replacement Therapy of Oestrogen Deficiency Symptoms in Postmenopausal Women	Adopted in October 2005
CPMP/EWP/633/02 <i>Revision 1</i>	Guideline on the Clinical Development of Medicinal Products for the Treatment of HIV Infection	Adopted in November 2005

Reference number	Document title	Status
CPMP/EWP/205/95 <i>Revision 3</i>	Guideline on the Evaluation of Anticancer Medicinal Products in Man	Adopted in December 2005

CHMP Gene Therapy Working Party

Reference number	Document title	Status
EMEA/CHMP/203831/05	Concept Paper on Scientific Requirements for the Environmental Risk Assessment of Gene Therapy Medicinal Products	Released for consultation in November 2005
EMEA/CHMP/203821/05	Concept Paper on the Development of a Guideline on the Non-Clinical Studies prior to Clinical use of Gene Therapy Medicinal Products	Released for consultation in November 2005
EMEA/273974/05	Note for Guidance on the Quality, Preclinical and Clinical aspects of Gene Transfer Medicinal Products - Annex on Non-Clinical testing for Inadvertent Germline transmission of Gene Transfer Vectors.	Released for consultation in November 2005

CHMP Paediatrics Working Party

Reference number	Document title	Status
EMEA/CHMP/PEG/194605/05	Concept Paper on the Impact of Liver Immaturity when investigating medicinal products intended for Neonatal use	Released for consultation in July 2005
EMEA/196218/05	Note of Explanation on Reflection Paper on Formulations of Choice for the Paediatric Population (EMEA/CHMP/PEG/194810/2005)	Released for consultation in June 2005
EMEA/CHMP/PEG/194810/2005	Reflection Paper: Formulations of Choice for the Paediatric Population	Released for consultation in June 2005
EMEA/175192/04	EMEA/PEG Procedure for Identifying Paediatric Needs	Adopted in June 2005
EMEA/CHMP/327847/05	Assessment of the Paediatric Needs Cardiovascular Products	Released for consultation in October 2005
EMEA/CHMP/234105/05	Assessment of the Paediatric Needs Rheumatology	Released for consultation in July 2005
EMEA/CHMP/18922/05	Assessment of the Paediatric Needs Pain	Released for consultation in June 2005
EMEA/CHMP/366844/2005	Assessment of the Paediatric Needs Chemotherapy I	Released for consultation in October 2005
EMEA/CHMP/405911/2005	Assessment of the Paediatric Needs Epilepsy	Released for consultation in November 2005
EMEA/CHMP/405908/2005	Assessment of the Paediatric Needs Immunology	Released for consultation in November 2005

CHMP Pharmacogenetics Working Party

	Document title	Status
EMEA/CHMP/6806/05	Concept Paper on the development of a guideline on bio banks issues relevant to pharmacogenetics	Released for consultation until June 2005.
EMEA/CHMP/20227/04	Guideline on Pharmacogenetics Briefing Meeting	Released for consultation until September 2005.

CHMP Pharmacovigilance Working Party

Reference number	Document title	
-	Volume 9A of the Rules Governing Medicinal Products in the EU	Revised version of Volume 9 (in relation to human medicines) released by the EC on 21 December 2005 for public consultation until 17 March 2006
EMA/MB/63019/2006	CHMP Guideline on the Assessment of Periodic Safety Update Reports	Adopted by the CHMP in November 2005 for coming into force on 1 January 2006 and publication in final Volume 9A
CHMP/313666/2005	CHMP Guideline on the Exposure to Medicinal Products during Pregnancy: Need for Post-Authorisation Data	Adopted by the CHMP in November 2005 for coming into force on 1 May 2006, already published and also to be included in final Volume 9A
CHMP/235910/2005	CHMP Guideline on the Conduct of Pharmacovigilance for Medicines Used by the Paediatric Population	Released by the CHMP in July 2005 for public consultation until 31 January 2006
CHMP/PhVWP/372004/2005	Concept Paper for a CHMP Guideline on the Conduct of Pharmacovigilance for Vaccines	Released by the CHMP in November 2005 for public consultation until 28 February 2006

CHMP Safety Working Party

	Document title	Status
CPMP/SWP/4447/00	Guideline on Environmental Risk Assessment of Medicinal Products for Human Use	Guideline re-released for consultation in January 2005
CPMP/SWP/5199/02	Guideline on the Limits for Genotoxic Impurities	Draft Guideline re-released for consultation in June 2004
EMA/CHMP/SWP/149188/2004	Guideline on the Need for Pre-clinical Testing of Human Pharmaceuticals in Juvenile Animals	Draft Guideline released for consultation in 4Q 2005
EMA/CHMP/SWP/258498/2005	Guideline on the Non-Clinical Development of Fixed Combinations of Medicinal Products	Draft Guideline released for consultation in 4Q 2005
EMA/CHMP/SWP/94227/2004	Guideline on the Investigation of Dependence Potential of Medicinal Products	Draft Guideline released for consultation in 2Q 2005
EMA/CHMP/SWP/5382/2003	Note for Guidance on the Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products: Annex on Nonclinical Testing for Inadvertent Germline Transmission of Gene Transfer Vectors	Draft Annex released for consultation in 4Q 2005
ICH S7B	Non Clinical Studies for Assessing Risk of Repolarisation Associated Ventricular Tachyarrhythmia	SWP contribution
	ICH Consideration Paper for the minimisation of the risk of germline transmission	SWP contribution

CHMP Scientific Advice Working Party

No guidelines/working documents in 2005

CHMP Vaccine Working Party

Reference number	Document title	Status
EMA/CHMP/VWP/157496/2005	Pandemic influenza vaccines recommendations to CHMP	Adopted
EMA/159813/2005	Workshop on regulatory and scientific issues related to concomitant administration of vaccines	Adopted
EMA/CHMP/VWP/181228/2005	Guideline on Pandemic influenza core SPC	Adopted
EMA/CHMP/VWP/164653/2005	Note for Guidance on the clinical evaluation of vaccines	Released for consultation

CHMP Cell-based Products Working Party

Reference number	Document title	Status

No guidelines/working documents in 2005

CHMP Working Party on Similar Biological (Biosimilar) Medicinal Products

Reference number	Document title	Status
CHMP/437/04	Guideline on Similar Biological Medicinal Products	Adopted in September 2005
EMA/CHMP/94526/05	Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guidance on Biosimilar Medicinal Products containing Recombinant Erythropoietins	Released for consultation in June 2005
EMA/CHMP/31329/05	Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guidance in Biosimilar Medicinal Products containing Recombinant Granulocyte-Colony Stimulating Factor	Released for consultation in June 2005
EMA/CHMP/42832/05	Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues	Released for consultation in May 2005
EMA/CHMP/94528/05	Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guideline on Similar Medicinal Products containing Somatropin	Released for consultation in May 2005
EMA/CHMP/32775/05	Annex Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as Active Substance: Non-Clinical and Clinical Issues - Guideline on Similar Medicinal Products containing Recombinant Human Insulin	Released for consultation in May 2005

CHMP Invented Name Review Group

Reference number	Document title	Status
CPMP/328/98, Rev. 4	Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure	Adopted in April 2005

CHMP Working Group on Quality Review of Documents

Reference number	Document title	Status
EMEA/5542/02	The new Linguistic Review Process of Product Information in the Centralised Procedure	Published on 20 October 2005
EMEA/277378/05	Handling of "Consultation with target patient groups" on PLs for CAPs for Human use	Published on 20 October 2005
EMEA/550757/05	Guidance on Pre-Accession Product Information Linguistic Review Process for Bulgaria & Romania (PALC II)	Published on 30 November 2005
	Updated Human QRD product information templates for centralised procedures (annotated and clean in all EU languages)	Published in July 2005
	Updated Veterinary QRD product information templates for centralised procedures (annotated and in all EU languages)	Published in July 2005
	Human QRD product information templates for MR/DC/Referral procedures (clean in all EU languages)	Published in December 2005
	Updated Appendix I to the QRD product information templates (Pregnancy & Lactation statements - in all EU languages)	Published in December 2005
	Updated Appendix II to the QRD product information templates (MedDRA terms - in all EU languages)	Published in December 2005
	Updated Appendix III to the QRD product information templates (Storage conditions - in all EU languages)	Published in December 2005
	Updated Appendix IV to the QRD product information templates (Labelling abbreviations for Exp. Date & Batch Nr - in all EU languages)	Published in December 2005
	Updated List of non standard abbreviations	Published in December 2005
	Updated Compilation of QRD terms	Published in December 2005
	Updated QRD decisions on stylistic matters	Published in December 2005
	Updated translations of Names of the EU-EEA countries	Published in December 2005

CVMP Safety Working Party

Reference number	Document title	Status
EMEA/CVMP/543/03-FINAL	Guideline on user safety for pharmaceutical veterinary medicinal products	Adopted January 2005 (coming into effect 13 July 2005)
EMEA/CVMP/209865/2004	Overview of comments received on draft Guideline on Injection Site Residues (EMEA/CVMP/542/03)	Adopted January 2005

Reference number	Document title	Status
EMA/ CVMP/41180/2005	Summary of the comments received on draft guideline on user safety for pharmaceutical veterinary medicinal products (EMA/ CVMP/543/03-CONSULTATION)	Adopted April 2005
EMA/ CVMP/66781/2005-CONSULTATION	Guideline on Safety and Residue Data Requirements for Veterinary Medicinal Products intended for Minor Uses and Minor Species	Released for consultation April 2005 (end of consultation 31 October 2005)
EMA/ CVMP/SWP/122154/2005-CONSULTATION	Concept Paper on a Guideline on the Assessment of pharmacological/pharmacodynamic data to establish a pharmacological ADI	Released for consultation May 2005 (end of consultation 31 July 2005)
CVMP/ VICH/645/01-Rev.1-FINAL	VICH Topic GL 28: "Studies to evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing"	Adopted May 2005
EMA/ CVMP/SWP/139646/2005-CONSULTATION	Concept Paper on Guidance on the approach on how to demonstrate whether a substance is capable of pharmacological action or not	Released for consultation November 2005 (end of consultation 21 February 2006)
EMA/ CVMP/223005/2005	Approaches on how to consider the excipients in the context of Council Regulation 2377/90	Adopted November 2005

CVMP Scientific Advisory Group on Antimicrobials

	Document title	Status
EMA/ CVMP/1034/04-Consultation	Concept paper on further guidance on interpretation of the data from VICH GL27	Released for consultation March 2005 (end of consultation 9 June 2005)
EMA/ CVMP/67951/2005-CONSULTATION	Concept Paper on revision of the current guideline on the SPC for antimicrobial products (EMA/ CVMP/612/01-FINAL)	Released for consultation June 2005 (end of consultation 31 August 2005)

Joint CHMP/ CVMP Quality Working Party

Reference number		Status
EMA/ CVMP/511/03 Annex to: EMA/ CVMP/ VICH/502/99	Annexes to Guideline on Impurities Residual Solvents	Adopted January 2005
EMA/ CVMP/134/02-Rev.1	Guideline on Active substance Master File Procedure	Adopted April 2005
EMA/ CVMP/QWP/114420/2005-CONSULTATION	Concept Paper on the development of a Guideline on Parametric Release	Released for consultation April 2005 (end of consultation 31 July 2005)
EMA/ CVMP/QWP/128710/2004-CONSULTATION	Guideline on Quality Data Requirements for Veterinary Medicinal Products intended for Minor Uses and Minor Species	Released for consultation April 2005 (end of consultation 31 October 2005)
EMA/ CVMP/205/04-FINAL	Guideline on plastic primary packaging materials	Adopted May 2005 (coming into effect 1 December 2005)
EMA/ CVMP/373/04-FINAL	Guideline on stability testing for applications for variations to a marketing authorisation	Adopted May 2005 (coming into effect 1 December 2005)
EMA/ CVMP/815/00-Rev.1	Guideline on Specifications: Test procedures and acceptance criteria for Herbal Substances, Herbal Preparations and Herbal Medicinal Products/Traditional Herbal Medicinal Products	Released for consultation June 2005 (end of consultation 15 September 2005)

Reference number	Document title	Status
CVMP/VICH/837/99-Rev.1-CONSULTATION	VICH Topic GL10(R) Quality: Impurities in new veterinary drug substances	Released for consultation June 2005 (end of consultation 1 September 2005)
CVMP/VICH/838/99-Rev.1-CONSULTATION	VICH Topic GL11(R) Quality: Impurities in new veterinary medicinal products	Released for consultation June 2005 (end of consultation 1 September 2005)
EMA/EMA/814/00-Rev.1	Guideline on Quality of Herbal Medicinal Products/Traditional Herbal Medicinal Product	Released for consultation July 2005 (end of consultation 30 September 2005)
EMA/EMA/VICH/899/99-Rev.1-CONSULTATION	VICH Topic GL3(R): Stability testing guidelines: New veterinary drug substances and medicinal products	Released for consultation October 2005(end of consultation 5 January 2006)
CVMP/VICH/810/04-FINAL	VICH Topic GL39 Step 7 Guideline on Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances	Adopted November 2005
CVMP/VICH/811/04-FINAL	VICH Topic GL40 Step 7 Guideline on Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products	Adopted November 2005

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference number	Document title	Status
EMA/EMA/900/03-FINAL	Guideline on Strategy for Triggering Investigations preceding Regulatory Actions by EU Competent Authorities	Adopted April 2005 (coming into effect 1 November 2005)
EMA/EMA/PhVWP/110607/2005-CONSULTATION	Veterinary Pharmacovigilance in the EU – A simple guide to reporting adverse reactions	Released for consultation April 2005 (end of consultation 18 October 2005)
EMA/EMA/893/04	Guideline on EU Veterinary Suspected Adverse Reaction report form for veterinarians and health professionals	Adopted June 2005
EMA/EMA/SOP/693/99-Rev.1	Procedure for Management of 15-day Suspected Adverse Reaction (SAR) reports to a centrally authorised veterinary medicinal product	Adopted June 2005
EMA/EMA/PhVWP/145320/2005-CONSULTATION	Concept Paper on a Periodic Safety Update Report (PSUR) assessment guideline for veterinary medicinal products	Released for consultation July 2005 (end of consultation 30 September 2005)
CVMP/VICH/547/00-CONSULTATION	VICH Topic GL24 Step 4 Pharmacovigilance of veterinary medicinal products: management of adverse event reports (AERs)	Released for consultation November 2005
CVMP/VICH/355996/05-CONSULTATION	VICH Topic GL42 Step 4 Guideline on Pharmacovigilance of veterinary medicinal products: data elements for submission of adverse event reports	Released for consultation November 2005

CVMP Efficacy Working Party

Reference number	Document title	Status
EMA/EMA/EWP/117899/2004-CONSULTATION	Guideline on Efficacy and Target Animal Safety Data Requirements for Veterinary Medicinal Products intended for Minor Uses and Minor Species	Released for consultation April 2005 (end of consultation 31 October 2005)

Reference number	Document title	Status
EMA/ECVMP/EWP/79590/2005-CONSULTATION	Concept Paper on Dossier Requirements for Oncology Products	Released for consultation June 2005 (end of consultation 30 September 2005)
EMA/ECVMP/EWP/202810/2005-CONSULTATION	Concept Paper on Revision of the Guideline for the Testing and Evaluation of the Efficacy of Antiparasitic Substances for the Treatment and Prevention of Tick and Flea Infestations in Dogs and Cats	Released for consultation September 2005 (end of consultation 31 December 2005)
EMA/ECVMP/83804/2005-CONSULTATION	Fixed combinations of veterinary pharmaceutical products	Released for consultation October 2005 (end of consultation 30 April 2006)

CVMP Immunologicals Working Party

Reference number	Document title	Status
EMA/ECVMP/743/00-Rev.2	Revised guideline on requirements and controls applied to bovine serum used in the production of immunological veterinary medicinal products	Adopted November 2005 (coming into effect 1 January 2006)
EMA/ECVMP/IWP/268282/2005-CONSULTATION	Concept paper on the need for a procedure to be followed when a batch of a vaccine is suspected to be contaminated with bovine viral diarrhoea (BVD) virus	Released for consultation December 2005 (end of consultation 28 February 2006)

CVMP General

Reference number	Document title	Status
EMA/ECVMP/115769/2005	Guideline For An Assessor Preparing Assessment Reports For Veterinary Medicinal Products	Adopted May 2005
EMA/ECVMP/064/05	Guideline on the Summary of Product Characteristics for Immunological Veterinary Medicinal Products	Released for consultation September 2005 (end of consultation 31 December 2005)
EMA/ECVMP/065/05	Guideline on the summary of product characteristics for Pharmaceutical Veterinary Medicinal Products	Released for consultation September 2005 (end of consultation 31 December 2005)

Committee for Orphan Medicinal Products (COMP)

Reference number	Document title	Status
EMA/COMP/66972/2004	Guideline on elements required to support the medical plausibility and the assumption of significant benefit for an orphan designation	Adopted in December 2005

Committee on Herbal Medicinal Products (HMPC)*

Reference number	Document title	Status	Date of release/adoption
EMA/HMPC/166326/05	Guideline on the clinical assessment of fixed combinations of herbal substances/herbal preparations	Draft released for public consultation	July 2005
EMA/HMPC/246736/05	Public statement on "CPMP List of herbal drugs with serious risks dated 1992"	Adopted	November 2005

* Including documents prepared by the HMPC Safety & Efficacy Drafting Group.

Reference number	Document title	Status	Date of release/adoption
EMEA/HMPC/138381/05	Public statement on the risks associated with the use of herbal products containing Aristolochia species	Adopted	November 2005
EMEA/HMPC/139215/05	Public statement on the use of herbal medicinal products containing asarone	Adopted	November 2005
EMEA/HMPC/138379/05	Public statement on Capsicum / capsaicin containing herbal medicinal products	Adopted	November 2005
EMEA/HMPC/138309/05	Public statement on chamomilla containing herbal medicinal products	Draft released for public consultation	April 2005
EMEA/HMPC/137212/05	Public statement on the use of herbal medicinal products containing estragole	Adopted	November 2005
EMEA/HMPC/138363/05	Public statement on the use of herbal medicinal products containing methyleugenol	Adopted	November 2005
EMEA/HMPC/138386/05	Public statement on the use of herbal medicinal products containing pulegone and menthofuran	Adopted	November 2005
EMEA/HMPC/138139/05	Public statement on the allergenic potency of herbal medicinal products containing soya/peanut protein	Draft released for public consultation	April 2005
EMEA/HMPC/108850/05	Compilation of General Questions addressed by the HMPC	Adopted	May 2005

HMPC Quality Drafting Group

Reference number	Document title	Status	Date of release/adoption
EMEA/HMPC/241953/05	Concept paper on the declaration of herbal substances/herbal preparations in finished herbal medicinal products	Released for public consultation	July 2005
EMEA/HMPC/246816/05	Public statement on good agricultural and collection practice for starting materials of herbal origin	Draft released for public consultation	July 2005

HMPC Organisational Matters Drafting Group

Reference number	Document title	Status	Date of release/adoption
EMEA/HMPC/261344/05	Concept paper on CTD for traditional herbal medicinal products	Draft released for public consultation	September 2005
EMEA/HMPC/107399/05	Guideline on the documentation to be submitted for inclusion in the List of herbal substances, preparations and combinations thereof	Adopted	September 2005
EMEA/HMPC/108877/05	Procedure for the appointment by the HMPC of Rapporteur	Adopted	September 2005
EMEA/HMPC/182352/05	Procedure for the preparation of Community monograph for herbal medicinal products with well established medicinal use	Draft released for public consultation	June 2005
EMEA/HMPC/182320/05	Procedure for the preparation of Community monograph for traditional herbal medicinal products	Draft released for public consultation	June 2005
EMEA/HMPC/261340/05	Template for a Community herbal monograph	Adopted	September 2005
EMEA/HMPC/100824/05	Structure of the list of herbal substances, preparations and combinations thereof	Adopted	September 2005

Reference number	Document title	Status	Date of release/adoption
EMEA/HMPC/119889/05	Template for a submission of a request for expert advice on herbal medicinal products	Adopted	September 2005
EMEA/HMPC/126542/05	Timetable for the establishment of a Community herbal monograph [not resulting from any referral procedure]	Adopted	September 2005

Annex 14 Arbitration and Community referrals overview 2005

Referrals made to the CHMP

Type of referral	Date of CHMP opinion	International non-proprietary name (INN)
Article 29(2) of Directive 2001/83/EC	January 2005	Ethinylestradiol + Levonorgestrel
Article 31 of Directive 2001/83/EC	April 2005	Atomoxetine, Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Mianserine, Milnacipran, Mirtazapine, Paroxetine, Reboxetine, Sertraline and Venlafaxine
Article 30 of Directive 2001/83/EC	April 2005	Calcium
Article 29(2) of Directive 2001/83/EC	April 2005	Rosuvastatin
Article 31 of Directive 2001/83/EC	June 2005	Celecoxib, Etoricoxib, Lumiracoxib
Article 18(1) of Council Regulation (EEC) No 2309/93	June 2005	Celecoxib, Parecoxib, Valdecoxib
Article 18(1) of Council Regulation (EEC) No 2309/93	June 2005	Combination Vaccines
Article 18(1) of Council Regulation (EEC) No 2309/93	June 2005	Duloxetine
Article 29(2) of Directive 2001/83/EC	June 2005	Lansoprazol
Article 6(12) of Commission Regulation (EC) No 10084/2003	July 2005	Perindopril
Article 29(2) of Directive 2001/83/EC	September 2005	Lansoprazol
Article 29(2) of Directive 2001/83/EC	September 2005	Ropinirole

Referrals made to the CVMP

Community harmonisation and pharmacovigilance referrals

Type of referral	Date of CVMP opinion	International non-proprietary name (INN)
Article 35	November 2005	Micotil

Annex 15

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 enquiries concerning pharmacovigilance for medicinal products for human use:

Panos TSINTIS
Direct telephone: (44-20) 75 23 71 08
E-mail: panos.tsintis@emea.eu.int

For enquiries concerning pharmacovigilance for medicinal products for veterinary use:

Fia WESTERHOLM
Direct telephone: (44-20) 74 18 85 81
E-mail: fia.westerholm@emea.eu.int

For enquiries concerning product defects and other quality-related matters:

E-mail: qualitydefects@emea.eu.int
Fax: (44-20) 74 18 85 90
Out-of-hours telephone: (44-7880) 55 06 97

Certificates of a medicinal product

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

For enquiries concerning certificates for centrally authorised medicines for human or veterinary use:

E-mail: certificate@emea.eu.int
Fax: (44-20) 74 18 85 95

EMEA PMF/VAMF certificates

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

For enquiries concerning PMF certificates:

Silvia DOMINGO
Direct telephone: (44-20) 74 18 85 52
Fax: (44-20) 74 18 85 45
E-mail: silvia.domingo@emea.eu.int

For enquiries concerning VAMF certificates:

Antoon GIJSENS
Direct telephone: (44-20) 75 23 71 14
Fax: (44-20) 74 18 85 45
E-mail: antoon.gijsens@emea.eu.int

Documentation services

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

These and other documents are available:

- on the Internet at: www.emea.eu.int/
- by e-mail request to: info@emea.eu.int
- by fax to: (44-20) 74 18 86 70
- by writing to:
EMEA Documentation service
European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
UK

European experts list

The EMEA works with approximately 3,500 European experts to perform its scientific evaluation work. A 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.eu.int

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